Official Title: Effectiveness of a Continuous Care Intervention by the Endocrinology and Nutrition Service in Primary Care to Improve the Control of Type 2 Diabetes Mellitus in Terres de l'Ebre, Catalonia

NCT Number: NCT ID not yet assigned

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Background

Diabetes Mellitus (DM) is a highly prevalent disease and 90% of cases are due to type 2 DM (T2DM) which is largely controlled in primary care (1). Until now, DM control guidelines were very glucose-centric (2). Recent updates recommend a multimorbidity risk control approach (3,4). The complexity of optimizing metabolic control is increasing, requiring multifactorial strategies for reducing cardiovascular risk beyond glucose management. Glycosylated hemoglobin (HbA1c) is the metric used so far in clinical trials that demonstrate the benefits of improved glycemic control and has a strong predictive value for diabetes complications (5,6,7).

Clinical practice guidelines are considered essential tools for planning, evaluating and improving the quality of health services. However, their implementation is a challenge for professionals. A study conducted in Spain demonstrated adherence to the therapeutic recommendations of clinical practice guidelines in patients with obesity, frail patients and with T2DM (9).

There are several factors that interfere with the complex management of T2DM in primary care. Some of the factors are: time, limited resources and clinical inertia on the part of professionals and adherence to treatment on the part of the patient (10).

Different strategies have been used to improve the control of T2DM, and the most notable improvements are observed when baseline HbA1c levels are high, especially above 8%, in diabetic patients. This suggests that interventions should focus on patients with poorer control. Regarding the strategies aimed at professionals and organizations that demonstrated effectiveness, the most efficient were feedback on the information obtained in audits, training of professionals and organizational changes (such as electronic records, clinical reminders and case management, in addition to economic incentives) (8).

Other strategies such as intervention by endocrinologists directed at primary care to improve diabetes management demonstrated that interventions supported by endocrinologists improved therapeutic inertia by achieving improvement in HbA1c (11).

In a study that assessed the impact of training sessions in primary care on subsequent referral to specialized diabetic foot services, a significant increase in the number of referrals to Diabetic Foot Units was observed after each training session, however, at the end of the period a reduction was again observed, indicating the need for periodic updates (12).

Several studies have demonstrated the real benefits of educational programs in DM and it has been found that education not only improves knowledge and decision-making, but also reduces the health and social cost of the disease (13,14).

The aim of the study is to evaluate the effectiveness of a continuity of care intervention led by the Endocrinology Service of the Hospital de Tortosa Verge de la Cinta (HTVC) in primary care, on the metabolic control of T2DM within the healthcare setting of Terres de l'Ebre.

Justification

We know that T2DM is a highly prevalent disease with great difficulty in optimizing metabolic control and it is necessary to implement multifactorial strategies to reduce the risk beyond glucose management. The vast majority of these patients are treated for many years of the evolution of the disease in primary care. We also know that strategies aimed at professionals and organizations have demonstrated effectiveness in improving health outcomes in patients. For this reason, we want to initiate a process of intervention of continuity of care from the Endocrinology Service of the HTVC in the primary care areas in order to improve the metabolic control of these patients.

Hypothesis

Multidisciplinary training on continuity of care, taking into account the perspectives of primary care professionals and delivered by the Endocrinology Service to primary care professionals, will improve the control of T2DM in the healthcare setting of Terres de l'Ebre.

Objective

To evaluate the effectiveness of a continuity of care intervention on the metabolic control of T2DM in the healthcare setting of Terres de l'Ebre, carried out by the HTVC Endocrinology Service in primary care and taking into account the opinion of primary care professionals.

Specific objectives:

From patient:

- Evaluate the percentage of improvement in HbA1c according to the professional's attendance at the training
- Evaluate the improvement of cardiovascular risk factors: cholesterol, blood pressure, smoking and obesity, in relation to attendance at continuity of care sessions
- Evaluate the patient characteristics that are associated with good metabolic control of T2DM patients in the healthcare setting of Terres de l'Ebre.
- Assess adherence to screening for chronic complications associated with T2DM according to the protocol of the Catalan Institute of Health (fundoscopy, microalbuminuria, foot examination: arterial index and peripheral sensitivity).
- Evaluate the association between attendance at diabetic foot training and referrals to the Diabetic Foot Unit.
- Evaluate the association between the degree of improvement in metabolic control and acute metabolic decompensations that have prompted emergency care.

As a professional (doctor or nurse):

- Evaluate the association between professional attendance at training and family medicine hospital referrals.
- Assess the association between professional attendance at training and medication changes.

- Evaluate the association between professional attendance at training and patient attendance at primary care.
- Evaluation of the association between attendance at diabetic foot training and referrals to the Diabetic Foot Unit.

From the qualitative study:

- Evaluate the opinion of the participating professionals before the start of the intervention in order to co -design it and adapt it to their needs.
- Evaluate the opinions and experiences reported by participants in the intervention in order to identify barriers and facilitators for its future implementation.

Materials and methods

Design

A randomized clinical trial of parallel groups will be conducted, randomizing primary care centers or Basic Health Areas (ABS). An ABS contains basic care units (UBA) of family doctors and nurses who attend to the same patients. The study will involve 11 primary care centers in the Terres de l'Ebre area of the Catalan Institute of Health, which has a total of 325 primary care centers. The primary care centers will be randomized by data extractors, using the 1:1 simple randomization method generating random numbers from 0-1. Numbers <0.5 were assigned to control and those >0.5 to intervention. The final result was 5 intervention centers and 6 control centers of the 11 randomized centers. The study will maintain blinding for participating patients, the data manager, the principal investigator, the statistician and the rest of the research team members. However, the primary care professionals who will receive the intervention, the trainers, those responsible for data extraction and the members of the training committee will not be blinded.

The type of analysis will be by intention to treat, in the year of the intervention and according to the patient's characteristics.

All primary care centers of the Catalan Health Institute of Terres de l'Ebre will be eligible to participate in the study. To start the clinical trial, the training and format will be agreed with the Primary Care Directorate and the management will inform the directors of the centers of the start of the study.

Study population

Patients assigned to Catalan Health Institute of Terres de l'Ebre primary care centers with a diagnosis of T2DM.

Inclusion criteria

Inclusion will begin in July 2025 as training sessions begin for professionals (doctors and nurses) of people who in January 2025 have an active diagnosis of T2DM in the eCAP (computerized clinical history of primary care) with a disease evolution time of at least 12 months.

Exclusion Criteria

People diagnosed with any of the following conditions will be excluded:

1. Type 1 DM
2. DM controlled by a specialist at the time of inclusion
3. Treatment with systemic corticosteroids
4. Neoplasms
5. Gestational diabetes
6. Pregnancy
7. Breastfeeding
8. Patients with a MACA diagnosis (life expectancy < 1 year)
9. Complex chronic patients (CCP)
10. Patients with dementia
11. Institutionalized patients
12. Patients admitted to social and health care facilities
13. Patients >90 years old
14. Serious psychiatric illness (psychosis, bipolar disorder, major depression)
15. Kidney transplantation
16. Dialysis
17. History of alcohol and drug abuse

Description of the intervention

A multidisciplinary, continuity of care intervention will be carried out by the Endocrinology Service of HTVC.

This service is made up of 4 endocrinologists and 4 nurses: 3 nurse educators and a nurse referent from the Diabetic Foot Unit. The training will be aimed at family doctors and primary care nurses.

Endocrinologists will provide sessions to family doctors and endocrinology nurses to primary care nurses. They will assess the needs of each center in order to standardize the training provided with the aim that all centers have the same information and training. To provide the training, Endocrinology professionals will travel to the intervention centers, biweekly with a doctor-nurse team between 13:00 and 15:00.

It will begin in July 2025 according to randomization of the primary care centers, the endocrinology professionals will be distributed by intervention teams (doctor/nurse) and will rotate to the ABS; every fortnight each team will go to a different ABS and to the same ABS every 10-12 weeks. There will be a total of 6 session modules and each module will have a theoretical section and one or two practical sections. The modules will be taught correlatively to all the ABS by the teams. In total, 15 sessions per ABS will be held per year.

The intervention period will last 1 year from July 2025 to July 2026.

The results will be evaluated at baseline, prior to the intervention, and at 6, 12 and 24 months after the start of the intervention.

Annex 1. Description of endocrine sessions for family doctors.

The training by the medical team will be structured into a total of 6 Modules, each of which will have a theoretical section and one or two practical sections.

Annex 2. Description of the sessions for nurse educators for primary school nurses.

Nursing training will be structured into 6 modules where each module will have a theoretical section and one or two practical sections.

Annex 3. Description of the nursing sessions of the Diabetic Foot Unit.

The nurse from the Diabetic Foot Unit will conduct guided and structured sessions on diabetic foot screening and control.

The trainers will deliver the sessions to all centers in a homogeneous manner, guaranteeing the same number of sessions per professional and center.

Study variables

Result variable:

1. HbA1C

Definition: HbA1C is an analytical value that reflects the average glycemia over approximately 3 months. It is the main tool for assessing glycemic control and has a strong predictive value for complications of DM (5,6,7).

Control levels: Numerous factors must be taken into account when establishing glycemic goals. The American Diabetes Association (ADA) suggests general goals, but emphasizes the importance of individualization based on key patient characteristics. The general goal is to obtain an HbA1c < 7% but more stringent goals may be recommended if they can be achieved safely and with an acceptable therapy burden and if life expectancy is sufficient to obtain the benefits of stringent goals. Less stringent goals (A1C up to 8%) may be recommended if the patient's life expectancy is such that the benefits of an intensive goal cannot be achieved, or if the risks and burdens outweigh the potential benefits (4).

Other variables:

1. Patient variables:
   1.1 Sociodemographic: sex, date of birth, region of origin or nationality (eCAP)
   1.2 Date of diagnosis of T2DM
   1.3 Personal morbidities or background (diagnoses):
   - Hypertension, date of diagnosis
   - Dyslipidemia, date of diagnosis
   - Obesity, date of diagnosis
   - Chronic renal failure, date of diagnosis
   - Heart failure, date of diagnosis
   - Ischemic heart disease, date of diagnosis
   - Peripheral arteriopathy, date of diagnosis

- Diabetic nephropathy, date of diagnosis
- Diabetic foot, date of diagnosis
- Retinopathy, date of diagnosis
- Ischemic stroke, date of diagnosis
- Undetermined stroke, date of diagnosis
- Intracranial hemorrhage, date of diagnosis

1.4 Toxic Habits:

- Smoker, date of diagnosis, date of discharge
- Alcohol, date of diagnosis, date of discharge

1.5 Clinical variables:

- Weight, date
- BMI, date
- Total cholesterol, date
- HDL cholesterol, date
- LDL cholesterol, date
- Triglycerides, date
- Systolic blood pressure, date
- Diastolic blood pressure, date
- Foot check, date
- Retinopathy review, date
- Electrocardiogram, date
- Capillary basal blood glucose, date
- Blood glucose control standard monitoring device, date
- Intensive blood glucose control device, date

1.6 Laboratory variables:

- Venous basal glycemia
- HbA1c
- Total cholesterol
- LDL cholesterol
- HDL cholesterol
- Triglycerides
- Creatinine
- Glomerular filtration
- Urine albumin/creatinine ratio
- Liver function: GOT, GPT, GGT, FA

1.7 Presence of chronic complications:

- Micro-angiopathic diseases: retinopathy, nephropathy, diabetic neuropathy
- Macro-angiopathic diseases: ischemic heart disease, stroke, peripheral vascular disease and heart failure, diabetic foot

1.8 Episodes of severe hypoglycemia:

- eCAP diagnostic hypoglycemia, date
- Capillary glycemia value, date
- Number of emergency room visits diagnosis of hypoglycemia, date

1.9 Diabetes treatments:

- Sulfonylureas

- Biguanides
- Glinides
- Thiazolidinediones
- Insulin
- Glucosurics or ISGLT2
- GLP1 receptor agonists
- Dpp4 inhibitors
- Trizepatide

1.10 Situational complexity variables:
- Home care
- Complex chronic patient
- Advanced chronic illness

1.11 Frequency variables:
- No. of hospital admissions in the last year, date, reason ICD10
- No. Emergency room visits in the last year, date, reason ICD10
- No. Hospital outpatient visits (service description), service, date
- No. of visits to primary care doctor
- No. of primary school nurse visits
- Primary care professional variables (doctor/nurse)
- Family doctor (number of sessions attended)
- Primary nurse (number of sessions attended)

2. Professional variables:
   2.1 Professional category: Doctor or nurse
   2.2 Attendance at care continuity sessions
3. Primary care center variables
   3.1 MEDEA sociocultural deprivation index
   3.2 AQUAS deprivation index

Sources of the data

The study variables will be collected in a pseudo-anonymized form from the Technical Secretariat of the Territorial Management of Terres de l'Ebre and will be obtained from the eCAP.

Training attendance data will be sent from ABS to Training Unit to Technical Secretariat.

Sample size

To detect an improvement of 0.5% in HbA1c with a variance of 1, in independent samples with an alpha of 0.05 and a power of 90% considering a 20% loss during follow-up 105 per group, 210 in total.

Statistical analysis

To detect statistically significant differences between the control and intervention groups, the Z test for differences in proportions will be performed on categorical variables and the non-parametric Mann Whitney U test for continuous variables.

To detect statistically significant differences between the control group and the intervention group, the Z test of differences in proportions will be performed. The measurement of the effect of the intervention will be studied with Cohen's d for the outcome variable (small effect d <0.5, large effect d>0.8) and confidence intervals will be calculated.

To quantify the association, generalized linear models will be calculated.

The statistical significance level will be set at 5% and statistical analyses will be performed with R v.4.0.2 (Vienna, Austria).

Qualitative study

Population and area of study

Family doctors and nurses from the Primary Care of the Catalan Health Institute of Terres de l'Ebre who belong to the intervention ABS.

The intervention ABS will be known after randomization. Two focus groups will be held pre and post intervention in two phases:

1. **Pre-intervention methodology:** 2 focus groups of professionals, doctors and nurses, will be carried out in 2 intervention ABS**.** Qualitative analysis of the focus groups will be carried out and the results will be applied to the design of the intervention to adapt it to the preferences of the primary care professional.
2. **Post-intervention qualitative methodology:** 2 focus groups of professionals, doctors and nurses, will be carried out in 2 ABS intervention after the intervention**.** Qualitative analysis of the focus groups will be carried out and the results will be applied to evaluate the acceptability of the intervention and the feasibility of its implementation.

Study design: Descriptive qualitative research that is framed within the socio - constructionist perspective (15).

Participant selection: The selection unit will be the ABS, which belongs to the intervention group assigned after randomization. These ABS will be selected for convenience and it will be taken into account that at least one basic area is rural, to have rural and urban representation. 2 focus groups will be held in 2 pre- and post-intervention intervention ABS. The professionals (doctors and nurses) of the selected intervention ABS will receive an email, inviting them to participate in the focus group. Mixed groups of doctors and nurses will be selected, from among the professionals who respond to the email and declare interest in participating. They will be selected in chronological order of response to the email. A waiting list will be created in chronological order of response in case there are resignations or no-shows on the day of the session.

Data collection: Between 6-12 professionals will be selected. The focus groups will follow a topic script (Annex 4 and 5). At the beginning of the session, the objectives of the study will be explained, and the information sheets will be given to the participant (Annex 6), later the voice recording authorization sheets (Annex 7) and informed

consent signatures will be collected (Annex 8).

The group's activities will be audio recorded, with the informed consent of the participants, and will be transcribed verbatim, anonymizing the informants' identifying data in the transcriptions.

Qualitative data analysis: The textual corpus will include the focus group transcripts and field notes. After successive readings of the single textual corpus and the formulation of pre- analytic intuitions, interpretative thematic content analyses will be carried out, which will be triangulated between different members of the research team. The meaning will be interpreted and an explanatory framework will be created with the contributions of the professionals.

Confidentiality of professional and patient data

The training will follow a structured program and validated by the Training Unit of the Territorial Management of Terres de l'Ebre in order to be able to accredit the hours of attendance at the training program of the professionals, as is done in usual practice. Each center management will send the minutes to the Training Unit as is usually done with in-service training.

The Training Unit will transfer the attendance records of each ABS, of the professionals and they will be transferred to the technical secretariat.

The technical secretariat will cross-check the identified data of primary care professionals (doctors and nurses) with the patients in each UBA who meet the inclusion criteria.

Anonymized database with an anonymous professional identifier and an anonymous identifier of patients assigned to each UBA that meet inclusion criteria, from the ABS also anonymized from the Territorial Management of the Catalan Health Institute of Terres de l'Ebre.

The data of primary care professionals will only be for attendance at each session, without sociodemographic data of professionals to prevent their identification.

In the case of the qualitative study, a professional external to the team will carry out the transcription and pseudo-anonymization.

Data protection

<u>Identification of the data and the subjects who will process them</u>

- The project processes personal data: Yes
- What data is processed: Records of attendance at training sessions, of patients from the eCAP and qualitative data from focus groups.
- Who processes them: The technical secretariat of the Catalan Health Institute, Territorial Management of Terres de l'Ebre, will be responsible for the processing. In the case of the qualitative study, a professional external to the team will carry out the transcription (see annex 9, confidentiality and non-disclosure agreement)

- Communications: The project database will be hosted on the servers of the Catalan Health Institute, Territorial Management of Terres de l'Ebre, which will act as data controller.

Legitimacy basis for processing the data and the origin of the data

- Is it planned to request consent from the patient (and professional) for the processing of their data for research purposes? Yes
- Legitimating basis for data processing: The data necessary to carry out the effectiveness study will not be identifiable by the research team. The data necessary to carry out the qualitative study will be obtained from the professionals participating in the project through their consent, in accordance with the provisions of articles 6.1.a) and 9.2.a) of the GDPR.
- Source of data: training attendance records, eCAP, verbatim transcripts of focus groups.

Data processing

- Tools used: Will electronic devices be used? No
- Where is the server located? The project data will be stored on servers at the institution (Catalan Health Institute, Territorial Management of Terres de l'Ebre).
- Are databases shared electronically with other centers or researchers used? No
- Description of security measures: Indication of measures to prevent undue access by unauthorized third parties: Each center management will send the minutes to the training unit as is usually done with in-service training. The Training Unit will transfer the attendance records of each ABS, of the professionals and they will be transferred to the technical secretariat. The technical secretariat will cross-reference the identified data of the primary care professional (doctor and nurse) with the patients of each UBA. The researchers will receive an anonymized database with an anonymous identifier of the professional and anonymous of the patients assigned to each UBA that meet the inclusion criteria, of the ABS also anonymized from the Territorial Management of the Catalan Health Institute of Terres de l'Ebre. The primary care professional data will only be for attendance at each session, without sociodemographic data of professionals to prevent their identification. Regarding the qualitative study, a confidentiality and non-disclosure contract will be signed with an external professional (in charge of data processing) (Annex 9).

International data transfers

- No international data transfer will take place.

Identification of treatments that may pose a high risk to the rights and freedoms of participants in the research project

- This project does not foresee advanced use of data. In accordance with the provisions of Article 35 of the GDPR, the project does not meet the necessary characteristics that require the performance of an impact assessment.

Work plan

Timetable

January - December 2024

- Final drafting of the study protocol
- Inform and agree with Primary Care Management on training
- Prepare training: program, content and teachers coordination with Training Unit
- Informative email to all Training referents of each ABS of the Territorial Management of Terres de l'Ebre (GTTE).
- Informative email to all ABS GTTE Directors.
- CEIM IISPV September 2024
- Calendar and contents and dates for training references and ABS directors of the GTTE.
- Scheduling training dates
- Verify the correct functioning of the attendance circuit at the ABS training reference sessions ---GTTE Training Unit ---Technical Secretariat
- Evaluate feasibility with technical secretariat
- Randomization
- Qualitative methodology preparation of focus groups

July 2025

- Pre-intervention focus groups
- Transcription of focus groups
- Content analysis of focus groups
- Planning session content based on focus group results
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection for training unit training references of each ABS
- Teacher feedback sessions regarding training
- Preparation of data extraction protocol for technical secretariat

August - September 2025

- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS
- Preparation of data extraction protocol for technical secretariat
- Teacher feedback sessions regarding training

October 2025

- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS
- Preparation of data extraction protocol for technical secretariat

November 2025

- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

- Preparation of data extraction protocol for technical secretariat

December 2025
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

January 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

February 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

March 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

April 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

May 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection training unit training references of each ABS

June 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Follow-up and reminder (without access to data) of collection of signatures for training unit training references of each ABS

July 2026
- Email reminder to ABS addresses and training center references
- Fortnightly training sessions and continuity of care
- Monitoring and reminder (without access to data) of signature collection for training unit training references of each ABS

August - September 2026
- Post-intervention focus groups
- Transcription of focus groups

- Content analysis of focus groups
- Qualitative analysis of focus groups.

October 2026

- First extraction with data extraction protocol application for technical secretariat **(Baseline data, 6 and 12 months from the start of the intervention)**

July 2025 --- January 2026 --- July 2026

- Validate variables
- Data cleaning
- Creating variables
- Data manager process

July 2026 --- July 2027

- First extraction with data extraction protocol application for technical secretariat **(Data 24 months from the start of the intervention)**
- Validate variables
- Data cleaning
- Creating variables
- Data manager process
- Statistical analysis
- Interpretation of results
- Scientific article writing
- Publication

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Annexes

Annex 1. Description of Endocrinologist sessions for family doctors

MODULE 1:

1.1. Module 1 - Theoretical

- Update of clinical practice guidelines in the management of patients with T2DM

1.2. Module 1 - Practical

- Presentation of practical cases by Endocrinologists
- Presentation of practical cases by family doctors

In this module, real/theoretical clinical cases will be discussed in order to improve the management of T2DM.

MODULE 2:

2.1. Module 2 - Theoretical: Oral Drugs

- The drugs available for the treatment of type 2 diabetes will be presented

2.2. Module 2 - Practical 1

2.3. Module 2 - Practical 2

- Real clinical cases of patients with monotherapy, bitherapy, and triple therapy will be discussed. The best drug combinations will be explored according to the patient's comorbidities and current clinical practice guidelines.

MODULE 3:

3.1. Module 3 - Theoretical: Insulinization

- Explanation of who, when and how to inject insulin
- Combination of oral drugs and insulin
- Type of insulin

3.2. Module 3 - Practical 1

3.3. Module 3 - Practical 2

- Real clinical cases of patients with indications for insulinization will be discussed, including how to modify drugs associated with insulin and according to comorbidities.

MODULE 4:

4.1. Module 4 - Theoretical: Screening for chronic complications

- How to screen for chronic complications and timeline
- Microangiopathic complications
- Macroangiopathic complications

4.2. Module 4 - Practical 1

4.3. Module 4 - Practical 2

- Real clinical cases of patients will be discussed on how to perform analytical monitoring and screening for chronic complications, as well as the management of chronic complications, especially microangiopathic complications.

MODULE 5:

5.1. Module 5 - Theoretical: Cardiovascular risk factors

- Define BP control goals and how to treat
- Define dyslipidemia control goals according to cardiovascular risk and how to treat it
- Define obesity control goals and how to approach them

5.2. Module 5 practical 1.

- Real clinical cases of patients with cardiovascular risk factors will be discussed to examine their approach to achieve global control of all cardiovascular risk factors.

MODULE 6:

6.1. Module 6 – Theoretical: Special situations

- How to act in patients undergoing treatment with corticosteroids
- How to act in patients with hyperglycemia > 300 mg/dl at onset
- How to act in patients with chronic renal failure who start dialysis
- Criteria for referring patients with T2DM to Endocrinology

6.2. Module 6 - Practical 1

- Real clinical cases of patients with different special situations will be discussed to explore the most appropriate management in each case.

Annex 2. Description of the sessions for nurse educators for primary school nurses

MODULE 1:

1.1. Module 1 - Theoretical: Structuring Diabetes Education

- Basic diabetes education program at the beginning of DM
- Individual diabetes education

1.2. Module 1 – Practical

- Tools will be provided for structuring diabetes education for diabetic patients
- Clinical cases will be discussed

MODULE 2:

2.1. Module 2 - Theoretical: Hygienic and dietary habits

- Healthy lifestyle habits
- Healthy diet patterns
- Strategies for quantifying carbohydrates: plate diet, measuring cup, exchanges...

2.2. Module 2 - Practical

- Each patient's treatment regimen

MODULE 3:

3.1. Module 3 - Theoretical: Insulinization

- Definition of the initial basic education of the patient who initiates insulinization
- Insulin in bolus-basal pattern
- How to adjust basal and multi-dose insulin. Basic concepts

3.2. Module 3 - Practical

- Clinical cases will be discussed to adjust insulin regimens and how to adjust the diet according to each regimen.

MODULE 4:

4.1. Module 4 - Theoretical: Technology

- Download glucometers and sensors
- How to visualize the data and adjust the treatment regimen

4.2. Module 4 - Practical

- Clinical cases will be discussed in which data has been downloaded from glucometers and/or sensors to assess what adjustments nursing can make.

MODULE 5:

5.1. Module 5 - Theoretical: Acute decompensation of diabetes

- Hypoglycemia: clinical, identification and resolution
- Hyperglycemia: clinical and resolution
- Lipodystrophies

5.2. Module 5 - Practical

- Discussion of practical cases on how to resolve hypo- and hyperglycemia and how to manage lipodystrophies.

MODULE 6:

6.1. Module 5 - Theoretical: Group diabetes education

- Description of a group education program

Annex 3. Description of the nursing sessions of the Diabetic Foot Unit

Module 1: Diabetic foot syndrome

- Definition and epidemiology
- Pathophysiology
- Neuropathic and vascular exploration
- Risk classification

Module 2:

- Clinical manifestations: neuropathic, neuro-ischemic and ischemic diabetic foot ulcer
- Derivation criteria: Algorithm

Module 3:

- Key points in the approach to the neuropathic foot
- Key points in the approach to the ischemic foot
- Provisional downloads
- Health education and foot care for diabetic patients

Module 4:

- Key messages from previous sessions
- Presentation of doubts from previous sessions
- Comment on clinical cases

NOTE: This is the theme defined to be taught to the different ABS but it will be adapted to the needs and pace of each center with the intention of making the training as homogeneous as possible for all ABS and that everyone has the same training at the end of the intervention.

Annex 4. Topic script for the PRE-INTERVENTION focus group

Previous information:

Endocrine doctors and nurses want to come to primary care to hold joint sessions with primary care doctors and nurses to improve the control of type 2 diabetics.

1. **Usefulness** of an Endocrinology continuity of care intervention in Primary Care. (Continuity of care intervention: that endocrinologists and endocrine nurses come to primary care centers to share patients and doubts)
2. **Limitations and barriers** of an Endocrinology continuity of care intervention in Primary Care
3. **Best format** for an Endocrinology continuity of care intervention in Primary Care
4. **Applicability** of an Endocrinology continuity of care intervention in Primary Care

Questions:

1. What is your vision of the **control** of type 2 diabetic patients in our territory, taking into account the approach taken between hospital and primary care?

If it doesn't come out before:

2. What are the positive aspects that facilitate the control of type 2 diabetics in our territory?

3. What are the negative aspects of controlling type 2 diabetes in our territory?

4. In what aspects could the control of these patients be improved?

5. What do you think about primary and hospital professionals working more collaboratively to improve the control of type 2 diabetics? Find out the advantages and disadvantages.

6. What does a collaborative model with these characteristics look like: “Hospital professionals will come to primary care and share difficult-to-control patients to share experience between primary care and hospital care. All participants will contribute experiences to improve the control of type 2 diabetes.

7. How would you like this collaborative model to be? Find out time, format, place…

Annex 5. Topic script for the POST-INTERVENTION focus group

1. **Usefulness** of the Endocrinology continuity of care intervention in Primary Care. (Continuity of care intervention: that endocrinologists and endocrine nurses come to primary care centers to share patients and doubts)
2. **Facilitators and barriers** to the Endocrinology continuity of care intervention in Primary Care
3. **Best format** for the Endocrinology continuity of care intervention in Primary Care
4. **Applicability** of the Endocrinology continuity of care intervention in Primary Care

Questions:

1. How would you describe your experience in this new program to improve the control of type 2 diabetic patients that has been carried out between hospital and primary care?

If it doesn't come out before:

2. What are the positive aspects of this new program?

3. What are the negative aspects of this new program?

4. In what aspects could this new program be improved?

5. What did you think of the continuity of care program that was designed jointly between the hospital and primary school? Would you change any specific aspect?

6. Would you recommend this new model to other territories?

Annex 6. Participant information sheet

Project title: Effectiveness of a continuity of care intervention of the Endocrinology and Nutrition Service in primary care to improve the control of type 2 Diabetes Mellitus in Terres de l'Ebre, Catalonia.

Objectives of the study and importance of your participation

This project aims to evaluate the effectiveness of a continuity of care intervention on the metabolic control of type 2 diabetes mellitus in the healthcare setting of Terres de l'Ebre, carried out by the Endocrinology Service of the Tortosa Verge de la Cinta Hospital (HTVC) in primary care and taking into account the opinion of primary care professionals.

The qualitative study of this project is designed, on the one hand, to co -design the intervention with the participating professionals in order to adapt it to their realities and, on the other hand, to know (at the end of the intervention) the opinion of the participating professionals, to evaluate the acceptability and feasibility of the intervention for its future implementation.

We request your participation in a discussion group to hear your opinion. This participation will be essential to detect areas for improvement and to be able to adjust the format of this intervention.

Implication of your participation

This research project requires your participation in a focus group that can last between 45 and 60 minutes. Your participation can be before or after the intervention. The focus group will take place in a primary care center in Terres de l'Ebre.

Voluntary participation

Your participation is completely voluntary and you may withdraw from the focus group at any time and without giving any reason. Withdrawing from the focus group will not negatively impact your participation in the intervention phase of the project.

Procedures

The focus group will be audio and video recorded and the participants' speeches will be literally transcribed by a professional external to the team who will sign a confidentiality agreement. The documents generated will be stored in a coded file that does not allow the participants to be identified. The information obtained is confidential and only the external professional and the research team will have access to the recordings, which will be deleted after 6 months.

Informed consent, confidentiality and anonymity.

In order to analyze the content of the discussion group, it is essential to record the session. For this reason, we request the participants' permission to do so. The entire

research team is committed to carrying out the process of data collection, analysis and preparation of the results confidentially and anonymously. The confidentiality of the data of the subjects included in the study will be guaranteed in accordance with the provisions of the " Ley Orgànica de protección de datos de característica personal" (3/2018 of December 5, LOPD) and in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27 on Data Protection (RGPD). The data that will be collected will be identified with a code for the study, so no information that could identify the participant will be included, and only the principal investigator of the study or the collaborating researchers will be able to work with their data. Thus, your identity will not be revealed to any other person, except if required by a health authority or in the event of a medical emergency.

Benefits and risks derived from your participation

You can benefit from the results obtained in this study since the information analyzed will allow you to improve the continuity of care intervention in which you will actively participate. There are no risks derived from your participation in this study.

Use and dissemination of results

The information obtained will be analyzed by the research team and the results will subsequently be disseminated at conferences or seminars and published in scientific journals. Participants will receive a summary of the discussion group before publication. The results will be published anonymously.

Who do I contact if I have questions or a problem arises?

If you need information or if any event arises during the study, you can contact the principal investigator of the study: Marcel·la Miret tel . 680978629 mmiretl.ebre.ics@gencat.cat

The participant has the right to submit a complaint to the Data Protection Delegate, at dpd@ticsalutsocial.cat, in case of perceived vulnerability of their right to data protection.

Therefore, by signing the informed consent, you agree to participate in this program under the conditions previously indicated.

Annex 7. Transfer of voice and image rights

Project title: Effectiveness of a continuity of care intervention of the Endocrinology and Nutrition Service in primary care to improve the control of type 2 Diabetes Mellitus in Terres de l'Ebre, Catalonia.

Name _____

Surname_____

DNI/NIE_____

I authorize the research team of the project "Effectiveness of a continuity of care intervention of the Endocrinology and Nutrition Service in primary care to improve the control of type 2 Diabetes Mellitus in Terres de l'Ebre, Catalonia" to record my voice and image during the conduct of this focus group.

This authorization implies a commitment not to transfer the recording to any company, not to use it for commercial purposes and to use it strictly for this study. This recording will be saved on a hard drive to which only the principal investigator of the project has access and will be deleted after 6 months when the transcription and analysis of the data have been completed.

Signature:

Place:

Date:

Annex 8. Informed consent

Project title: Effectiveness of a continuity of care intervention of the Endocrinology and Nutrition Service in primary care to improve the control of type 2 Diabetes Mellitus in Terres de l'Ebre, Catalonia.

I, (name and surname)

I have read the participant information sheet that I have been given.

I was able to ask questions about the study.

I have received sufficient information from the study.

I spoke with (name and surname of the researcher):

I understand that my participation is voluntary.

I understand that I can withdraw from the study at any time and without giving any explanation.

In accordance with the provisions of the Personal Data Protection Law (03/2018 of December 5 , LOPD), and in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27 on Data Protection (RGPD) and the national implementing regulations, I declare to have been informed of my rights, the purpose of the study with my data and the recipients of the information.

I freely give my consent to participate in the study.

Participant's name and surname

Participant's signature

Annex 9.

CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

On the one hand, _____, with ID _____ as *Principal Investigator* of the "Effectiveness of one continuity intervention Service assistance of Endocrinology and Nutrition in attention primary to improve the control of Diabetes Mellitus type 2 to Terres de l'Ebre, Catalonia" (approved by the Committee Ethical of Clinical Research of IDIAP Jordi Gol, with code _____), and

On the other hand, Mr. _____, with DNI/NIE _____ and address at _____, CP _____, Town _____, Country _____, in his own name and in his capacity as independent collaborator and data processor,

THEY DEMONSTRATE

_____ (*IP*) and _____ (*data processor*) are interested in collaborating in the transcription of *focus groups* carried out within the framework of the project mentioned above and acknowledge:

a. that in the course of such transcriptions _____ will occasionally have access to certain information relating to or belonging to participants who have signed an informed consent in which they were guaranteed the confidentiality of such information;
b. That such information, unless otherwise indicated, is in all cases of a secret and confidential nature and must be treated as such;
c. that the transmission of such information and/or documentation to third parties, as well as its disclosure, could harm the development of the research activity and place the person responsible in a situation of non-compliance with non-disclosure obligations that, in turn, he has assumed towards third parties;
d. that the aforementioned information and/or documentation are, in any case, the property of the research team or of those third parties who, in turn, have transmitted or transferred that information;
e. that _____ receives the aforementioned information and/or documentation as a mere transcriber of the interviews; and that, consequently, it has no rights of use or exploitation, regardless of their nature.

III. On the previous premises

D._____ is obliged:

- To maintain absolute confidentiality regarding any and all information received in accordance with the provisions herein; and not to transmit or disclose such information and/or documents to third parties except with the exclusive prior

written consent of the project's principal investigator, who reserves the right not to authorize the transfer of such information and/or documents. If the researcher authorizes the transfer of such information and/or documentation, _____ will be responsible for ensuring that the final assignees are aware of the terms of this agreement and also sign it.

- To use said information and/or documents solely for the purpose for which the collaboration is established (i.e., for transcription). Consequently, you agree not to use the information and documents for your own benefit or for the benefit of third parties.

- To keep such information and/or documentation in a secure location with restricted access to persons authorized to examine them.

- To return or delete any documentation, publication, material, or background information supported by any type of medium that constitutes confidential or secret information, as soon as the researcher requests it or once the requested transcriptions have been completed.

- To compensate the transmitting entity for any damages that may have been caused, both to the researcher himself or herself and to third parties who have entrusted confidential data, as a result of the breach of any of the obligations provided in this document.

- In the event of any dispute regarding any of the obligations set forth herein, the parties to this document shall be subject to Spanish law and, expressly waiving any other jurisdiction that may apply, to the Courts and Tribunals of the City of Barcelona.

The foregoing obligations will enter into force on the date of signature of this commitment and will remain in force during the development of the transcripts referred to in this statement; and, even after its completion, for two years thereafter.

And as proof of compliance with the foregoing, the declarant signs this document in Barcelona, on __ of ____ of 20__.

SIGNED:

*A photocopy of your ID or passport must be attached to this confidentiality document.