FORAIDMUCO : Pilot implementation of shared decision making in the treatment of diabetes in adult patients with cystic fibrosis: a mixed comparative evaluation of a training program dedicated to cystic fibrosis reference centers

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Abstract

Background: Diabetes affects half of cystic fibrosis (CF) patients aged 30 years and older. It progresses asymptomatically over a long period of time. Two treatment options are possible: start insulin now with the additional constraints of cystic fibrosis or wait while monitoring the patient's clinical condition and start insulin when symptoms develop and therefore later. This situation is particularly well suited to shared decision-making (SDM) between physician (healthcare team) and patient/relatives.

Objective: To conduct a qualitative analysis of the outcomes and experience of the implementation of SDM between physician/healthcare team and patient/relatives for CF related diabetes.

Methods: Three CF reference centres (CFRCs) will be trained in SDM using an online training including a validated decision aid and a live coaching for physicians and the medical team. Two control CFRCs will maintain their usual practices. A comparative here and elsewhere multicentric quasi-experimental study comparing the populations of the 2 groups will be realized. A qualitative analysis through observation of consultations, individual semi-structured interviews with patients and focus groups in CFRCs will be conducted. Questionnaires related to decision-making and experience of decision-making with and without SDM implementation will be administered to patients and physicians.

Results: Forty patients will be included (8 patients in each centre), i.e. 60 consultation observations (2 consultations per patient in the intervention groups given the modalities of the SDM process). Eight focus groups will be conducted in the 5 centres (2 groups in each intervention CFRC and one group in each control CFRC). This qualitative corpus plus responses to the patient and physician questionnaires will make it possible to know whether the practice of SDM in the CFRCs is increased by an implementation strategy and to analyze the experience of patients and caregivers regarding decision-making modalities.
Analysis of the outcomes and experience of the implementation of SDM are of importance to identify facilitators and barriers to SDM from patients' and CFRCs point of views.

Conclusions: Our study will give us keys to adapt, improve and disseminate more widely SDM. SDM could thus be used in routine clinical practice in CFRCs at the national level. Clinical Trial: NCT04891159 – May 18, 2021

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Contributions to the literature

- First study protocol in France in cystic fibrosis designed to *train* healthcare professionals to shared decision-making (SDM), *implement* and *evaluate* the outcomes of the approach
- Training material and healthcare professionals trained in SDM could boost the implementation of the approach in cystic fibrosis in French-speaking countries where so called clinical champions in SDM are needed
- Patients experiencing SDM could also support the approach and participate to the SDM acculturation process.

Background

Many patients want to play an active role in their own care [1], and many healthcare professionals want the same for their patients [2]. Shared decision-making (SDM) in the physician-patient encounter is one way of meeting this wish. In SDM, ‘‘the information exchange is two ways [...]. The defining characteristic of deliberation [...] is its interactional nature’’ (i.e., between the physician and the patient or potential others), and ‘‘both parties work towards reaching an agreement and both parties have an investment in the ultimate decision made’’ [3].
SDM often relies on information and decision support tools (decision aids), which provide written support for exchanges. These are increasingly digitalized and adapted to patients' health literacy levels [4]. They present management options with their benefits and risks, informing patients and enabling them to participate in the decision-making process if they wish so. They can be used both during and outside the consultation.

For several years now, national and international healthcare policies have been encouraging the implementation of SDM for reasons ranging from ethical imperatives [5] to the reduction of unjustified variations in clinical practice [6]. However, despite the legal framework encouraging SDM in several countries (France [7], Germany [8], UK [9], USA [10]), the implementation of SDM in clinical practice is not yet widespread [11].
SDM research has focused on physician- or patient-mediated interventions to promote SDM [12]. Légaré *et al* (2014) in their Cochrane review [13] showed that a combination of both physician- and patient-mediated interventions is more likely to be successful. With regard to physician-mediated interventions, SDM training can teach healthcare professionals to involve patients in the decision-making process. A number of studies have shown the positive effects of training programs, such as improving physicians' SDM skills and increasing patient participation and satisfaction [14-15]. Joseph-Williams *et al* [16] in their systematic review also showed that patients want to be informed so that they can play an active role in decision-making. Patient-initiated interventions can also enhance the patient's ability to participate in the decision-making process. Patients who have learned to use tools that encourage them to ask questions to healthcare professionals participate more actively [17-18]. Finally, decision aids are a means of increasing SDM. The Cochrane systematic review by Stacey *et al* [4] based on 105 randomized controlled trials showed the beneficial effects of decision aids in improving doctor-patient communication (without increasing patient anxiety), improving patient knowledge, respecting patient rights, physician and patient satisfaction, improving the quality of care as well as reducing decision-making conflict.
In 2017, we developed a decision aid based on the Ottawa Personal Decision Aid Guide [29] and the IPDAS Collaboration criteria [33], on the theme of cystic fibrosis diabetes treatment. Psychometric tests carried out at the Cystic Fibrosis Reference Center (CFRC) in Lyon showed that the tool was valid and reliable [30].

In recent years, initiatives have been developing to implement SDM in routine clinical practice. Elwyn *et al* [19] in their systematic review of studies of decision support interventions conclude that the majority of studies do not base their design on an implementation theory or model. While this review focused on the routine implementation of decision support interventions to promote SDM, there are other strategies for implementing SDM. For example, a large-scale, multi-component SDM implementation program involving training of healthcare professionals in SDM and decision aids has been carried out within the NHS in the UK (MAGIC Making Good Decisions in Collaboration

Program). It showed that successful implementation of SDM in routine clinical practice (primary care, urology, obstetrics, oncology) was based on taking into account stakeholder attitudes, involving all stakeholders at an early stage and analyzing barriers and facilitators [20]. Such an approach is in line with the recommendations for implementation research developed by Grol and Grimshaw [21].

SDM seemed to us particularly relevant in cystic fibrosis, where there are complex treatment options with variable short, medium and long-term side effects, and where the disease and its treatments have a high impact on the patient's quality of life. This genetic disease affects almost 7,000 people in France [22], and requires lifelong multidisciplinary care. From the moment of diagnosis, patients are regularly monitored in CFRCs. As a result, the doctor, the multidisciplinary team and the patient/relatives have often known each other for a long time, forging a strong relationship based on mutual understanding and confidence.
Patients' quality of life is severely impaired by pulmonary exacerbations and regular digestive disorders. The patient's care load is considerable, combining daily respiratory physiotherapy, daily aerosol therapy and multi-daily drug treatments. The social constraints (follow-up appointments every 3 months, daily medication intake, diet) associated with the disease and its treatment are considerable [23]. In addition, complications arise during the course of the disease, as in the case of diabetes. After the age of 30, half of all patients develop diabetes [24-25]. Diabetes adds significant morbidity [25-26]. Cystic fibrosis diabetes is quite specific, differing from type 1 diabetes and type 2 diabetes. It has the particularity of being asymptomatic for a long time, with normal fasting blood glucose levels. For this reason, international recommendations suggest annual screening for diabetes from the age of 10, with an oral glucose tolerance test (OGTT) [27]. If diabetes is confirmed by the results of the OGTT test, the question arises of how to treat it with insulin. If the patient's clinical condition is stable and fasting blood glucose is normal, there are two possible treatment options: start insulin as soon as the diagnosis is made, or defer initiation of insulin therapy and reserve it for cases where the patient is experiencing impaired respiratory function, increased frequency of exacerbations or weight loss. Each of these options is complemented by the appropriate dietary and exercise measures generally recommended for all cystic fibrosis patients.
To our knowledge, very little work has been done on SDM in cystic fibrosis [28] and none on SDM for the treatment of cystic fibrosis diabetes.

Methods/Design

Research assumption

We hypothesize that the practice of SDM by CFRC healthcare teams for the decision to treat cystic fibrosis diabetes will be favored by the implementation of a SDM intervention based on e-learning training integrating an information and decision support tool and a live coaching for physicians and the medical team.

Aim

Primary objective

To evaluate the pilot implementation of a SDM intervention, i.e. the adoption of a SDM between the healthcare professional and the patient with cystic fibrosis diabetes, in patients managed in

centers receiving the intervention, compared with patients managed according to usual decision-making practice in control centers.

SDM is a decision-making process in which the healthcare professional (plus medical team) and the patient (plus his-her relatives) exchange information on treatment options and then deliberate to reach a common agreement on the decision to take. It is based here on an information and decision support tool used during the consultation.

The SDM intervention evaluated comprises 5 components:
1) On-line SDM training (e-learning) for the entire CFRC medical team;
2) Individual coaching for physicians and medical team;
3) SDM implementation :
- Consultation n°1 including patient activation and delivery of the information and decision support tool to the patient
- Consultation 2: discussion and decision-making
- Between the two consultations, the patient has a cooling-off period of 8 to 15 days; the physician discusses the content of the consultation with the CFRC team.
4) Link with institutional patient engagement initiatives ;
5) Integration of SDM into CFRC multidisciplinary concertation meetings.

Secondary objectives

1. Evaluate the effects of SDM on patients' level of knowledge of management options with benefits and risks, anxiety and decisional conflict compared with patients managed in centers without intervention.

2. Evaluate the effects of SDM on the physician-patient relationship in terms of information and decision-making.

<u>In centers with intervention :</u>

3. Evaluate the implementation of the SDM approach.

4. Evaluate the experience of the implementation of SDM regarding the treatment of diabetes in cystic fibrosis patients,
- for patients: observations of SDM consultations, individual semi-directive interviews based on an interview guide containing key items relating to information and participation in decision-making (barriers, helps) based on our previous work in the field, and questionnaires (SDM-Q9; CollaboRATE; knowledge; STAI; SURE).
- for healthcare professionals: focus groups with CFRC teams held at the start of the intervention and afterwards in each CFRC in the intervention group.

5. Identify the individual and organizational factors that influence the implementation of SDM in the treatment of diabetes in cystic fibrosis patients by healthcare professionals: focus groups with CFRC teams, semi-structured interviews with patients and exchanges with institutional decision makers such as quality services.

In control centers :

6. Describe the process and experience of making decisions about diabetes treatment:

- cystic fibrosis patients, in usual practice: observations of consultations dedicated to the discussion of insulin therapy, individual semi-directive interviews and questionnaires;
- by CFRC healthcare professionals: focus groups with teams from each CFRC (focus groups held once in each CFRC, during the course of the study).

Design and setting of the study

Based on our previous work on SDM in cystic fibrosis [30] and the CFIR of Damschroder *et al* [31], this quasi-experimental here-elsewhere study compares the populations of 3 centers receiving the intervention with those of 2 centers not receiving it (controls).
The 5 centers will be studied at the same time, to reduce the risk of contamination of the control group. The evaluation will follow a mixed-methods approach, combining qualitative methods (consultations observations, individual semi-directive interviews with patients and focus groups with healthcare professionals) with quantitative methods (self-administrated questionnaires). A convergent mixed-methods approach will be used, with concomitant data collection, separate analysis and subsequent linking of results.

Characteristics of participants

Patient inclusion criteria

Over 18 years of age, with cystic fibrosis, followed up in one of the 5 CFRCs

Be able to understand French
Have an oral glucose tolerance test (OGTT) at the stage of diabetes or with a blood glucose holter considered by the clinician to be pathological, justifying possible insulin initiation
Have normal fasting blood sugar levels
Stable clinical pulmonary and nutritional status, enabling the 2 treatment options to be considered
Having received the information and not exercised their right to object

Patient exclusion criteria

Transplant patient
Patients receiving insulin therapy

Inclusion criteria for healthcare professionals

Medical and paramedical professionals working in the adult CFRC (physicians, nurses, dieticians, psychologists, physiotherapists, etc.) who have not exercised their right to object.

Description of intervention and comparisons

SDM implementation program

Divided into several parts and as already mentioned, theoretically based on the CFIR [30] and on existing literature on the implementation of SDM [13]. Structured into 5 components (A to E) focusing on healthcare professionals and patients:

A. **Healthcare professionals SDM training in the 3 CFRCs:** a 2-hour e-learning course will be the

common core of the training. It comprises 7 modules:
1. Training objectives.
2. Review of national and international literature on SDM.
3. Understanding SDM.
4. Cystic fibrosis diabetes.
5. Developing an information and decision support tool.
6. Communicate benefits and risks to the patient.
7. Encourage active patient participation by means of a video of 2 simulated consultations with a doctor from the CFRC in Lyon and a patient who has volunteered to take part in the project since its inception: one consultation leading to a shared decision to start insulin now and the other to start later.

The e-learning will be supplemented by a presentation by one of the researcher specialized in SDM at the 3 CFRCs to answer questions/comments from the teams.

B. **Individual coaching for physicians and medical team after e-learning**: this will be carried out by the SDM methodologist to improve physicians' adoption of SDM practice. In line with research on this method [32], coaching will be provided verbally. The SDM methodologist will observe one or two consultations in each of the CFRCs, providing both oral and written feedback. Her feedback will be standardized across the 3 CFRCs on the 3 essential components of SDM (bilateral information/deliberation/common agreement on the decision taken).

C. **Implementing SDM :**

a. Initial consultation with the patient to discuss diabetes treatment options, detailing the benefits and risks of each option. Physician and patient inform each other, discuss throughout the consultation with the help of the information and decision support tool, elicit their preferences and work towards reaching an agreement on the decision to take.
b. Patient activation strategy: this patient-mediated method is based on the "Ask 3 questions" tool used in international SDM implementation studies [33]. It consists of short questions that patients can ask their doctor, to enable them to participate more fully in decision-making if they so wish (Ask 3 questions: What are my options? ; 2. What are the possible benefits and harms of those options? ; 3. How likely are the benefits and harms of each option to occur ?) [33]. This tool is displayed in the waiting room before the consultation.
c. The physician gives the patient a paper version of the information and decision support tool [30].
d. The physician presents the exchanges with the patient to the CFRC team trained in SDM, to obtain their feedbacks.
e. A cooling-off period of 8 to 15 days is required before the second consultation. During this period, the patient can discuss with his or her family, general practitioner or any other healthcare professional outside the CFRC, as well as with the CFRC team, and can call, based on the information and decision support tool, if he or she so wishes.
f. A second consultation takes place after this period of reflection to make the decision (in this case, to take insulin now or later). Several attitudes are possible:

- Clear patient preference for one option, patient decides alone;
- Refusal by the patient to choose an option: the physician decides on the basis of the therapeutic thesaurus. It should be noted, however, that this is not the paternalistic model, insofar as it is the patient who, after being informed, asks the doctor to decide;
- Common agreement on the decision taken (decision taken together), shared decision-making.

D. **Link with institutional initiatives to promote patient involvement** by means of a short questionnaire describing the current situation on the topic, a questionnaire used in the field of oncology. At the start of the study, this questionnaire will be supplemented by a phone interview with the hospital quality manager or referent.

As CFRC teams are integrated into university hospitals that are implementing patient engagement initiatives, it will be important to collaborate with their management teams to work together on integrating the SDM approach into these hospitals.

E. **Integrating SDM into CFRC multidisciplinary concertation meetings**. In order to best integrate SDM into the 3 CFRCs in the intervention group, we will organize a meeting in each of them to see how to integrate SDM into the recommendations for practice in multidisciplinary concertation meetings, and we will take into account the organizational and practice specificities of each of these 2 CFRCs.

Standard care

Insulin therapy decisions are made according to the usual practice defined in each CFRC, with decision-making procedures specific to each center and each CFRC physician/dietician/nutritionist/team.
The decision-making process generally involves two consultations.

Outcomes and measures

- Adoption or non-adoption of SDM: SDM-Q9 questionnaire [34-35], CollaboRate questionnaire [36], OPTION questionnaire [37-38].
- Level of patient knowledge: knowledge questionnaire developed by the authors on the basis of their previous work [39] and the literature, since no validated knowledge questionnaire exists.
- Patient anxiety level: Spielberger anxiety questionnaire [40].
- Patients' level of decisional conflict: SURE questionnaire [41].
- Patients' experience of information and decision-making procedures, and more specifically of SDM implementation
- Individual and organizational factors influencing SDM implementation

Inclusion visit (V0)

When the patient comes to the CFRC following the HGPO, the physician will check the patient's eligibility criteria.
During this visit, he will present the study and give the patient the information note. The physician will record the patient's non-opposition in the consultation report.
The methodologist in social sciences must be informed of the patient's inclusion by sending an email containing the patient's first and last initials and the date of the V1 visit, so that she can contact the investigating center to schedule her visit.

Visit V1

In the CFRCs of the control group: the physician will present the patient with information on diabetes management according to his or her usual practice.
In the CFRCs in the intervention group, the physician will present the patient with information on diabetes management according to SDM (options, benefits and risks), using the information and decision support tool. The patient will be "activated" prior to the consultation, inviting him or her to ask questions using the "Ask 3 questions" tool.

During the V1 visit for the control and intervention groups:

- The investigator will fill in the patient's clinical data and the SDM-Q-9 adapted to physician immediately after the consultation.
- The patient fills in the questionnaires immediately after the consultation (the questionnaires are handed over by the methodologist or a member of the CFRC).
- The methodologist in social sciences :
  - ✓ observe the physician-patient interaction during the consultation and complete the OPTION questionnaire,
  - ✓ will conduct an individual semi-directive interview with the patient immediately after the consultation,
  - ✓ will ensure that the patient completes the SURE, CollaboRate, SDM-Q-9 and Spielberger anxiety questionnaires. If the patient does not read French, she will read the questionnaires to the patient and fill them in with his-her agreement.
  - ✓ will collect the patient's socio-demographic characteristics.

Decision-making visit (V2)

In the CFRC control group: insulin therapy decision-making according to the physician's usual practice.

In the CFRCs of the intervention group: the decision-making visit will take place after a cooling-off period of 8 to 15 days following the V1 consultation. A discussion based on feedbacks from this period will take place between the physician and the patient, and either there is a common agreement on the decision taken (shared decision-making), or the decision is taken by the patient, or the decision is taken by the physician at the patient's demand.

During this visit,

- The investigator will complete the SDM-Q-9 adapted to physician immediately after the consultation.
- The patient fills in the questionnaires immediately after the consultation (the questionnaires are handed over by the methodologist in social sciences or a member of the CFRC).
- The methodologist in social sciences :
  - ✓ observe the physician-patient interaction during the consultation and complete the OPTION questionnaire,
  - ✓ will conduct an individual semi-directive interview with the patient immediately after the consultation,
  - ✓ will ensure that the patient completes SURE, CollaboRate, SDM-Q-9 and the Spielberger Inventory. If the patient does not read French, she will read the questionnaires to the patient and fill

them in with his-her agreement.
In the control and intervention groups: the methodologist in social sciences will attend the face-to-face consultation (possibly by videoconference if conditions require and allow) and will conduct the individual interview with the patient immediately after the consultation. If the patient is not available, the interview can take place up to V1+48 hours.

End of search

The end of the research for patients in both groups is defined by the end of the individual interview at V2, or V1 for the control group if a decision is made following the consultation.

Healthcare professional focus groups

Two focus groups will be conducted in the intervention CFRCs (one at the start of the study and one at the end), and one in each of the 2 control centers by the methodologist in social sciences, on the basis of a moderation guide containing the key items on which participants will be invited to discuss (barriers, facilitators of information and decision-making, dedicated time with and without SDM and information and decision support tool, etc.). The discussion group will be made up of 4 to 8 healthcare professionals (physicians, nurses, physiotherapists, dieticians, psychologists, etc.), depending on the center, and will be as representative as possible of the CFRC's healthcare professional categories. In the intervention centers, the participating healthcare professionals will not necessarily have taken the e-learning training course. However, the group should be identical for both discussion groups, unless a member is absent or leaves.

Data collection

Data analysis

Sample size

As this is a pilot study, forty patients will be included and interviewed over a 12-month period. The number of patients included corresponds to the active patient file of the five CFRCs over the 12-month inclusion period.

Five physicians (1 in each center) will be involved in the study.

Analysis

All patients and healthcare professionals included in the study in accordance with the inclusion and non-inclusion criteria.

Primary endpoint

Adoption or non-adoption of SDM from the patient's and healthcare professional's point of view.

Secondary endpoints
Patient knowledge
Patient anxiety levels
Patients' level of decisional conflict

Patients' experience of information and decision-making procedures, and more specifically of SDM implementation

Effect of SDM on the physician

Individual and organizational factors influencing SDM implementation

Statistical methods

✓ Descriptive analysis

A descriptive analysis of the characteristics of the patient population included (age, sex, history and severity of disease) and of the healthcare professionals on the CFRC teams (physicians, nurses, dieticians, psychologists, physiotherapists, etc., age, sex, profession, previous training in SDM) will be carried out in the 2 study groups. Quantitative characteristics will be described by mean and standard deviation, or by quartiles and minimum and maximum values, depending on the shape of the distribution. Qualitative characteristics will be described by the numbers and percentages in each category. The comparability of characteristics will be checked using the Chi² test for qualitative variables and the Wilcoxon test for quantitative variables.

Data on the implementation of SDM in the intervention group will also be the subject of a descriptive analysis on the proportion of patients with at least one SDM consultation, and the proportion of patients with 2 SDM consultations.

✓ Analysis

Primary endpoint

- Adoption of SDM as perceived by the patient and measured using the SDM-Q-9 questionnaire will be analyzed in patients with no missing data on this criterion, although an approach to managing missing data may be considered. The frequency distribution of the 6 modalities of the 9 SDM-Q-9 questions will be described for each group on the patient unit. A total score will be obtained by summing the scores for each of the 9 questions. A transformation will be applied to obtain a total score between 0 and 100, with 0 indicating non-adoption of SDM as perceived by the patient and conversely 100 indicating adoption of SDM as perceived by the patient. The total score will be described in each group by mean, standard deviation, median, quartiles and range, and will be compared between the 2 groups with a non-parametric Wilcoxon test.

- For patients in the intervention group, the variation in responses to each of the SDM-Q9 questions between the 2 consultations will be tested using the MacNémar test (test adapted to paired data). Total SDM-Q9 scores between the 2 consultations will be compared using the Wilcoxon signed ranks test.

- The same analysis will be carried out on the healthcare professional unit to compare the adoption of SDM as perceived by the healthcare professional. Discordances between patient and healthcare professional responses to each of the 9 questions on the SDM-Q9 questionnaire will be described

and tested using the MacNémar test. The total SDM-Q9 score obtained on the patient unit and the professional unit will be compared by the Wilcoxon signed ranks test.

Secondary endpoints

- In accordance with the scoring rules of the OPTION grid, an OPTION score will be calculated for each patient-healthcare professional dyad if 100% of the 5 OPTION grid items have been completed. A total score between 0 and 20 will then be obtained by summing the answers to the 5 OPTION grid items between 0 and 4. The total score will be converted between 0 and 100, high values indicating exemplary behavior by the dyad in adopting SDM. The OPTION score will be expressed as the mean and standard deviation for each group, and will be compared using the Wilcoxon test.

- In accordance with the scoring rules of the SURE questionnaire, a SURE score will be calculated for each patient if 100% of the 4 questionnaire items have been completed. A total score between 0 and 4 (a high value indicates a decisional conflict) will then be obtained by summing the binary responses of the 4 questionnaire items. The SURE score will be expressed as the mean and standard deviation for each group, and will be compared using the Wilcoxon test. The percentage of patients whose SURE score is less than or equal to 3 (indicating a decisional conflict) will also be calculated in each group and compared using the Chi^2 test.

- In accordance with the scoring rules of the collaboRATE questionnaire, a collaboRATE score will be calculated for each patient if 100% of the 3 questionnaire items have been completed. A total score between 0 and 9 (high values indicating a high level of SDM) will then be obtained by averaging the answers to the 3 questions between 0 and 9 on the questionnaire. The collaboRATE score will be expressed as the mean and standard deviation for each group, and will be compared using the Wilcoxon test.

- A Spielberger score will be calculated for each patient if 100% of the 20 questionnaire items have been completed. A total score between 20 and 80 (high values indicating a high level of anxiety) will then be obtained by summing the scores associated with the 20 items. For questions 3, 4, 6, 7, 9, 12, 13, 14, 17 and 18, 1 point is awarded for 'Not at all', 2 points for 'Somewhat', 3 points for 'Moderately' and 4 points for 'Very much'. For questions 1, 2, 5, 8, 10, 11, 15, 16, 19, 20, the scoring will be reversed, i.e. 4 points for 'Not at all', 3 points for 'A little', 2 points for 'Moderately' and 1 point for 'A lot'. The Spielberger score will be expressed as the mean and standard deviation for each group, and will be compared using the Wilcoxon test.

- Semi-structured individual interviews designed to assess, firstly, in the control and intervention groups, the experience of information and decision-making procedures and, secondly, in the intervention groups only, the effects of SDM on patients' and healthcare professionals' experience of care, will be analyzed by means of a thematic content analysis conducted using Nvivo (10) and 2 researchers participating in the study, based on the interview guide developed and previously tested with patients at the CFRC in Lyon.

- The focus groups conducted in the control and intervention groups, designed to analyze the individual and organizational factors influencing the implementation or non-implementation of SDM, will be transcribed on the basis of notes taken during the focus groups and will be and analyzed on the basis of the interview guide developed.

Discussion

The proposed study is a non-randomized pilot study. The methodological objective is nevertheless to develop for the first time at national level a SDM implementation project with CFRCs motivated to participate. The aim is also to propose an original study based on mixed methods combining quantitative and qualitative analysis, using validated evaluation tools (particularly in French) and conducted with patients and healthcare professionals for whom the potential benefits are multiple: to support in decision-making concerning diabetes treatment, to improve communication between physician, healthcare team and patient, to improve the quality of experience of decision-making steps, to acculturate healthcare professionals to SDM and formalize their practice thanks to SDM training.

The protocol and information and decision support tool developed could serve as a basis for other situations in the field of cystic fibrosis, as in the case of lung transplantation, subject to adaptations to be made. There are many opportunities for shared decision-making in cystic fibrosis, but little is known about patients' experience of SDM [42].

Both the training material and the teams already trained could prove to be a key to future success, with those trained becoming trainers for other centers, boosting the development of work in the field. International comparisons could also be developed, notably within the framework of the Réseau francophone de la Prise de Décision Partagée (FREeDOM Collaboration), which brings together healthcare professionals, patients, researchers and public decision-makers, notably from Quebec, Switzerland and Belgium, interested in adapting the approach developed in their countries.

Declarations

- Ethics approval and consent to participate: HCL Ethics committee Conformity MR004 n°21_5356
- Consent for publication : the manuscript does not contain data from any individual person
- Availability of data and materials : Data sharing is not applicable to this article as no datasets were generated or analysed during the current study
- Competing interests : The authors declare that they have no competing interests
- Funding : Vaincre la mucoviscidose Association
- Authors' contributions : NM, SH, SP, CV, JH, ID, QR developed the methodology. NM wrote the first draft of the article. All authors read and approved the final manuscript.
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- Study conforms to the StaRi checklist (see additional file)

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Supplementary Files

Title and abstract.
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