STUDY PROTOCOL

TITLE

SELF-CARE BEHAVIOURS OF TYPE 2 DIABETES MELLITUS PATIENTS:

A MULTICENTER PROSPECTIVE OBSERVATIONAL STUDY WITH 2 YEARS

FOLLOW-UP

ACRONYM

SCuDOS - Self-Care of Diabetes Observational Study

Version 1.1 – 29/11/2023

Status: Draft

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Confidentiality statement

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Background

Chronic diseases represent a challenging issue for global health and constitute one of the main expenditures for healthcare organisations worldwide [1]. Patients' empowerment is considered a key principle in chronic illness management: available reports suggest that future health systems' sustainability will mainly depend on people's ability to manage their chronic conditions [2]. Chronically ill patients need to learn many specific behaviours in order to adhere to complex therapeutic regimes, to maintain their well-being and quality of life, to manage symptoms and to reduce disease complications [3]. All these behaviours, requiring knowledge, motivation, experience and skills, have been referred by many authors to the concept of self-care [4].

Self-care has been defined as "a process of maintaining health through health promoting practices and managing illness" [5, 6]. Key concepts of self-care of chronic diseases are self-care maintenance, self-care monitoring, and self-care management. Self-care maintenance comprises those behaviours used by patients with a chronic disease to maintain physical and emotional stability. Self-care monitoring refers to the process of observing oneself for changes in signs and symptoms. Self-care management includes those behaviours acted in response to signs and symptoms when they occur [6]. Several studies observed that self-care in chronic diseases improves quality of life, also reducing mortality and costs of healthcare services [7–9]. Although self-care is considered as a relevant intermediate outcome in chronic illness care, previous studies observed that chronically ill patients show low levels of self-care in recognising and managing their symptoms, in taking drug therapies, and in performing recommended behaviours [10–14].

Rationale

Diabetes mellitus (DM) has been considered as one of the most serious chronic disease for morbidity and mortality all over the world [1, 15, 16]. It has been estimated that in 2019 the number

of persons affected by diabetes amounted to 463 million globally. Previsions showed that in 2045 the number will grow to about 700 million. DM accounted for 11.3% of global all-cause mortality among people aged between 20 to 79 years [15]. In Italy, about 5.3% of the population is affected by DM, for a total of 3.2 million people [17].The prevalence of DM increases in older population and it has been estimated that diabetes will represent a real epidemic disease in the near future, impacting negatively on the health status of communities and the sustainability of health systems internationally [15, 18]. Type 2 diabetes mellitus (T2DM) accounts for more than 90% of diabetes cases [19], is associated with higher rate of cardiovascular disease [16], and leads to serious microvascular and macrovascular complications [15, 20, 21].

International scientific societies recognised self-care as a key factor for T2DM patients to maintain better health status and to avoid severe disease complications [21–24]. Self-care was shown to improve metabolic control [25, 26] and quality of life [27, 28] and to reduce cardiovascular risk [29], hospitalisations [30] and incidence of disease-related complications [31–33] in T2DM patients.

Although self-care has been recognised to be a crucial issue for people with T2DM, just a few studies were conducted in Italy to investigate patients' self-care behaviours, and their results need to be integrated by further research. In fact, some of the available studies used self-care measurement tools with several limitations [34, 35], as pointed out by systematic reviews [36, 37]. Further researches investigated self-care as one of the numerous study variables and the description of self-care behaviours was partial [38, 39]. Finally, many studies did not allow strong inferences about outcomes associated to self-care, because of their cross-sectional design or very short follow-up periods [12, 34, 39–41].

Measuring self-care, besides the benefits of standardisation, can help in better understanding the complexity and the dynamicity of the phenomenon in T2DM patients. The *Self-Care of Diabetes Inventory* (SCODI) has showed to be a valid and reliable tool to measure self-care maintenance, self-

care monitoring, and self-care management in the T2DM population [42, 43]. In these evaluations, HbA1c has a key role in clinical assessment of patient's metabolic control and it has also been validated as a surrogate endpoint of microvascular complications associated with diabetes [44–47].

Therefore, the present study could provide relevant information about the experience of people with T2DM, useful to better understand their self-care behaviours and to develop tailored healthcare interventions. Furthermore, study results could contribute to improve diabetes healthcare service organisation and to reduce disease-related costs. Details about study objectives, methods, tools, procedures and attended results will be described further on.

1. Objectives and Indicators

1.1 General Study Purpose

The general purpose of this study is to explore the experience of self-care in T2DM patients, to understand how to provide a higher quality assistance reducing complications and improving resource utilisation. The theoretical framework of the study will be the Middle-Range Theory of Self-Care of Chronic Illness, developed by Riegel and colleagues [6].

1.1.1 Primary objective:

- to estimate associations between self-care maintenance, self-care monitoring, and self-care management at baseline and HbA1c after a 12 months follow-up in T2DM patients;

1.1.2 Secondary objectives:

- to estimate associations between self-care maintenance, self-care monitoring, and self-care management at baseline and HbA1c after a 24 months follow-up in T2DM patients;
- to estimate associations between self-care maintenance, self-care monitoring, and self-care management and clinical outcomes (unplanned medical referral, access to emergency department, hospitalisation, indicators of metabolic control, incidence of diabetes complications, quality of life, death) over a 24 months years follow-up in T2DM patients.

- to describe self-care maintenance, self-care monitoring, and self-care management and their directions over a 24 months follow-up in T2DM patients;
- to identify clinical and socio-demographic determinants of self-care maintenance, self-care monitoring, and self-care management in T2DM patients;
- to estimate the association between the trends of self-care maintenance, self-care monitoring, and self-care management and HbA1c over a 24 months follow-up;
- to integrate available data about validity and reliability of the SCODI;

1.2 Study Indicators

1.2.1 Resource utilisation/health outcomes indicators

- Number of extra (both scheduled and unscheduled) diabetes medical or nursing referral (compared to the general planned routine) per year;
- Number of all-cause accesses to emergency departments per year;
- Number of all-cause hospitalisations per year;
- All-cause death;
- Participation to formal diabetes education programs during last year.

1.2.2 Clinical Indicators

- Glycated haemoglobin (HbA1c);
- Time from the diagnosis of T2DM;
- Presence or absence and number of diabetes-related complications;
- Presence or absence and number of comorbidities;
- Ongoing medications and number of medications (including injections if patients are treated by insulin);
- Smoking habits;
- Lipid Profile (Total Cholesterol, HDL Cholesterol, LDL Cholesterol, Triglycerides);

- Liver Profile (ALT, AST, GGT);
- Renal Profile (Creatinine, estimated Glomerular Filtration Rate);
- Height, weight, and Body Mass Index (BMI);
- Arterial Blood Pressure and Heart Rate.

1.2.3 Person-centred indicators

- Self-care maintenance (measured by the Self-Care of Diabetes Inventory, SCODI);
- Self-care monitoring (measured by the Self-Care of Diabetes Inventory, SCODI);
- Self-care management (measured by the Self-Care of Diabetes Inventory, SCODI);
- Self-care confidence (measured by the Self-Care of Diabetes Inventory, SCODI);
- Functional status (measured by the Short Form 12 questionnaire, SF12);
- Mental status (measured by the Short Form 12 questionnaire, SF12);
- 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);
- Quality of sleep (measured by the Pittsburgh Sleep Quality Index, PSQI).

1.2.4 Socio-demographic indicators

- Age;
- Gender;
- Educational level;
- Job employment;
- Income level;
- Presence of formal or informal caregiver.

2. Study design

The study uses a multi-centred prospective observational design with 2 years follow-up.

3. Subject selection

Subjects will be contacted during their outpatient visit in Diabetes Centres and then asked to be enrolled in the study by investigators in a consecutive sequence, according to the following inclusion and exclusion criteria.

3.1 Inclusion criteria

- Diagnosis of T2DM, as described in the available guidelines [49];
- Age over 18 years old;
- Adequate comprehension of Italian language;
- Signed and dated informed consent.

3.2 Exclusion criteria

- Presence of documented psychiatric or neurodegenerative disease;
- Pregnancy;
- Any condition that, by the investigators' judgement, may limit adherence to study procedures.

Disposition of subjects enrolled will be presented and their number at each visit will be tabulated. The reason for inclusion/exclusion will be tabulated and listed.

3.3 Sample size/Power evaluation

We expect to enrol around 300 patients who respect inclusion/exclusion criteria and are willing to participate to the study. An overall sample size of 300 subjects (of which 150 are expected to be at a low level of self-care monitoring) achieves 80% power at a 0.0500 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 monitoring after a follow-up of 12 months. This power takes into account a possible 20% of lost to follow-up. These assumptions are based on our preliminary data [42, 43] and consider a cut-off defining low and high level of self-care maintenance of 70/100 in a standardised

scale. The study has been sized on self-care monitoring, but similar results could be expected also in self-care maintenance and self-care management.

3.4 Withdrawal

Patients may withdraw from the study at any time at their own request by withdrawing consent, or they may be withdrawn at any time at the discretion of the investigator for safety, behavioural, or administrative reasons. Every effort should be made to contact the patient for the follow-ups. In any circumstance, every effort should be made to document patient outcome, if possible.

4. Study procedures

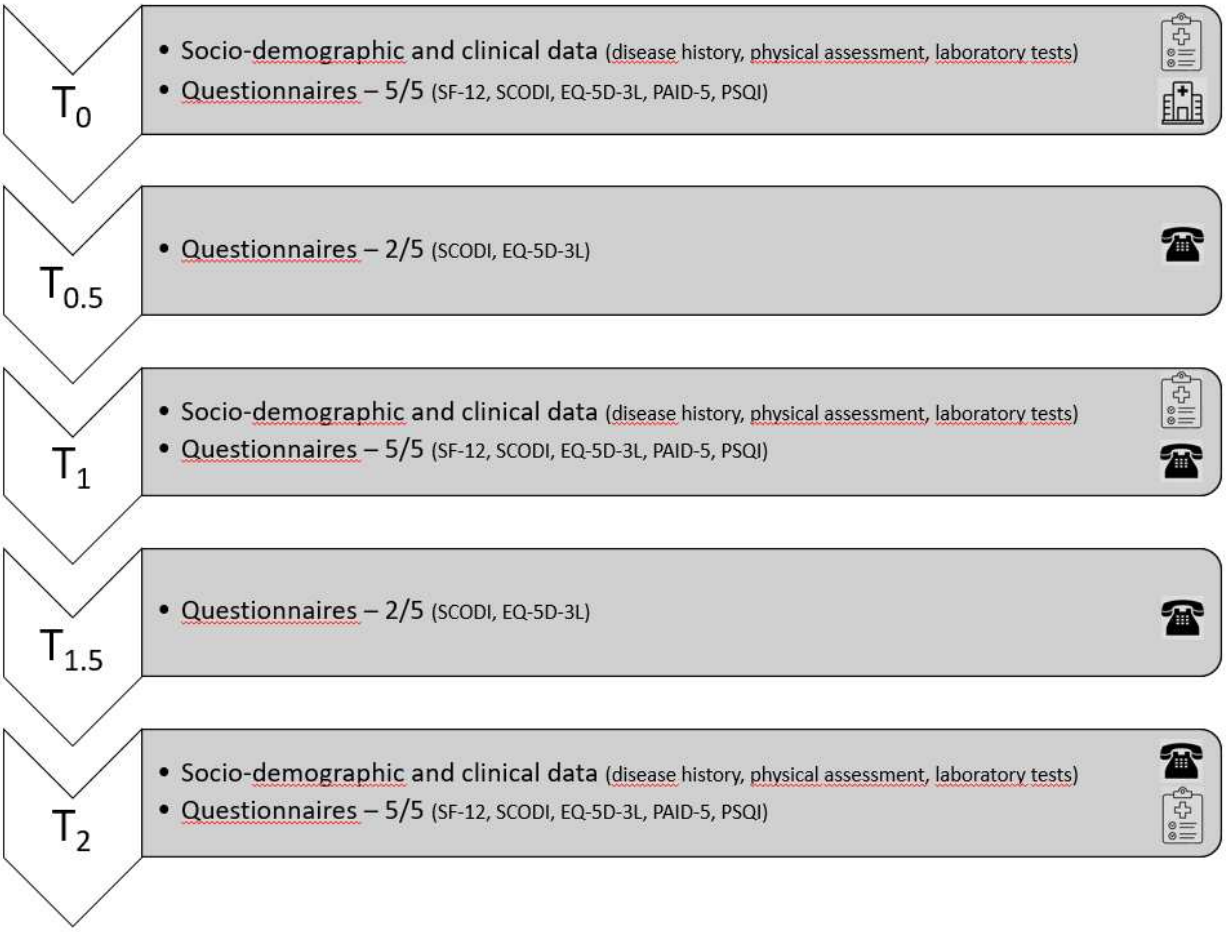
Since the informed consent has been signed, socio-demographic and clinical data will be collected by medical records. At the beginning or at the end of the clinical standard outpatient visit, patients will be asked to complete study questionnaires. For the study procedures details, please refer to the schedule of events (Attachment 1).

5. Data collection

At the baseline (T_0), socio-demographic and clinical data will be collected by medical records. Furthermore, five self-report questionnaires will be administered to participants.. Follow-up data, consisting of the same clinical data and questionnaires, will be collected by telephone at 12 (T_1)and 24 months (T_2). Moreover, intermediate follow-ups at 6 ($T_{0.5}$) and 18 months ($T_{1.5}$) will consist of the telephone administration of only 2 questionnaires. An overview of each timepoint data collection is shown in Figure 1, while the study procedures details are presented in the schedule of events (Attachment 1). For the questionnaires, short forms have been chosen to reduce the number of items and to improve respondent rates and adherence to protocol. All questionnaires were demonstrated to be valid and reliable, and they are widely used in research and clinical practice both at national and international level. Details about study questionnaires are reported below. All data will be recorded in eCRF..

The end of the study will be the date of conclusion of T_2 data collection period, coinciding with 24 months (+ maximum 28 days) from the baseline (T_0).

Figure 1. Data collection in each timepoint of the study



Notes: SF-12= Short Form 12; SCODI= Self-Care of Diabetes Inventory; EQ-5D-3L= EuroQol 5-Dimensions 3 Levels; PAID-5= Problem Areas in Diabetes Questionnaire Short Form; PSQI= Pittsburgh Sleep Quality Index.

5.1. Short Form 12 - SF-12 (Italian, Version 1.0)

This questionnaire is the short version of SF-36 and it has been chosen to evaluate the functional and mental well-being status. It is a validated tool, widely used, therefore it might help in data comparability. It has a 4 week retrospective span and inquires personal and social discomfort,

disabilities and self-description of the level of health perceived. It can be self-administered and it counts 12 items [51].

5.2. Self-care of Diabetes Inventory - SCODI (Italian Version 1.0)

This instrument has been developed by University of Milano-Bicocca and University of Pennsylvania grounded in Riegel Middle-Range Theory of Self-Care of Chronic Illness [6]. It can be self-administered and it counts 40 items. It is valid and reliable [42]. The SCODI questionnaire provides four measures: self-care maintenance, self-care monitoring, self-care management and self-care confidence. Each SCODI scale will provide a standardised 0-100 score. Higher scores mean better self-care.

5.3 EQ-5D-3L (Italian, Version 2)

The EQ-5D-3L is a self-report tool, composed by a 5 items multiple questions section that investigate movement, hygiene, daily living activities tolerance, pain/discomfort and anxiety/depression. A Visual Analogue Scale is included in order to assess a general health status level as perceived by patients [52, 53].

5.4 Problem Areas in Diabetes Questionnaire Short Form - PAID-5 (Italian)

The PAID-5 is composed by 5 items and it can be self-administered. It has satisfactory sensitivity and specificity for recognition of diabetes-related emotional distress. The final score is between 0 and 100 points: a score higher than 40 points has been significantly associated to development of depression and other negative psychological outcomes [54].

5.5 Pittsburgh Sleep Quality Index – PSQI (Italian)

The Pittsburgh Sleep Quality Index is a valid and reliable tool for assessing sleep quality [55, 56]. It comprises 19 items and it is self-administered. It provides a good and reliable differentiation between normal and pathological groups, with higher scores (cut-off 5 and higher) reported by people characterised by more impaired sleep quality [56].

6. Data analysis

Continuous data will be summarised with number of observations, mean value, standard deviation, median, quartiles, minimum, maximum, and 95% confidence intervals for the mean. Categorical data will be summarised by means of absolute and relative frequencies (counts and percentages).

Scores of SCODI's self-care scales will be standardised to 100 [42].

To estimate associations between self-care maintenance, self-care monitoring, and self-care-management 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 (cut-off 70/100) and they will be compared by the log-rank test. The Cox model will be used to account for confounders. A Cox model will be also used to evaluate the impact of the SCODI (as continuous score) on health and clinical outcomes.

Self-care behaviours will be described by a boxplot and their relation with health and clinical outcomes over the whole follow-up will be modelled by longitudinal models.

Multiple linear regression analyses will be performed in order to identify clinical and socio-demographic determinants of self-care.

Explorative and confirmative factor analyses will be used to further evaluate the construct validity of the SCODI. Cronbach Alpha and further inter-item coefficients will be used to measure on a large sample the internal consistency of the tool.

7. Data integrity and quality assurance

7.1 Monitoring and inspections

The monitoring plan will comprise the site initiation visit, monitoring visits and the closure visit at the end of study by the study promoter.

Institutional review board (IRB)/independent ethics committee (IEC) will have complete access to all the study documentation in case of inspection.

7.2 Integrity of data collection

Investigators must enter the information required by the protocol into the electronic Patient Data Collection Forms (eCRFs). Data entry will be a responsibility of the investigational site.

7.3 Data Management

Data Management is a responsibility of the promoter, which will supervise the study as quality control program.

Expert personnel will review the eCRFs for completeness and accuracy. Errors, omissions, or questions will be entered on data query forms, which will be returned to the investigational centre for resolution. After the investigator response is received by the data management centre, the resolutions will be entered into the database. A copy of the signed data query form will be kept with the print-out of the eCRFs by the investigational centre.

Appropriate measures, including encryption of data files containing person identifiable data, will be used to ensure confidentiality of patients' data.

7.4 Study documentation and storage

Data records must be kept for the maximum period permitted by the hospital or institution, and at least 15 years after the end of the study.

The investigator must agree to archive the documentation (this includes both electronic and paper-based records) of the study in an archive after completion or discontinuation of the study, if not otherwise notified.

The deletion process must ensure confidentiality of data and must be done in accordance with local requirements.

7.5 Record keeping

To enable evaluations and/or audits from regulatory authorities, the investigator agrees to keep records, including the identity of all participating patients, their telephone numbers, all original signed informed consent forms, all CRFs, source documents, and adequate documentation of relevant correspondence. The records should be retained by the investigator according to the International Conference on Harmonisation (ICH), local regulations, or as specified in the Study Agreement. The encrypted file of the register containing patients' identities associated with their identification numbers and their telephone numbers will be sent to the promoter by tracked email, in order to allow the promoter to carry out telephone follow-ups. At the end of the telephone follow-ups, the file and the related emails will be destroyed by the promoter.

An electronic database will be created by the promoter and regular backup are assured.

At the end of the study, the database will be locked and a backup copy, saved on a non-rewritable CD, will be stored together with study documentation.

8. Ethical and legal aspects

8.1 Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approval

It is responsibility of the investigator to have prospective approval of the study protocol, protocol amendments, informed consent forms, and other relevant documents, if applicable, from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the investigator file.

The principal investigator agrees to provide the IRB/IEC with all appropriate material, including a copy of the informed consent.

The study will not be initiated until the investigator obtains written approval of the research plan and the informed consent document from the appropriate IRB/IEC.

8.2 Protocol amendments

Every change in this protocol will be considered as an amendment and submitted prospectively to the IRB/IEC for approval.

8.3 Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects [57], ICH Guidelines for Good Clinical Practice (GCP), and the Declaration of Helsinki [58].

8.4 Patient Information and Consent

All parties will ensure protection of patient personal data and will not include patient names on any sponsor forms, reports, publications, or in any other disclosures, except where required by laws. The informed consent form must be in compliance with ICH GCP, local regulatory requirements, and legal requirements.

The informed consent form used in this study, and any changes made during the course of the study, must be prospectively approved by the IRB/IEC before use.

The investigator must ensure that each study patient, or his/her legally acceptable representative, is fully informed about the nature and objectives of the study and possible risks associated with participation. The investigator, or a person designated by the investigator, will obtain written informed consent from each patient before any study-specific activity is performed. The investigator will retain the original of each patient's signed consent form.

8.5 Privacy

Regulatory authorities and/or IEC/IRB may request access to all source documents, data capture records, and other study documentation for one-site audit or inspection. Direct access to these documents must be guaranteed by the investigator, who must provide support at all times for these activities.

Data confidentiality will be maintained in all the phases of the study according to national and international regulation (European Union General Data Protection Regulation 2016/679 and amendments).

The patients' names will be asked by the promoter only for the telephone follow-up, as specified in the paragraph *7.5 Record keeping*. A sequential identification number will be attributed to each patient enrolled in the study and to each centre. This number will identify the patient and must be included on all case report forms. In order to avoid identification errors, date of birth may also be reported on forms.

8.6 Insurance Policy

This is an observational study and patients are followed according to usual clinical practice, with the exception of the completion of questionnaires and the participation of interviews. No specific insurance is required for the study.

8.7 Funding and conflict of interest

No funding are allocated for this study. If a possibility to get funded arise before completion of the study, the project will be submitted for funding and an amendment will be presented to the IEC/IRB.

No conflict of interest to be declared.

9. Publication of Study Results

All data produced are property of study promoters (in the legal person of Professor Davide Ausili – University of Milano-Bicocca) and will be made public after all data have been analysed and the study results are available. Eventual publications using single centre data will be prospectively agreed with the promoter and, in any case study promoters will be involved in the manuscript authorship.

Attachment 1 – Schedule of events

Protocol Activities	**T_0** Baseline	**$T_{0.5}$** Month 6 ± 28 days	**T_1** Month 12 ± 28 days	**$T_{1.5}$** Month 18 ± 28 days	**T_2** 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 by the researcher	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, BMI, blood pressure and pulse rate*	x		x		x
LABORATORY STUDIES					
HbA1c (mmol and %)	x		x		x
Lipidic 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	x	x
Quality of Life (EQ-5D-3L)	x	x	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, hospitalisation, access to emergency care,*	x		x		x

death, received diabetes education in the last year.					

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