BMJ Open

Health literacy in context: struggling to self-manage diabetes. A longitudinal qualitative study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046759
Article Type:	Original research
Date Submitted by the Author:	09-Nov-2020
Complete List of Authors:	Debussche, Xavier; Institut national de la santé et de la recherche médicale, Centre d'Investigations Cliniques 1410 ; Centre Hospitalier Universitaire de la Reunion, Endocrinology Diabetology Balcou-Debussche, Maryvette; Reunion University, ICARE EA7389 Austral Cooperative Institute for Research in Education Ballet, Delphine; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education Caroupin-Soupoutevin, Jessica; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education
Keywords:	PUBLIC HEALTH, QUALITATIVE RESEARCH, DIABETES & ENDOCRINOLOGY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

Health literacy in context: struggling to self-manage diabetes.

A longitudinal qualitative study

Xavier Debussche, Maryvette Balcou-Debussche, Delphine Ballet, Jessica Caroupin-Soupoutevin

Xavier Debussche. MD, MSc Nutrition, Endocrinology Diabetology department, CIC 1410 INSERM, CHU Félix Guyon, Saint-Denis Réunion, France

Maryvette Balcou-Debussche. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Delphine Ballet. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Jessica Caroupin-Soupoutevin. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Corresponding author : Dr Xavier Debussche, Service d'Endocrinologie Diabétologie, CIC 1410 INSERM, CHU Félix Guyon, Allée des Topazes, 97400 Saint-Denis Réunion. +33 650 108005

e-mail : xavier.debussche@inserm.fr

Word count 4089

Abstract

Objectives. Considering health literacy needs is a key element in responsiveness of health services to diabetes self-management in vulnerable people. This qualitative study aimed to provide a detailed analysis of the health literacy of people with type 2 diabetes in relation to their daily self-care practices.

Design. Nested qualitative study in the ERMIES randomized controlled trial testing a 2 years structured care in type 2 diabetes. First round of semi-directed interviews at the beginning of the trial with thematic analysis of content. Second round at the completion with directed interviews guided by the first round's themes together with health literacy questionnaire.

Settings. Interviews conducted at home.

Participants. Forty-four (31 females/13 males, 30-79 yrs, HbA1c≥7.5%) consecutive participants out of 100 recruited in the ERMIES trial from 4 diabetology outpatient settings (Reunion island). Forty-two completers.

Results. Three poles structured into eight themes characterized practices in context: health knowledge, disease management, expertise and social support. The relationships of participants in each of the eight themes were differentiated, ranging from functional to interactive and critical. Treatment and follow-up were essentially functional, while diet and exercise remained more interactive. Social support and relationship to health professionals were important determinants of disease management.

Conclusions. Treatment management and disease monitoring remain primarily the job of health professionals, as opposed to diet, physical activity and social support being part of ordinary practice. Decision-making, as a shared social task, as well as resources for participation in health services, should be considered for relevant interventions in type 2 diabetes.

Keywords. Health literacy; healthcare pathways; health behaviours; type 2 diabetes; patient-provider relationship; self-care; Health Literacy Questionnaire (HLQ).

Strengths and limitations of this study

- This is the first longitudinal qualitative study examining health literacy and health practices in patients struggling with uncontrolled type 2 diabetes enrolled in a 2-yr structured intensive managed care
- Interviews were conducted at home, taking into account the social contexts in real life and health literacy needs were assessed too via the multidimensional Health Literacy Questionnaire
- Thematic content analysis illuminates the inter-individual and intra-individual variations of health literacy related to disease management, the importance of social contexts and of the relation type to providers
- The study took place in Reunion island characterized by deeper social disparities compared to mainland France and was nested in a comparative trial, so that any extrapolation must be done with caution

Introduction

Long term management of diabetes and prevention of complications is challenging [1,2]. Patients struggle with the everyday constraints, treatment adherence, and follow-up monitoring [3–6]. Beside medical diagnostic and therapeutic measures, self-management education and support has been shown crucial in helping persons with diabetes manage the disease while maintaining quality of life [7–11]. France, with a high level of health insurance coverage, has been confronted to a health system primarily dedicated to acute care, struggling to establish a real chronic care coordination [12]. In spite of a slight improvement in the quality of care between 2001 and 2007, the French ENTRED study has shown that only 17% of type 2 diabetes patients participated in self-management education, mainly in hospital setting [13]. Only 2% of treated diabetic patients received all of the recommended monitoring regular exams and follow-up [14]. In contrast to a self-efficacy rated as high by many patients regarding nutrition, exercise, treatment management and self-monitoring of blood glucose [13], the level of medication adherence is quite low [15] , and the complications of diabetes remain frequent and severe, with increasing social and regional disparities [16]. Reunion island, a French overseas department, as an example, is characterized by a higher prevalence of complications despite good accessibility to quality care [16,17].

Health literacy (HL) refers to the cognitive and social skills which determine the ability of individuals to gain access to, understand, remember and use information in ways which promote and maintain good health [18]. HL has been linked to numerous health indicators and outcomes [19] and is a potential key component of health perceptions and practices [20–22]. In diabetes, HL has been mainly assessed through functional tests of reading ability, understanding, and/or numeracy and has been linked to numerous outcomes [23]. Beyond functional HL, communicative and critical HL are central [24]. Communicative HL skills integrate the complex cognitive and social skills needed to perform daily activities, to extract information and infer meaning from different forms of communication, to apply new information to changing circumstances, and to interact with health services. Critical literacy refers to skills that can be applied to analyse critical information and adapt to better control life situations.

Understanding the complex interplay of self-care practices in diabetes in the light of HL skills and resources has been seldom explored [25,26]. Qualitative studies are needed to better understand the capacity of individuals to implement health-relevant and meaningful practices and to adapt them to the strengths and limitations of the environments in which they are implemented. The present study aimed to qualitatively analyse health literacy in its multiple dimensions in relation to self-care practices, in the context of structured care in 4 ambulatory diabetes care facilities in La Réunion.

Methods

Study design and population

The present study was part of the mixed ERMIES randomized controlled trial (NCT01425866 ClinicalTrials.gov). The main objective of ERMIES was to evaluate the efficacy of a structured self-management education intervention in under-controlled type 2 diabetes (HbA1c> 7.5%). Out of 4 diabetology outpatient settings of the island of Reunion, 100 people were included between October 2011 and November 2014 [27,28]. Participants underwent a 3-month self-management education course, and then attended quarterly a medical and biological check-up for 2 years. The intervention group was invited every 4 months to attend a structured group session.

The nested qualitative study included 44 subjects. Interviews were conducted in 2012 with consecutive participants included in ERMIES who agreed to participate in the qualitative study. A second round of interviews took place at the completion of the study in 2015 for 42 out of the 44. When included, all participants were informed of the conditions of the research. They signed a written consent for conducting a qualitative survey by interviews that would be conducted at home. When making an appointment (before each interview) new information with oral agreement was given.

The ERMIES study received the ethical agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study.

Patient and public involvement in research

Patients were not involved in setting the research question; nor did they participate in the design or implementation of the qualitative study. No patients were asked to advise on interpretation or writing up of results. However, during the second round of interviews, the results of the first-round interview's analysis were exposed and discussed with some participants who wished to do so.

The results of the research will be provided to study participants, and to local stakeholders, in order to join in the health literacy needs assessment as part of the eLS-OIIS project, whose objective is to help adapting health services responsiveness to persons with chronic diseases in Reunion island [29].

Qualitative study

First round of interviews

Research assistants conducted the interviews, one hour each on average, at the participants' homes. Interviews focused on diabetes, self-monitoring, access to information, relationships to education and learning, participant positioning, decision-making, environment and support. The participants were invited to describe their behaviour in hospital, domestic and occupational settings, and in socio-cultural contexts such as family events. Specific topics included were the history and progression of the illness, knowledge acquired and sources, food practices, physical activity, monitoring and treatment of diabetes, and the participants' perceptions of the health care providers and services. Each interview was recorded and then fully transcribed by the research assistants in the language chosen by the respondent. Transcripts of interviews held in Creole were subsequently translated into French.

The 44 interviews were studied using content analysis of recurrent themes [30]. Categories and signifiers were developed using the constant comparison method [31]. The themes which emerged were tested and modified during additional cycles of data collection. The saturation of data, with a wealth of social configurations and relations to health, hospital and home environment, could be obtained despite the practical constraints of the recruitment of participants immediately after the inclusion in the ERMIES study. The work was done on the N-Vivo 10 QSR International qualitative analysis software, which allowed the qualitative data collected to be processed and several themes constituting the management of diabetes in the ordinary context to be determined. For each of these themes, we identified three types of relationships in reference to the categories of HL established by Nutbeam [24] :

- A "functional relationship to ...", i.e. an instrumental relationship to (diet, physical activity ...), tasks being exercised without a critical look in everyday situations.

- An "interactive relation to ..." that engages cognitive and social skills used to participate actively in everyday activities, infer the meaning of different forms of communication and apply the new information to changing circumstances.

- A "critical relation to ..." that mobilizes more sophisticated cognitive and social skills, applied to a critical analysis of information and their use to exercise greater control over the events of life.

The first names used here for the quotations are fictitious.

Second round of interviews

Based on the analysis of the initial interviews, we created a qualitative data collection grid that was proposed in 2015 to 42 participants (2 out of the 44 dropped out). This grid, covering the 8 themes and the 3 levels of "relations to" was completed both by the interviewee and the interviewer. All interviews and exchanges around the grid were recorded and transcribed in full, which, in case of distances in the responses, made it possible to listen to each speech again.

The coding and analysis were subjected to a triangulation process carried out by three members of the research team (DB, JC, MBD). The data from the 44 interviews and the second round’s grids of interviews of behaviour at home were crossed-referenced in two ways: for each participant (which made it possible to produce case studies of participants), but also by specific themes (food, physical activity etc.) taking the whole of the corpus into account. This work made it possible to show intra and inter-individual variations relating to the talks and practices in relation to the disease and its management, the world of healthcare, the social and familial environment, and involvement in conduct for prevention and health (food, physical activity).

During the second round in 2015, HL was assessed too using the Health Literacy Questionnaire (HLQ) for 39 participants among 42. The HLQ is a multidimensional questionnaire with robust psychometric properties [32], translated and validated in French [33], and composed of 44 items exploring 9 dimensions of HL (Table 1).

Results

Socio-demographic and clinical characteristics of participants are described in table 2. Most aged 50-79 yrs, were unemployed (n=12) or retired (n=19), with low income. Nine participants did not complete high school and 10 displayed difficulties in reading and writing.

First round interviews

Day-to-day management of the disease took place in a variety of forms and contexts: at home, in the family, in the health and medical context or setting, during leisure time or in the socio-professional sphere. A set of 8 themes could be individualized from the coding of the interviews that constituted the ordinary management of diabetes. These 8 themes are grouped into 3 poles which interact through complex dynamics (table 3).

The consistency of the individual work through these 8 themes, its continuity and its inclusion in the different relationships (functional, interactive or critical) were, to varying degrees according to the participants, constitutive of the management of health and illness (fig 1).

Health knowledge and access to knowledge

Relationship to knowledge and access to knowledge was primarily functional (for 29 out of 44 participants).

'*Diabetes is too much sugar in the blood*' (Sylvain, 46 years old, craftsman).

'I try to listen (to the radio or TV), I try to understand, but it goes into my head but I don't understand.'

(Irène, 72 yr, retreated)

For some participants, the relationship to knowledge was more interactive (n=11). Participants were able to make connections between at least two elements, such as the links between diabetes and a balanced diet or regular physical activity.

Regarding access to knowledge, 13 were interactive.

'…Sometimes, if my daughter arrives with her computer, she searches, I ask, and then […] documents are sent to me all the time, so I read, there are testimonies, there are drugs, how to do it, how not to do it. So I'm following all this very closely' (Constance, 64 yrs, retreated).

At the critical level, a few participants (n=4) refer to a complex system, in which interactions between the different components contribute to the evolution of the disease and its complications.

Only 2 participants appear to have a critical relationship to knowledge access.

'*Diabetes, in terms of price, drugs, it's linked to research, to laboratories that also put what they want, and then there are crazy people who can write anything. So on this side, there is a lack of control over what is shown on the Internet. (...) It's a gold mine, but you have to know if it's gold, real or synthetic.*' (Damien, 73 yrs, retreated)

The 'ordinary' management of disease

Food and exercise

Many participants (24/44) exhibited a functional relationship to diet.

'*To eat, I eat about as the hospital tells us to do and what it gives us*'. Delphine, 50 yrs, unemployed.

One third (14/44) were more interactive:

'I even get to correct something when I make a mistake at a meal the next time. I know how to follow my diet and how to promote it in relation to my diabetes.' Ludivine, 76 yrs, retreated.

or even critical (4/44):

'it's in the way you cook things... for example, eat a cod cari, well, you have to put oil in it, otherwise how else? well, that's exceptional, ... we have a fish cari, if for example I do toothfish, I almost don't put oil in it because toothfish is already a fish that is fatty, even if it's good fat'. Blandine, 57 yrs, account manager.

Similarly, the relationship to exercise was mainly functional (29/44)

'I go to the health network for sport but that's fine they do about 15 days but then there's nobody left, we can't do it alone, we don't really know how to do it, ... Irène, 69 yrs, retreated.

Treatment and monitoring

The relationship to treatment and monitoring was functional for the majority of participants (36 and 39 respectively on a total of 44).

'I take all the medicines as required [...] I have an appointment with doctor X; he will see if I need to add a medicine'' (Beatrice 64 yrs, occasional saleswoman)

'You have to trust the treatment, because the doctor has prescribed it for us...' (Charles, 56 yrs, Gardien)

'So the doctor can check the blood sugar level: it's how high and all that,...' (Brigitte, 62 yrs, retreated)

A few participants were more interactive, especially regarding self-monitoring:

'On Tuesday, I had 1 hour of Taiichi, my test was 1.30 in the morning, 2.04 after breakfast, 1.31 at noon. I did Taiichi, 1.96 after lunch, so the benefit of Taiichi continues.[...] Wednesday

I was at 1.59 and after breakfast I was at 3.02 but I know why: I ate a banana [...] at noon I went shopping [...] I left my car as far away as possible so that I could walk, [...] (Ludivine, 73 yrs, retreated)

Only one participant exhibited critical relationship to treatment and monitoring:

'I have my insulin, three injections a day and then I check with the meter […] If necessary, I'll do other checks during the day, [...] Well at one point, I had stopped [the bike] because it was too hot and so there, as I didn't change my treatment, obviously the treatment was too strong and so I had hypoglycemia…'. (Guillaume, 66 yrs, retreated, artist)

Expertise, support and social network

The relationships with health care providers was functional for 26/44.

'There's the nurse who comes to prep my medicine […], I just didn't understand, because I can't read very well, so I used to take the drugs in a mess, any way ... and now the nurse comes, she prepares everything in the morning.' (Tatiana, 70 yrs, unemployed)

but more often interactive (16/44) than for treatment or follow-up.

' I'm more used to Dr. X, he knows my problems so I prefer to see him personally, he helps me a lot morally [...] And then there's Nurse Y who explains very well, who's a good nurse, frankly I have nothing to say, well maybe they serve to support me too, morally and medically, that's it.' (Constance, 51 yrs, retreated)

All of those who displayed functional relationship to HCP were functional too for treatment (except 1 interactive) and disease follow-up. Interestingly, the interactive nature of the relation to HCP was not associated with interaction in treatment for 11 out of 16 or in monitoring (14/16).

Social support

In most cases, participants did not feel isolated in the management of their illness: 26 out of 44 participants receive real family or friends support, which was expressed as much in the form of solidarity as in the family sharing. This relational frame crystallizes around eating practices '*Everyone at home eats the same since I became diabetic*' (Adeline, 73, retired), physical activity '*Sometimes when you decide, it's either her or me, you walk a little bit*' (Sylvain, 47, artisan) or in understanding the disease: '*It's true that my husband, working in the hospital, it helped me a lot*' (Blandine, 60, employee). This support differs according to the relative, as Clarisse (55 years old, no professional activity) testifies: '*Yes, maybe not with my partner but my children, and then there is my family nearby, my sisters, my brothers, my parents, so no worries*'. In some cases, the person concerned with diabetes prefers to spare his or her family by taking charge of the management of the disease himself or herself. '*For me, it is not a handicap, diabetes is there, we manage and that's it. (...). I never talk about it (diabetes), it's my case*' (Sabine, 69, retired).

Functional, but also interactive social support was frequently associated with functional follow-up (16/17 and 23/26) and functional treatment (15/17 and 21/26), but not always with functional relationship to food (11/17 and 15/16) or exercise (11/17 and 17/26).

Second round of interviews

The interviews conducted twice with 42 participants at the beginning and at the end of the ERMIES study highlighted the changes over time in the variables that make up the relationship with disease management, but in different ways according to individuals and contexts.

Overall, health knowledge and access to knowledge exhibited a shift towards a more interactive and critical relationship among participants. The most important shift was observed on the management aspects, particularly regarding food, with lot of participants moving functional to interactive (fig 2). With regard to physical activity, the many passages from interactive to critical showed that participants understood the benefits of physical activity and were able to better integrate it into their practices. The move towards a more interactive or even critical posture was also objective for disease follow-up and monitoring. However, the relationship to treatment remained mostly at a very functional level (28 out of 42) and few participants modulated and adjusted the treatment on their own. There was a clear shift for many participants towards a more interactive relationship with HCP. Social support was also less functional.

Fig.3 displays the repartition of scores for each scale of the Health Literacy Questionnaire for the 39 participants who filled in the questionnaire during the second round of interviews. Overall, the greatest difficulties were in having, finding, using or appraising health information: 23 expressed difficulties in ability to find good health information (HLQ8), and 14 in understanding well enough health information to know what to do (HLQ9); 12 disagreed or strongly disagreed as ‘having sufficient information to manage my health’ (HLQ2), and 17 in appraising health information (HLQ5). On the contrary, only 6 disagreed or strongly disagreed on Feeling understood and supported by health care providers (HLQ1), when 9 expressed difficulties in the Ability to actively engage with health care providers (HLQ6), and 13 in Navigating the health care system (HLQ7). Overall, they were a majority agreeing (n=28) or strongly agreeing (n=5) in ‘Actively managing my health’(HLQ3), or in having social support for health (HLQ4; agree: 17; strongly agree: 6).

Discussion

In diabetes, both patients and HCP are confronted in the real world with the daily and long-term management of the disease [4,34,35]. HL is a potential determinant in attaining lifestyle behaviour, medication adherence, and adequate monitoring of the disease [36,37].

This qualitative study, in which 86 interviews were conducted at the initiation and after the completion of a structured 2-year follow-up, showed the multidimensional nature of HL in relation to self-care practices and disease management. Ordinary management of diabetes consisted of distinct postures for lifestyle behaviours on one side, and for medical aspects on the other: participants mainly had a more active (interactive or critical) relationship to diet and exercise than to treatment and monitoring. This was even more sizeable after 3 years, with most participants remaining functional for treatment and monitoring, while being interactive or even critical for exercise and diet. Social support and patient-provider relationship were important elements associated with a more interactive posture as regard to disease management. These results were strengthened by higher scores on the HLQ scales related to health care providers and services (Feeling understood and supported by health care providers, Ability to actively engage with health care providers, Navigating the health care system), and lower scores on the HLQ scales related to health information (having, finding, using or appraising).

In this population of participants struggling with insufficiently controlled type 2 diabetes, our results highlight the predominant perceptions and attitude of patients regarding treatment and monitoring remaining under the expertise of HCP. O'Connor et al [38] reported that patients who did not improve glucose control were more positive about their care providers, unquestioning acceptance of the doctor's role and treatment. At the opposite, a less passive approach to HCP, as well as a strategic non-compliance with medication have been described as key elements in succeeding in diabetes management and well-being [39]. Timely information and support from HCP, adapted to the actual individual constraints allow sustainable efforts for self-management [40].

Using the Health literacy Questionnaire, studies have shown difficulties in actively managing health, health information finding, understanding and appraisal, as well as ability to engage with health care providers [32,41,42]. Friis et al [43] reported the high treatment burden in patients with chronic multimorbidity and difficulties in understanding health information. This is in line with the apparent contrast found in the present study between the level of sense of being supported by HCP and struggling with diabetes control and handling of own useful and relevant health information. For many participants, letting the caregivers take the reins of conducting and adapting medication, as well as providing long-term monitoring, made it possible for them to get involved in the challenging daily tasks of making the required nutritional and exercise changes. Studies in UK revealed also the importance of HCP attitudes regarding blood glucose readings for the continuing and relevant self-monitoring [44]. Moreover, patients lacked understanding of what to do faced to blood glucose results, as what could be noticed too in the present study.

Social support appeared here to be frequently associated with active management of disease. Maintaining self-management is a hard daily task, demanding individual investment as well as social, familial, not just taking regularly medications and coping with lifestyle [4,45]. On the basis of individual dispositions issuing from time and experience, the power of the everyday context surrounding key practices to control and overcome illness have to be considered [3,40]. Low personal resources, e.g regarding the appropriation of health information, together with burdensome family and social situations may explain difficulties in engagement with self-management [40].

The main strength of this study is its longitudinal design, with interviews repeated after the completion of a structured managed care. Interviews were conducted at home, taking into account particular features and social contexts, in a sample of participants who displayed actual difficulties in managing insufficiently controlled diabetes, and mostly in a long-standing duration of diabetes. Nevertheless, this study has some limitations. Firstly, the context of the study must be acknowledged, during a comparative intervention trial with structured intensive managed care under the coordination of specialized secondary outpatient centres, and in Reunion island, a French outmost territory, with deeper contrasted social disparities compared to metropolitan France. Hence any extrapolation must be done with caution, even if, conversely, this context makes it possible to better grasp elements specific to disadvantaged populations. First round interviews were held in the weeks after the inclusion in the trial. This may have influenced the discourse on practices and relationships with caregivers, even though before the initiation of the education course. The second round of interviews took place after 2 to 3 years, following a structured managed care, so that the attitudes and relationships to HCP, treatment issues, and monitoring could have been influenced. Nevertheless, the results underline furthermore the needs of participants for other types of support from HCP and services, as exhibited by the combination of the HLQ profiles obtained together with the second round interviews: education and support have to work on the actual contextual factors that make sense in decision making and sharing and in the appropriation of relevant health practices on an everyday basis. More specifically, the transition from a passive attitude towards monitoring and the elements allowing for the relevant adaptation of treatment and health practices should be the subject of a process of appropriation in which the particular contexts should be apparent.

This longitudinal qualitative study in vulnerable participants struggling with type 2 diabetes and low HL, shows that decision making and handling of treatment and disease monitoring remains primarily the purview of HCP. Not all self-care practices are equivalent in terms of awareness, understanding their usefulness, and appraising their effect. Moreover, the ability and the willingness of engaging in some self-practices like self-monitoring and follow-up awareness, as well as treatment adjustment is often weak. However, this seemingly passive attitude is counterbalanced by feeling supported and trusted by health care providers, and is not inconsistent with an otherwise active attitude of engaging in lifestyle behaviours. For the latter, social support and shared social tasks are critical. The multidimensional nature of diabetes management and of HL, both embedded in social configurations, has to be acknowledged. Conceiving and designing interventions and services aiming at improving diabetes self-management should take into account these dimensions of self-care and assess the differentiated HL dimensions according to individual variations and contexts.

List of abbreviations

HCP: health care providers

HLQ: Health Literacy Questionnaire

Declarations

Ethics approval and consent to participate

The ERMIES study received the agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study. All participants were informed of the conditions of the research. They signed a written consent for conducting a qualitative survey by interviews that would be conducted at home. When making an appointment (before each interview) new information was given with oral agreement.

Consent for publication

Not applicable

Availability of data and material

Not applicable. The nested qualitative part of the ERMIES study did not use any quantitative dataset. Qualitative data constituted by full transcript of interviews are subjects to confidentiality and highly sensible data. If needed, and on reasonable request, it is possible to obtain an anonymous dataset.

Competing interests

The authors declare that they have no competing interests.

Author contributions

Conception and design of the nested qualitative study were performed by MBD, DB, JCS and XD. Material preparation and data collection were performed by MBD, DB and JCS. Data analysis by DB, MBD, and JCS. The first draft of the manuscript was written by XD. MBD was a major contributor in writing the manuscript. All authors read, amended and approved the manuscript.

Acknowledgements

The authors wish to thank all the participants of the qualitative study, and all the staff from Hospital secondary centers and from the RéuCARE diabetes management network, engaged in the follow-up, education support, and treatment of participants recruited as well as in the logistic of the ERMIES study. Authors are grateful too to the team of the CIC-EC, and of the DRCI of the CHU de La Réunion, especially Liliane Cotte, Fidéline Filleul, Vanessa Basque, Emilie Techer, for strong support of the ERMIES study.

ERMIES Investigators Study Group : Fawzi Bakiri, Maryvette Balcou-Debussche, Marie-Claude Boyer, Muriel Cogne, Xavier Debussche, François Favier, Adrian Fianu, Ania Flaus-Furmaniuk,

Jean-Hugues Gatina, Nathalie Le Moullec, Victorine Lenclume, Jean-Christophe Maiza, Olivier Perrichot, Céline Regnier, Olivier Rollot, Stéphane Schneebeli, Yogananda Thirapathi, Jean-Luc Yvin. Members of the ERMIES Study Group were co-investigators and invested in the implementation and the conduct of the ERMIES RCT study.

Funding

This project received a grant from IRESP, French Research Institute in Public Health (AAP ETP 2013-03), and the ERMIES trial was funded by PHRC interregional, French Inter-regional Hospital Program for Clinical Research 2010 (GIRCI Sud Ouest OutreMer; French Ministry of Health API-04-04). The sponsor institution of the study is the Regional Teaching Hospital of La Réunion, France. The funders bodies had no role in the design of the study and collection, analysis, interpretation of data and in writing the manuscript.

References

1 Wang CY, Neil DL, Home P. 2020 vision – An overview of prospects for diabetes management and prevention in the next decade. *Diabetes Res Clin Pract* 2018;**143**:101–12. doi:10.1016/j.diabres.2018.06.007

2 Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol* 2017;**14**:88–98. doi:10.1038/nrendo.2017.151

3 Balcou-Debussche M, Debussche X. Hospitalisation for type 2 diabetes: the effects of the suspension of reality on patients' subsequent management of their condition. *Qual Health Res* 2009;**19**:1100–15.

4 Hinder S, Greenhalgh T. 'This does my head in'. Ethnographic study of self-management by people with diabetes. *BMC Health Serv Res* 2012;**12**:83. doi:10.1186/1472-6963-12-83

5 Davies MJ, D'Alessio DA, Fradkin J, *et al.* Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2018;**2012**:dci180033. doi:10.2337/DCI18-0033

6 Debussche X. Is adherence a relevant issue in the self-management education of diabetes? A mixed narrative review. *Diabetes, Metab Syndr Obes Targets Ther* 2014;**Volume 7**:357. doi:10.2147/DMSO.S36369

7 Haas L, Maryniuk M, Beck J, *et al.* National standards for diabetes self-management education and support. *Diabetes Care* 2014;**37 Suppl 1**:S144-53. doi:10.2337/dc14-S144

8 Chatterjee S, Davies MJ, Heller S, *et al.* Diabetes structured self-management education programmes: a narrative review and current innovations. *Lancet Diabetes Endocrinol* 2018;**6**:130–42. doi:10.1016/S2213-8587(17)30239-5

9 Lawton J, Peel E, Parry O, *et al.* Lay perceptions of type 2 diabetes in Scotland: bringing health services back in. *Soc Sci Med* 2005;**60**:1423–35.

10 Pamungkas RA, Chamroonsawasdi K, Vatanasomboon P. A systematic review: Family support integrated with diabetes self-management among uncontrolled type II diabetes mellitus patients. *Behav Sci (Basel)* 2017;**7**:1–17. doi:10.3390/bs7030062

11 Care D, Suppl SS. Improving care and promoting health in populations: Standards of medical care in Diabetesd2018. *Diabetes Care* 2018;**41**:S7–12. doi:10.2337/dc18-S001

12 Chevreul K, Berg Brigham K, Bouché C. The burden and treatment of diabetes in France. *Global Health* 2014;**10**:6. doi:10.1186/1744-8603-10-6

13 Fournier C, Gautier A, Mosnier-Pudar H, *et al.* ENTRED 2007: Results of a French national survey on self-management education to people with diabetes... still a long

way to go! *Educ Thérapeutique du Patient - Ther Patient Educ* 2014;**6**:10102. doi:10.1051/tpe/2014006

14 Robert J, Roudier C, Poutignat N, *et al.* Prise en charge des personnes diabétiques de type 2 en France en 2007 et tendances par rapport à 2001. *Bull Epidemiol Hebd* 2009;:455–60.

15 Tiv M, Viel J-F, Mauny F, *et al.* Medication Adherence in Type 2 Diabetes: The ENTRED Study 2007, a French Population-Based Study. *PLoS One* 2012;**7**:e32412. doi:10.1371/journal.pone.0032412

16 Fosse-Edorh S, Fagot-Campagna A, Detournay B, *et al.* Impact of socio-economic position on health and quality of care in adults with Type 2 diabetes in France: the Entred 2007 study. *Diabet Med* 2015;:1438–44. doi:10.1111/dme.12783

17 Debussche X, Pholsena M, Fournier A, *et al.* High prevalence of proteinuric nephropathy screened in patients with type 2 diabetes consulting community-based general practitioners in French overseas departments and territories. ALBUM study. *Rev du Prat* 2014;**64**.

18 Kickbusch I, Pelikan JM, Apfel F, *et al. Health literacy : The solid facts*. World Health Organisation Europe 2013. http://www.euro.who.int/en/publications/abstracts/health-literacy.-the-solid-facts

19 Dewalt DA, Berkman ND, Sheridan S, *et al.* Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med* 2004;**19**:1228–39. doi:10.1111/j.1525-1497.2004.40153.x

20 Aaby A, Friis K, Christensen B, *et al.* Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease. *Eur J Prev Cardiol* 2017;**24**:1880–8.

doi:10.1177/2047487317729538

21 Gazmararian JA, Kripalani S, Miller MJ, *et al.* Factors associated with medication refill adherence in cardiovascular-related diseases. *J Gen Intern Med* 2006;**21**:1215–21. doi:10.1111/j.1525-1497.2006.00591.x

22 Shiyanbola OO, Unni E, Huang Y-M, *et al.* The association of health literacy with illness perceptions, medication beliefs, and medication adherence among individuals with type 2 diabetes. *Res Soc Adm Pharm* 2018;**14**:824–30. doi:10.1016/J.SAPHARM.2017.12.005

23 Al Sayah F, Williams B, Johnson JA. Measuring health literacy in individuals with diabetes: a systematic review and evaluation of available measures. *Heal Educ Behav* 2013;**40**:42–55. doi:10.1177/1090198111436341

24 Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;**67**:2072–8.http://www.sciencedirect.com/science/article/pii/S0277953608004577

25 Balcou-Debussche M. *De l'éducation thérapeutique du patient à la littératie en santé. Problématisation socio-anthropologique d'objets didactiques contextualisés*. Paris: : Editions des Archives Contemporaines 2016.

26 Samerski S. Health literacy as a social practice: Social and empirical dimensions of knowledge on health and healthcare. *Soc Sci Med* 2019;**226**:1–8. doi:10.1016/j.socscimed.2019.02.024

27 Debussche X, Collin F, Fianu A, *et al.* Structured self-management education maintained over two years in insufficiently controlled type 2 diabetes patients: the ERMIES randomised trial in Reunion Island. Cardiovasc. Diabetol. 2012;**11**:91.

28 Debussche X, Balcou-Debussche M. Analyse des profils de littératie en santé chez des personnes diabétiques de type 2 : la recherche ERMIES-Ethnosocio. *Sante Publique*

(Paris) 2018;**30**:S157-68.

29 Bakker MM, Putrik P, Aaby ASE, *et al.* Acting together – WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Heal Panor* 2019;**5**:233–43.

30 Ritchie J, Lewis J. *Qualitative Research Practice: a guide for social scientists and researchers.* London: : SAGE 2003.

31 Glaser BG, Strauss AL. *The discovery of Grounded Theory*. Chicago, IL: : Aldine 1967.

32 Osborne RH, Batterham RW, Elsworth GR, *et al.* The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;**13**:658. doi:10.1186/1471-2458-13-658

33 Debussche X, Lenclume V, Balcou-Debussche M, *et al.* Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk: Validity testing of the Health Literacy Questionnaire. *SAGE Open Med* 2018;**6**. doi:10.1177/2050312118801250

34 Lawton J. Lay experiences of health and illness: past research and future agendas. *Sociol Health Illn* 2003;**25**:23–40. doi:doi:10.1111/1467-9566.00338

35 Balcou-Debussche M. *L'éducation des malades chroniques. Une approche ethnosociologique*. Paris: : Éditions des Archives Contemporaines 2006.

36 Greenhalgh T. Health literacy: towards system level solutions. *Bmj* 2015;**350**:h1026-. doi:10.1136/bmj.h1026

37 Heijmans M, Waverijn G, Rademakers J, *et al.* Functional, communicative and critical health literacy of chronic disease patients and their importance for self-management. *Patient Educ Couns* 2015;**98**:41–8. doi:10.1016/J.PEC.2014.10.006

38 O'Connor PJ, Crabtree BF, Yanoshik MK. Differences between diabetic patients who

do and do not respond to a diabetes care intervention: a qualitative analysis. *Fam Med* 1997;**29**:424–8.https://pubmed.ncbi.nlm.nih.gov/9193915

39 Campbell R, Pound P, Pope C, *et al.* Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Soc Sci Med* 2003;**56**:671–84.http://www.ncbi.nlm.nih.gov/pubmed/12560003

40 Frost J, Garside R, Cooper C, *et al.* A qualitative synthesis of diabetes self-management strategies for long term medical outcomes and quality of life in the UK. *BMC Health Serv Res* 2014;**14**:348. doi:10.1186/1472-6963-14-348

41 Goeman D, Conway S, Norman R, *et al.* Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *J Diabetes Res* 2016;**2016**:1–12. doi:10.1155/2016/2483263

42 Friis K, Lasgaard M, Osborne RH, *et al.* Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29 473 Danish citizens. *BMJ Open* 2016;**6**:e009627. doi:10.1136/bmjopen-2015-009627

43 Friis K, Lasgaard M, Pedersen MH, *et al.* Health literacy, multimorbidity, and patient-perceived treatment burden in individuals with cardiovascular disease. A Danish population-based study. *Patient Educ Couns* Published Online First: 2019. doi:10.1016/j.pec.2019.05.013

44 Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. BMJ. 2007;**335**:493. doi:10.1136/bmj.39302.444572.DE

45 Balcou-Debussche M. Social inscription of TPE, heterogeneity and patient's vulnerability. Analysis of results obtained in the plural context of Mayotte. *Educ Ther*

Patient/Ther Patient Educ 2013;**5**:113–21.http://dx.doi.org/10.1051/tpe/2012020

TABLES

Table 1. Health Literacy Questionnaire scales.

HLQ scales	1st part of the questionnaire Response options from 1 -strongly disagree- to 4 -strongly agree-	
HLQ 1	**Feeling understood and supported by healthcare professionals**	4 items
HLQ 2	**Having sufficient information to manage my health**	4 items
HLQ 3	**Actively managing my health**	5 items
HLQ 4	**Social support for health**	5 items
HLQ 5	**Appraisal of health information**	5 items

HLQ scales	2nd part of the questionnaire Response options from 1-cannot do or always difficult- to 5 -always	
HLQ 6	**Ability to actively engage with healthcare professionals**	5 items
HLQ 7	**Navigating the healthcare system**	6 items
HLQ 8	**Ability to find good health information**	5 items
HLQ 9	**Understand health information enough to know what to do**	5 items

Table 2. Socio-demographics and clinical characteristics of the sample (n=44)

Sexe	F/M	31/13
Age (years)	[30-49]	9
	[50-59]	12
	[60-69]	12
	[70-79]	11
Household composition	Live alone	13
	Live alone, with children	4
Education level	Primary school or less	9
	Middle school	24
	High school	6
	University Undergraduate	5
Occupational status	Full- or part-time employment	13
	Unemployed	12
	Retired	19
Income)	Less than 1200 €	29
	1,200-1,999 €	7
	2,000-3,999 €	7
	≥ 4,000 €	1
Literacy	Difficulties in reading/writing	10
Diabetes, known duration	< 9 yrs	11
	10-19 yrs	19

	≥ 20 yrs	14
HbA1c at inclusion	7.5-7.9%	8
	8-8.9%	20
	9.0-11.9%	16
Diabetes treatment at inclusion	Oral agents (± GLP1 agonists)	21
	Insulin (± oral ± GLP1 agonists)	23
Self-monitoring of blood glucose	Once a day, fasting	15
	2- 3 times a day, before meals	15
	Before and after meals	14
Known complications	Renal	18
	Heart	10
	Eye	2
	Feet	5
	Arteries	9
	None	14

Table 3. The 3 main poles and 8 themes of disease management issues.

Poles	**Themes**
Health knowledge	Knowledge base
	Access to knowledge
Management of the disease	Food
	Exercise
	Treatment
	Monitoring
Expertise, support and social network	Relationships with professionals
	Health and social support

Figure Legends

Fig 1. Disease management. Functional, interactive and critical relationships to the 8 themes. First round interviews, n=44.

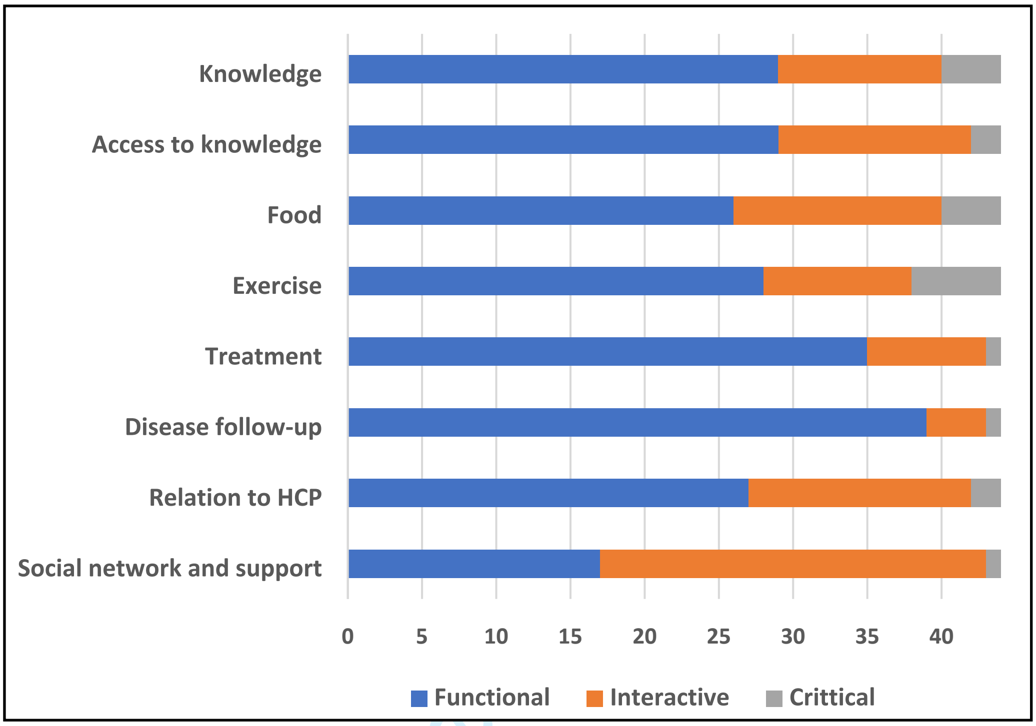
Fig 2. Functional, interactive, and critical relationships to the 8 themes of disease management: Progress from 2012 (1st round interviews) to 2015 (2nd round interviews). Ermies ethno-socio study, n=42.

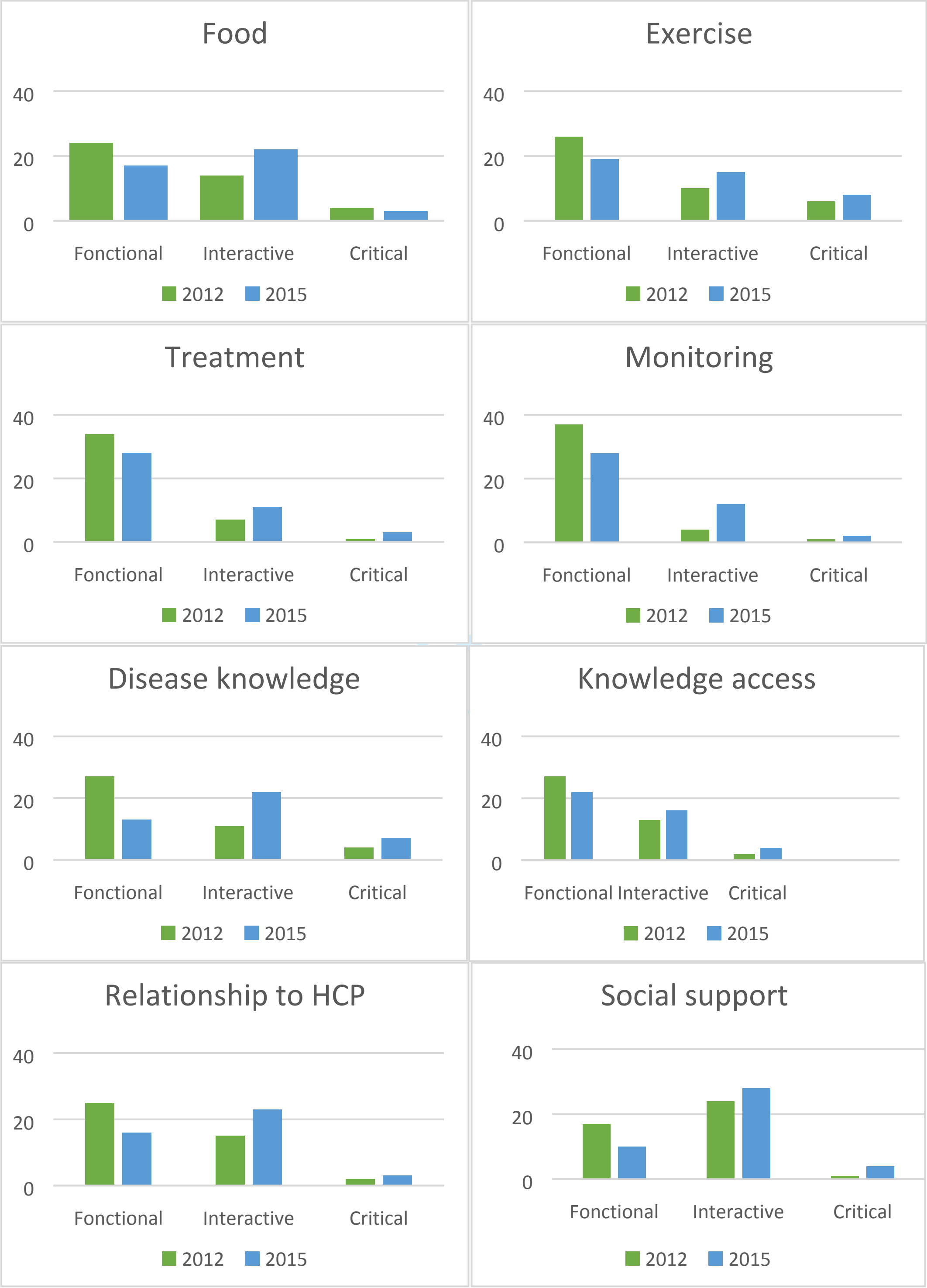
Fig 3. Repartition of individual health literacy profiles among the 9 scales of the Health Literacy Questionnaire. Ermies-ethnosocio study, n=39.

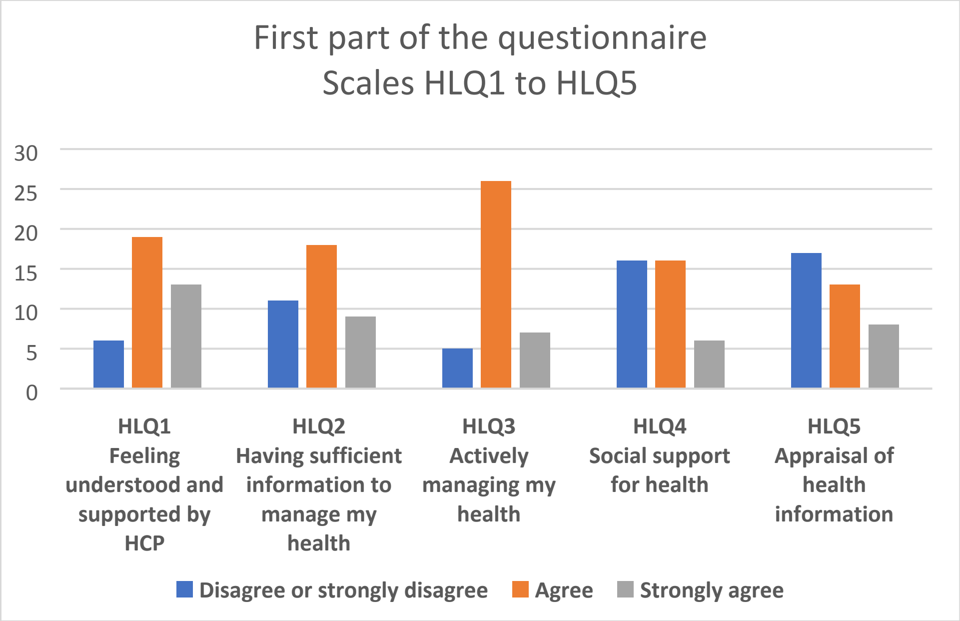
Cut-off scores were:

- for scales (1-5) of the 1st part of the HLQ: <3 Disagree or strongly disagree; 3-3.5 Agree; ≥3.5 Strongly agree

- for scales (6-9) of the 2nd part of the HLQ: <3.5 Difficult; 3.5-4.5 Usually easy; ≥4.5 Always easy.


Knowledge
Access to knowledge
Food
Exercise
Treatment
Disease follow-up
Relation to HCP
Social network and support
0
5
10
15
20
25
30
35
40
Functional
Interactive
Crittical


Food
40
20
0
Fonctional
Interactive
Critical
2012
2015
Exercise
40
20
0
Fonctional
Interactive
Critical
2012
2015
Treatment
40
20
0
Fonctional
Interactive
Critical
2012
2015
Monitoring
40
20
0
Fonctional
Interactive
Critical
2012
2015
Disease knowledge
40
20
0
Fonctional
Interactive
Critical
2012
2015
Knowledge access
40
20
0
Fonctional
Interactive
Critical
2012
2015
Relationship to HCP
40
20
0
Fonctional
Interactive
Critical
2012
2015
Social support
40
20
0
Fonctional
Interactive
Critical
2012
2015


First part of the questionnaire
Scales HLQ1 to HLQ5
30
25
20
15
10
5
0
HLQ1 Feeling understood and supported by HCP
HLQ2 Having sufficient information to manage my health
HLQ3 Actively managing my health
HLQ4 Social support for health
HLQ5 Appraisal of health information
Disagree or strongly disagree
Agree
Strongly agree

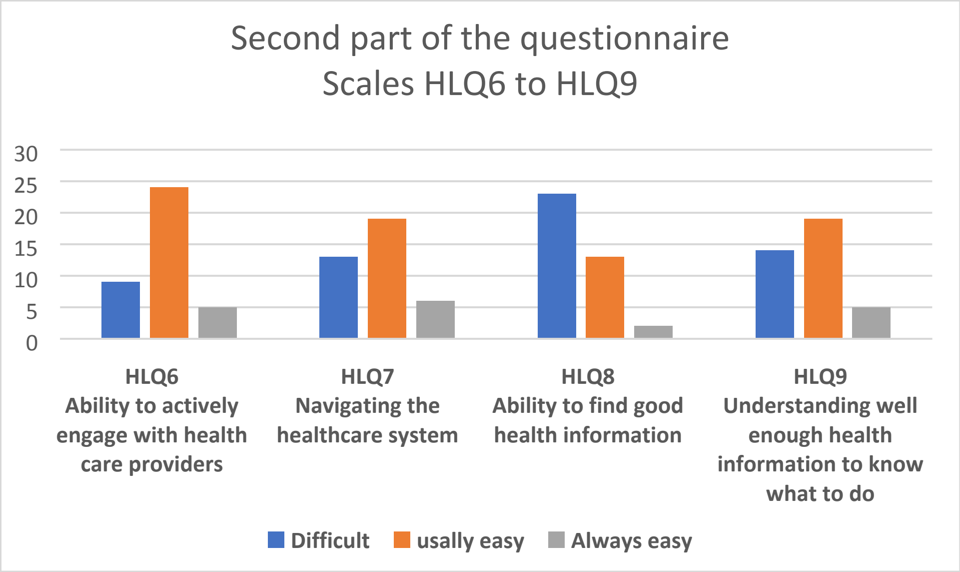

Second part of the questionnaire
Scales HLQ6 to HLQ9
30
25
20
15
10
5
0
HLQ6 Ability to actively engage with health care providers
HLQ7 Navigating the healthcare system
HLQ8 Ability to find good health information
HLQ9 Understanding well enough health information to know what to do
Difficult
usally easy
Always easy

Table 1

Standards for Reporting Qualitative Research (SRQR)[a]

No.		Topic	Item
		Title and abstract	
S1	✓	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	✓	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
		Introduction	
S3	✓	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	✓	Purpose or research question	Purpose of the study and specific objectives or questions
		Methods	
S5	✓	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale[b]
S6	✓	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	✓	Context	Setting/site and salient contextual factors; rationale[b]
S8	✓	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	✓	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	✓	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	✓	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	✓	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	✓	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	✓	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale[b]
S15	✓	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
		Results/findings	
S16	✓	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	✓	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
		Discussion	
S18	✓	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	✓	Limitations	Trustworthiness and limitations of findings

(Table continues)

BMJ Open

Health literacy in context: struggling to self-manage diabetes. A longitudinal qualitative study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046759.R1
Article Type:	Original research
Date Submitted by the Author:	14-Jun-2021
Complete List of Authors:	Debussche, Xavier; Institut national de la santé et de la recherche médicale, Centre d'Investigations Cliniques 1410 ; Centre Hospitalier Universitaire de la Reunion, Endocrinology Diabetology Balcou-Debussche, Maryvette; Reunion University, ICARE EA7389 Austral Cooperative Institute for Research in Education Ballet, Delphine; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education Caroupin-Soupoutevin, Jessica; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Public health, Qualitative research
Keywords:	PUBLIC HEALTH, QUALITATIVE RESEARCH, DIABETES & ENDOCRINOLOGY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Health literacy in context: struggling to self-manage diabetes.

A longitudinal qualitative study

Xavier Debussche, Maryvette Balcou-Debussche, Delphine Ballet, Jessica Caroupin-Soupoutevin

Xavier Debussche. MD, MSc Nutrition, Endocrinology Diabetology department, CIC 1410 INSERM, CHU Félix Guyon, Saint-Denis Réunion, France

Maryvette Balcou-Debussche. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Delphine Ballet. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Jessica Caroupin-Soupoutevin. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Corresponding author : Dr Xavier Debussche, Service d'Endocrinologie Diabétologie, CIC 1410 INSERM, CHU Félix Guyon, Allée des Topazes, 97400 Saint-Denis Réunion. +33 650 108005

e-mail: xavier.debussche@inserm.fr

Word count 4663

Abstract

Objectives. Considering health literacy needs is a key component of health services responsiveness to diabetes self-management among vulnerable individuals. The purpose of this qualitative study was to provide a detailed analysis of the health literacy of people with type 2 diabetes in relation to their daily self-care practices.

Design. Nested qualitative study in the ERMIES randomized controlled trial testing a 2-year structured care in type 2 diabetes. First round of semi-directed interviews at the beginning of the trial with thematic analysis of content. Second round at the completion with directed interviews guided by the first round's themes together with health literacy questionnaire.

Settings. Interviews conducted at home.

Participants. Forty-four (31 females/13 males, 30-79 yrs, HbA1c≥7.5%) consecutive participants out of 100 recruited in the ERMIES trial from 4 diabetology outpatient settings (Reunion Island). Forty-two seen twice.

Results. Three poles structured into eight themes characterized practices in context: health knowledge, disease management, expertise and social support. The relationships of participants in each of the eight themes were differentiated, ranging from functional to interactive and critical. Treatment and follow-up were essentially functional, while diet and exercise remained more interactive. Social support and relationship to health professionals were important determinants of disease management.

Conclusions. Treatment management and disease monitoring remain primarily the job of health professionals, as opposed to diet, physical activity and social support being part of ordinary practice. Decision-making, as a shared social task, as well as resources for participation in health services, should be considered for relevant interventions in type 2 diabetes.

Keywords. Health literacy; healthcare pathways; health behaviours; type 2 diabetes; patient-provider relationship; self-care; Health Literacy Questionnaire (HLQ).

Strengths and limitations of this study

- This longitudinal qualitative study examined health literacy and health practices in vulnerable patients struggling with uncontrolled type 2 diabetes enrolled in a 2-yr structured intensive managed care
- Interviews were conducted at home, considering the social contexts of health literacy related to disease management in real life, and health literacy needs were assessed too via the multidimensional Health Literacy Questionnaire

- The study took place in Reunion Island characterized by deeper social disparities compared to mainland France and the studied population was mainly female, with few included men

- Qualitative data issued from interviews may have been influenced by the context of the comparative trial, with first round interviews held in the weeks after inclusion, and second interviews after 2 years of a structured managed care

INTRODUCTION

Long term management of diabetes is challenging [1,2]. Patients struggle with the everyday constraints, treatment adherence, and monitoring [3–6]. Beside medical diagnostic and therapeutic measures, self-management education and support has been shown crucial in helping persons with diabetes manage the disease while maintaining quality of life [7–11]. France, with a high level of health insurance coverage, has been confronted to a health system primarily dedicated to acute care, struggling to establish a real chronic care coordination [12]. In spite of a slight improvement in the quality of care between 2001 and 2007, the French ENTRED study has shown that only 17% of type 2 diabetes patients participated in self-management education, mainly in hospital setting [13]. Only 2% of treated diabetic patients received all of the recommended monitoring regular exams and follow-up [14]. In contrast to a self-efficacy rated as high by many patients regarding nutrition, exercise, treatment management and self-monitoring of blood glucose [13], the level of medication adherence is quite low [15] , and the complications of diabetes remain frequent and severe, with increasing social and regional disparities [16]. Reunion island, a French overseas department, as an example, is characterized by a higher prevalence of complications despite good accessibility to quality care [16,17].

Health literacy (HL) refers to the cognitive and social skills which determine the ability of individuals to gain access to, understand, remember and use information in ways which promote and maintain good health [18]. HL has been linked to numerous health indicators and outcomes [19] and is a potential key component of health perceptions and practices [20–22]. In diabetes, HL has been mainly assessed through functional tests of reading ability, understanding, and/or numeracy and has been linked to numerous outcomes [23]. Beyond functional HL, communicative and critical HL are central [24]. Communicative HL skills integrate the complex cognitive and social skills needed to perform daily activities, to extract information and infer meaning from different forms of communication, to apply new information to changing circumstances, and to interact with health services. Critical literacy refers to skills that can be applied to analyse critical information and adapt to better control life situations.

Understanding the complex interplay of self-care practices in diabetes in the light of HL skills and resources has been seldom explored [25-28]. Qualitative studies are needed to better understand the capacity and resources of individuals to implement health-relevant and meaningful practices and to adapt them to the strengths and limitations of the environments in which they are implemented. The present study aimed to qualitatively analyse health literacy in its multiple dimensions in relation to self-care practices, in the context of structured care in 4 ambulatory diabetes care facilities in La Réunion.

METHODS

Study design and population

The present study was part of the mixed ERMIES randomized controlled trial. The main objective of ERMIES was to evaluate the efficacy of a structured self-management education intervention in under-controlled type 2 diabetes (HbA1c> 7.5%). The detailed protocol of the trial (NCT01425866 ClinicalTrials.gov) is described elsewhere [29]. Out of 4 diabetology outpatient settings of the island of Reunion, 100 people were included between October 2011 and November 2014 [29,30]. Patients of both arms benefited from a structured initial group education course conducted by trained educators, blind to the subsequent group allocation, within the 12 weeks following inclusion (appendix 1). The intervention group was invited every 4 months to attend a structured group session. All included patients attended a quarterly medical follow-up in the diabetology unit during the study period (96 weeks).

The nested qualitative study included 44 subjects. Interviews were conducted in 2012 with the first 44 consecutive participants included in ERMIES who agreed to participate in the qualitative study. Among the 44 included the nested qualitative study, 42 participated to the second-round interviews in 2015, and 2 declined. Five out of 42 dropped out from the trial (appendix 2) but accepted to respond to the second-round interviews.

When included, all participants were informed of the conditions of the research. They signed a written consent for a qualitative study by means of interviews conducted in their homes. At the time of the appointment (before each interview), a new information with oral agreement was given.

The ERMIES study received the ethical agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study.

Patient and public involvement in research

Patients were not involved in setting the research question; nor did they participate in the design or implementation of the qualitative study. No patients were asked to advise on interpretation or writing up of results. However, during the second round of interviews, the results of the first-round interview's analysis were exposed and discussed with some participants who wished to do so.

The results of the research will be provided to study participants, and to local stakeholders, in order to join in the health literacy needs assessment as part of the eLS-OIIS project, whose objective is to help adapting health services responsiveness to persons with chronic diseases in Reunion island [31].

Qualitative study

First round of interviews

The research involved two research assistants trained in the socio-anthropological approach. The work on the interviews and analyses was built up through teamwork and regulated as the research developed, taking into account the contexts in which the patients were interviewed. The analyses of all the interviews were carried out by the two researchers independently of each other: these analyses were then crossed, discussed and reinterpreted in the event of differing interpretations. The result thus corresponds not to a single interpretation of the data, but to an intelligibility constructed, negotiated and regulated within the team, at every stage of the scientific process. Interviews, one hour each on average, were conducted at the participants' homes and focused on diabetes, self-monitoring, access to information, relationships to education and learning, participant positioning, decision-making, environment and support. The participants were invited to describe their behaviour in hospital, domestic and occupational settings, and in socio-cultural contexts such as family events. Specific topics included were the history and progression of the illness, knowledge acquired and sources, food practices, physical activity, monitoring and treatment of diabetes, and the participants' perceptions of the health care providers and services. The usual sociodemographic data and information about diabetes (duration, HbA1c, self-management of blood glucose, treatment, complications) were collected from the participants at the time of the first-round interviews.

Each interview was recorded and then fully transcribed by the research assistants in the language chosen by the respondent. Transcripts of interviews held in Creole were subsequently translated into French. The 44 interviews were investigated through thematic discourse analysis understood as communication patterns of both a social and linguistic nature [32]. The categories and signifiers were developed using the constant comparison method [33]. The themes which emerged were tested and modified during additional cycles of data collection. The saturation of data, with a wealth of social configurations and relations to health, hospital and home environment, could be obtained despite the practical constraints of the recruitment of participants immediately after the inclusion in the ERMIES study. The analysis was carried out using the N-Vivo 10 QSR International qualitative analysis software. Several themes constituting the management of diabetes in the ordinary context could be determined. For each of these themes, we identified three types of relationships in reference to the categories of HL established by Nutbeam [24]:

- A "functional relationship to ...", i.e. an instrumental relationship to (diet, physical activity ...), tasks being exercised without a critical look in everyday situations.
- An "interactive relation to ..." that engages cognitive and social skills used to participate actively in everyday activities, infer the meaning of different forms of communication and apply the new information to changing circumstances.
- A "critical relation to ..." that mobilizes more sophisticated cognitive and social skills, applied to a critical analysis of information and their use to exercise greater control over the events of life.

The first names used here for the quotations are fictitious.

Second round of interviews

Based on the analysis of the initial interviews, we created a qualitative data collection grid that was proposed in 2015 to 42 participants (2 out of the 44 declined the interview). This grid (appendix 3), covering the 8 themes and the 3 levels of "relations to" was completed both by the interviewee and the interviewer. All interviews and exchanges around the grid were recorded and transcribed in full, which, in case of distances in the responses, made it possible to listen to each speech again.

The coding and analysis were subjected to a triangulation process carried out by three members of the research team (DB, JC, MBD). The data from the 44 interviews and the second round's grids of interviews of behaviour at home were crossed-referenced in two ways: for each participant (which made it possible to produce case studies of participants), but also by specific themes (food, physical activity etc.) taking the whole of the corpus into account. This work made it possible to show intra and inter-individual variations relating to the talks and practices in relation to the disease and its management, the world of healthcare, the social and familial environment, and involvement in conduct for prevention and health (food, physical activity).

During the second round in 2015, HL was assessed too using the Health Literacy Questionnaire (HLQ) for 39 participants among 42. The HLQ is a multidimensional questionnaire with robust psychometric properties [34], translated and validated in French [35], and composed of 44 items exploring 9 dimensions of HL (Appendix 4).

RESULTS

Socio-demographic and clinical characteristics of the 44 participants are described in table 1. The gender distribution (31 of 44 were females) was roughly the same as the overall ERMIES trial population (67%) as well as median age, education, employment, and income.

First round interviews

Day-to-day management of the disease took place in a variety of forms and contexts: at home, in the family, in the health and medical context or setting, during leisure time or in the socio-professional sphere. A set of 8 themes could be individualized from the coding of the interviews that constituted the ordinary management of diabetes. These 8 themes are grouped into 3 poles which interact through complex dynamics (table 2).

The consistency of the individual work through these 8 themes, its continuity and its inclusion in the different relationships (functional, interactive or critical) were, to varying degrees according to the participants, constitutive of the management of health and illness (fig 1).

Health knowledge and access to knowledge

Relationship to knowledge and access to knowledge was primarily functional (for 29 out of 44 participants).

'*Diabetes is too much sugar in the blood*' (Sylvain, 46 years old, craftsman).

'*I try to listen (to the radio or TV), I try to understand, but it goes into my head but I don't understand.*' (Irène, 72 yr, retreated)

For some participants, the relationship to knowledge was more interactive (n=11). Participants were able to make connections between at least two elements, such as the links between diabetes and a balanced diet or regular physical activity.

Regarding access to knowledge, 13 were interactive.

'*…Sometimes, if my daughter arrives with her computer, she searches, I ask, and then […] documents are sent to me all the time, so I read, there are testimonies, there are drugs, how to do it, how not to do it. So I'm following all this very closely*' (Constance, 64 yrs, retreated).

At the critical level, a few participants (n=4) refer to a complex system, in which interactions between the different components contribute to the evolution of the disease and its complications.

Only 2 participants appear to have a critical relationship to knowledge access.

'*Diabetes, in terms of price, drugs, it's linked to research, to laboratories that also put what* *they want, and then there are crazy people who can write anything. So on this side, there is a lack of control over what is shown on the Internet. (...) It's a gold mine, but you have to know if it's gold, real or synthetic*.' (Damien, 73 yrs, retreated)

The 'ordinary' management of disease

Food and exercise

Many participants (24/44) exhibited a functional relationship to diet.

'*To eat, I eat about as the hospital tells us to do and what it gives us*'. Delphine, 50 yrs, unemployed.

Others (14/44) were more interactive:

'*I even get to correct something when I make a mistake at a meal the next time. I know how to follow my diet and how to promote it in relation to my diabetes.*' Ludivine, 76 yrs, retreated.

Or even critical (4/44):

'*it's in the way you cook things... for example, eat a cod cari, well, you have to put oil in it, otherwise how else? well, that's exceptional, ... we have a fish cari, if for example I do toothfish, I almost don't put oil in it because toothfish is already a fish that is fatty, even if it's good fat*'. Blandine, 57 yrs, account manager.

Similarly, the relationship to exercise was mainly functional (29/44)

'*I go to the health network for sport but that's fine they do about 15 days but then there's nobody left, we can't do it alone, we don't really know how to do it, ...* Irène, 69 yrs, retreated.

Treatment and monitoring

The relationship to treatment and monitoring was functional for the majority of participants (36 and 39 respectively on a total of 44).

'I take all the medicines as required [...] I have an appointment with doctor X; he will see if I need to add a medicine'' (Beatrice 64 yrs, occasional saleswoman)

'You have to trust the treatment, because the doctor has prescribed it for us...' (Charles, 56 yrs, Gardien)

'So the doctor can check the blood sugar level: it's how high and all that,...' (Brigitte, 62 yrs, retreated)

A few participants were more interactive, especially regarding self-monitoring:

'On Tuesday, I had 1 hour of Taiichi, my test was 1.30 in the morning, 2.04 after breakfast, 1.31 at noon. I did Taiichi, 1.96 after lunch, so the benefit of Taiichi continues.[...] Wednesday I was at 1.59 and after breakfast I was at 3.02 but I know why: I ate a banana [...] at noon I went shopping [...] I left my car as far away as possible so that I could walk, [...] (Ludivine, 73 yrs, retreated)

Only one participant exhibited critical relationship to treatment and monitoring:

'I have my insulin, three injections a day and then I check with the meter [...] If necessary, I'll do other checks during the day, [...] Well at one point, I had stopped [the bike] because it was too hot and so there, as I didn't change my treatment, obviously the treatment was too strong and so I had hypoglycemia...'. (Guillaume, 66 yrs, retreated, artist)

Expertise, support and social network

The relationships with health care providers was functional for 26/44.

'There's the nurse who comes to prep my medicine [...], I just didn't understand, because I can't read very well, so I used to take the drugs in a mess, any way ....' (Tatiana, 70 yrs, unemployed) but more often interactive (16/44) than for treatment or follow-up.

' I'm more used to Dr. X, he knows my problems so I prefer to see him personally, he helps me a lot morally [...] And then there's Nurse Y who explains very well, who's a good nurse, frankly

I have nothing to say, well maybe they serve to support me too, morally and medically, that's it.' (Constance, 51 yrs, retreated)

All of those who displayed functional relationship to HCP were functional too for treatment (except 1 interactive) and disease follow-up. Interestingly, the interactive nature of the relation to HCP was not associated with interaction in treatment for 11 out of 16 or in monitoring (14/16).

Social support

In most cases, participants did not feel isolated in the management of their illness: 26 out of 44 participants receive real family or friends support, which was expressed as much in the form of solidarity as in the family sharing. This relational frame crystallizes around eating practices '*Everyone at home eats the same since I became diabetic*' (Adeline, 73, retired), physical activity '*Sometimes when you decide, it's either her or me, you walk a little bit*' (Sylvain, 47, artisan) or in understanding the disease: '*It's true that my husband, working in the hospital, it helped me a lot*' (Blandine, 60, employee). This support differs according to the relative, as Clarisse (55 years old, no professional activity) testifies: '*Yes, maybe not with my partner but my children, and then there is my family nearby, my sisters, my brothers, my parents, so no worries*'. In some cases, the person concerned with diabetes prefers to spare his or her family by taking charge of the management of the disease himself or herself. '*For me, it is not a handicap, diabetes is there, we manage and that's it. (...). I never talk about it (diabetes), it's my case*' (Sabine, 69, retired).

Functional, but also interactive social support was frequently associated with functional follow-up (16/17 and 23/26) and functional treatment (15/17 and 21/26), but not always with functional relationship to food (11/17 and 15/16) or exercise (11/17 and 17/26).

Second round of interviews

The interviews conducted twice with 42 participants at the beginning and at the end of the ERMIES study highlighted the changes over time in the variables that make up the relationship with disease management, but in different ways according to individuals and contexts. The 2 participants who declined the second interview, but completed the trial, were both in the control group, and exhibited at the first round interview a functional relationship to all themes except social support that was interactive.

Overall, health knowledge and access to knowledge evolved into a more interactive and critical relationship among participants, slightly more markedly in the intervention group.. The most important shift was observed on the management aspects, particularly regarding food, with lot of participants moving functional to interactive (fig 2). With regard to physical activity, the many passages from interactive to critical showed that participants understood the benefits of physical activity and were able to better integrate it into their practices. For these two themes, changes were observed in both the intervention and control groups. The move towards a more interactive or even critical posture was also objective for disease follow-up and monitoring, but here more so in the intervention group. However, the relationship to treatment remained mostly at a very functional level (28 out of 42) '*The nurse prepares that, and I take my oral medication. And I have the prescriptions for all the medicines I take it*' (Marguerite, 79, retreated, intervention group), and few participants modulated and adjusted the treatment on their own regardless of the allocation group. There was a clear shift for many participants towards a more interactive relationship with HCP, slightly more in the intervention group. Social support was also less functional.

The 5 participants who dropped out from the trial were younger than those who completed the study, with low income, and 2 of them had difficulties in reading and writing. All five had an essentially functional relationship with treatment and follow-up of the disease, leaving the decision and conduct to the physician and other health care professionals, although two of them were interactive in their relationships with providers.

Fig.3 displays the repartition of scores for each scale of the HLQ for the 39 participants who filled in the questionnaire during the second round of interviews. Overall, the greatest difficulties were in having, finding, using or appraising health information: 23 expressed difficulties in ability to find good health information (HLQ8), and 14 in understanding well enough health information to know what to do (HLQ9); 12 disagreed or strongly disagreed as ‘having sufficient information to manage my health’ (HLQ2), and 17 in appraising health information (HLQ5). On the contrary, only 6 disagreed or strongly disagreed on Feeling understood and supported by health care providers (HLQ1), when 9 expressed difficulties in the Ability to actively engage with health care providers (HLQ6), and 13 in Navigating the health care system (HLQ7). Overall, they were a majority agreeing (n=28) or strongly agreeing (n=5) in ‘Actively managing my health’(HLQ3), or in having social support for health (HLQ4; agree: 17; strongly agree: 6).

DISCUSSION

In diabetes, both patients and HCP are confronted in the real world with the daily and long-term management of the disease [4,36,37]. HL is a potential determinant in attaining lifestyle behaviour, medication adherence, and adequate monitoring of the disease [38,39]. This qualitative study, in which 86 interviews were conducted at the initiation and after the completion of a structured 2-year follow-up, showed the multidimensional nature of HL in relation to self-care practices and disease management. Ordinary management of diabetes consisted of distinct postures for lifestyle behaviours on one side, and for medical aspects on the other: participants mainly had a more active (interactive or critical) relationship to diet and exercise than to treatment and monitoring. This was even more sizeable after 3 years, with most participants remaining functional for treatment and monitoring, while being interactive or even critical for exercise and diet. Social support and patient-provider relationship were important elements associated with a more interactive posture as regard to disease management.

In the present study a fine qualitative approach of disease management analysed through the theoretical lens of the Nutbeam's health literacy scheme yielded useful insights for a comprehensive description of strengths and weaknesses at the individual and contextual level for patients struggling with disease management [24]. The HLQ was used as a complement to describe the health literacy needs expressed by participants. The HLQ is a validity driven questionnaire and grounded in real world settings [34]. Correspondence with the health literacy profiles using the 9 scales of the HLQ should be cautious and grasped in a complementary way. Indeed, the qualitative data were strengthened by the higher scores on the HLQ scales related to health care providers and services (Feeling understood and supported by health care providers, Ability to actively engage with health care providers, Navigating the health care system), and lower scores on the HLQ scales related to health information (having, finding, using or appraising).

In this population of participants struggling with insufficiently controlled type 2 diabetes, our results highlight the predominant perceptions and attitude of patients regarding treatment and monitoring remaining under the expertise of HCP. O'Connor et al [40] reported that patients who did not improve glucose control were more positive about their care providers, unquestioning acceptance of the doctor's role and treatment. At the opposite, a less passive approach to HCP, as well as a strategic non-compliance with medication have been described as key elements in succeeding in diabetes management and well-being [41]. Timely information and support from HCP, adapted to the actual individual constraints allow sustainable efforts for self-management [42].

Studies have shown difficulties in actively managing health, health information finding, understanding and appraisal, as well as ability to engage with health care providers [34,43,44]. Using the HLQ, Friis et al [45] reported the high treatment burden in patients with chronic multimorbidity and difficulties in understanding health information. This is in line with the apparent contrast found in the present study between the level of sense of being supported by HCP and struggling with diabetes control and handling of own useful and relevant health information. For many participants, letting the caregivers take the reins of conducting and adapting medication, as well as providing long-term monitoring, made it possible for them to get involved in the challenging daily tasks of making the required nutritional and exercise changes. Studies in UK revealed also the importance of HCP attitudes regarding blood glucose readings for the continuing and relevant self-monitoring [46]. Moreover, patients lacked understanding of what to do faced to blood glucose results, as what could be noticed too here.

Social support appeared to be frequently associated with active management of disease. Maintaining self-management is a hard daily task, demanding individual investment as well as social, familial, not just taking regularly medications and coping with lifestyle [4,47]. On the basis of individual dispositions issuing from time and experience, the power of the everyday context surrounding key practices to control and overcome illness have to be considered [3,42]. Low personal resources, e.g regarding the appropriation of health information, together with burdensome family and social situations may explain difficulties in engagement with self-management [42].

Gender distribution of participants with most females is worth noting, and this was in line with the distribution in the whole ERMIES sample (67%). Lower inclusion rate of males vs women have been previously noticed in other studies in Reunion [48–50]. According to the national health insurance's data the prevalence of declared and/or treated diabetes in Reunion island is higher in women than in men (9.6% versus 7,9 %) [51], suggesting a possible under-diagnosis and a higher drop-out from care of type 2 diabetes in men. Beside gender, qualitative data obtained here from drop-out patients, who were younger, with low income at the second-round interviews suggest greater difficulties regarding understanding and appraising health information, social support and interactions with health care providers.

The main strength of this study is its longitudinal design, with interviews repeated after the completion of a structured managed care and a multidimensional health literacy assessment via the HLQ. Interviews were conducted at home, taking into account particular features and social contexts, in a sample of participants who displayed actual difficulties in managing insufficiently controlled diabetes. Nevertheless, this study has some limitations. Firstly, it took place during a comparative intervention trial with structured intensive managed care under the coordination of specialized secondary outpatient centres, and in Reunion island, a French outmost territory, with deeper contrasted social disparities compared to metropolitan France. The studied population was mainly female, and the question of the lower implication of men in self-care was difficult to analyse. Hence any extrapolation must be done with caution, even if, conversely, this context makes it possible to better grasp elements specific to disadvantaged populations. First round interviews were held in the weeks after the inclusion in the trial. This may have influenced the discourse on practices and relationships with caregivers, even though before the initiation of the education course. The second round interviews took place after 2 years, following a structured managed care, so that the attitudes and relationships to HCP, treatment issues, and monitoring could have been influenced. Nevertheless, the results underline furthermore the needs of participants for other types of support from HCP and services, as exhibited by the combination of the HLQ profiles obtained together with the second round interviews: education and support have to work on the actual contextual factors that make sense in decision making and sharing and in the appropriation of relevant health practices on an everyday basis. More specifically, the transition from a passive attitude towards monitoring and the elements allowing for the relevant adaptation of treatment and health practices should be the subject of a process of appropriation in which the particular contexts should be apparent.

This longitudinal qualitative study in vulnerable participants struggling with type 2 diabetes and low HL, shows that decision making, handling of treatment and disease monitoring remains primarily the purview of HCP. Not all self-care practices are equivalent in terms of awareness, understanding their usefulness, and appraising their effect. Moreover, the ability and the willingness of engaging in some self-practices like self-monitoring, follow-up awareness and treatment adjustment is often weak. However, this seemingly passive attitude is counterbalanced by feeling supported and trusted by health care providers and is not inconsistent with an otherwise active attitude of engaging in lifestyle behaviours. For the latter, social support and shared social tasks are critical.

The multidimensional nature of diabetes management and of HL, both embedded in social configurations, has to be acknowledged. Conceiving and designing interventions and services aiming at improving diabetes self-management should take into account these dimensions of self-care and assess the differentiated HL dimensions according to individual variations and contexts.

List of abbreviations

HCP: health care providers

HLQ: Health Literacy Questionnaire

Declarations

Ethics approval and consent to participate

The ERMIES study received the agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study. All participants were informed of the conditions of the research. They signed a written consent for conducting a qualitative survey by interviews that would be conducted at home. When making an appointment (before each interview) new information was given with oral agreement.

Consent for publication

Not applicable

Availability of data and material

Not applicable. The nested qualitative part of the ERMIES study did not use any quantitative dataset. Qualitative data constituted by full transcript of interviews are subjects to confidentiality and highly sensible data. If needed, and on reasonable request, it is possible to obtain an anonymous dataset.

Competing interests

The authors declare that they have no competing interests.

Author contributions

Conception and design of the nested qualitative study were performed by MBD, DB, JCS and XD. Material preparation and data collection were performed by MBD, DB and JCS. Data analysis by DB, MBD, and JCS. The first draft of the manuscript was written by XD. MBD was a major contributor in writing the manuscript. All authors read, amended and approved the manuscript.

Acknowledgements

The authors wish to thank all the participants of the qualitative study, and all the staff from Hospital secondary centers and from the RéuCARE diabetes management network, engaged in the follow-up, education support, and treatment of participants recruited as well as in the logistic of the ERMIES study. Authors are grateful too to the team of the CIC-EC, and of the DRCI of the CHU de La Réunion, especially Liliane Cotte, Fidéline Filleul, Vanessa Basque, Emilie Techer, for strong support of the ERMIES study.

ERMIES Investigators Study Group : Fawzi Bakiri, Maryvette Balcou-Debussche, Marie-Claude Boyer, Muriel Cogne, Xavier Debussche, François Favier, Adrian Fianu, Ania Flaus-Furmaniuk, Jean-Hugues Gatina, Nathalie Le Moullec, Victorine Lenclume, Jean-Christophe Maiza, Olivier Perrichot, Céline Regnier, Olivier Rollot, Stéphane Schneebeli, Yogananda Thirapathi, Jean-Luc Yvin. Members of the ERMIES Study Group were co-investigators and invested in the implementation and the conduct of the ERMIES RCT study.

Funding

This project received a grant from IRESP, French Research Institute in Public Health (AAP ETP 2013-03), and the ERMIES trial was funded by PHRC interregional, French Inter-regional Hospital Program for Clinical Research 2010 (GIRCI Sud Ouest OutreMer; French Ministry of Health API-04-04). The sponsor institution of the study is the Regional Teaching Hospital of

La Réunion, France. The funders bodies had no role in the design of the study and collection, analysis, interpretation of data and in writing the manuscript.

References

1 Wang CY, Neil DL, Home P. 2020 vision – An overview of prospects for diabetes management and prevention in the next decade. *Diabetes Res Clin Pract* 2018;**143**:101–12. doi:10.1016/j.diabres.2018.06.007

2 Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol* 2017;**14**:88–98. doi:10.1038/nrendo.2017.151

3 Balcou-Debussche M, Debussche X. Hospitalisation for type 2 diabetes: the effects of the suspension of reality on patients' subsequent management of their condition. *Qual Health Res* 2009;**19**:1100–15.

4 Hinder S, Greenhalgh T. 'This does my head in'. Ethnographic study of self-management by people with diabetes. *BMC Health Serv Res* 2012;**12**:83. doi:10.1186/1472-6963-12-83

5 Davies MJ, D'Alessio DA, Fradkin J, *et al.* Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2018;**2012**:dci180033. doi:10.2337/DCI18-0033

6 Debussche X. Is adherence a relevant issue in the self-management education of diabetes? A mixed narrative review. *Diabetes, Metab Syndr Obes Targets Ther* 2014;**Volume 7**:357. doi:10.2147/DMSO.S36369

7 Haas L, Maryniuk M, Beck J, *et al.* National standards for diabetes self-management education and support. *Diabetes Care* 2014;**37 Suppl 1**:S144-53. doi:10.2337/dc14-

S144

8 Chatterjee S, Davies MJ, Heller S, *et al.* Diabetes structured self-management education programmes: a narrative review and current innovations. *Lancet Diabetes Endocrinol* 2018;**6**:130–42. doi:10.1016/S2213-8587(17)30239-5

9 Lawton J, Peel E, Parry O, *et al.* Lay perceptions of type 2 diabetes in Scotland: bringing health services back in. *Soc Sci Med* 2005;**60**:1423–35.

10 Pamungkas RA, Chamroonsawasdi K, Vatanasomboon P. A systematic review: Family support integrated with diabetes self-management among uncontrolled type II diabetes mellitus patients. *Behav Sci (Basel)* 2017;**7**:1–17. doi:10.3390/bs7030062

11 Care D, Suppl SS. Improving care and promoting health in populations: Standards of medical care in Diabetesd2018. *Diabetes Care* 2018;**41**:S7–12. doi:10.2337/dc18-S001

12 Chevreul K, Berg Brigham K, Bouché C. The burden and treatment of diabetes in France. *Global Health* 2014;**10**:6. doi:10.1186/1744-8603-10-6

13 Fournier C, Gautier A, Mosnier-Pudar H, *et al.* ENTRED 2007: Results of a French national survey on self-management education to people with diabetes... still a long way to go! *Educ Thérapeutique du Patient - Ther Patient Educ* 2014;**6**:10102. doi:10.1051/tpe/2014006

14 Robert J, Roudier C, Poutignat N, *et al.* Prise en charge des personnes diabétiques de type 2 en France en 2007 et tendances par rapport à 2001. *Bull Epidemiol Hebd* 2009;:455–60.

15 Tiv M, Viel J-F, Mauny F, *et al.* Medication Adherence in Type 2 Diabetes: The ENTRED Study 2007, a French Population-Based Study. *PLoS One* 2012;**7**:e32412. doi:10.1371/journal.pone.0032412

16 Fosse-Edorh S, Fagot-Campagna A, Detournay B, *et al.* Impact of socio-economic

position on health and quality of care in adults with Type 2 diabetes in France: the Entred 2007 study. *Diabet Med* 2015;:1438–44. doi:10.1111/dme.12783

17 Debussche X, Pholsena M, Fournier A, *et al.* High prevalence of proteinuric nephropathy screened in patients with type 2 diabetes consulting community-based general practitioners in French overseas departments and territories. ALBUM study. *Rev du Prat* 2014;**64**.

18 Kickbusch I, Pelikan JM, Apfel F, *et al. Health literacy : The solid facts*. World Health Organisation Europe 2013. http://www.euro.who.int/en/publications/abstracts/health-literacy.-the-solid-facts

19 Dewalt DA, Berkman ND, Sheridan S, *et al.* Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med* 2004;**19**:1228–39. doi:10.1111/j.1525-1497.2004.40153.x

20 Aaby A, Friis K, Christensen B, *et al.* Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease. *Eur J Prev Cardiol* 2017;**24**:1880–8. doi:10.1177/2047487317729538

21 Gazmararian JA, Kripalani S, Miller MJ, *et al.* Factors associated with medication refill adherence in cardiovascular-related diseases. *J Gen Intern Med* 2006;**21**:1215–21. doi:10.1111/j.1525-1497.2006.00591.x

22 Shiyanbola OO, Unni E, Huang Y-M, *et al.* The association of health literacy with illness perceptions, medication beliefs, and medication adherence among individuals with type 2 diabetes. *Res Soc Adm Pharm* 2018;**14**:824–30. doi:10.1016/J.SAPHARM.2017.12.005

23 Al Sayah F, Williams B, Johnson JA. Measuring health literacy in individuals with

diabetes: a systematic review and evaluation of available measures. *Heal Educ Behav* 2013;**40**:42–55. doi:10.1177/1090198111436341

24 Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;**67**:2072–8.http://www.sciencedirect.com/science/article/pii/S0277953608004577

25 Balcou-Debussche M. *De l'éducation thérapeutique du patient à la littératie en santé. Problématisation socio-anthropologique d'objets didactiques contextualisés*. Paris: : Editions des Archives Contemporaines 2016.

26 Samerski S. Health literacy as a social practice: Social and empirical dimensions of knowledge on health and healthcare. *Soc Sci Med* 2019;**226**:1–8. doi:10.1016/j.socscimed.2019.02.024

27 Sarkar U, Karter AJ, Liu JY, *et al.* The literacy divide: Health literacy and the use of an internet-based patient portal in an integrated health system-results from the diabetes study of Northern California (DISTANCE). *J Health Commun* 2010;**15**:183–96. doi:10.1080/10810730.2010.499988

28 Rowsell A, Muller I, Murray E, *et al.* Views of people with high and low levels of health literacy about a digital intervention to promote physical activity for diabetes:a qualitative study in five countries. *J Med Internet Res* 2015;**17**:1–12. doi:10.2196/jmir.4999

29 Debussche X, Collin F, Fianu A, *et al.* Structured self-management education maintained over two years in insufficiently controlled type 2 diabetes patients: the ERMIES randomised trial in Reunion Island. Cardiovasc. Diabetol. 2012;**11**:91.

30 Debussche X, Balcou-Debussche M. Analyse des profils de littératie en santé chez des personnes diabétiques de type 2 : la recherche ERMIES-Ethnosocio. *Sante Publique (Paris)* 2018;30:157-68.

31 Bakker MM, Putrik P, Aaby ASE, *et al.* Acting together – WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Heal Panor* 2019;**5**:233–43.

32 Ritchie J, Lewis J. *Qualitative Research Practice: a guide for social scientists and researchers.* London: : SAGE 2003.

33 Glaser BG, Strauss AL. *The discovery of Grounded Theory*. Chicago, IL: : Aldine 1967.

34 Osborne RH, Batterham RW, Elsworth GR, *et al.* The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 2013;**13**:658. doi:10.1186/1471-2458-13-658

35 Debussche X, Lenclume V, Balcou-Debussche M, *et al.* Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk: Validity testing of the Health Literacy Questionnaire. *SAGE Open Med* 2018;**6**. doi:10.1177/2050312118801250

36 Lawton J. Lay experiences of health and illness: past research and future agendas. *Sociol Health Illn* 2003;**25**:23–40. doi:doi:10.1111/1467-9566.00338

37 Balcou-Debussche M. *L’éducation des malades chroniques. Une approche ethnosociologique*. Paris: : Éditions des Archives Contemporaines 2006.

38 Greenhalgh T. Health literacy: towards system level solutions. *Bmj* 2015;**350**:h1026. doi:10.1136/bmj.h1026

39 Heijmans M, Waverijn G, Rademakers J, *et al.* Functional, communicative and critical health literacy of chronic disease patients and their importance for self-management. *Patient Educ Couns* 2015;**98**:41–8. doi:10.1016/J.PEC.2014.10.006

40 O’Connor PJ, Crabtree BF, Yanoshik MK. Differences between diabetic patients who do and do not respond to a diabetes care intervention: a qualitative analysis. *Fam*

Med 1997;**29**:424–8.https://pubmed.ncbi.nlm.nih.gov/9193915

41 Campbell R, Pound P, Pope C, *et al.* Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Soc Sci Med* 2003;**56**:671–84.http://www.ncbi.nlm.nih.gov/pubmed/12560003

42 Frost J, Garside R, Cooper C, *et al.* A qualitative synthesis of diabetes self-management strategies for long term medical outcomes and quality of life in the UK. *BMC Health Serv Res* 2014;**14**:348. doi:10.1186/1472-6963-14-348

43 Goeman D, Conway S, Norman R, *et al.* Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *J Diabetes Res* 2016;**2016**:1–12. doi:10.1155/2016/2483263

44 Friis K, Lasgaard M, Osborne RH, *et al.* Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29 473 Danish citizens. *BMJ Open* 2016;**6**:e009627. doi:10.1136/bmjopen-2015-009627

45 Friis K, Lasgaard M, Pedersen MH, *et al.* Health literacy, multimorbidity, and patient-perceived treatment burden in individuals with cardiovascular disease. A Danish population-based study. *Patient Educ Couns* Published Online First: 2019. doi:10.1016/j.pec.2019.05.013

46 Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. BMJ. 2007;**335**:493. doi:10.1136/bmj.39302.444572.DE

47 Balcou-Debussche M. Social inscription of TPE, heterogeneity and patient's vulnerability. Analysis of results obtained in the plural context of Mayotte. *Educ Ther Patient/Ther Patient Educ* 2013;**5**:113–21.http://dx.doi.org/10.1051/tpe/2012020

48 Debussche X, Rollot O, LePommelet C, *et al.* Quarterly and individual outpatient lifestyle counseling after initial inpatient education in type 2 diabetes: the REDIA-prev2 randomized controlled trial in Reunion island. *Diabetes Metab* 2012;**38**:46–53.

49 Favier F, Jaussent I, Moullec N Le, *et al.* Prevalence of Type 2 diabetes and central adiposity in La Reunion Island, the REDIA Study. *Diabetes Res Clin Pract* 2005;**67**:234–42. doi:10.1016/j.diabres.2004.07.013

50 Fianu A, Bourse L, Naty N, *et al.* Long-term effectiveness of a lifestyle intervention for the primary prevention of type 2 diabetes in a low socio-economic community - an intervention follow-up study on reunion island. *PLoS One* 2016;**11**:1–16. doi:10.1371/journal.pone.0146095

51 Ndong JR, Romon I, Druet C, *et al.* Caractéristiques, risque vasculaire, complications et qualité des soins des personnes diabétiques dans les départements d'outre-mer et comparaison à la métropole : Entred 2007-2010, France. *BEH* 2010;**42**–**43**:432–6.

TABLES

Table 1. Socio-demographics and clinical characteristics of the sample (n=44)

		All n=44	Intervention n=23	Control n=21
Sexe	F/M	31/13	14/9	17/4
Age (years)	[30-49]	9	4	5
	[50-59]	12	8	4
	[60-69]	12	4	8
	[70-79]	11	7	4
Household composition	Live alone	13	8	5
	Live alone, with children	4	2	2
Education level	Primary school or less	9	7	2
	Middle school	24	11	13
	High school	6	2	4
	University Undergraduate	5	3	2
Occupational status	Full- or part-time employment	13	5	8
	Unemployed	12	8	4
	Retired	19	10	9
Income)	Less than 1200 €	29	15	14

	1,200-1,999 €	7	4	3
	2,000-3,999 €	7	3	4
	≥ 4,000 €	1	1	0
Literacy	Difficulties in reading/writing	10	5	5
Diabetes, known duration	< 9 yrs	11	7	3
	10-19 yrs	19	8	11
	≥ 20 yrs	14	7	7
HbA1c at inclusion	7.5-7.9%	8	5	3
	8-8.9%	20	8	12
	9.0-11.9%	16	10	6
Diabetes treatment at inclusion	Oral agents (± GLP1 agonists)	20	10	10
	Insulin (± oral ± GLP1 agonists)	24	13	11
Self-monitoring of blood glucose	Once a day, fasting	15	10	5
	2- 3 times a day, before meals	15	6	9
	Before and after meals	14	7	7
Known complications	Renal	18	13	5
	Heart	10	7	3
	Eye	22	1	1
	Feet	5	3	2

Arteries	9	6	3
None	14	6	8

[†]Among participants in the control group who participated to the first round of interviews, 2 declined the second-round interview:

- 1F, 50 yrs, full-time employment, 2000-3999 €, middle school, diabetes > 20 yrs duration, insulin, HbA1c 8-8,9%, SMBG 6 per day, no complications;
- 1M, 62 yrs, retreated, 1200-1999 €, high school, diabetes 10-19 yrs, oral agents, HbA1c 8-8,9%, SMBG 3 per day pre-prandial, complications: heart, arteries.

Table 2. The 3 main poles and 8 themes of disease management issues.

Poles	Themes
Health knowledge	Knowledge base Access to knowledge
Management of the disease	Food Exercise Treatment Monitoring
Expertise, support and social network	Relationships with professionals Health and social support

Figure Legends

Fig 1. Disease management. Functional, interactive and critical relationships to the 8 themes. First round interviews, n=44.

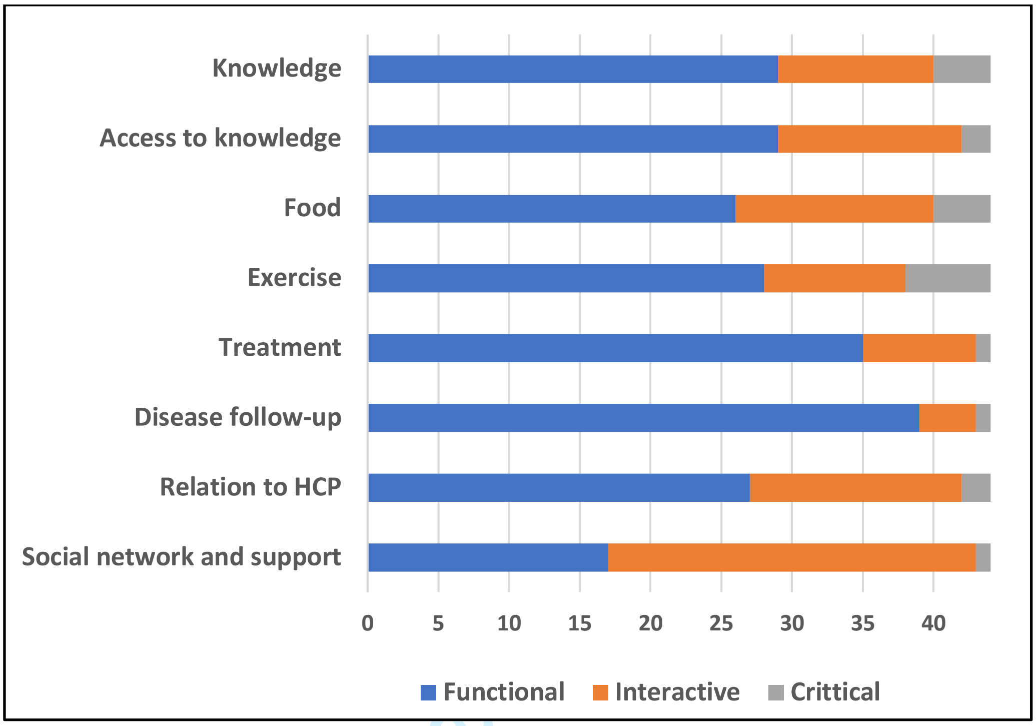
Fig 2. Functional, interactive, and critical relationships to the 8 themes of disease management: Progress from 2012 (1st round interviews) to 2015 (2nd round interviews). Ermies ethno-socio study, n=42.

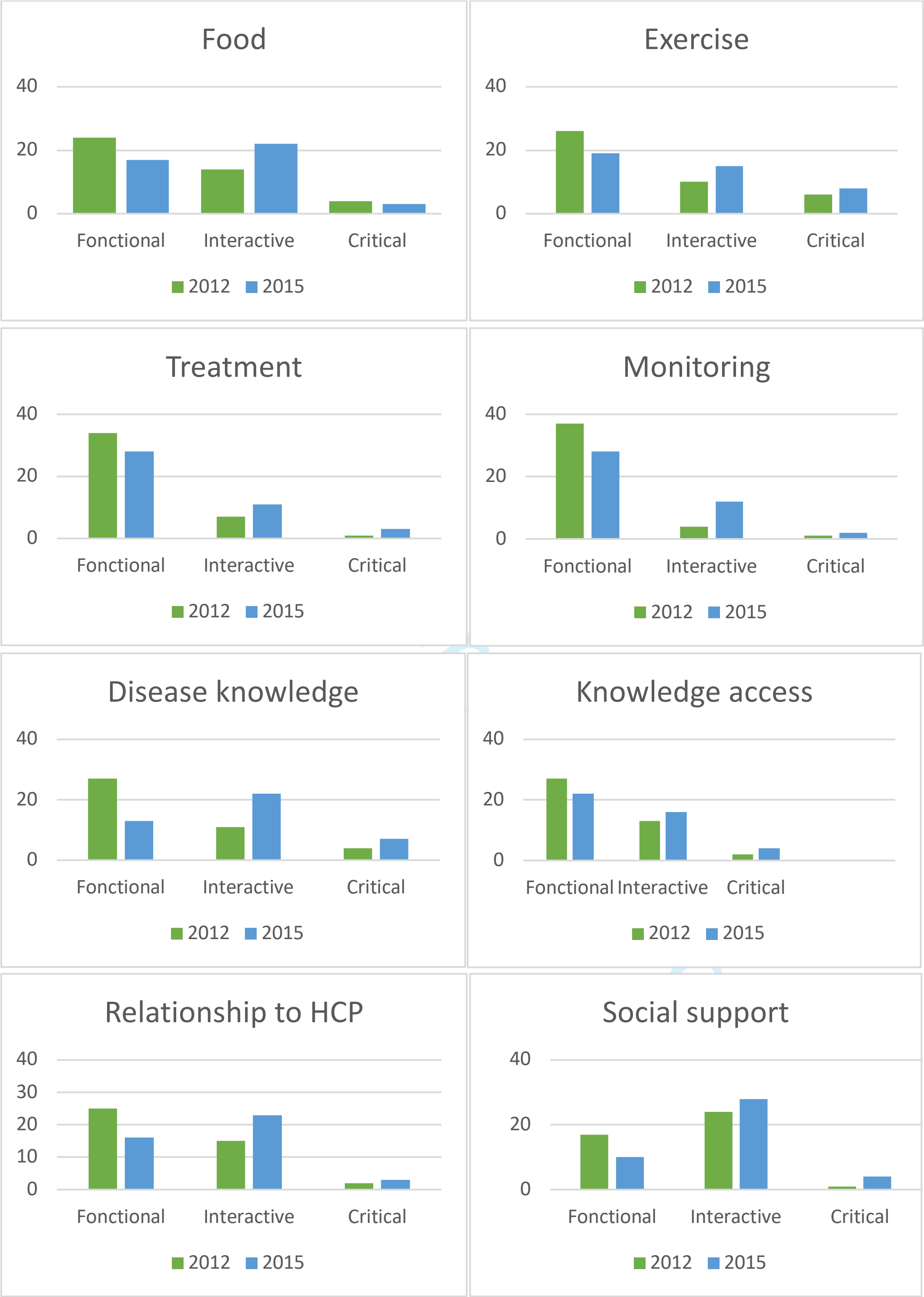
Fig 3. Repartition of individual health literacy profiles among the 9 scales of the Health Literacy Questionnaire. Ermies-ethnosocio study, n=39.

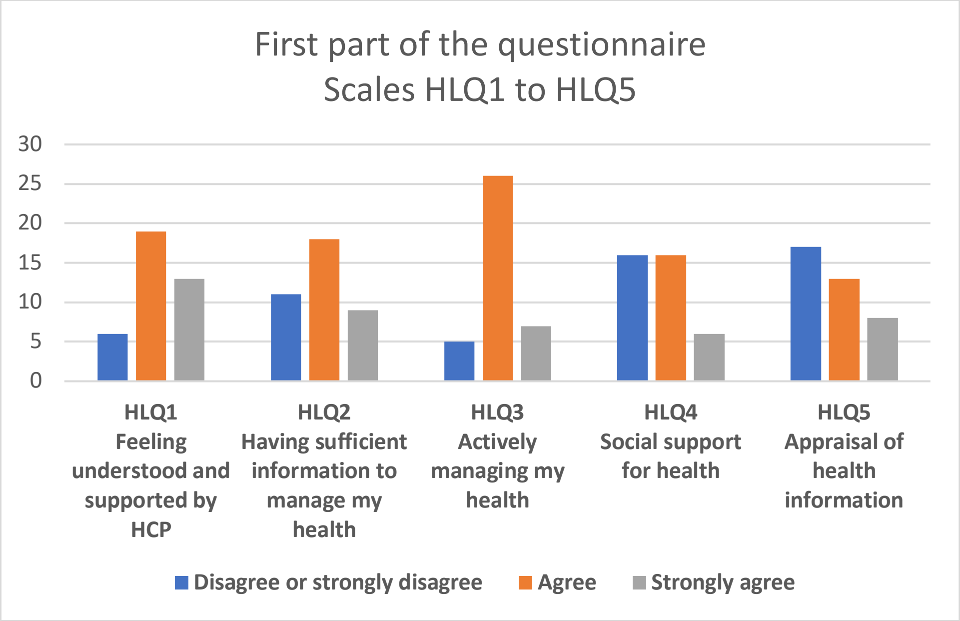
Cut-off scores were:

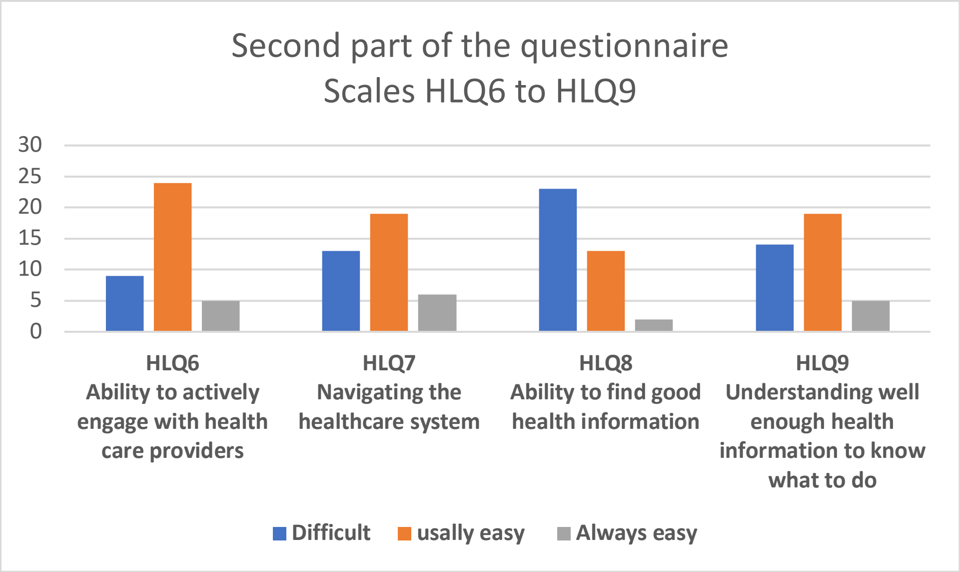
- for scales (1-5) of the 1st part of the HLQ: <3 Disagree or strongly disagree; 3-3.5 Agree; ≥3.5 Strongly agree

- for scales (6-9) of the 2nd part of the HLQ: <3.5 Difficult; 3.5-4.5 Usually easy; ≥4.5 Always easy.


Knowledge
Access to knowledge
Food
Exercise
Treatment
Disease follow-up
Relation to HCP
Social network and support
0
5
10
15
20
25
30
35
40
Functional
Interactive
Crittical


Food
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Exercise
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Treatment
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Monitoring
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Disease knowledge
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Knowledge access
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Relationship to HCP
40
30
20
10
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015
Social support
40
20
0
Fonctional
Interactive
Critical
🟩 2012
🟦 2015


First part of the questionnaire
Scales HLQ1 to HLQ5
30
25
20
15
10
5
0
HLQ1 Feeling understood and supported by HCP
HLQ2 Having sufficient information to manage my health
HLQ3 Actively managing my health
HLQ4 Social support for health
HLQ5 Appraisal of health information
Disagree or strongly disagree
Agree
Strongly agree


Second part of the questionnaire
Scales HLQ6 to HLQ9
30
25
20
15
10
5
0
HLQ6 Ability to actively engage with health care providers
HLQ7 Navigating the healthcare system
HLQ8 Ability to find good health information
HLQ9 Understanding well enough health information to know what to do
Difficult
usally easy
Always easy

Appendix 1. Self-management education course

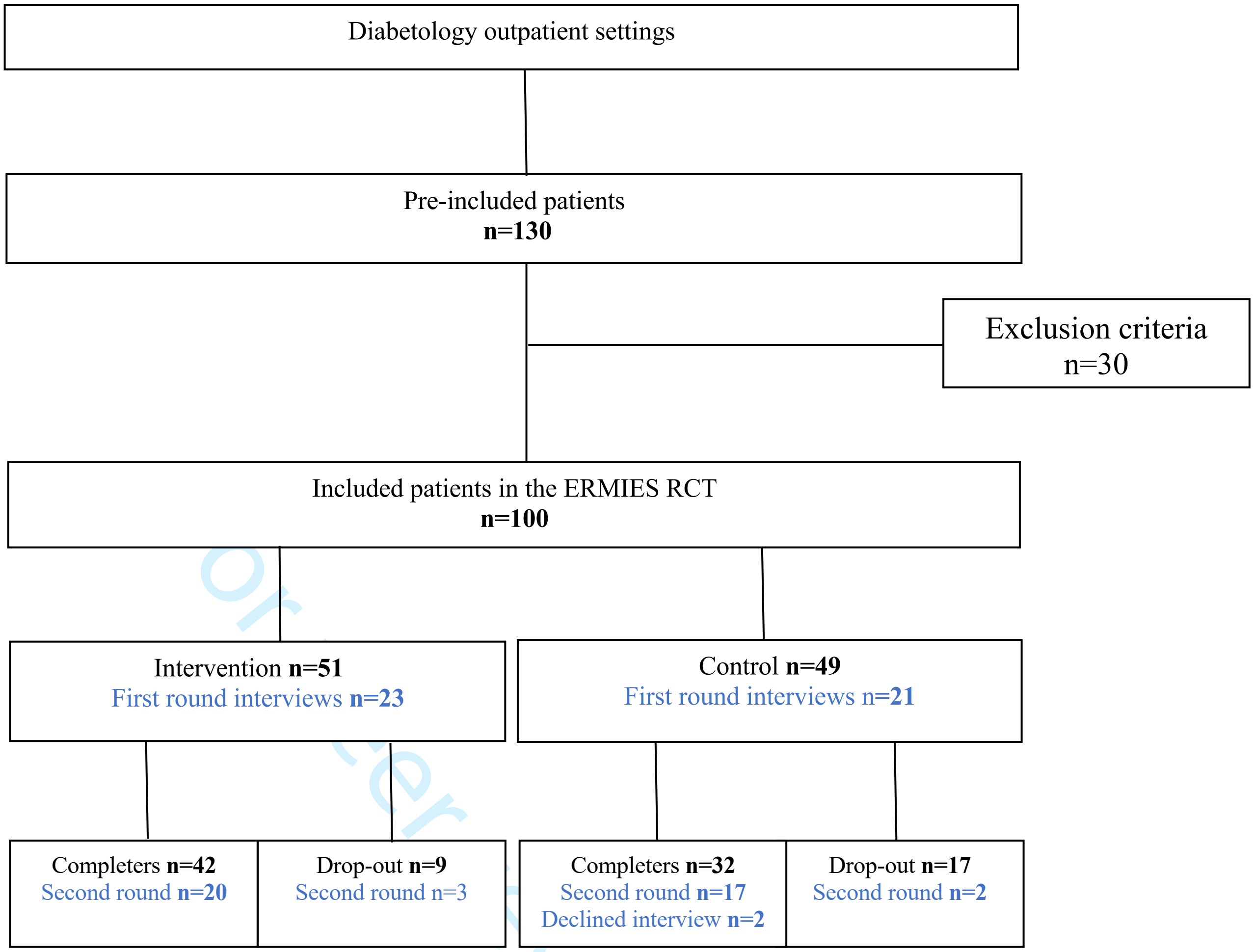
1. Initial education cycle

The initial cycle consists of 3 to 7 educational weekly or bi-weekly 2-hour group sessions for 4 to 10 patients:

- Personalised assessment group session (120 minutes): patients work on their own clinical and biological factors that can influence health maintenance (blood glucose, blood pressure, lipids, weight, waist circumference, smoking), before looking at lifestyle measure effects and specific impacts of eventual changes. They then scrutinise the feasibility of action planning and implementation in real life, and goal-setting taking into account all individual, social, and contextual dimensions. At the end of this session, each learner can schedule 2 to 6 specific additional focused sessions, according his/her needs and goal-setting.
- Two to 6 specific additional focused sessions of 90 to 120 minutes, spaced at intervals of 1 to 2 weeks (3 weeks maximum). These sessions are selected on the six following themes: self-monitoring and adaptation of treatment - physical activity - food and control of fat intake – understanding of diabetes and treatment – challenges of insulin therapy – prevention of foot lesions.

2. On-going SME support:

- Personalised empowerment follow-up including group sessions of 90 to 120 minutes each, with three to ten patients at 16, 32, 48, 64, 80 and 96 weeks. Each session will be scheduled at the end of the previous session. Patients will work on the progress of their indicators as follows: medical (HbA1c levels, blood sugar, arterial pressure, lipids, waist circumference, smoking, treatments); health coping and goal setting (action(s) initially decided on, actual implementation, obstacles); cognitive (review of knowledge gained through the first session assessment session and additional sessions). The summary of the session comprises objectives for action(s) to be implemented and the scheduling of optional additional sessions to support practical implementation.



Qualitative study nested in the ERMIES trial. Flow chart of participants

Appendix 3

Functional, interactive and critical relationship to the 8 themes of disease management

Themes	Functional	Interactive	Critical
Physical activity	I walk or move every day because I've been told to be active for diabetes	I am physically active because it improves my diabetes	I am physically active whenever possible, in relation to the life I have in hand (not only because of my diabetes). Being active is really good for me
Food	When I buy food and cook, I do try to respect the recommendations I received (from the doctor, the dietician...)	I understand that food should be balanced and diversified: I adjust my diet as best I can according to the situations of everyday life	Eating a balanced diet does not mean you have to deprive yourself. With the disease, I learned to buy and cook differently, while taking into account the cost, tastes, desires and availability of food
Treatment	I try to follow the treatment prescribed to me as best I can	I follow my treatment as best I can because I realize that it is useful	I know the role of each treatment and I adjust it according to the type of life I have, so as to achieve as good a balance as possible
Follow-up	I keep up with my diabetes on a daily basis and show my results to my doctor regularly	I test when I can and discuss my diabetes care with my doctor (or other provider).	Once I understood diabetes and its evolution, I can live a normal life, while having regular tests to avoid complications.
Social support and network	I try not to bother anyone with my illness	I realize that I am not alone and that I can count on others	I just live like everyone else and I nearly forget that I have diabetes
Relation to health care providers	I do whatever my doctor (or other provider) tells me	I have discussions with my doctor (or other) about diabetes because I want to understand what is going on	I know my diabetes and visit health care providers only when needed.
Access to knowledge	I stick to what my doctor says about my diabetes	Whenever I come across something about diabetes, I look	I don't listen to anything: I know where the sources are and I stick to that

		at it and try to get something out of it	
Knowledge	Diabetes is something that's wrong: it's not up to me or what I do	Diabetes is one or more things that need to be monitored independently of each other, but which I can do something about (e.g. diet and/or physical activity, etc.).	Diabetes is a set of interacting elements (the body, the organs, the environment, etc.) that puts me at risk of complications if I don't pay attention, but that I can also stabilise (or improve) if I monitor all these elements at the same time, taking into account the life I lead

Appendix 4. Health Literacy Questionnaire scales.

HLQ scale	1st part of the questionnaire Response options from 1 -strongly disagree- to 4 -strongly agree-	
HLQ 1	Feeling understood and supported by healthcare professionals	4 items
HLQ 2	Having sufficient information to manage my health	4 items
HLQ 3	Actively managing my health	5 items
HLQ 4	Social support for health	5 items
HLQ 5	Appraisal of health information	5 items

HLQ scale	2nd part of the questionnaire Response options from 1-cannot do or always difficult- to 5 -always	
HLQ 6	Ability to actively engage with healthcare professionals	5 items
HLQ 7	Navigating the healthcare system	6 items
HLQ 8	Ability to find good health information	5 items
HLQ 9	Understand health information enough to know what to do	5 items

Table 1

Standards for Reporting Qualitative Research (SRQR)[a]

No.		Topic		Item
		Title and abstract		
S1	✓	Title	Page 1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	✓	Abstract	Design p. 2	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
		Introduction		
S3	✓	Problem formulation	p.4-5	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	✓	Purpose or research question	p.5	Purpose of the study and specific objectives or questions
		Methods		
S5	✓	Qualitative approach and research paradigm	p. 7.8	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale[b]
S6	✓	Researcher characteristics and reflexivity	p. 7	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	✓	Context	p 5.6	Setting/site and salient contextual factors; rationale[b]
S8	✓	Sampling strategy	p. 6.	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	✓	Ethical issues pertaining to human subjects	p. 6.	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	✓	Data collection methods	p. 7. 9	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	✓	Data collection instruments and technologies	p. 8 – appendix 3	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	✓	Units of study	p.6 – appendix 2 p.9 – table 9.	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	✓	Data processing	p. 7. 8	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	✓	Data analysis	p. 7. 8 p. 9	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale[b]
S15	✓	Techniques to enhance trustworthiness		Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
		Results/findings		
S16	✓	Synthesis and interpretation	p. 9-15	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	✓	Links to empirical data	p. 9-15	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
		Discussion		
S18	✓	Integration with prior work, implications, transferability, and contribution(s) to the field	p. 16.-17.18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	✓	Limitations	p. 18-19	Trustworthiness and limitations of findings

(table continues)

BMJ Open

Health literacy in context: struggling to self-manage diabetes. A longitudinal qualitative study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046759.R2
Article Type:	Original research
Date Submitted by the Author:	12-Oct-2021
Complete List of Authors:	Debussche, Xavier; Institut national de la santé et de la recherche médicale, Centre d'Investigations Cliniques 1410 ; Centre Hospitalier Universitaire de la Reunion, Endocrinology Diabetology Balcou-Debussche, Maryvette; Reunion University, ICARE EA7389 Austral Cooperative Institute for Research in Education Ballet, Delphine; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education Caroupin-Soupoutevin, Jessica; Université de la Réunion, ICARE EA7389 Austral Cooperative Institute for Research in Education
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Public health, Qualitative research
Keywords:	PUBLIC HEALTH, QUALITATIVE RESEARCH, DIABETES & ENDOCRINOLOGY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

Health literacy in context: struggling to self-manage diabetes.

A longitudinal qualitative study

Xavier Debussche, Maryvette Balcou-Debussche, Delphine Ballet, Jessica Caroupin-Soupoutevin

Xavier Debussche. MD, MSc Nutrition, Endocrinology Diabetology department, CIC 1410 INSERM, CHU Félix Guyon, Saint-Denis Réunion, France

Maryvette Balcou-Debussche. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Delphine Ballet. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Jessica Caroupin-Soupoutevin. I*care* Cooperative Austral Institute for Research in Education, EA7389, INSPE-University of Réunion, Saint-Denis, France

Corresponding author : Dr Xavier Debussche, Service d'Endocrinologie Diabétologie, CIC 1410 INSERM, CHU Félix Guyon, Allée des Topazes, 97400 Saint-Denis Réunion. +33 650 108005

e-mail: xavier.debussche@inserm.fr

Word count 4853

Abstract

Objectives. Considering health literacy needs is a key component of health services responsiveness to diabetes self-management among vulnerable individuals. The purpose of this qualitative study was to provide a detailed analysis of the health literacy of people with type 2 diabetes in relation to their daily self-care practices.

Design. Nested qualitative study in the ERMIES randomized controlled trial testing a 2-year structured care in type 2 diabetes. First round of semi-directed interviews at the beginning of the trial with thematic analysis of content. Second round at the completion with directed interviews guided by the first round's themes together with health literacy questionnaire.

Settings. Interviews conducted at home.

Participants. Forty-four (31 females/13 males, 30-79 yrs, HbA1c≥7.5%) consecutive participants out of 100 recruited in the ERMIES trial from 4 diabetology outpatient settings (Reunion Island). Forty-two respondents to the 2nd round interviews.

Results. Three poles structured into eight themes characterized practices in context: health knowledge, disease management, expertise and social support. The relationships of participants in each of the eight themes were differentiated, ranging from functional to interactive and critical. Treatment and follow-up were essentially functional, while diet and exercise remained more interactive. Social support and relationship to health professionals were important determinants of disease management.

Conclusions. Treatment management and disease monitoring remain primarily the job of health professionals, as opposed to diet, physical activity and social support being part of ordinary practice. Decision-making, as a shared social task, as well as resources for participation in health services, should be considered for relevant interventions in type 2 diabetes.

Keywords. Health literacy; healthcare pathways; health behaviours; type 2 diabetes; patient-provider relationship; self-care; Health Literacy Questionnaire (HLQ)**.**

Strengths and limitations of this study

- This longitudinal qualitative study examined health literacy and health practices in vulnerable people struggling with uncontrolled type 2 diabetes enrolled in a 2-yr structured intensive managed care
- Interviews were conducted at home, considering the social contexts of health literacy related to disease management in real life, and health literacy needs were assessed too via the multidimensional Health Literacy Questionnaire

- The study took place in Reunion Island characterized by deeper social disparities compared to mainland France and the studied population was mainly female, with few included men

INTRODUCTION

Long term management of diabetes is challenging [1,2]. People with type 2 diabetes struggle with the everyday constraints, treatment adherence, and monitoring [3–6]. Beside medical diagnostic and therapeutic measures, self-management education and support has been shown crucial in helping persons with diabetes manage the disease while maintaining quality of life [7–11]. France, with a high level of health insurance coverage, has been confronted to a health system primarily dedicated to acute care, struggling to establish a real chronic care coordination [12]. In spite of a slight improvement in the quality of care between 2001 and 2007, the French ENTRED study has shown that only 17% of people with type 2 diabetes participated in self-management education, mainly in hospital setting [13]. Only 2% of persons treated for type 2 diabetes received all of the recommended monitoring regular exams and follow-up [14]. In contrast to a self-efficacy rated as high regarding nutrition, exercise, treatment management and self-monitoring of blood glucose [13], the level of medication adherence is quite low [15] , and the complications of diabetes remain frequent and severe, with increasing social and regional disparities [16]. Reunion island, a French overseas department, as an example, is characterized by a higher prevalence of complications despite good accessibility to quality care [16,17].

Health literacy (HL) refers to the cognitive and social skills which determine the ability of individuals to gain access to, understand, remember and use information in ways which promote and maintain good health [18,19]. HL has been linked to numerous health indicators and outcomes [20] and is a potential key component of health perceptions and practices [21–23]. In diabetes, HL has been mainly assessed through functional tests of reading ability, understanding, and/or numeracy and has been linked to numerous outcomes [24]. Beyond functional HL, communicative and critical HL are central [25]. Communicative

HL skills integrate the complex cognitive and social skills needed to perform daily activities, to extract information and infer meaning from different forms of communication, to apply new information to changing circumstances, and to interact with health services. Critical literacy refers to skills that can be applied to analyse critical information and adapt to better control life situations.

Understanding the complex interplay of self-care practices in diabetes in the light of HL skills and resources has been seldom explored [26-29]. Qualitative studies are needed to better understand the capacity and resources of individuals to implement health-relevant and meaningful practices and to adapt them to the strengths and limitations of the environments in which they are implemented. The present study aimed to qualitatively analyse health literacy in its multiple dimensions in relation to self-care practices, in the context of structured care in 4 ambulatory diabetes care facilities in La Réunion.

METHODS

Study design and population

The present study was part of the mixed ERMIES randomized controlled trial. The main objective of ERMIES was to evaluate the efficacy of a structured self-management education intervention in under-controlled type 2 diabetes (HbA1c> 7.5%). The detailed protocol of the trial (NCT01425866 ClinicalTrials.gov) is described elsewhere [30]. Out of 4 diabetology outpatient settings of the island of Reunion, 100 people were included between October 2011 and November 2014 [30,31]. Participants of both arms benefited from a structured initial group education course conducted by trained educators, blind to the subsequent group allocation, within the 12 weeks following inclusion (appendix 1). The intervention group was invited every 4 months to attend a structured group session. All included participants attended a quarterly medical follow-up in the diabetology unit during the study period (96 weeks).

The nested qualitative study included 44 subjects. Interviews were conducted in 2012 with the first 44 consecutive participants included in ERMIES who agreed to participate in the qualitative study. Among the 44 included the nested qualitative study, 42 participated to the second-round interviews in 2015, and 2 declined. Five out of 42 dropped out from the trial (appendix 2) but accepted to respond to the second-round interviews.

When included, all participants were informed of the conditions of the research. They signed a written consent for a qualitative study by means of interviews conducted in their homes. At the time of the appointment (before each interview), a new information with oral agreement was given.

The ERMIES study received the ethical agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study.

Participant and public involvement in research

Participants were not involved in setting the research question; nor did they participate in the design or implementation of the qualitative study. No participants were asked to advise on interpretation or writing up of results. However, during the second round of interviews, the results of the first-round interview's analysis were exposed and discussed with some participants who wished to do so.

The results of the research will be provided to study participants, and to local stakeholders, in order to join in the health literacy needs assessment as part of the eLS-OIIS project, whose objective is to help adapting health services responsiveness to persons with chronic diseases in Reunion island [32].

Qualitative study

First round of interviews

The research involved two research assistants trained in the socio-anthropological approach. The work on the interviews and analyses was built up through teamwork and regulated as the research developed, taking into account the contexts in which the participants were interviewed. The analyses of all the interviews were carried out by the two researchers independently of each other: these analyses were then crossed, discussed and reinterpreted in the event of differing interpretations. The result thus corresponds not to a single interpretation of the data, but to an intelligibility constructed, negotiated and regulated within the team, at every stage of the scientific process. Interviews, one hour each on average, were conducted at the participants' homes and focused on diabetes, self-monitoring, access to information, relationships to education and learning, participant positioning, decision-making, environment and support. The participants were invited to describe their behaviour in hospital, domestic and occupational settings, and in socio-cultural contexts such as family events. Specific topics included were the history and progression of the illness, knowledge acquired and sources, food practices, physical activity, monitoring and treatment of diabetes, and the participants' perceptions of the health care providers (HCP) and services. The usual sociodemographic data and information about diabetes (duration, HbA1c, self-management of blood glucose, treatment, complications) were collected from the participants at the time of the first-round interviews.

Each interview was recorded and then fully transcribed by the research assistants in the language chosen by the respondent. Transcripts of interviews held in Creole were subsequently translated into French. The 44 interviews were investigated through thematic discourse analysis understood as communication patterns of both a social and linguistic nature [33]. The categories and signifiers were developed using the constant comparison method [34]. The themes which emerged were tested and modified during additional cycles of data collection. The saturation of data, with a wealth of social configurations and relations to health, hospital and home environment, could be obtained despite the practical constraints of the recruitment of participants immediately after the inclusion in the ERMIES study. The analysis was carried out using the N-Vivo 10 QSR International qualitative analysis software. Several themes constituting the management of diabetes in the ordinary context could be determined. For each of these themes, we identified three types of relationships in reference to the categories of HL established by Nutbeam [25]:

- A "functional relationship to ...", i.e. an instrumental relationship to (diet, physical activity ...), tasks being exercised without a critical look in everyday situations.
- An "interactive relation to ..." that engages cognitive and social skills used to participate actively in everyday activities, infer the meaning of different forms of communication and apply the new information to changing circumstances.
- A "critical relation to ..." that mobilizes more sophisticated cognitive and social skills, applied to a critical analysis of information and their use to exercise greater control over the events of life.

The first names used here for the quotations are fictitious.

Second round of interviews

Based on the analysis of the initial interviews, we created a qualitative data collection grid that was proposed in 2015 to 42 participants (2 out of the 44 declined the interview). This grid (appendix 3), covering the 8 themes and the 3 levels of "relations to" was completed both by the interviewee and the interviewer. All interviews and exchanges around the grid were recorded and transcribed in full, which, in case of distances in the responses, made it possible to listen to each speech again.

The coding and analysis were subjected to a triangulation process carried out by three members of the research team (DB, JC, MBD). The data from the 44 interviews and the second round's grids of interviews of behaviour at home were crossed-referenced in two ways: for each participant (which made it possible to produce case studies of participants), but also by specific themes (food, physical activity etc.) taking the whole of the corpus into account. This work made it possible to show intra and inter-individual variations relating to the talks and practices in relation to the disease and its management, the world of healthcare, the social and familial environment, and involvement in conduct for prevention and health (food, physical activity). Hence, it was possible to describe the individual changes and the evolution of the type of relationship (functional, interactive, critical) for each of the 8 themes from 1st to 2nd rounds.

The inter-rater reliability of the coding of the type of relationship (functional, interactive, critical) to the themes was 62%. When the coding was discordant, the 3 researchers confronted their points of view to reach a consensus.

During the second round in 2015, HL was assessed using the Health Literacy Questionnaire (HLQ) for 39 of the 42 participants. The HLQ is a multidimensional questionnaire with robust psychometric properties [19], translated and validated in French [35], and composed of 44 items exploring HL through 9 independent scales of 4-6 items (Appendix 4). The individual score for each scale is calculated as the mean of the corresponding items.

RESULTS

Socio-demographic and clinical characteristics of the 44 participants are described in table 1. The gender distribution (31 of 44 were females) was roughly the same as the overall ERMIES trial population (67%) as well as median age, education, employment, and income.

First round interviews

Day-to-day management of the disease took place in a variety of forms and contexts: at home, in the family, in the healthcare context or setting, during leisure time or in the socio-professional sphere. A set of 8 themes could be individualized from the coding of the interviews that constituted the ordinary management of diabetes. These 8 themes are grouped into 3 poles which interact through complex dynamics (table 2).

The consistency of the individual work through these 8 themes, its continuity and its inclusion in the different relationships (functional, interactive or critical) were, to varying degrees according to the participants, constitutive of the management of health and illness (fig 1).

Health knowledge and access to knowledge

Relationship to knowledge and access to knowledge was primarily functional (for 29 out of 44 participants).

'*Diabetes is too much sugar in the blood*' (Sylvain, 46 years old, craftsman).

'I try to listen (to the radio or TV), I try to understand, but it goes into my head but I don't understand.' (Irène, 72 yr, retreated)

For some participants, the relationship to knowledge was more interactive (n=11). Participants were able to make connections between at least two elements, such as the links between diabetes and a balanced diet or regular physical activity.

Regarding access to knowledge, 13 were interactive.

'…Sometimes, if my daughter arrives with her computer, she searches, I ask, and then […]

documents are sent to me all the time, so I read, there are testimonies, there are drugs, how to do it, how not to do it. So I'm following all this very closely' (Constance, 64 yrs, retreated).

At the critical level, a few participants (n=4) refer to a complex system, in which interactions between the different components contribute to the evolution of the disease and its complications.

Only 2 participants appear to have a critical relationship to knowledge access.

'*Diabetes, in terms of price, drugs, it's linked to research, to laboratories that also put what they want, and then there are crazy people who can write anything. So on this side, there is a lack of control over what is shown on the Internet. (...) It's a gold mine, but you have to know if it's gold, real or synthetic*.' (Damien, 73 yrs, retreated)

The 'ordinary' management of disease

Food and exercise

Many participants (24/44) exhibited a functional relationship to diet.

'*To eat, I eat about as the hospital tells us to do and what it gives us*'. Delphine, 50 yrs, unemployed.

Others (14/44) were more interactive:

'*I even get to correct something when I make a mistake at a meal the next time. I know how to follow my diet and how to promote it in relation to my diabetes.*' Ludivine, 76 yrs, retreated.

Or even critical (4/44):

'*it's in the way you cook things... for example, eat a cod cari, well, you have to put oil in it, otherwise how else? well, that's exceptional, ... we have a fish cari, if for example I do toothfish, I almost don't put oil in it because toothfish is already a fish that is fatty, even if it's good fat*'. Blandine, 57 yrs, account manager.

Similarly, the relationship to exercise was mainly functional (29/44)

'I go to the health network for sport but that's fine they do about 15 days but then there's nobody left, we can't do it alone, we don't really know how to do it, ... Irène, 69 yrs, retreated.

Treatment and monitoring

The relationship to treatment and monitoring was functional for the majority of participants (36 and 39 respectively on a total of 44).

'I take all the medicines as required [...] I have an appointment with doctor X; he will see if I need to add a medicine'' (Beatrice 64 yrs, occasional saleswoman)

'You have to trust the treatment, because the doctor has prescribed it for us...' (Charles, 56 yrs, Gardien)

'So the doctor can check the blood sugar level: it's how high and all that,…' (Brigitte, 62 yrs, retreated)

A few participants were more interactive, especially regarding self-monitoring:

'On Tuesday, I had 1 hour of Taiichi, my test was 1.30 in the morning, 2.04 after breakfast, 1.31 at noon. I did Taiichi, 1.96 after lunch, so the benefit of Taiichi continues.[...] Wednesday I was at 1.59 and after breakfast I was at 3.02 but I know why: I ate a banana [...] at noon I went shopping [...] I left my car as far away as possible so that I could walk, [...] (Ludivine, 73 yrs, retreated)

Only one participant exhibited critical relationship to treatment and monitoring:

'I have my insulin, three injections a day and then I check with the meter […] If necessary, I'll do other checks during the day, […] Well at one point, I had stopped [the bike] because it was too hot and so there, as I didn't change my treatment, obviously the treatment was too strong and so I had hypoglycemia…'. (Guillaume, 66 yrs, retreated, artist)

Expertise, support and social network

The relationships with HCP was functional for 26/44.

'There's the nurse who comes to prep my medicine [...], I just didn't understand, because I can't read very well, so I used to take the drugs in a mess, any way ....' (Tatiana, 70 yrs, unemployed) but more often interactive (16/44) than for treatment or follow-up.

' I'm more used to Dr. X, he knows my problems so I prefer to see him personally, he helps me a lot morally [...] And then there's Nurse Y who explains very well, who's a good nurse, frankly I have nothing to say, well maybe they serve to support me too, morally and medically, that's it.' (Constance, 51 yrs, retreated)

All of those who displayed functional relationship to HCP were functional too for treatment (except 1 interactive) and disease follow-up. Interestingly, the interactive nature of the relation to HCP was not associated with interaction in treatment for 11 out of 16 or in monitoring (14/16).

Social support

In most cases, participants did not feel isolated in the management of their illness: 26 out of 44 participants receive real family or friends support, which was expressed as much in the form of solidarity as in the family sharing. This relational frame crystallizes around eating practices '*Everyone at home eats the same since I became diabetic*' (Adeline, 73, retired), physical activity '*Sometimes when you decide, it's either her or me, you walk a little bit*' (Sylvain, 47, artisan) or in understanding the disease: '*It's true that my husband, working in the hospital, it helped me a lot*' (Blandine, 60, employee). This support differs according to the relative, as Clarisse (55 years old, no professional activity) testifies: '*Yes, maybe not with my partner but my children, and then there is my family nearby, my sisters, my brothers, my parents, so no worries*'. In some cases, the person concerned with diabetes prefers to spare his or her family by taking charge of the management of the disease himself or herself. ‘*For me, it is not a handicap, diabetes is there, we manage and that's it. (...). I never talk about it (diabetes), it's my case*’ (Sabine, 69, retired).

Functional, but also interactive social support was frequently associated with functional follow-up (16/17 and 23/26) and functional treatment (15/17 and 21/26), but not always with functional relationship to food (11/17 and 15/16) or exercise (11/17 and 17/26).

Second round of interviews

The interviews conducted with 42 participants at the beginning and at the end of the ERMIES study highlighted the changes over time in the variables that make up the relationship with disease management, but in different ways according to individuals and contexts. The 2 participants who declined the second interview, but completed the trial, were both in the control group, and exhibited at the first round interview a functional relationship to all themes except social support that was interactive.

Overall, health knowledge and access to knowledge evolved into a more interactive and critical relationship among participants, slightly more markedly in the intervention group. The most notable change was observed in the management aspects, particularly in relation to food, with many participants shifting from a functional to an interactive relationship (fig 2). With regard to physical activity, the many shifts from interactive to critical showed that participants understood the benefits of physical activity and were able to better integrate it into their practices. For these two themes, changes were observed in both the intervention and control groups. The move towards a more interactive or even critical posture was also objective for disease follow-up and monitoring, but here more so in the intervention group. However, the relationship to treatment remained mostly at a very functional level (28 out of

42) ‘*The nurse prepares that, and I take my oral medication. And I have the prescriptions for all the medicines I take it*’ (Marguerite, 79, retreated, intervention group), and few participants modulated and adjusted the treatment on their own regardless of the allocation group. There was a clear shift for many participants towards a more interactive relationship with HCP, slightly more in the intervention group. The relationship to social support was also less functional.

The 5 participants who dropped out from the trial were younger than those who completed the study, with low income, and 2 of them had difficulties in reading and writing. All five had an essentially functional relationship with treatment and follow-up of the disease, leaving the decision and conduct to the physician and other health care professionals, although two of them were interactive in their relationships with providers.

Table 3 displays the mean scores through the 9 dimensions of the HLQ for the 39 participants who filled in the questionnaire during the second round of interviews. Overall, the greatest difficulties were in having sufficient information to manage health (HLQ2), in appraising health information (HLQ5) for the 1st part of the questionnaire, in ability to find good health information (HLQ8) and in understanding well enough health information to know what to do (HLQ9) for the second part of the questionnaire. On the contrary, scores were higher for scale 1 ‘Feeling understood and supported by HCP’ and scale 6 ‘Ability to actively engage with HCP’.

DISCUSSION

Both people with type 2 diabetes and HCP are confronted in the real world with the daily and long-term management of the disease [4,36,37]. HL is a potential determinant in attaining lifestyle behaviour, medication adherence, and adequate monitoring of the disease

[38,39]. This qualitative study, in which 86 interviews were conducted at the initiation and after the completion of a structured 2-year follow-up, showed the multidimensional nature of HL in relation to self-care practices and disease management. Ordinary management of diabetes consisted of distinct postures for lifestyle behaviours on one side, and for medical aspects on the other: participants mainly had a more active (interactive or critical) relationship to diet and exercise than to treatment and monitoring. This was even more sizeable after 3 years, with most participants remaining functional for treatment and monitoring, while being interactive or even critical for exercise and diet. Social support and patient-provider relationship were important elements associated with a more interactive posture as regard to disease management.

In the present study a fine qualitative approach of disease management analysed through the theoretical lens of the Nutbeam's health literacy scheme yielded useful insights for a comprehensive description of strengths and weaknesses at the individual and contextual level for people struggling with disease management [25]. The HLQ was used as a complement to describe the health literacy needs expressed by participants. The HLQ is a validity driven questionnaire and grounded in real world settings [19]. Correspondence with the health literacy profiles using the 9 scales of the HLQ should be cautious and grasped in a complementary way. Indeed, the qualitative data were strengthened by the higher scores on the HLQ scales related to HCP and services (Feeling understood and supported by HCP, HLQ1, Ability to actively engage with HCP, HLQ6, Navigating the health care system, HLQ7), and lower scores on the HLQ scales related to health information (having, finding, appraising). Similar HLQ profiles were found in community-dwelling people with type 2 diabetes in Australia, with the highest scores in dealing with HCP (HLQ1, HLQ6), and the lowest in having, appraising or finding health information (HLQ2, HLQ5, HLQ8) [40].

In this population of participants struggling with insufficiently controlled type 2 diabetes, our results highlight the predominant perceptions and attitude regarding treatment and monitoring remaining under the expertise of HCP. O'Connor et al [41] reported that people with diabetes who did not improve glucose control were more positive about their care providers, unquestioning acceptance of the doctor's role and treatment. At the opposite, a less passive approach to HCP, as well as a strategic non-compliance with medication have been described as key elements in succeeding in diabetes management and well-being [42]. Timely information and support from HCP, adapted to the actual individual constraints allow sustainable efforts for self-management [43].

Studies have shown difficulties in actively managing health, health information finding, understanding and appraisal, as well as ability to engage with HCP [19,40,44]. Using the HLQ, Friis et al [45] reported the high treatment burden in persons with chronic multimorbidity and difficulties in understanding health information. This is in line with the apparent contrast found in the present study between the level of sense of being supported by HCP and struggling with diabetes control and handling of own useful and relevant health information. For many participants, letting the caregivers take the reins of conducting and adapting medication, as well as providing long-term monitoring, made it possible for them to get involved in the challenging daily tasks of making the required nutritional and exercise changes. Studies in UK revealed also the importance of HCP attitudes regarding blood glucose readings for the continuing and relevant self-monitoring [46]. Moreover, persons with diabetes lacked understanding of what to do faced to blood glucose results, as what could be noticed too here.

This qualitative study highlights the potential shift from functional to interactive or even critical attitude obtained after a 2-yr long integrative care including structured self-management education in people with poorly controlled diabetes. Other studies have shown the role of interactive and critical health literacy in successful self-management of chronic disease [16]. However, this shift highly differs by individual, medical, healthcare and social contexts [16,47]. Taking into account health literacy profiles and adapt self-management education to these health literacy needs is crucial in chronic diseases [3,48-50].

Social support appeared to be frequently associated with active management of disease. Maintaining self-management is a hard daily task, demanding individual investment as well as social, familial, not just taking regularly medications and coping with lifestyle [4,49]. On the basis of individual dispositions issuing from time and experience, the power of the everyday context surrounding key practices to control and overcome illness have to be considered [3,43]. Low personal resources, e.g regarding the appropriation of health information, together with burdensome family and social situations may explain difficulties in engagement with self-management [43].

Gender distribution of participants with most females is worth noting, and this was in line with the distribution in the whole ERMIES sample (67%). Lower inclusion rate of males vs women have been previously noticed in other studies in Reunion [51–53]. According to the national health insurance's data the prevalence of declared and/or treated diabetes in Reunion island is higher in women than in men (9.6% versus 7,9 %) [54], suggesting a possible under-diagnosis and a higher drop-out from care of type 2 diabetes in men. Beside gender, qualitative data obtained here from drop-out participants, who were younger, with low income at the second-round interviews suggest greater difficulties regarding understanding and appraising health information, social support and interactions with HCP.

The main strength of this study is its longitudinal design, with interviews repeated after the completion of a structured managed care and a multidimensional health literacy assessment via the HLQ. Interviews were conducted at home, taking into account particular features and social contexts, in a sample of participants who displayed actual difficulties in managing insufficiently controlled diabetes. Nevertheless, this study has some limitations. Firstly, it took place during a comparative intervention trial with structured intensive managed care under the coordination of specialized secondary outpatient centres, and in Reunion island, a French outmost territory, with deeper contrasted social disparities compared to metropolitan France. The studied population was mainly female, and the question of the lower implication of men in self-care was difficult to analyse. Hence any extrapolation must be done with caution, even if, conversely, this context makes it possible to better grasp elements specific to disadvantaged populations. First round interviews were held in the weeks after the inclusion in the trial. This may have influenced the discourse on practices and relationships with caregivers, even though before the initiation of the education course. The second round interviews took place after 2 years, following a structured managed care, so that the attitudes and relationships to HCP, treatment issues, and monitoring could have been influenced. Nevertheless, the results underline furthermore the needs of participants for other types of support from HCP and services, as exhibited by the combination of the HLQ profiles obtained together with the second round interviews: education and support have to work on the actual contextual factors that make sense in decision making and sharing and in the appropriation of relevant health practices on an everyday basis. More specifically, the transition from a passive attitude towards monitoring and the elements allowing for the relevant adaptation of treatment and health practices should be the subject of a process of appropriation in which the particular contexts should be apparent.

This longitudinal qualitative study in vulnerable participants struggling with type 2 diabetes and low HL, shows that decision making, handling of treatment and disease monitoring remains primarily the purview of HCP. Not all self-care practices are equivalent in terms of awareness, understanding their usefulness, and appraising their effect. Moreover, the ability and the willingness of engaging in some self-practices like self-monitoring, follow-up awareness and treatment adjustment is often weak. However, this seemingly passive attitude is counterbalanced by feeling supported and trusted by HCP and is not inconsistent with an otherwise active attitude of engaging in lifestyle behaviours. For the latter, social support and shared social tasks are critical. HCP have a key role in helping chronically ill people to take long-term control of health information and services, while bearing in mind the prevalent functional relationship with monitoring and treatment adaptation.

The multidimensional nature of diabetes management and of HL, both embedded in social configurations, has to be acknowledged. Conceiving and designing interventions and services aiming at improving diabetes self-management should take into account these dimensions of self-care and assess the differentiated HL dimensions according to individual variations and contexts.

List of abbreviations

HCP: health care providers

HLQ: Health Literacy Questionnaire

Declarations

Ethics approval and consent to participate

The ERMIES study received the agreement of the CPP Sud Ouest Outremer III 20/01/2011, amendment of 10/05/2011 for the nested longitudinal qualitative study. All participants were informed of the conditions of the research. They signed a written consent for conducting a qualitative survey by interviews that would be conducted at home. When making an appointment (before each interview) new information was given with oral agreement.

Consent for publication

Not applicable

Availability of data and material

Not applicable. The nested qualitative part of the ERMIES study did not use any quantitative dataset. Qualitative data constituted by full transcript of interviews are subjects to confidentiality and highly sensible data. If needed, and on reasonable request, it is possible to obtain an anonymous dataset.

Competing interests

The authors declare that they have no competing interests.

Author contributions

Conception and design of the nested qualitative study were performed by MBD, DB, JCS and XD. Material preparation and data collection were performed by MBD, DB and JCS. Data analysis by DB, MBD, and JCS. The first draft of the manuscript was written by XD. MBD was a major contributor in writing the manuscript. All authors read, amended and approved the manuscript.

Acknowledgements

The authors wish to thank all the participants of the qualitative study, and all the staff from Hospital secondary centers and from the RéuCARE diabetes management network, engaged in the follow-up, education support, and treatment of participants recruited as well as in the logistic of the ERMIES study. Authors are grateful too to the team of the CIC-EC, and of the

DRCI of the CHU de La Réunion, especially Liliane Cotte, Fidéline Filleul, Vanessa Basque, Emilie Techer, for strong support of the ERMIES study.

ERMIES Investigators Study Group : Fawzi Bakiri, Maryvette Balcou-Debussche, Marie-Claude Boyer, Muriel Cogne, Xavier Debussche, François Favier, Adrian Fianu, Ania Flaus-Furmaniuk, Jean-Hugues Gatina, Nathalie Le Moullec, Victorine Lenclume, Jean-Christophe Maiza, Olivier Perrichot, Céline Regnier, Olivier Rollot, Stéphane Schneebeli, Yogananda Thirapathi, Jean-Luc Yvin. Members of the ERMIES Study Group were co-investigators and invested in the implementation and the conduct of the ERMIES RCT study.

Funding

This project received a grant from IRESP, French Research Institute in Public Health (AAP ETP 2013-03), and the ERMIES trial was funded by PHRC interregional, French Inter-regional Hospital Program for Clinical Research 2010 (GIRCI Sud Ouest OutreMer; French Ministry of Health API-04-04). The sponsor institution of the study is the Regional Teaching Hospital of La Réunion, France. The funders bodies had no role in the design of the study and collection, analysis, interpretation of data and in writing the manuscript.

References

1 Wang CY, Neil DL, Home P. 2020 vision – An overview of prospects for diabetes management and prevention in the next decade. *Diabetes Res Clin Pract* 2018;**143**:101–12. doi:10.1016/j.diabres.2018.06.007

2 Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. *Nat Rev Endocrinol* 2017;**14**:88–98. doi:10.1038/nrendo.2017.151

3 Balcou-Debussche M, Debussche X. Hospitalisation for type 2 diabetes: the effects of the suspension of reality on patients' subsequent management of their condition.

Qual Health Res 2009;**19**:1100–15.

4 Hinder S, Greenhalgh T. ‘This does my head in’. Ethnographic study of self-management by people with diabetes. *BMC Health Serv Res* 2012;**12**:83. doi:10.1186/1472-6963-12-83

5 Davies MJ, D’Alessio DA, Fradkin J, *et al.* Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2018;**2012**:dci180033. doi:10.2337/DCI18-0033

6 Debussche X. Is adherence a relevant issue in the self-management education of diabetes? A mixed narrative review. *Diabetes, Metab Syndr Obes Targets Ther* 2014;**Volume 7**:357. doi:10.2147/DMSO.S36369

7 Haas L, Maryniuk M, Beck J, *et al.* National standards for diabetes self-management education and support. *Diabetes Care* 2014;**37 Suppl 1**:S144-53. doi:10.2337/dc14-S144

8 Chatterjee S, Davies MJ, Heller S, *et al.* Diabetes structured self-management education programmes: a narrative review and current innovations. *Lancet Diabetes Endocrinol* 2018;**6**:130–42. doi:10.1016/S2213-8587(17)30239-5

9 Lawton J, Peel E, Parry O, *et al.* Lay perceptions of type 2 diabetes in Scotland: bringing health services back in. *Soc Sci Med* 2005;**60**:1423–35.

10 Pamungkas RA, Chamroonsawasdi K, Vatanasomboon P. A systematic review: Family support integrated with diabetes self-management among uncontrolled type II diabetes mellitus patients. *Behav Sci (Basel)* 2017;**7**:1–17. doi:10.3390/bs7030062

11 Care D, Suppl SS. Improving care and promoting health in populations: Standards of medical care in Diabetes 2018. *Diabetes Care* 2018;**41**:S7–12. doi:10.2337/dc18-S001

12 Chevreul K, Berg Brigham K, Bouché C. The burden and treatment of diabetes in France. *Global Health* 2014;**10**:6. doi:10.1186/1744-8603-10-6

13 Fournier C, Gautier A, Mosnier-Pudar H, *et al.* ENTRED 2007: Results of a French national survey on self-management education to people with diabetes... still a long way to go! *Educ Thérapeutique du Patient - Ther Patient Educ* 2014;**6**:10102. doi:10.1051/tpe/2014006

14 Robert J, Roudier C, Poutignat N, *et al.* Prise en charge des personnes diabétiques de type 2 en France en 2007 et tendances par rapport à 2001. *Bull Epidemiol Hebd* 2009;:455–60.

15 Tiv M, Viel J-F, Mauny F, *et al.* Medication Adherence in Type 2 Diabetes: The ENTRED Study 2007, a French Population-Based Study. *PLoS One* 2012;**7**:e32412. doi:10.1371/journal.pone.0032412

16 Fosse-Edorh S, Fagot-Campagna A, Detournay B, *et al.* Impact of socio-economic position on health and quality of care in adults with Type 2 diabetes in France: the Entred 2007 study. *Diabet Med* 2015;:1438–44. doi:10.1111/dme.12783

17 Debussche X, Pholsena M, Fournier A, *et al.* High prevalence of proteinuric nephropathy screened in patients with type 2 diabetes consulting community-based general practitioners in French overseas departments and territories. ALBUM study. *Rev du Prat* 2014;**64**.

18 Kickbusch I, Pelikan JM, Apfel F, *et al. Health literacy : The solid facts*. World Health Organisation Europe 2013. http://www.euro.who.int/en/publications/abstracts/health-literacy.-the-solid-facts

19 Osborne RH, Batterham RW, Elsworth GR, *et al.* The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC*

Public Health 2013;**13**:658. doi:10.1186/1471-2458-13-658

20 Dewalt DA, Berkman ND, Sheridan S, *et al.* Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med* 2004;**19**:1228–39. doi:10.1111/j.1525-1497.2004.40153.x

21 Aaby A, Friis K, Christensen B, *et al.* Health literacy is associated with health behaviour and self-reported health: A large population-based study in individuals with cardiovascular disease. *Eur J Prev Cardiol* 2017;**24**:1880–8. doi:10.1177/2047487317729538

22 Gazmararian JA, Kripalani S, Miller MJ, *et al.* Factors associated with medication refill adherence in cardiovascular-related diseases. *J Gen Intern Med* 2006;**21**:1215–21. doi:10.1111/j.1525-1497.2006.00591.x

23 Shiyanbola OO, Unni E, Huang Y-M, *et al.* The association of health literacy with illness perceptions, medication beliefs, and medication adherence among individuals with type 2 diabetes. *Res Soc Adm Pharm* 2018;**14**:824–30. doi:10.1016/J.SAPHARM.2017.12.005

24 Al Sayah F, Williams B, Johnson JA. Measuring health literacy in individuals with diabetes: a systematic review and evaluation of available measures. *Heal Educ Behav* 2013;**40**:42–55. doi:10.1177/1090198111436341

25 Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;**67**:2072–8.http://www.sciencedirect.com/science/article/pii/S0277953608004577

26 Balcou-Debussche M. *De l’éducation thérapeutique du patient à la littératie en santé. Problématisation socio-anthropologique d’objets didactiques contextualisés*. Paris: : Editions des Archives Contemporaines 2016.

27 Samerski S. Health literacy as a social practice: Social and empirical dimensions of

knowledge on health and healthcare. *Soc Sci Med* 2019;**226**:1–8. doi:10.1016/j.socscimed.2019.02.024

28 Sarkar U, Karter AJ, Liu JY, *et al.* The literacy divide: Health literacy and the use of an internet-based patient portal in an integrated health system-results from the diabetes study of Northern California (DISTANCE). *J Health Commun* 2010;**15**:183–96. doi:10.1080/10810730.2010.499988

29 Rowsell A, Muller I, Murray E, *et al.* Views of people with high and low levels of health literacy about a digital intervention to promote physical activity for diabetes:a qualitative study in five countries. *J Med Internet Res* 2015;**17**:1–12. doi:10.2196/jmir.4999

30 Debussche X, Collin F, Fianu A, *et al.* Structured self-management education maintained over two years in insufficiently controlled type 2 diabetes patients: the ERMIES randomised trial in Reunion Island. Cardiovasc. Diabetol. 2012;**11**:91.

31 Debussche X, Balcou-Debussche M. Analyse des profils de littératie en santé chez des personnes diabétiques de type 2 : la recherche ERMIES-Ethnosocio. *Sante Publique (Paris)* 2018;30:157-68.

32 Bakker MM, Putrik P, Aaby ASE, *et al.* Acting together – WHO National Health Literacy Demonstration Projects (NHLDPs) address health literacy needs in the European Region. *Public Heal Panor* 2019;**5**:233–43.

33 Ritchie J, Lewis J. *Qualitative Research Practice: a guide for social scientists and researchers.* London: : SAGE 2003.

34 Glaser BG, Strauss AL. *The discovery of Grounded Theory*. Chicago, IL: : Aldine 1967.

35 Debussche X, Lenclume V, Balcou-Debussche M, *et al.* Characterisation of health literacy strengths and weaknesses among people at metabolic and cardiovascular risk:

Validity testing of the Health Literacy Questionnaire. *SAGE Open Med* 2018;**6**. doi:10.1177/2050312118801250

36 Lawton J. Lay experiences of health and illness: past research and future agendas. *Sociol Health Illn* 2003;**25**:23–40. doi:doi:10.1111/1467-9566.00338

37 Balcou-Debussche M. *L'éducation des malades chroniques. Une approche ethnosociologique*. Paris: : Éditions des Archives Contemporaines 2006.

38 Greenhalgh T. Health literacy: towards system level solutions. *Bmj* 2015;**350**:h1026. doi:10.1136/bmj.h1026

39 Heijmans M, Waverijn G, Rademakers J, *et al.* Functional, communicative and critical health literacy of chronic disease patients and their importance for self-management. *Patient Educ Couns* 2015;**98**:41–8. doi:10.1016/J.PEC.2014.10.006

40 Goeman D, Conway S, Norman R, *et al.* Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support. *J Diabetes Res* 2016;**2016**:1–12. doi:10.1155/2016/2483263

41 O'Connor PJ, Crabtree BF, Yanoshik MK. Differences between diabetic patients who do and do not respond to a diabetes care intervention: a qualitative analysis. *Fam Med* 1997;**29**:424–8.https://pubmed.ncbi.nlm.nih.gov/9193915

42 Campbell R, Pound P, Pope C, *et al.* Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Soc Sci Med* 2003;**56**:671–84.http://www.ncbi.nlm.nih.gov/pubmed/12560003

43 Frost J, Garside R, Cooper C, *et al.* A qualitative synthesis of diabetes self-management strategies for long term medical outcomes and quality of life in the UK. *BMC Health Serv Res* 2014;**14**:348. doi:10.1186/1472-6963-14-348

44 Friis K, Lasgaard M, Osborne RH, *et al.* Gaps in understanding health and engagement

with healthcare providers across common long-term conditions: a population survey of health literacy in 29 473 Danish citizens. *BMJ Open* 2016;**6**:e009627. doi:10.1136/bmjopen-2015-009627

45 Friis K, Lasgaard M, Pedersen MH, *et al.* Health literacy, multimorbidity, and patient-perceived treatment burden in individuals with cardiovascular disease. A Danish population-based study. *Patient Educ Couns* Published Online First: 2019. doi:10.1016/j.pec.2019.05.013

46 Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. BMJ. 2007;**335**:493. doi:10.1136/bmj.39302.444572.DE

47 Wang RH, Hsu HC, Lee YJ, et al. Patient empowerment interacts with health literacy to associate with subsequent self-management behaviors in patients with type 2 diabetes: A prospective study in Taiwan. Patient Educ Couns. 2016;99:1626–31. doi:10.1016/j.pec.2016.04.001.

48 Gaag M van der, Heijmans M, Spoiala C, Rademakers J. The importance of health literacy for self-management: A scoping review of reviews: https://doi.org/101177/17423953211035472. 2021;:174239532110354. doi:10.1177/17423953211035472.

49 Balcou-Debussche M. Social inscription of TPE, heterogeneity and patient's vulnerability. Analysis of results obtained in the plural context of Mayotte. *Educ Ther Patient/Ther Patient Educ* 2013;**5**:113–21.http://dx.doi.org/10.1051/tpe/2012020

50 Bakker MM, Putrik P, Rademakers J, van de Laar M, Vonkeman H, Kok MR, et al. Addressing Health Literacy Needs in Rheumatology: Which Patient Health Literacy

Profiles Need the Attention of Health Professionals? | Enhanced Reader. Arthritis Care Res (Hoboken). 2021;73:100–9.

51 Debussche X, Rollot O, LePommelet C, *et al.* Quarterly and individual outpatient lifestyle counseling after initial inpatient education in type 2 diabetes: the REDIA-prev2 randomized controlled trial in Reunion island. *Diabetes Metab* 2012;**38**:46–53.

52 Favier F, Jaussent I, Moullec N Le, *et al.* Prevalence of Type 2 diabetes and central adiposity in La Reunion Island, the REDIA Study. *Diabetes Res Clin Pract* 2005;**67**:234–42. doi:10.1016/j.diabres.2004.07.013

53 Fianu A, Bourse L, Naty N, *et al.* Long-term effectiveness of a lifestyle intervention for the primary prevention of type 2 diabetes in a low socio-economic community - an intervention follow-up study on reunion island. *PLoS One* 2016;**11**:1–16. doi:10.1371/journal.pone.0146095

54 Ndong JR, Romon I, Druet C, *et al.* Caractéristiques, risque vasculaire, complications et qualité des soins des personnes diabétiques dans les départements d’outre-mer et comparaison à la métropole : Entred 2007-2010, France. *BEH* 2010;**42**–**43**:432–6.

TABLES

Table 1. Socio-demographics and clinical characteristics of the sample (n=44)

		All n=44	Intervention n=23	Control n=21
Sexe	F/M	31/13	14/9	17/4
Age (years)	[30-49]	9	4	5
	[50-59]	12	8	4
	[60-69]	12	4	8
	[70-79]	11	7	4
Household composition	Live alone	13	8	5
	Live alone, with children	4	2	2
Education level	Primary school or less	9	7	2
	Middle school	24	11	13
	High school	6	2	4
	University Undergraduate	5	3	2
Occupational status	Full- or part-time employment	13	5	8
	Unemployed	12	8	4
	Retired	19	10	9
Income)	Less than 1200 €	29	15	14

	1,200-1,999 €	7	4	3
	2,000-3,999 €	7	3	4
	≥ 4,000 €	1	1	0
Literacy	Difficulties in reading/writing	10	5	5
Diabetes, known duration	< 9 yrs	11	7	3
	10-19 yrs	19	8	11
	≥ 20 yrs	14	7	7
HbA1c at inclusion	7.5-7.9%	8	5	3
	8-8.9%	20	8	12
	9.0-11.9%	16	10	6
Diabetes treatment at inclusion	Oral agents (± GLP1 agonists)	20	10	10
	Insulin (± oral ± GLP1 agonists)	24	13	11
Self-monitoring of blood glucose	Once a day, fasting	15	10	5
	2- 3 times a day, before meals	15	6	9
	Before and after meals	14	7	7
Known complications	Renal	18	13	5
	Heart	10	7	3
	Eye	22	1	1
	Feet	5	3	2

Arteries	9	6	3
None	14	6	8

[†]Among participants in the control group who participated to the first round of interviews, 2 declined the second-round interview:

- 1F, 50 yrs, full-time employment, 2000-3999 €, middle school, diabetes > 20 yrs duration, insulin, HbA1c 8-8,9%, SMBG 6 per day, no complications;
- 1M, 62 yrs, retreated, 1200-1999 €, high school, diabetes 10-19 yrs, oral agents, HbA1c 8-8,9%, SMBG 3 per day pre-prandial, complications: heart, arteries.

Table 2. **The 3 main poles and 8 themes of disease management issues.**

Poles	**Themes**
Health knowledge	Knowledge base Access to knowledge
Management of the disease	Food Exercise Treatment Monitoring
Expertise, support and social network	Relationships with professionals Health and social support

Table 3: Health Literacy Questionnaire profiles of the sample (n=39)

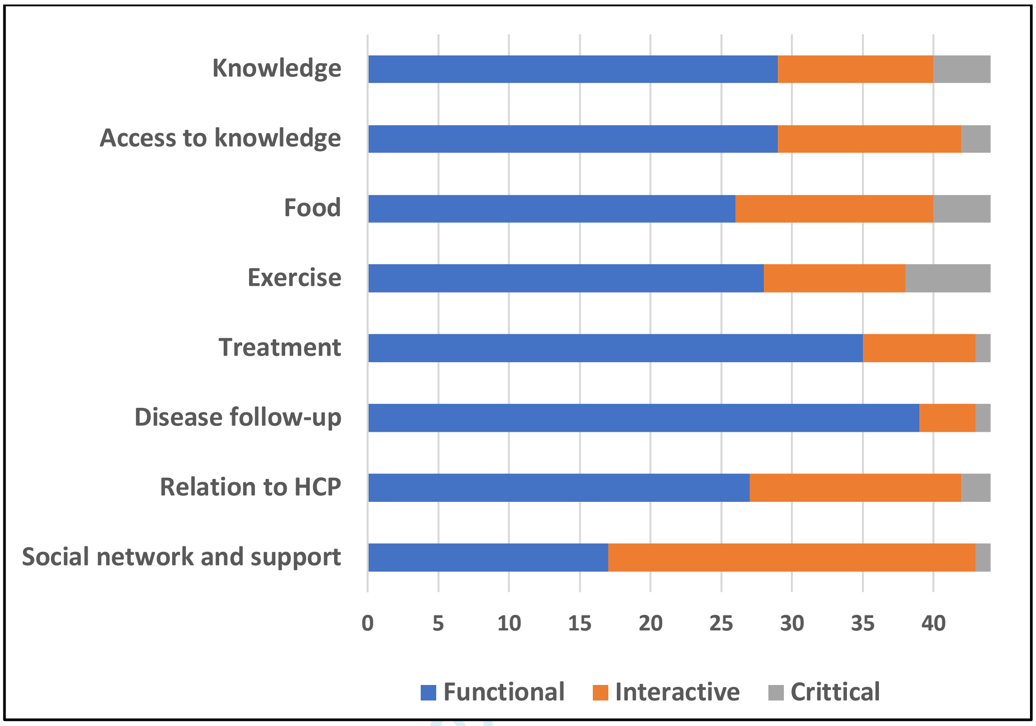
	HLQ scales	Mean (SD) [CI 95%]
	1st part of the questionnaire	Scores 1 to 4*
1	Feeling understood and supported by healthcare professionals	3,31 (0,53) [3,15-3,48]
2	Having sufficient information to manage my health	3,05 (0,63) [2,85-3,25]
3	Actively managing my health	3,16 (0,45) [3,02-3,30]
4	Social support for health	3,03 (0,54) [2,86-3,20]
5	Appraisal of health information	2,95 (0,54) [2,78-3,12]
	2nd part of the questionnaire	Score 1 to 5**
6	Ability to actively engage with healthcare professionals	3,87 (0,63) [3,68-4,07]
7	Navigating the healthcare system	3,72 (0,70) [3,50-3,94]
8	Ability to find good health information	3,34 (0,69) [3,12-3,55]
9	Understand health information enough to know what to do	3,52 (0,79) [3,27-3,76]

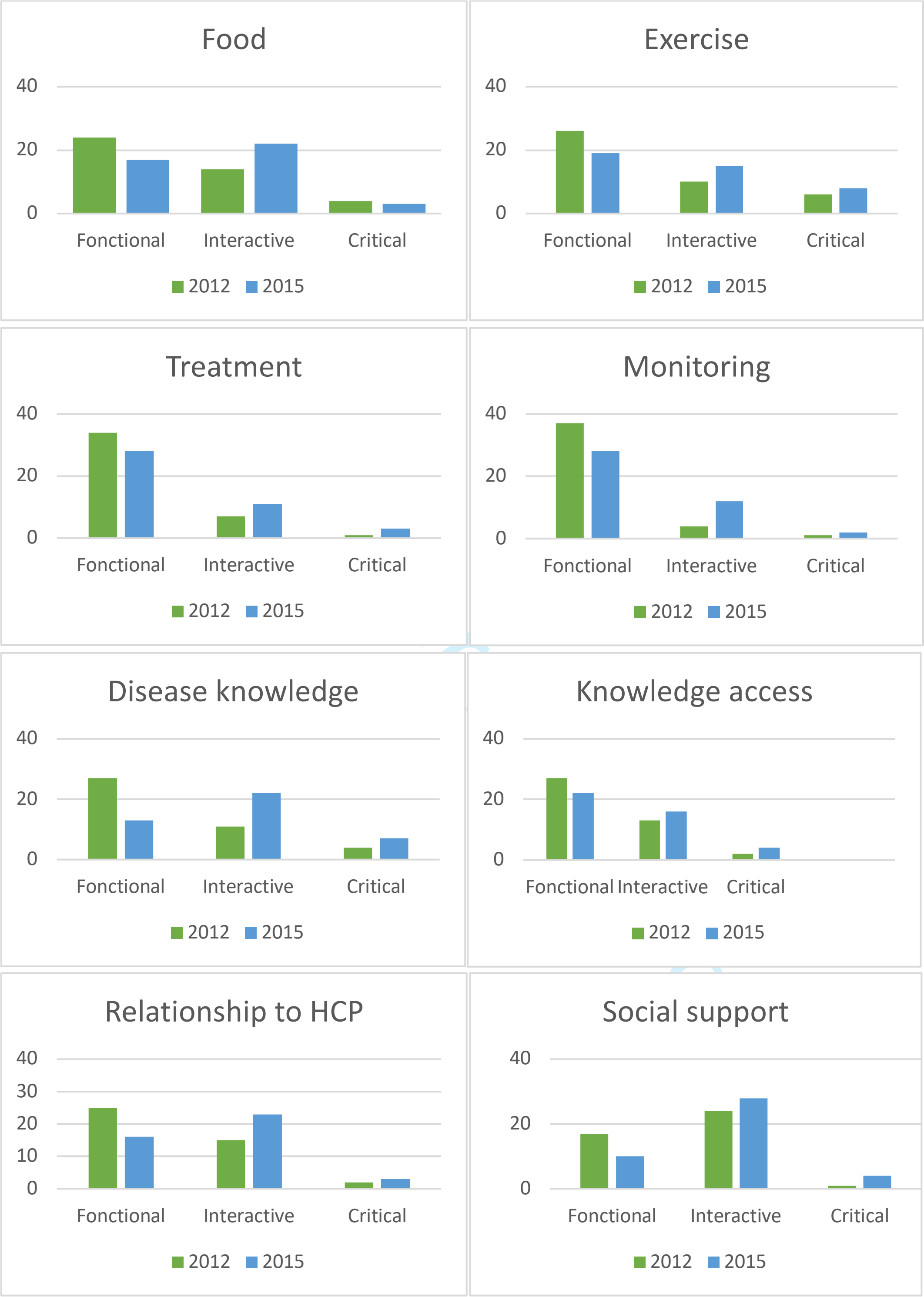
* Response options from 1 -strongly disagree- to 4 -strongly agree-
** Response options from 1-cannot do or always difficult- to 5 -always difficult

Figure Legends

Fig 1. Disease management. Functional, interactive and critical relationships to the 8 themes. First round interviews, n=44.

Fig 2. Number of patients with functional, interactive, and critical relationships to the 8 themes of disease management in 2012 (1st round interviews) and 2015 (2nd round interviews). Ermies ethno-socio study, qualitative thematic analysis of interviews, n=42 participants.


Knowledge
Access to knowledge
Food
Exercise
Treatment
Disease follow-up
Relation to HCP
Social network and support
0
5
10
15
20
25
30
35
40
Functional
Interactive
Crittical


Food
40
20
0
Fonctional
Interactive
Critical
2012
2015
Exercise
40
20
0
Fonctional
Interactive
Critical
2012
2015
Treatment
40
20
0
Fonctional
Interactive
Critical
2012
2015
Monitoring
40
20
0
Fonctional
Interactive
Critical
2012
2015
Disease knowledge
40
20
0
Fonctional
Interactive
Critical
2012
2015
Knowledge access
40
20
0
Fonctional
Interactive
Critical
2012
2015
Relationship to HCP
40
30
20
10
0
Fonctional
Interactive
Critical
2012
2015
Social support
40
20
0
Fonctional
Interactive
Critical
2012
2015

Appendix 1. Self-management education course

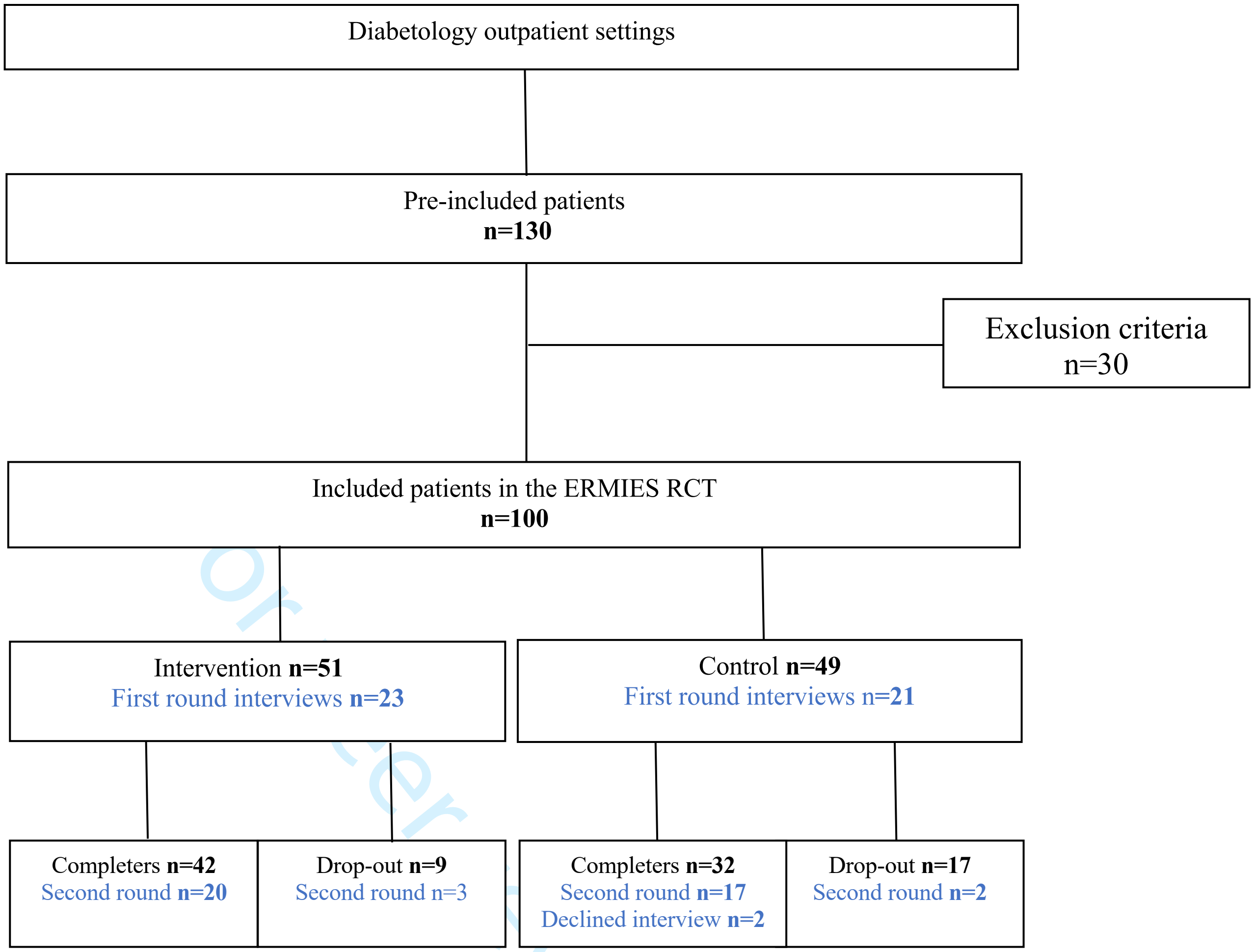
1. Initial education cycle

The initial cycle consists of 3 to 7 educational weekly or bi-weekly 2-hour group sessions for 4 to 10 patients:

- Personalised assessment group session (120 minutes): patients work on their own clinical and biological factors that can influence health maintenance (blood glucose, blood pressure, lipids, weight, waist circumference, smoking), before looking at lifestyle measure effects and specific impacts of eventual changes. They then scrutinise the feasibility of action planning and implementation in real life, and goal-setting taking into account all individual, social, and contextual dimensions. At the end of this session, each learner can schedule 2 to 6 specific additional focused sessions, according his/her needs and goal-setting.
- Two to 6 specific additional focused sessions of 90 to 120 minutes, spaced at intervals of 1 to 2 weeks (3 weeks maximum). These sessions are selected on the six following themes: self-monitoring and adaptation of treatment - physical activity - food and control of fat intake – understanding of diabetes and treatment – challenges of insulin therapy – prevention of foot lesions.

2. On-going SME support:

- Personalised empowerment follow-up including group sessions of 90 to 120 minutes each, with three to ten patients at 16, 32, 48, 64, 80 and 96 weeks. Each session will be scheduled at the end of the previous session. Patients will work on the progress of their indicators as follows: medical (HbA1c levels, blood sugar, arterial pressure, lipids, waist circumference, smoking, treatments); health coping and goal setting (action(s) initially decided on, actual implementation, obstacles); cognitive (review of knowledge gained through the first session assessment session and additional sessions). The summary of the session comprises objectives for action(s) to be implemented and the scheduling of optional additional sessions to support practical implementation.



Qualitative study nested in the ERMIES trial. Flow chart of participants

Appendix 3

Functional, interactive and critical relationship to the 8 themes of disease management

Themes	Functional	Interactive	Critical
Physical activity	I walk or move every day because I've been told to be active for diabetes	I am physically active because it improves my diabetes	I am physically active whenever possible, in relation to the life I have in hand (not only because of my diabetes). Being active is really good for me
Food	When I buy food and cook, I do try to respect the recommendations I received (from the doctor, the dietician...)	I understand that food should be balanced and diversified: I adjust my diet as best I can according to the situations of everyday life	Eating a balanced diet does not mean you have to deprive yourself. With the disease, I learned to buy and cook differently, while taking into account the cost, tastes, desires and availability of food
Treatment	I try to follow the treatment prescribed to me as best I can	I follow my treatment as best I can because I realize that it is useful	I know the role of each treatment and I adjust it according to the type of life I have, so as to achieve as good a balance as possible
Follow-up	I keep up with my diabetes on a daily basis and show my results to my doctor regularly	I test when I can and discuss my diabetes care with my doctor (or other provider).	Once I understood diabetes and its evolution, I can live a normal life, while having regular tests to avoid complications.
Social support and network	I try not to bother anyone with my illness	I realize that I am not alone and that I can count on others	I just live like everyone else and I nearly forget that I have diabetes
Relation to health care providers	I do whatever my doctor (or other provider) tells me	I have discussions with my doctor (or other) about diabetes because I want to understand what is going on	I know my diabetes and visit health care providers only when needed.
Access to knowledge	I stick to what my doctor says about my diabetes	Whenever I come across something about diabetes, I look	I don't listen to anything: I know where the sources are and I stick to that

		at it and try to get something out of it	
Knowledge	Diabetes is something that's wrong: it's not up to me or what I do	Diabetes is one or more things that need to be monitored independently of each other, but which I can do something about (e.g. diet and/or physical activity, etc.).	Diabetes is a set of interacting elements (the body, the organs, the environment, etc.) that puts me at risk of complications if I don't pay attention, but that I can also stabilise (or improve) if I monitor all these elements at the same time, taking into account the life I lead

Appendix 4. Health Literacy Questionnaire scales.

HLQ scale	1st part of the questionnaire Response options from 1 -strongly disagree- to 4 -strongly agree-	
HLQ 1	**Feeling understood and supported by healthcare professionals**	4 items
HLQ 2	**Having sufficient information to manage my health**	4 items
HLQ 3	**Actively managing my health**	5 items
HLQ 4	**Social support for health**	5 items
HLQ 5	**Appraisal of health information**	5 items

HLQ scale	2nd part of the questionnaire Response options from 1-cannot do or always difficult- to 5 -always	
HLQ 6	**Ability to actively engage with healthcare professionals**	5 items
HLQ 7	**Navigating the healthcare system**	6 items
HLQ 8	**Ability to find good health information**	5 items
HLQ 9	**Understand health information enough to know what to do**	5 items

Table 1

Standards for Reporting Qualitative Research (SRQR)[a]

No.		Topic		Item
		Title and abstract		
S1	✓	Title	page 1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	✓	Abstract	Design p. 2	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
		Introduction		
S3	✓	Problem formulation	p.4-5	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	✓	Purpose or research question	p.5	Purpose of the study and specific objectives or questions
		Methods		
S5	✓	Qualitative approach and research paradigm	p.7.8	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale[b]
S6	✓	Researcher characteristics and reflexivity	p.7	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	✓	Context	p 5.6	Setting/site and salient contextual factors; rationale[b]
S8	✓	Sampling strategy	p.6.	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	✓	Ethical issues pertaining to human subjects	p.6.	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	✓	Data collection methods	p.7.9	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	✓	Data collection instruments and technologies	p.8 - appendix 3	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	✓	Units of study	p.6 - appendix 2 p.9 - table 9.	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	✓	Data processing	p.7.8	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	✓	Data analysis	p.7.8 p.9	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale[b]
S15	✓	Techniques to enhance trustworthiness		Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
		Results/findings		
S16	✓	Synthesis and interpretation	p.9-15	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	✓	Links to empirical data	p.9-15	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
		Discussion		
S18	✓	Integration with prior work, implications, transferability, and contribution(s) to the field	p.16-17-18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	✓	Limitations	p.18-19	Trustworthiness and limitations of findings

(table continues)