Supporting diabetes self-management

Focus on education implementation and emotional health

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Résumé

La gestion que le patient fait de sa maladie et de son traitement est désormais identifiée comme un élément clé de la prise en charge et de l'évolution du diabète. L'éducation à l'autogestion du diabète rassemble une série de pratiques visant à améliorer les connaissances et compétences des patients dans leur gestion de la maladie et de leur traitement. Cette thèse explore deux éléments pouvant influencer la capacité du patient à gérer sa maladie et son traitement au quotidien. Le premier élément relève de l'implémentation de l'éducation à l'autogestion du diabète : les interventions d'éducation au diabète sont-elles délivrées comme prévues auprès de ces patients ? Le second élément aborde le vécu émotionnel du patient : la dépression, l'anxiété ou la détresse associée à cette maladie chronique entravent-elles l'utilisation des connaissances adéquates dans l'autogestion du diabète ? Et l'intelligence émotionnelle serait-elle un facteur protecteur contre le développement de ces troubles émotionnels associés à la maladie ?

Abstract

Patient's diabetes self-management is now considered as a key element for diabetes care and the progress of the disease. Diabetes self-management education gathers a series of practices to improve patients' knowledge and abilities to self-manage the disease and treatment. This thesis explores two elements which can impact on daily patient's diabetes self-management. The first element relates to diabetes self-management education implementation: Are the diabetes education interventions implemented to the patients as initially intended? The second element is related to the patient's emotional experience: Do depression, anxiety or diabetes-related distress hinder the utilisation of appropriate knowledge to self-manage the disease? And does the emotional intelligence act as a protective factor against the development of emotional disorders related to the disease?

General introduction

General introduction

Issues and objectives of the thesis

Diabetes: a challenge at various levels

Please consider the following situation: *Vincent is 54, because of visual problems, he goes to see his ophthalmologist who identifies some signs of retinopathy. He advises Vincent to consult is general practitioner. The blood test reveals a* ***hyperglycemia*** *of 258 mg/dl. The* ***diabetes*** *diagnostic is subsequently confirmed by a fasting blood glucose test. Vincent knows well this chronic disease as his mother died when she was 70 from a related* ***complication****. For his treatment, Vincent must take some pills and perform 2 injections of insulin per day. He should also try to lose weight by being more physically active and eating healthier. Vincent feels* ***overwhelmed*** *by all these requested changes. He is also afraid of dying from an associated complication. To* ***manage his disease properly****, he needs to be assist by a diabetologist, and also by diabetes nurses who will teach him to self-control blood sugar, to inject insulin, etc. He also refers to a dietician for an adapted nutrition plan. However, this* ***educational support*** *is not sufficient to address his distress with the risk of complications. Vincent needs a* ***psychological assistance*** *to help him to reduce this distress that has a daily impact on his capacity to perform his requested self-management behaviors.*

This situation depicts the individual challenge that represents diabetes and the importance of an educational support and, in some cases, of a psychological assistance. Unfortunately, more and more people have currently to deal with living with this chronic disease. Diabetes mellitus presents a major health challenge for the 21st century. Over the past decades, it has increasingly drawn the attention of researchers and practitioners working in the field of disease prevention, treatment and education. Three main reasons can justify this particular interest. The first one is related to the very high and growing prevalence of this disease. Between 1980 and 2015, the global diabetes prevalence has risen from 4.7% to 8.5% (World Health Organization, 2016). The International Diabetes Federation expects that more than 10% of the adult population will be inflicted by this disease in 2040, mainly due to the ageing of the population and to poor lifestyle (International Diabetes Federation, 2015). The second reason comes from the physiopathology of the diabetes. Poor glycemic control, which characterized diabetes, leads to a series of acute and chronic complications. This makes diabetes one of the first causes of blindness, cardiovascular diseases, kidney failure, and amputations (World Health Organization, 2016). In highly developed countries, life expectancy is estimated to be reduced by 10 years for people with type 2 diabetes and by 20 years for those with type 1 diabetes (Lluch, Maghiros, Mora, & Talaya, 2012). The third reason is a consequence of the first two, and is concerned with diabetes-related costs. Because of its high prevalence and the costs associated to its treatment and complications, diabetes represents a major expense: depending on the country, between 5 and 20% of health care expenditures are related to diabetes (International Diabetes Federation, 2015).

Self-management education as a key pillar in diabetes care

To respond to the human and economical challenges posed by diabetes, research has been organized focusing on diabetes screening and prevention, diabetes treatment to improve glycemic control and patient comfort, and self-management of the disease and treatment by the patients. Although it is not possible to recover from diabetes, adequate treatment makes it possible to live with the disease. In order to avoid diabetes-related health complications, the patient should therefore learn to **manage** the daily treatment of his or her condition. This can be facilitated by health professionals, but is also influenced by cultural, organizational or patients' personal characteristics, as summarized in figure 1 (Jack, 2004).

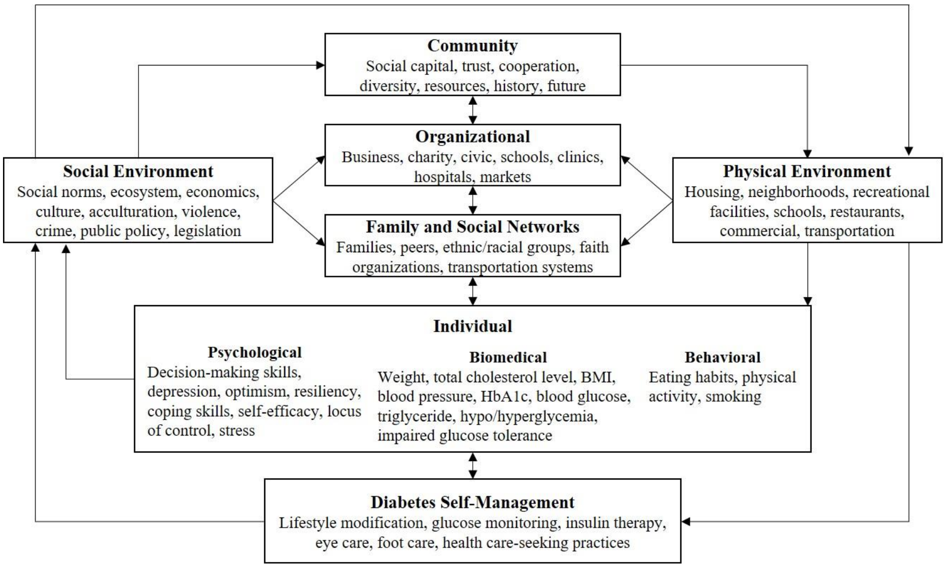

Figure 1: Cultural, environmental, and biomedical synthesis of diabetes self-management (Jack, 2004)

In this context, health professionals have to support and help the patient to reach his/her own treatment goals by providing the knowledge and skills that are required for daily self-care. This is done via **diabetes self-management education**. In 1917, before the discovery of insulin, the physician Elliott Jospin wrote the first document about the importance of diabetes self-management. He recommended nurses to educate the patients about nutrition, physical activity and testing glycosuria (Weinger & Carver, 2009). With the introduction of insulin in 1924, diabetes self-management was extended to insulin injections. Since then, it has continuously expanded, and in 1984, a group of health professionals set up the first standards for diabetes education (Anon, 1984). Today, diabetes self-management education is considered has a pillar of diabetes care. This education designates an heterogenous group of practices which vary in terms of educational approach (individual education, in groups, self-help groups, etc.), targeted self-management behaviors (nutrition, physical activity, glucose monitoring, medical treatment, etc.), involved health professionals (general practitioners, endocrinologists, nurses, physiotherapists, dieticians, psychologists, podiatrists, etc.), theoretical basis (*health belief model, empowerment model, social cognitive theory*, etc.) and practical model (*5A's model : assess, advise, agree, assist and arrange*).

This thesis concerns two of the potential factors which can impact on diabetes self-management. The first factor is related to the delivery of diabetes self-management education. The second factor refers to some difficult emotional experiences of diabetes which can also impact on self-management activities.

The Diabetes Literacy project

The study of the first factor was conducted within the *Diabetes Literacy* project, a three-year project (2012-2015) co-funded by the European Union under its 7th framework Programme. This project, which was performed in collaboration with nine other research institutes[1], had three aims: Firstly, perform a *comparative analysis of the national diabetes strategies and frameworks* that exist in the 28 European Member States. The goal of this analysis was to get an overview of the current diabetes self-management education practices that exist in the different European countries as well as in Israel, the US (California) and Taiwan. Secondly, evaluate the potential *factors that influence the (cost-) effectiveness* of diabetes self-management education programs, in terms of the delivery mode (individual, group, self-help, IT-based), the characteristics of the organization that offers education (organization of health services), the patient characteristics (notably the level of health literacy) and the program implemental (provider's adherence to the program protocol). Third, *design and pilot a web-based support* that is suitable for people with lower levels of health literacy. The outcomes of this project were intended to inform policy decisions to improve the care for the growing number of people with diabetes.

As part of this European project, the first axis of this thesis focuses on the evaluation of one of the potential factors that may impact the effectiveness of diabetes self-management education, i.e., **implementation fidelity**. Indeed, the success of a diabetes education program not only depends on the strategy and methodology that is used, but also on the

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[1] Clalit Health Services, Tel Aviv, Israel; Center for Evidence-based Healthcare, University Hospital and Medical Faculty Carl Gustav Carus, TU Dresden, Germany; University of Southampton, Southampton, UK; UCSF Center for Vulnerable Populations, San Francisco, USA; UCD School of Business, University College Dublin, Dublin, Ireland; Ludwig Boltzman Institute of Health Promotion Research, Vienna, Austria; Maastrich University, the Nederlands; Taipei Medical University, Taipei, Taiwan; Aarhus University, Denmark.

quality with which it is implemented. Given the demonstrated efficacy of existing strategies to improve glycemic control, increase physical activity and improve diet, the main public health challenge is not to find new efficacious treatments, but to implement the proven programs with consistency and efficiency (Engelgau, Venkat-Narayan, Saaddine, Vinicor, 2003). A key element of the quality of implementation is its fidelity, or the degree to which the intervention is delivered as intended (Carroll, Patterson, Wood, Booth, Rick, Balain, 2007). There are several reasons why implementation fidelity merits attention (Dusenbury, Brannigan, Falco, Hansen, 2003): (a) Without information about the program delivery, the absence of significant effects may lead to a false attribution of the lack of an intervention's effectiveness to the shortcomings of the intervention itself, when it could have resulted from poor implementation. This phenomenon has been dubbed the ‘‘type III error’’ (Dobson, Cook, 1980); (b) Information about IF can help one understand why an intervention succeeded or failed; (c) Assessing IF can help to identify which components have been adapted to meet the specific needs of the health system and its patients, and how these adaptations influenced the outcomes; (d) Information on IF can help to assess the future feasibility of implementing the intervention, thus serving formative in addition to summative evaluation purposes.

Emotional experiences of diabetes

Besides the quality of the diabetes education program and of the way in which it is implemented, a patient's capacity to self-manage his or her diabetes can also be affected by the patient's **emotional experience of the disease**. Diabetes-related distress has been associated with poorer diabetes self-management behaviors, poorer glycemic control and higher risks of complications (Barnard & Lloyd, 2012; Lustman, Clouse, Griffith, Carney, & Freedland, 1997). The second part of this thesis will investigate the way diabetes-related distress, depressive and anxiety symptoms can interfere with diabetes self-care. Emotional intelligence will be investigated as a protective factor against the development of these troubles and their negative impact on diabetes self-management.

Research questions, objectives and thesis organization

The questions that are addressed in this thesis can be situated on two axes: The first axis, developed during the Diabetes Literacy project, raises the question of the delivery of diabetes education: (1) How is the implementation fidelity operationalized and measured in studies presenting self-management diabetes education interventions? and (2) How does implementation fidelity influence the effectiveness of such diabetes self-management education interventions? The second axis concerns the difficult emotional experiences that can be associated to diabetes: (3) Do depressive symptoms and/or diabetes-related distress interfere with patient's capacity to use his or her knowledge, skills and competences (as contained in the notion of “health literacy”) to perform diabetes self-management behaviors? and (4) Can emotional intelligence be considered as a protective factor against the development of diabetes-related distress and its consequences in terms of poorer diabetes self-management?

Table 1: Studies undertaken to answer the four research questions

Objective	Method	Chapter	Related article
(1) Determine how implementation fidelity is operationalized and measured in studies presenting self-management diabetes education interventions	Literature review	Chapter 3	Schinckus, L., Van den Broucke, S., & Housiaux, M. (2014). Assessment of implementation fidelity in diabetes self-management education programs: A systematic review. Patient Education and Counseling, 96(1), 13–21.
(2) Assess the impact of implementation fidelity on diabetes self-management education programs effectiveness	Pre-post multilevel study (patients-providers)	Chapter 4	Schinckus, L., Van den Broucke, S., Levin-Zamir, D., Müller, G., Hayter, V., Schillinger, D., … Chang, P. (submitted). To adapt or not to adapt: exploring associations between implementation fidelity and diabetes self-management education effectiveness.
(3) Examine the moderating impact of depression and diabetes-related distress on the impact of health literacy and self-efficacy on diabetes self-management behaviors	Cross-sectional study	Chapter 6	Schinckus, L., Dangoisse, F., Van den Broucke, S., & Mikolajczak, M. (In Press). When knowing is not enough: Emotional distress and depression reduce the positive effects of health literacy on diabetes self-management.
(4) Examine the mediating impact of diabetes-related distress on the impact of emotional intelligence on diabetes self-management behaviors	Cross-sectional study	Chapter 7	Schinckus, L., Avalosse, H., Van den Broucke, S., & Mikolajczak, M. (submitted). The role of emotional intelligence in diabetes self-management behaviors: the mediating effect of diabetes-related distress.

The thesis is structured around 4 research questions and 7 chapters. The first section contains two theoretical chapters that state the context of our research, present the diabetes disease (chapter 1) and the importance of diabetes self-management and education (chapter 2). The second section is composed of two chapters concerning implementation fidelity: the way this concept is operationalized and assessed in the literature about diabetes self-management education program (chapter 3), and the impact of this fidelity on diabetes education program effectiveness (chapter 4). The third section is made of the last three chapters that target the question of the emotional experience of diabetes. Chapter 5 is a theoretical chapter summarizing the literature about the different emotional troubles (depression, distress, anxiety) and emotion regulation among diabetes people. Chapters 6 and 7 are empirical chapters that explore the moderating and mediating impact of diabetes-related distress on diabetes self-management behaviors

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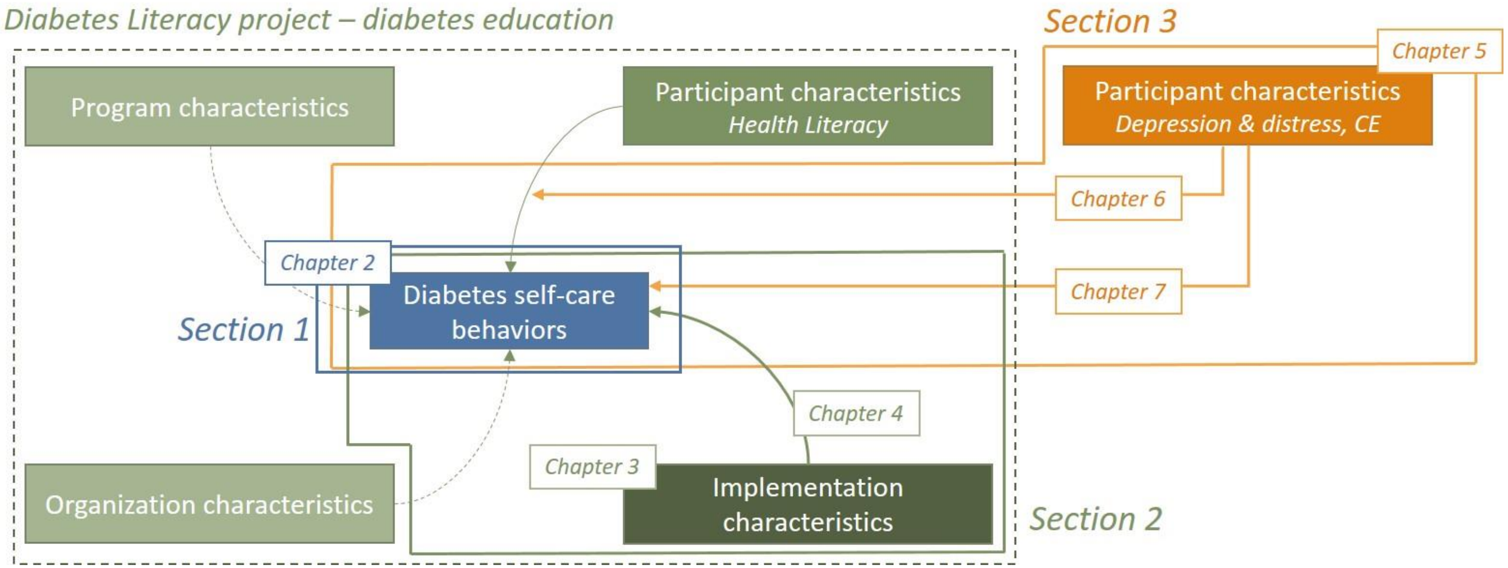

Figure 2: Organization of the thesis

Chapitre 1

Le diabète

Présentation de la maladie et des complications associées

Ce premier chapitre a pour objectif de présenter le diabète sucré et certains éléments physiopathologiques de cette maladie : épidémiologie, étiologie, symptômes et complications. La connaissance de ces éléments est en effet indispensable afin de saisir les enjeux de l'objet du second chapitre : l'autogestion du diabète et les facteurs susceptibles d'améliorer ou d'entraver cette autogestion.

Le diabète

Présentation de la maladie et des complications associées

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1. Définition

Le terme « diabète » est communément utilisé pour désigner un ensemble de maladies métaboliques caractérisées par une hyperglycémie chronique, un excès de glucose dans le sang (Buysschaert, 2011). Chez un sujet non diabétique, l'insuline est en charge de réguler la glycémie en permettant l'utilisation du glucose sanguin par les cellules du corps. L'hyperglycémie, chez une personne diabétique, résulte d'un déficit de sécrétion (diabète de type 1) ou d'utilisation (diabète de type 2) de l'insuline.

Le diabète constitue désormais la plus grande crise de santé mondiale. 415 millions de personnes sont atteintes dans le monde et 318 millions sont à risque de développer un diabète dans les prochaines années. En Europe, on estime que 59,8 millions d'individus étaient touchés par le diabète en 2015, soit 9,1% de la population des 20 à 79 ans (International Diabetes Federation, 2015). Ces chiffres justifient le terme « pandémique » pour qualifier l'évolution du diabète.

2. Classification

On distingue quatre catégories, dites « étiologiques », du diabète : le diabète de type 1, le diabète de type 2, les diabètes secondaires et le diabète gestationnel.

2.1 Le diabète de type 1

2.1.1 Définition et étiopathogénie

Le diabète de type 1 découle de la disparition des cellules β des îlots du Langerhans, responsables de la production de l'insuline. Cette disparition est due, dans la plupart des cas à une réaction auto-immune des lymphocytes T qui, s'infiltrant au sein des îlots, conduisent à la production d'anticorps. Ces anticorps vont, au cours de plusieurs années, mener à la destruction progressive de toutes les cellules β. C'est lorsque plus de 80% des cellules ont disparu que le manque d'insuline va conduire à l'hyperglycémie (Buysschaert, 2011).

Les arguments en faveur de cette explication auto-immune sont multiples (Buysschaert, 2011) : premièrement, la présence fréquente d'autres maladies auto-immunes parmi les personnes atteintes de diabète de type 1. Ensuite, des examens réalisés par autopsie révèlent chez ces sujets une disparition des cellules β, une concentration de lymphocytes T et autres cellules immunitaires au sein des îlots, ainsi que la présence d'auto-anticorps anti-cellules d'îlots. Le dernier argument en faveur de l'auto-immunité comme origine du diabète de type 1 est l'efficacité du traitement immunosuppresseur pour la rémission partielle ou temporaire du diabète de type 1.

L'origine de cette auto-immunité peut être imputée à la fois à des facteurs génétiques et environnementaux (Buysschaert, 2011). Parmi les facteurs génétiques, ce sont les gènes qui codent pour le système de reconnaissance des anticorps (*human leucocyte antigen*, HLA) qui semblent prédisposer certains sujets à développer un diabète de type 1. Au sein de paires de jumeaux vrais monozygotes, on estime à 30 à 40% de risque que le second développe un diabète de type 1 si le premier en est atteint (Hyttinen, Kaprio, Kinnunen, Koskenvuo, & Tuomilehto, 2003; Redondo et al., 1999). Ces facteurs génétiques n'expliquant que partiellement l'apparition du diabète de type 1, l'implication de facteurs environnementaux a été considérée. Parmi les possibles facteurs environnementaux, on retrouve certains virus (e.g. Conrad et al., 1997; Gale, 2008; Pak, Eun, McArthur, & Yoon, 1988) dont la structure équivalente à celle des cellules β pourrait engendrer une première réaction des anticorps. Ces mêmes anticorps se retourneraient ensuite contre les cellules β dans une réaction auto-immune. Par ailleurs, des études récentes indiquent que certaines atteintes virales, lorsqu'elles surviennent à un moment et une dose précise, auraient une action protectrice contre l'auto-immunité dans le cadre du diabète de type 1 (e.g. Filippi, Estes, Oldham, & von Herrath, 2009). D'autres facteurs environnementaux concernent l'alimentation : le lait maternel, le nicotinamide (inclus dans le groupe de vitamine B), le zinc, les vitamines C, D et E ont été identifiés dans la littérature comme de possibles facteurs de protection contre l'apparition du diabète de type 1. Contrairement aux composés N-nitroso (dérivés des nitrates présents dans notre alimentation) et au lait de vache qui sont désignés comme des facteurs de risque de développement de diabète de type 1 durant l'enfance (Virtanen & Knip, 2003).

2.1.2 Déclaration de la maladie et diagnostic

La métaphore du « *coup de tonnerre dans un ciel serein* » (Association Belge du Diabète, 2011, p. 12) est généralement utilisée pour se référer aux symptômes qui apparaissent lorsque la destruction des cellules β conduit à une insulino-déficience et donc, une hyperglycémie chronique. Les quatre symptômes révélateurs du stade clinique du diabète de type 1 sont : une soif excessive (polydipsie), un besoin fréquent d'uriner, y compris pendant la nuit (polyurie), un amaigrissement malgré un appétit important, et une perte d'énergie. En général, ces signes conduisent le patient, ou son entourage dans le cas d'un enfant, à consulter le médecin. Le diagnostic du diabète s'établit ensuite sur base de la présence de ces symptômes, une glycémie supérieure à 200 mg/dl et surtout d'un test de glycémie à jeun affichant un résultat supérieur ou égal à 126 mg/dl.

2.1.3 Prévalence

Bien qu'il ne représente que 7 à 12% des cas de diabète, le diabète de type 1 est en progression. Les causes de cette augmentation demeurent incertaines bien que des modifications environnementales et certaines infections virales soient soupçonnées. Le diabète de type 1 se déclare généralement à la puberté (Buysschaert, 2011). En Belgique, la prévalence du diabète de type 1 est de 0.25 à 0.30% (Buysschaert, 2011). Une étude réalisée à Anvers montrait que pour 100 000 habitants de moins de 40 ans, près de 10 cas de diabète de type 1 étaient diagnostiqués chaque année (Weets et al., 2002). En Europe, les taux d'incidence les plus élevés de diabète de type 1 concernent la Finlande et la Suède (International Diabetes Federation, 2015).

2.1.4 Traitements

Le diabète de type 1 étant insulinodéficient, son traitement médicamenteux consiste essentiellement en l'apport d'insuline. C'est en 1922 que le premier patient diabétique est traité par injection d'insuline purifiée extraite de pancréas de bœuf et de porc (Karamitsos, 2011). Depuis les années 80, l'insuline est produite en laboratoire et est identique à celle fabriquée par le corps humain. Les insulines qualifiées « analogues » sont des insulines dont la structure a été légèrement modifiée afin d'adapter la vitesse et la durée de leur action. On distingue désormais les insulines analogues à action très rapide et très courte (3 à 4h), les insulines à action rapide et courte (environ 6h), les insulines intermédiaires à action lente et prolongée (environ 12h) et les insulines analogues à action lente et « plate » (20 à 24h). Il existe également des insulines dites « prémélangées » qui combinent deux insulines à durées d'action différentes.

Ces différentes durées d'action permettent d'imiter le schéma classique de production d'insuline : un taux d'insuline de base et un apport supplémentaire lors des repas pour permettre l'utilisation du glucose par les cellules. Il s'agit du traitement « basal-prandial » à 4 injections qui implique l'injection d'une insuline ultra lente au coucher et des injections d'insuline rapide ou ultra-rapide lors des repas. Ces injections d'insuline prandiale doivent être adaptées en fonction de la glycémie au moment de l'injection, de l'apport en glucides du repas, de l'activité physique qui sera réalisée ensuite et de l'historique des jours précédents (Association Belge du Diabète, 2011).

2.2 Le diabète de type 2

2.2.1 Définition et étiopathogénie

Le diabète de type 2, anciennement qualifié de type « gras », ne résulte pas directement d'un manque de production d'insuline, mais d'une résistance à l'action de l'insuline au niveau des muscles et du foie (Buysschaert, 2011). Cette résistance va, dans un premier temps, engendrer un accroissement de la production d'insuline par le pancréas afin de permettre l'utilisation du glucose par les cellules. Cependant, cette augmentation de la production d'insuline va progressivement conduire à l'épuisement des cellules β du pancréas et à une interruption de la production d'insuline, ou insulinodéficience.

Le diabète de type 2 résulte, dans la plupart des cas, d'une interaction entre des facteurs génétiques prédisposant et des facteurs environnementaux (Monnier & Fumat, 2014) : une alimentation trop riche et un manque d'activité physique sont responsables de l'insulinorésistance des cellules. Chez un individu sans prédisposition génétique, cette insulinorésistance est compensée par une production accrue d'insuline par le pancréas. Cependant, chez les personnes présentant des gènes prédisposant au diabète de type 2, les cellules β du pancréas s'épuisent à répondre au besoin accru d'insuline et ne parviennent plus à compenser l'insulinorésistance, conduisant à l'augmentation progressive de la glycémie jusqu'à un diabète avéré (K. S. Polonsky, Sturis, & Bell, 1996). Dans le cas des diabètes monogéniques, les prédispositions génétiques suffisent à déclencher la maladie. Il s'agit des diabètes de type MODY (« maturity onset diabetes of the young ») qui se caractérise par un pattern d'hérédité de type dominant, l'absence d'anticorps anti-îlots (qui le différencie du diabète de type 1), une absence d'obésité, et des taux de triglycérides et de cholestérol normaux (qui le différencie du diabète de type 2). Le type MODY représente 1 à 2% des cas de diabète. Suivant le gène impliqué, on distingue le MODY1, MODY2, MODY3 et MODY4. Un séquençage d'ADN permet d'établir le diagnostic d'un diabète MODY.

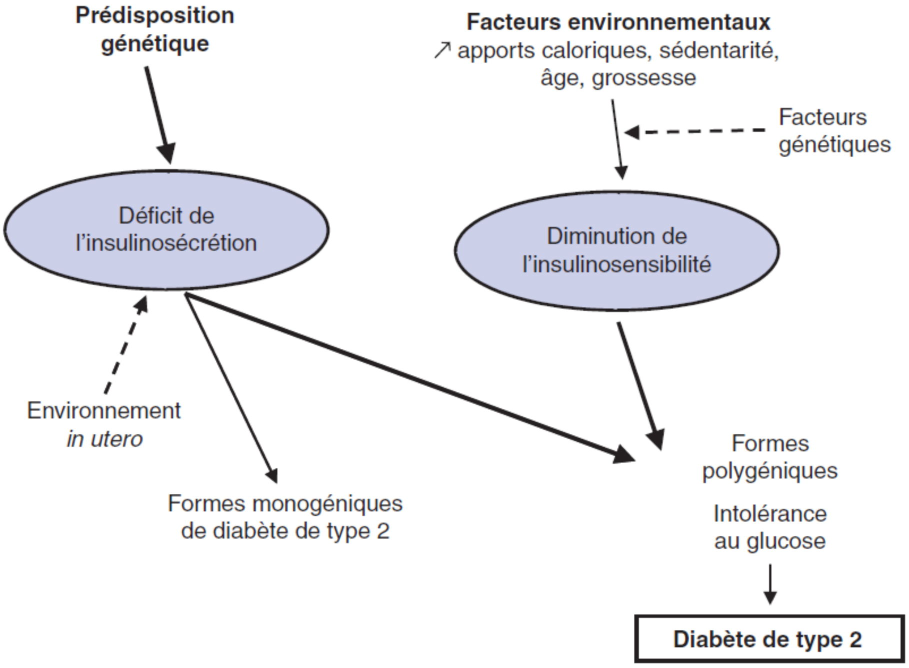

Figure 3 : Interactions entre le déficit de l'insulinosécrétion et l'insulinorésistance (Monnier & Fumat, 2014)

Certains facteurs génétiques favorisent également l’insulinorésistance. Bien que l’on s’accorde sur le rôle de ces facteurs génétiques dans l’apparition du diabète, on ignore encore quels sont les gènes les plus impliqués et on présuppose l’interaction de plusieurs gènes (Scott et al., 2007). Outre les facteurs génétiques, des facteurs environnementaux *in utero*, tels qu’un manque de nutriments ou d’acide aminés et un faible poids à la naissance peuvent également être associés à un risque accru de déficit d’insulinosécrétion (Buysschaert, 2011; Monnier & Fumat, 2014). La présence d’un diabète gestationnel chez la mère accroit également le risque de développement d’un diabète de type 2 (Buysschaert, 2011).

En amont du diabète de type 2, on peut retrouver une série de symptômes rassemblés sous l’appellation du syndrome métabolique. Il existe plusieurs définitions du syndrome métabolique, toutes ne s’accordent pas quant aux critères permettant de le définir, mais en général on retrouve : une glycémie anormalement élevée due à une insulinorésistance (et un taux d’insuline élevé), une hypercholestérolémie, de l’hypertension, une obésité abdominale (Table 2, P. L. Huang, 2009).

Table 2 : Définitions du syndrome métabolique (Huang, 2009)

	NCEP ATP III (2005 révision)	**WHO (1998)**	**EGIR (1999)**	**IDF (2005)**
Critère nécessaire	Aucun	Insulinorésistance ou diabète de type 2	Hyperinsulinémie	Obésité abdominale
Critères supplémentaires	Trois des cinq critères suivants :	+ deux des cinq critères suivants :	+ deux des quatre critères suivants :	+ deux des quatre critères suivants
Obésité	Tour de taille > 101 cm (H) ou 89 cm (F)	Ration taille/hanche > 0.9 (H) et 0.85 (F) ou BMI > 30	Tour de taille ≥ 94 cm (H) et 80 cm (F)	*Critère nécessaire*
Hyperglycémie	Glycémie à jeun ≥ 100 mg/dl	*Critère nécessaire*	*Critère nécessaire*	Glycémie à jeun ≥ 100 mg/dl
Dyslipidémie	Triglycérides ≥ 150 mg/dl	Triglycérides ≥ 150 mg/dl ou HDL-C < 35 mg/dl (H) ou 39 mg/dl (F)	Triglycérides ≥ 177 mg/dl ou HDL-C < 39 mg/dl	Triglycérides ≥ 150 mg/dl
Dyslipidémie (second critère)	HDL cholestérol < 40 mg/dl (H) ou 50 mg/dl (F)			HDL cholestérol < 40 mg/dl (H) ou 50 mg/dl (F)
Hypertension	Pression systolique > 130 mmHg ou diastolique > 85 mmHg	≥140/90 mmHg	≥140/90 mmHg	>130/85 mmHg
Autre critère		Microalbuminurie		

La combinaison de ces différents symptômes augmente les risques de diabète de type 2 et de maladies cardiovasculaires (P. L. Huang, 2009). Dans 80% des cas, le diabète de type 2 s’accompagne d’un syndrome métabolique (Buysschaert, 2011).

2.2.2 Déclaration de la maladie

Contrairement au diabète de type 1 dont l'insulinodéficience va conduire brutalement à l'apparition de signes d'hyperglycémie (soif intense, besoin fréquent d'uriner, amaigrissement malgré un bon appétit et un état de fatigue chronique), l'insulinorésistance du diabète de type peut s'installer insidieusement au cours de plusieurs années sans se faire ressentir (Monnier & Fumat, 2014). Au cours de ces années, le patient peut développer un syndrome métabolique préalable au diabète, et finalement un diabète avéré, mais méconnu. C'est parfois l'apparition d'une complication associée à l'hyperglycémie qui conduit à la découverte du diabète de type 2.

2.2.3 Prévalence

Le diabète de type 2 représente près de 90% des cas de diabète dans les pays à revenu élevé (International Diabetes Federation, 2015). Il touche essentiellement les personnes de plus de 40 ans. Considérant l'obésité croissante et le vieillissement de la population, le diabète de type 2 suit une progression pandémique dans tous les pays du monde (International Diabetes Federation, 2015). L'Organisation Mondiale de la Santé estime que d'ici 2040, 622 millions de personnes seront atteintes de diabète, dont la plupart de diabète de type 2 (International Diabetes Federation, 2015).

2.2.4 Traitements

Trois phases peuvent être distinguées dans le traitement du patient atteint de diabète de type 2 : les mesures hygiénodiététiques, la prise d'antidiabétiques oraux et le passage à l'insulinothérapie. Si le diabète est repéré à un stade précoce, la perte de poids engendrée par la mise en place d'une activité physique et l'amélioration de l'alimentation peut suffire temporairement à équilibrer la glycémie. Dans la plupart des cas cependant, la prise d'antidiabétiques oraux est nécessaire. Ces médicaments peuvent agir en (a) stimulant la production d'insuline, (b) sensibilisant les cellules à l'insuline, (c) réduisant l'action de la salive et du suc pancréatique sur les glucides et en atténuant ainsi le pic glycémique après le repas (inhibiteurs des α-glucosidases), (d) limitant la réabsorption du glucose au niveau des reins et favorisant son élimination par les urines (inhibiteurs du co-transporteur sodium-glucose de type 2) (Buysschaert, 2011). Ces médicaments peuvent être pris seuls ou en combinaison avec d'autres. Malgré cette médication orale, l'installation progressive de l'insulinodéficience contraint généralement le patient atteint de diabète de type 2 à passer sous traitement insulinique. Un taux d'hémoglobine glyquée supérieur à 8% malgré l'adhésion du patient à sa médication orale conduit à la décision du passage à l'insuline. Dans un premier temps, un traitement combinant un insulinostimulant ou un insulinosensibilisant avec une injection d'insuline au coucher peut être envisagé. Pour mieux contrôler la glycémie lors des repas, un traitement à deux ou trois injections peut être ensuite considéré. Il s'agira pour le patient de réaliser une injection d'insuline lente au coucher et une insuline ultrarapide avant le (les) repas le (les) plus riche(s) en glucides.

Finalement, un schéma basal-prandial[1] peut être appliqué pour assurer plus de flexibilité et un meilleur contrôle glycémique en fonction des repas (Buysschaert, 2011).

2.3 Les diabètes secondaires

Cette appellation distingue les diabètes résultant d'une autre pathologie ou d'un traitement. Cela concerne notamment les atteintes du pancréas (pancréatite alcoolique, cancer du pancréas, ablation d'une partie du pancréas, mucoviscidose, etc.), les effets de certains médicaments (la pentamidine dans le traitement d'une pneumopathie, certains corticoïdes, etc.) et certaines infections virales (entérovirus, rougeole, cytomégalovirus, etc.). Le traitement du diabète passe, quand cela est possible, par le traitement de la cause première et sera donc spécifique à cette origine (Monnier & Fumat, 2014).

2.4 Le diabète gestationnel

Le diabète lors de la grossesse peut se référer à deux situations fort différentes : la première concerne les patientes préalablement atteintes de diabète et qui souhaitent avoir un enfant, et la seconde se réfère au diabète gestationnel. Cette seconde situation est particulièrement problématique, car, sauf en cas de récidive, la patiente ne s'attend généralement pas au diagnostic et doit acquérir des connaissances et compétences rapidement en vue de mieux gérer la maladie et éviter les risques de complications pour le fœtus et limiter les risques de pré-éclampsie et d'éclampsie[2] lors de l'accouchement. Le diabète gestationnel est défini comme un trouble de tolérance au glucose qui résulte d'une insulinorésistance « physiologique » qui s'accompagne d'une insulinodéficience (Buysschaert, 2011). Dans tous les cas, le traitement implique la mise en place de règles hygiéno-diététiques. En fonction du poids de la patiente avant la grossesse, un apport calorique est fixé pour chaque repas (Monnier & Fumat, 2014). On recommande également à la patiente de maintenir ou adopter une activité physique régulière (Buysschaert, 2011). Si ces règles ne suffisent pas à équilibrer la glycémie, un traitement par insuline est prescrit. Celui-ci comporte 1 à 4 injections d'insuline suivant le cas de la patiente. Par mesure de précaution, un traitement par antidiabétiques oraux n'est pas envisagé dans le cas d'une grossesse. Après l'accouchement, un suivi de la patiente sera réalisé en vue de déterminer le niveau de tolérance au glucose. Une étude a en effet montré qu'un peu plus de 25% des femmes ayant expérimenté un diabète de grossesse contractaient un diabète de type 2 au cours des 15 années suivantes, le risque étant plus élevé pour les femmes d'origine asiatique (Lee, Hiscock, Wein, Walker, & Permezel, 2007).

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[1] Injection d'une insuline à action lente (« basale ») au coucher et injection d'insuline à action rapide ou ultra-rapide au moment des repas (« prandiale »).

[2] La pré-éclampsie est une complication pouvant survenir durant la seconde moitié de la grossesse. Elle est caractérisée par une hypertension artérielle. En cas de non prise en charge, cette condition clinique peut évoluer vers une crise convulsive généralisée, appelée éclampsie qui est une menace vitale pour la mère et l'enfant

3. Les complications associées

Le diabète est associé à une série de complications aiguës et chroniques. La physiopathologie associée à ces complications relève avant tout de l'hyperglycémie chronique, mais également de la fluctuation de la glycémie et des hypoglycémies (Monnier & Fumat, 2014).

3.1 Complications aiguës

Les complications aiguës regroupent les complications métaboliques (le coma hypoglycémique, l'acidocétose, le coma hyperosmolaire, l'acidose lactique) et les infections suscitées par l'hyperglycémie (Buysschaert, 2011).

3.1.1 Les complications métaboliques

L'hypoglycémie et le coma hypoglycémique

L'hypoglycémie survient lorsque le taux de glucose dans le sang est inférieur à 70 mg/dl. A ce seuil, l'individu peut présenter différents signes tels que des maux de tête, des tremblements, une vue trouble, etc. Lorsque le taux de glycémie descend encore, les neurones du cerveau ne sont plus suffisamment approvisionnés. Si le patient ne rectifie pas sa glycémie, il y a un risque de coma hypoglycémique. Le traitement consiste alors à administrer du sucre au patient, soit par voie orale s'il est encore conscient, soit par injection de glucagon (Buysschaert, 2011).

L'acidocétose

Il s'agit d'une complication grave qui survient essentiellement auprès des personnes atteintes de diabète de type 1 et présentant une carence importante en insuline. Elle se caractérise par la présence de corps cétoniques dans les urines (acétonurie), une augmentation de l'acidité dans le sang (acidose sanguine), ainsi qu'une baisse du niveau de potassium dans le sang. Ces corps cétoniques proviennent de l'utilisation des acides gras afin de compenser le manque de sucre. L'acidocétose survient après plusieurs jours d'hyperglycémie, soit par non-observance du traitement, soit suite à une infection ou encore par ignorance du diabète. Aux symptômes de l'hyperglycémie s'ajoutent généralement une respiration rapide et profonde, une haleine particulière due à l'acétone, une tachycardie, et une baisse de la tension artérielle. L'évolution naturelle en cas de non traitement est celle du coma avec risque de décès (le taux de mortalité avoisinant 4 à 5%). Le traitement est donc à mettre en place d'urgence et consiste à rétablir le pH sanguin par apports de bicarbonates, à rééquilibrer la glycémie par injection d'insuline, à réhydrater le patient et à rétablir l'équilibre des électrolytes par apport de sodium et de potassium.

Le coma hyperosmolaire

Cette complication survient le plus généralement chez les personnes atteintes de diabète de type 2 non-insulinodépendant et se caractérise par une déshydratation massive et une augmentation du sodium dans le sang suite à une hyperglycémie importante. Le manque d'insuline est cependant moins sévère que dans la situation d'acidocétose et n'aboutit pas à la présence de corps cétoniques dans le sang. La polyurie issue de l'hyperglycémie n'est pas compensée par le patient qui ne s'hydrate pas suffisamment. Par osmose, l'eau des cellules passe progressivement vers le milieu extracellulaire. Progressivement, une insuffisance rénale fonctionnelle apparait et conduit à l'augmentation de sodium sanguin. Le patient présente alors des troubles de la conscience, un état de stupeur pouvant évoluer vers le coma hyperosmolaire. La perte d'eau lors d'une telle complication est généralement de 5 litres et le taux de mortalité approche les 20% (Monnier & Fumat, 2014). Le traitement consistera dès lors à réhydrater le patient, d'abord de façon intense (6 à 8 litres les 12 premières heures), puis de façon plus progressive par administration de solution salé isotonique (sérum physiologique) (Buysschaert, 2011).

L'acidose lactique

L'acidose lactique est provoquée par une augmentation du taux de lactate dans le plasma. Cette complication peut survenir chez les sujets diabétiques et non-diabétiques suite à un manque d'apport d'oxygène au sein des tissus, ou un problème d'épuration par le foie (Buysschaert, 2011). Cependant, chez les personnes atteintes de diabète, le traitement par metformine (antidiabétique oral qui limite la synthèse du glucose au niveau du foie) peut augmenter les risques d'acidose lactique chez les sujets présentant des contre-indications (telles qu'une insuffisance rénale, cardiaque, hépatique, ou un alcoolisme). L'acidose lactique se manifeste d'abord par des crampes musculaires, des douleurs abdominales, une hyperventilation, des troubles anxieux et de la conscience. Si elle n'est pas traitée, l'acidose lactique peut mener à un effondrement de la pression sanguine (collapsus cardiovasculaire) et une absence d'urine dans la vessie (anurie). Le taux de mortalité est alors supérieur à 30% (Monnier & Fumat, 2014). Le traitement préventif consiste principalement à ne pas prescrire de metformine aux sujets présentant une contre-indication. Si elle fait suite à un traitement par metformine, une intervention chirurgicale d'épuration rénale est indiquée (Buysschaert, 2011; Monnier & Fumat, 2014).

3.1.2 Les complications infectieuses

Les personnes atteintes de diabète sont plus soumises aux risques d'infections respiratoires, urinaires et cutanées (Buysschaert, 2011). L'hyperglycémie favorise en effet le dysfonctionnement du système immunitaire. Le tableau 3 liste les différentes infections associées au diabète (Casqueiro, Casqueiro, & Alves, 2012)

Table 3 : Infections associées au diabète (Casqueiro et al., 2012)

Infections respiratoires	**Infections urinaires**	**Infections gastro-intestinales**
Streptoccus pneumoniae Grippe H1N1 Tuberculose	Bactériurie asymptomatique Cystites Abcès périnéphrique	Infection H pylori Candidose orale ou œsophagienne Emphisematous cholecystitis Hépatite C - Hépatite B Entérovirus
Infections de la tête et du cou	**Infections de la peau**	**Autres infections**
Otite externe invasive Mucormycose rhinocérabrale	Infection des pieds Fasciite nécrosante Gangrène de Fournier	Virus de l'immunodéficience humaine

Outre le risque accru d'infections liées à l'hyperglycémie, les infections elles-mêmes ont un effet délétère sur le contrôle de la glycémie (Buysschaert, 2011). En effet, l'infection va généralement conduire à la sécrétion d'hormones de stress (telles que le cortisol ou l'adrénaline) qui provoquent la libération de sucre dans le sang et donc, une hyperglycémie. Le patient affaibli par l'infection sera également moins enclin à réaliser une activité physique, ce qui diminue encore l'efficacité de l'insuline.

3.2 Complications chroniques

Parmi les complications chroniques, on distingue les complications atteignant les micro-vaisseaux (yeux, nerfs, reins, etc.) et celles atteignant les macro-vaisseaux (cœur et artères).

3.2.1 Les complications micro-angiopathiques

Rétinopathie diabétique

La rétinopathie diabétique est la première cause de cécité parmi les personnes de moins de 60 ans dans les pays à haut revenu (Sinclair, 2006). La majorité des personnes atteintes de diabète développent des signes de rétinopathie 25 ans après le début de leur maladie (Buysschaert, 2011). Les symptômes apparaissent plusieurs années après le début de l'installation de la complication. La rétinopathie diabétique se caractérise par des hémorragies (rétinienne, intravitréenne ou prérétinienne), des anomalies vasculaires (microanévrysmes, anomalies veineuses, etc.), la présence de petits amas blancs (nodules cotonneux ou dysoriques) et d'oedèmes (Monnier & Fumat, 2014) au sein de la rétine. L'équilibre de la glycémie est le premier élément à mettre en place en vue d'éviter cette complication. Une visite régulière chez le médecin ophtalmologue avec examen du fond de l'œil, et éventuellement des examens supplémentaires, doit permettre d'identifier la complication à un stade précoce (Buysschaert, 2011). En cas de diagnostic précoce, un équilibre de la glycémie doit être maintenu tant que possible et un traitement par laser sera réalisé en vue de réduire la progression de la rétinopathie (Buysschaert, 2011).

Neuropathie diabétique

Près de la moitié des personnes atteintes de diabète développent une neuropathie après 25 ans de maladie (Monnier & Fumat, 2014). Le risque de manifester cette complication augmente avec le déséquilibre de la glycémie et l'âge, et dépend également de facteurs tels que le sexe (les hommes y sont plus confrontés que les femmes), l'obésité, la consommation d'alcool ou de tabac. La neuropathie diabétique peut impliquer le système nerveux périphérique et le système nerveux autonome.

Dans le cas de l'atteinte du système périphérique, les manifestations sont très variées. Elle concerne généralement les fibres sensitives des membres inférieurs, et plus rarement des mains. Le patient souffre alors d'une perte de sensibilité qui, dans le cas d'un accident non ressenti (par exemple, une lésion non perçue au niveau du pied), peut avoir de graves conséquences. Une atteinte des fibres motrices peut également être observée dans quelques cas. Cette atteinte aura pour conséquence une diminution de la force des muscles avec déformation des membres (Buysschaert, 2011).

L'atteinte du système nerveux autonome peut avoir des répercussions au niveau du fonctionnement des systèmes cardio-vasculaire, digestif et uro-génital. L'atteinte de la branche parasympathique du système nerveux autonome va, dans un premier temps, provoquer une tachycardie et un emballement du cœur même en situation de repos. L'atteinte du système orthosympathique survient dans un second temps et va avoir l'effet inverse : une baisse de tension artérielle trop importante lors du passage de la position couchée à debout et l'absence de tachycardie (Buysschaert, 2011). Au niveau digestif, la neuropathie autonome se manifeste par le syndrome de l'estomac paresseux avec sensation de nausées et de vomissements, ou des épisodes de diarrhées importantes, mais indolores. Au niveau du système uro-génitale, la neuropathie peut conduire à une perte du tonus de la vessie. Le patient perçoit alors moins son besoin d'uriner (Monnier & Fumat, 2014). La rétention de l'urine augmente les risques d'infection urinaire (Buysschaert, 2011). Plus de 30% des patients atteints de diabète seraient concernés par des troubles génitaux (Monnier & Fumat, 2014). Chez les hommes, ils se manifestent par un dysfonctionnement érectile et/ou des anomalies de l'éjaculation. Parmi les femmes, ces troubles se caractérisent par une baisse des sécrétions vaginales et/ou une anorgasmie. L'atteinte du système nerveux autonome peut aussi avoir un impact sur le système sudoral (sécheresse des membres inférieurs et sueurs compensatrices au niveau de la tête et du haut du tronc) et le système de dilatation de la pupille (Monnier & Fumat, 2014).

Un bon contrôle glycémique et la limitation des facteurs de risques (obésité, consommation d'alcool, de tabac, etc.) sont primordiaux pour prévenir l'apparition de neuropathie diabétique (Buysschaert, 2011; Monnier & Fumat, 2014). Une fois le diagnostic de neuropathie établi, le traitement consiste à cibler les mécanismes physiopathologiques en vue de soulager les symptômes déjà présents et éviter l'apparition de nouvelles manifestations du trouble. Le traitement clinique dépend essentiellement de la symptomatologie du patient (Buysschaert, 2011; Monnier & Fumat, 2014).

Néphropathie diabétique

La néphropathie est une altération du fonctionnement des reins qui se caractérise par la présence d'une protéine, l'albumine, à un taux trop élevé dans les urines (albuminurie > 300 mg par 24 heures) (Monnier & Fumat, 2014). Entre 20 et 30% des patients atteints de diabète développent une néphropathie avérée après 20 à 25 ans de diabète (Buysschaert, 2011). Dans la majorité des pays occidentaux, la néphropathie diabétique constitue la première cause de traitement par dyalise. La néphropathie apparait en trois phases : Une première phase asymptomatique où les reins augmentent de taille et s'accompagnant d'une hyperfiltration glomérulaire ; La seconde phase désigne l'apparition de protéines dans les urines, une rétention sodée, une hypertension artérielle et une altération du fonctionnement rénal ; La troisième phase marque le diagnostic d'une insuffisance rénale chronique. A ce stade, l'insuffisance rénale et l'hypertension s'aggravent mutuellement et accroissent dès lors le risque d'accident cardiovasculaire (Monnier & Fumat, 2014).

Un bon contrôle glycémique prévient l'apparition de la néphropathie et retarde son évolution vers l'insuffisance rénale. Une fois diagnostiqué, le patient doit veiller à réduire les risques cardiovasculaires, adapter son comportement alimentaire (vis-à-vis de la consommation de sel, de protéines, de liquides, de potassium, etc.) et sa médication (l'insuffisance rénale empêchant l'élimination de certains antidiabétiques oraux par voie rénale).

3.2.2 Les complications macro-angiopathiques

La macroangiopathie désigne le rétrécissement des artères suite à l'apparition d'un dépôt. Ce rétrécissement augmente alors les risques d'infarctus au niveau du cœur, d'accident vasculaire cérébral et d'artériopathie des membres inférieurs. L'hyperglycémie et l'insulinorésistance sont les facteurs liés au diabète qui augmentent les risques de macroangiopathie. L'hypertension, l'obésité, des facteurs génétiques, la sédentarité ou la consommation de tabac sont d'autres facteurs de risque associés à ce type de complications (Buysschaert, 2011).

Complications cardiovasculaires

75% des personnes atteintes de diabète décèdent des suites d'une complication cardiovasculaire (Monnier & Fumat, 2014). On estime que le diabète est un « équivalent de maladie coronaire », signifiant que le risque de complications cardiovasculaires est aussi important pour une personne diabétique sans antécédents cardiovasculaires que pour un sujet non diabétique ayant des antécédents coronaires (Buysschaert, 2011). Cependant, alors que dans la population générale ces complications touchent principalement des hommes plus âgés, on remarque que les complications cardiovasculaires survenant suite à un diabète concernent davantage les femmes et apparaissent de façon plus précoce dans la vie de l'individu. Les risques de mortalité associés sont également plus élevés (Buysschaert, 2011). Le traitement de ces complications doit tendre vers un strict contrôle de la glycémie et la prévention des facteurs de risque : réduction de l'obésité, arrêt tabagique, réduction de la tension artérielle, etc. (Buysschaert, 2011).

Artériopathie des membres inférieurs

Le rétrécissement des artères peut avoir pour conséquence une diminution de l'arrivée du sang vers les muscles des membres inférieurs. Cette diminution n'est pas immédiatement perçue, elle se manifeste d'abord par une douleur à l'effort (lorsque les muscles nécessitent plus de sang), puis par une douleur permanente, même au repos. En cas d'afflux sanguin insuffisant, des signes de nécrose, de gangrène ou d'ulcère peuvent apparaitre au niveau des orteils ou de la jambe. Outre l'équilibre de la glycémie et la prévention des facteurs de risque, le traitement peut comprendre des actes chirurgicaux en vue de revasculariser les membres inférieurs. Lorsque des lésions cutanées apparaissent (gangrènes ou ulcères), des soins infirmiers avec pansements réguliers sont nécessaires. Selon la sévérité de la lésion, une amputation du (de plusieurs) orteil(s) ou de la jambe peut être envisagée.

L'artériopathie n'est pas seule responsable des complications associées au pied du diabétique. Comme indiqué précédemment, la neuropathie périphérique et les risques d'infection peuvent également augmenter les risques de lésion menant à l'amputation. La neuropathie périphérique sensorielle est responsable de la perte de sensibilité du pied. Le patient peut dès lors ignorer l'existence d'une lésion et ne pas mettre en place les soins adéquats. La neuropathie périphérique motrice peut engendrer une déformation du pied, augmentant les risques de lésions. L'hyperglycémie chronique augmente encore les risques d'infection en cas de lésion. Compte tenu de l'addition de ces complications, le nombre d'amputations parmi les personnes atteintes de diabète est plus de 20 fois plus important que parmi les non-diabétiques. On estime qu'un diabétique sur 15 sera amputé au cours de sa vie.

3.3 Conséquences pour l'espérance de vie et le bien-être du patient

Ces complications chroniques et aigües ont un impact en termes d'espérance de vie pour les personnes atteintes de diabète. Dans une étude menée au Royaumes Unis, on estimait que les personnes atteintes de diabète de type 2 avaient une espérance de vie réduite en moyenne de 10 ans. L'espérance de vie d'une personne atteinte de diabète de type 1 est quant à elle réduite d'environ 20 ans (Lluch et al., 2012). Aux vues de ces graves complications, il n'est pas rare qu'un patient présentant une complication ou percevant les risques associés à un moins bon équilibre glycémique ressente une détresse associée à sa maladie. Les chapitres 5, 6 et 7 seront consacrés à l'étude de certains vécus émotionnels difficiles à l'égard du diabète et de son traitement.

4. Les coûts associés au diabète

De par l'importance de sa prévalence, des coûts directs associés au traitement quotidien de la maladie et indirects dus à la prise en charge des nombreuses complications occasionnées par le déséquilibre de la glycémie, le diabète représente une part significative des dépenses en matière de santé. La Fédération Internationale du Diabète estime qu'en moyenne 12% des dépenses en matière de santé sont consacrées au traitement du diabète (International Diabetes Federation, 2015). En Belgique, le coût du diabète par patient est estimé à 5 049 € par an (International Diabetes Federation, 2014). Un rapport de l'Institut National d'Assurance Maladie Invalidité révélait que les dépenses pharmaceutiques pour le traitement du diabète avait plus que doublé entre 2002 et 2011, passant de 71 à 144 millions d'euros dépensés pour le traitement de cette maladie (Institut National d'Assurance Maladie Invalidité, 2012).

5. Conclusion

Le diabète constitue désormais l'une des plus grandes crises de santé mondiales. Avec près de 9,1% de la population adulte touchée, le terme « pandémique » est désormais utilisé pour qualifier l'évolution de cette maladie (International Diabetes Federation, 2015). Parmi les individus concernés, 90% sont atteints de diabète de type 2. Une forme de diabète qui évolue insidieusement, car l'hyperglycémie s'installe progressivement. Le diabète est alors parfois diagnostiqué plusieurs années après le début de la maladie, suite à la découverte d'une complication associée. L'augmentation de l'espérance de vie, une alimentation trop riche et un manque d'activité physique sont grandement responsables de l'explosion de la prévalence de ce type de diabète. Autrefois essentiellement diagnostiqué auprès d'une population de plus de 40 ans, on le décèle de plus en plus parmi les enfants souffrant d'obésité.

Le diabète de type 1 impressionne moins par sa prévalence (7 à 11% des cas de diabète). Néanmoins ses symptômes et le traitement impliquant directement l'injection d'insuline constituent une charge importante pour le patient nouvellement diagnostiqué. Bien que les facteurs environnementaux associés au diabète de type 1 soient moins clairement identifiés que dans le cas du type 2, on note également une progression de sa prévalence. Cette prévalence étant plus élevée parmi les enfants du continent européen (International Diabetes Federation, 2015).

Qu'il soit de type 1 ou de type 2, le diabète présente de graves risques de complications, en particulier si celui-ci est mal équilibré. Ces complications peuvent survenir brusquement (complications aigües) ou progressivement et définitivement (complications chroniques). Certaines de ses complications constituent un réel handicap dans la vie quotidienne (rétinopathie, amputation, insuffisance rénale, etc.), et/ou sont associées à un risque élevé de mortalité (complications cardiovasculaires, coma hyperosmolaire, acidose lactique, etc.). Toutes ces complications étant associées au déséquilibre de la glycémie, il n'est pas rare que plusieurs d'entre elles coexistent auprès d'un patient présentant un mauvais contrôle de sa glycémie.

Ce premier chapitre nous a permis de mettre en avant les enjeux humains et économiques majeurs dans la prise en charge du diabète. Maintenir **l'équilibre glycémique** est dès lors essentiel en vue de réduire les risques de complications et les coûts associés. Le second chapitre présentera un élément clé de la prise en charge du diabète permettant d'améliorer l'équilibre glycémique: **l'autogestion du diabète** et les processus éducatifs mis en place en vue d'améliorer cette autogestion. Les chapitres suivants se pencheront ensuite sur deux facteurs susceptibles d'influencer l'autogestion du diabète. Le premier facteur considéré est relatif à l'implémentation de l'éducation : **la fidélité** avec laquelle un programme d'éducation à l'autogestion au diabète est implémenté auprès des patients influence-t-elle l'efficacité du programme ? Le second facteur se réfère au **vécu émotionnel** du patient, et plus précisément la dépression, l'anxiété et la détresse associée à la maladie qui peuvent entraver la bonne gestion du diabète. Ces deux facteurs sont susceptibles d'influencer l'autogestion du diabète, et donc indirectement l'équilibre glycémique et le risque de complications.

Chapitre 2

L’éducation à l’autogestion du diabète

L’importance de l’autogestion et les façons de la promouvoir auprès des patients atteints de diabète

Ce second chapitre abordera la question de l’autogestion du diabète. Nous commencerons par définir le concept de l’autogestion et les comportements qu’il sous-tend. Nous résumerons la littérature sur son implication pour l’équilibre glycémique, les risques de complications et de mortalité. Nous envisagerons ensuite l’éducation à l’autogestion, les différentes manières d’améliorer la capacité des patients à gérer leur maladie et leur traitement ainsi que leur efficacité. Nous aborderons également le concept d’éducation thérapeutique du patient. Finalement, nous nous focaliserons sur la situation en Belgique quant à l’éducation offerte au patient et son insertion dans la prise en charge.

L'éducation à l'autogestion du diabète

L'importance de l'autogestion et les façons de la promouvoir auprès des patients

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1. L'autogestion du diabète

1.1 Définition

Le terme autogestion (*self-management*) apparait pour la première fois dans les années 1960, dans un livre traitant de la rééducation des enfants atteints d'asthme chronique (Creer, Renne, & Christian, 1976). Par ce nouveau concept, les auteurs souhaitaient souligner le rôle actif de la personne dans son traitement. Depuis lors, ce terme a été fortement repris dans le contexte des maladies chroniques (Lorig & Holman, 2003), et notamment dans la prise en charge du diabète. Richard & Shea (2011, p. 261) définissent l'autogestion comme « la capacité de l'individu, en conjonction avec sa famille, sa communauté et les professionnels de la santé, à gérer les symptômes, traitements, changements de style de vie ainsi que les conséquences psychosociales, culturelles et spirituelles de sa condition de santé ».

1.2 Les comportements d'autogestion du diabète

Comme vu dans le chapitre 1, le traitement du diabète ne pouvant mener à une guérison, son objectif principal sera de maintenir une glycémie relativement stable, avec une hémoglobine glyquée en-dessous du seuil de 7% (American Diabetes Association, 2017), afin d'éviter les risques de complications aigües et chroniques liées à une glycémie trop élevée. L'équilibre glycémique implique donc une série de comportements et stratégies à suivre au quotidien de la part du patient. Ceux-ci ont été listés par l'American Association of Diabetes Educators (AADE) comme : une alimentation équilibrée, la pratique d'une activité physique, le contrôle sanguin de la glycémie, la compliance à la médication, de bonnes capacités de résolution de problèmes et de réduction des risques de complication et de bonnes stratégies de coping. Ces comportements et stratégies sont associés à un meilleur contrôle glycémique et une réduction des risques de complications (Tomky et al., 2008). L'autogestion du diabète désigne dès lors l'ensemble des actions personnelles permettant de gérer le diabète, son traitement et de prévenir la progression de la maladie (Mosby, 2012). Dans les sections qui suivent, nous discuterons de ces comportements et stratégiesplus en détail.

1.2.1 L'alimentation saine

Bien que listé comme premier comportement d'autogestion, l'American Diabetes Association (ADA) s'accorde, dès 1994, à dire qu'il n'y a pas de régime alimentaire unique pour le traitement du diabète (American Diabetes Association, 1994). Pour être efficace, le régime de la personne atteinte de diabète doit être individualisé. Le terme thérapie nutritionnelle médicale (*medical nutrition therapy*) est utilisé par l'ADA pour désigner ce régime individualisé visant à améliorer le contrôle glycémique du patient (American Diabetes Association, 2006). Tout comme le traitement médicamenteux, la thérapie nutritionnelle varie en fonction du type de diabète (insulinorésistant ou insulinodépendant) et des besoins nutritionnels, et tient également compte du plaisir que procure l'alimentation pour le patient (Franz, 2007). La thérapie nutritionnelle médicale n'est donc pas synonyme d'alimentation saine, car ce qui se révèlera équilibré pour un patient ne le sera pas forcément pour un autre. Par exemple, pour une personne en surpoids ayant développé un diabète de type 2, l'objectif sera prioritairement de réduire l'apport énergétique en réduisant les graisses. Pour une personne atteinte de diabète de type 1 et sous insulinothérapie avec schéma basal-prandial (insuline lente avec injection d'insuline supplémentaire pour chaque repas), l'objectif sera de comptabiliser l'apport en carbohydrates à chaque repas en vue d'adapter les doses d'insuline injectées. En raison de la diversité des régimes possibles, il peut être difficile d'analyser l'impact de ces thérapies nutritionnelles sur le contrôle glycémique. Une revue intégrative de la littérature a cependant montré que les patients atteints de diabète de type 2 suivant une thérapie nutritionnelle à faible teneur en graisses voyaient une amélioration de leur contrôle glycémique (Nowlin, Hammer, & D'Eramo Melkus, 2012).

1.2.2 La pratique d'une activité physique régulière

L'activité physique désigne toute activité qui augmente les dépenses énergétiques (Colberg et al., 2016). Cette définition inclut donc également l'exercice physique planifié et structuré. On distingue les exercices aérobiques et les exercices de résistance. Les exercices aérobiques ont montré leur efficacité dans l'amélioration de la sensibilité à l'insuline et le contrôle glycémique des personnes atteintes de diabète de type 2 (Jelleyman et al., 2015) et de type 1 (Chimen et al., 2012). Le diabète étant associé à un déclin accéléré de la force musculaire, les exercices de résistance sont utiles pour maintenir une force musculaire, diminuer la résistance à l'insuline, réduire la masse graisseuse et améliorer également le contrôle glycémique parmi les personnes souffrant de diabète de type 2 (Gordon, Benson, Bird, & Fraser, 2009). Les recommandations de l'ADA en matière d'activité physique dépendent du type de diabète et de la condition physique du patient. Ces recommandations sont indiquées dans le tableau 4 (Colberg et al., 2016).

Table 4: ADA recommendations for physical activity depending on the diabetes type (Colberg et al., 2016)

Type 1 diabetes	Type 2 diabetes	Gestational diabetes
Youth and adults with type 1 diabetes can benefit from being physically active, and activity should be recommended to all. Blood glucose responses to physical activity in all people with type 1 diabetes are highly variable based on activity type/timing and require different adjustments. Additional carbohydrate intake and/or insulin reductions are typically required to maintain glycemic balance during and after physical activity. Frequent blood Glucose checks are required to implement carbohydrate intake and insulin dose adjustment strategies. Insulin users can exercise using either basal-bolus injection regimens or insulin pumps, but there are advantages and disadvantages to both insulin delivery methods. Continuous glucose monitoring during physical activity can be used to detect hypoglycemia when used as an adjunct rather than in place of capillary glucose tests.	Daily exercise, or at least not allowing more than 2 days to elapse between exercise sessions, is recommended to enhance insulin action. Adults with type 2 diabetes should ideally perform both aerobic and resistance exercise training for optimal glycemic and health outcomes. Children and adolescents with type 2 diabetes should be encouraged to meet the same physical activity goals set for youth in general. Structured lifestyle interventions that include at least 150min/week of physical activity and dietary changes resulting in weight loss of 5%–7% are recommended to prevent or delay the onset of type 2 diabetes in populations at high risk and with prediabetes.	Women with preexisting diabetes of any type should be advised to engage in regular physical activity prior to and during pregnancy. Pregnant women with or at risk for gestational diabetes mellitus should be advised to engage in 20–30 min of moderate-intensity exercise on most or all days of the week.

L'ADA a également établi des recommandations en matière de réduction de temps de sédentarité. Tout adulte, et en particulier ceux souffrant de diabète de type 2, devrait diminuer la durée des comportements sédentaires au quotidien. Pour améliorer la glycémie, toute activité réalisée en position assise devrait être interrompue toutes les trente minutes pour des périodes d'activité physique légère. Ces recommandations ne remplacent évidemment pas celles concernant la pratique d'une activité physique à part entière (Colberg et al., 2016).

1.2.3 Le contrôle sanguin de la glycémie

L'autocontrôle de la glycémie sanguine par le patient est le troisième comportement d'autogestion considéré par l'AADE. L'autocontrôle implique l'utilisation de deux appareils : le glucomètre et les tigettes permettant l'analyse de la glycémie capillaire, et l'auto-piqueur et ses lancettes permettant le prélèvement de la goutte de sang nécessaire à l'analyse. Après lavage et essuyage des mains, le patient se pique la face latérale d'un doigt afin de prélever la goutte de sang à déposer sur la tigette du glucomètre.

Le contrôle sanguin de la glycémie ne concerne pas toutes les personnes atteintes de diabète. Les patients diabétiques de type 1 et de type 2 sous insuline contrôlent généralement leur glycémie. En ce qui concerne les personnes atteintes d'un diabète de type 2 et sous médication orale, l'ADA suggère que l'autocontrôle de la glycémie peut également leur permettre d'atteindre un meilleur équilibre glycémique (American Diabetes Association, 2008). Cette recommandation est également suivie par l'International Diabetes Federation (IDF) qui considère que l'autocontrôle de la glycémie devrait être rendu accessible à tout patient diabétique, qu'il soit sous insuline ou médication orale, et ce dès le diagnostic de la maladie (International Diabetes Federation Clinical Guidelines Task Force, 2006). Cependant, un essai clinique randomisé mené sur des personnes nouvellement diagnostiquées diabétiques de type 2 a indiqué que l'autocontrôle glycémique n'améliorait pas significativement l'équilibre glycémique, mais augmentait les symptômes de dépression de 6% par rapport au groupe contrôle (O'Kane, Bunting, Copeland, & Coates, 2008).

En Belgique, le nombre de tests pris en charge par les mutuelles est déterminé par le type de diabète et le nombre d'injections d'insuline réalisées sur la journée. Les personnes atteintes de diabète de type 1 (Groupe A de la nouvelle convention diabète), de diabète de type 2 avec plus de 3 injections ou de diabète de grossesse insulinotraité (Groupe B) bénéficient d'au moins 90 tigettes par mois, soit pour trois tests par jour. Les personnes diabétiques de type 2 ayant 2 injections par jour, ou une seule injection d'insuline parfois combinée avec l'injection d'un antidiabétique (Groupe C), ne bénéficient que de 25 tigettes par mois, soit moins d'un test de glycémie par jour (Institut National d'Assurance Maladie-Invalidité, 2016). Les frais de tigettes en cas de tests supplémentaires sont à la charge du patient. Les mutuelles n'interviennent pas dans l'autocontrôle de la glycémie des patients non-insulinotraités. Depuis le 1er juillet 2016, les patients atteints de diabète de type 1 peuvent également bénéficier d'un lecteur de glycémie continu. Ce lecteur est muni d'un capteur sous-cutané formé d'une électrode recouverte d'une enzyme qui réagit en fonction du taux de sucre. Le capteur est couplé à un transmetteur qui envoie ces données à un récepteur. Le lecteur permet alors d'observer les fluctuations du taux de glucose tout au long de la journée.

1.2.4 La compliance à la médication

Cette compliance concerne les médicaments utilisés pour maintenir ou améliorer l'équilibre glycémique : les injections d'insuline, la prise d'antidiabétiques oraux (insulinostimulants, insulinosensibilisants, etc.). Pour adhérer parfaitement à son traitement, le patient doit prendre la **dose** de médicament à **fréquence** et **intervalle** convenus avec son médecin (Cramer, 2004). Pour la prise d'antidiabétiques oraux, une revue de la littérature a montré que l'adhésion au traitement diminuait avec le nombre de doses prescrites : 79% des patients adhéraient à leur traitement quand celui-ci impliquait une prise par jour, contre 66% quand cela impliquait deux prises et 38% lorsque le traitement impliquait trois prises de médicament (Cramer, 2004). Cette même revue de la littérature indiquait que l'adhésion à l'insuline des personnes atteintes de diabète de type 2 était de 62 à 64%. D'autres études et méta-analyses plus récentes ont relevé des pourcentages similaires (Iglay et al., 2015;

Kirkman et al., 2015) qui correspondent à ce qui est rapporté dans la littérature pour l'adhésion au traitement des maladies chroniques (Bowry, Shrank, Lee, Stedman, & Choudhry, 2011; World Health Organization, 2003). Une autre étude a révélé qu'en moyenne, les patients insulinotraités oubliaient ou ne prenaient pas leur insuline comme prévu 4 jours par mois (Peyrot, Barnett, Meneghini, & Schumm-Draeger, 2012). Les raisons principales données à ces manquements étaient : une trop grande occupation, un voyage, le saut de repas, les problèmes de stress, ou la gêne en public. Les patients jeunes et ne présentant pas d'autres soucis de santé semblent plus à risque de faible adhésion à leur traitement (Kirkman et al., 2015). Les raisons et facteurs de risque pour une moins bonne adhésion au traitement sont à considérer sérieusement car le manque de compliance à la médication est associée à un moins bon contrôle glycémique (Aikens & Piette, 2013; Rhee, 2005; Rozenfeld, Hunt, Plauschinat, & Wong, 2008), et par conséquent, un risque accru de complications et de mortalité.

1.2.5 La résolution de problèmes

La résolution de problèmes se réfère aux situations impromptues pouvant mettre à mal les dispositions généralement prises afin de maintenir l'équilibre glycémique (par exemple, une hypoglycémie suite à un effort trop intense ou un repas manqué). La capacité du patient à résoudre cette situation problématique et à éviter qu'elle se reproduise dans le futur est primordiale. L'AADE propose un modèle cyclique de résolution de problème où, via l'analyse et l'évaluation, le patient (1) essaie de comprendre les causes et les risques associés à l'apparition du problème, (2) tire les leçons afin de limiter les facteurs d'apparitions et risques associés à l'avenir, (3) discute de ces solutions avec l'éducateur en diabétologie, le médecin et autres figures de soutien, et finalement (4) essaie d'appliquer ces solutions à son quotidien (American Association of Diabetes Educators, 2017)

1.2.6 La réduction des risques

Il s'agit des stratégies supplémentaires à mettre en place en vue d'éviter les complications associées au diabète telles que les problèmes cardiaques, l'insuffisance rénale, la neuropathie, la perte de vision, etc. Ces comportements concernent l'arrêt de fumer, les visites régulières chez le médecin, chez l'ophtalmologue et le dentiste, les soins des pieds et l'écoute générale du corps.

Les risques de maladies respiratoires (cancer du poumon, broncho-pneumopathie chronique obstructive) et de mortalité liés à la consommation de tabac sont bien connus dans la population générale. Pour les personnes atteintes de diabète, les risques associés à cette consommation sont encore plus importants. La nicotine augmente le taux de catécholamines, des hormones qui réduisent la sécrétion ainsi que la sensibilité à l'insuline. La nicotine augmente également la pression artérielle, les triglycérides, et le périmètre abdominal, ayant pour conséquence un risque accru de complications macro-vasculaires telles que les accidents vasculaires cérébraux ou les infarctus du myocarde (Chiolero, Faeh, Paccaud, & Cornuz, 2008; Facchini, Hollenbeck, Jeppesen, Ida Chen, & Reaven, 1992). Chez les personnes souffrant de diabète, fumer accroit de 48% le risque de mortalité, de

52% le risque d'infarctus du myocarde et de 44% celui d'un accident vasculaire cérébral (Qin, Chen, Lou, & Yu, 2013).

Des visites régulières chez le médecin généraliste et l'endocrinologue sont également nécessaires afin d'éviter les risques de complications et de contrôler l'évolution de la maladie. En Belgique, un patient conventionné doit consulter son endocrinologue tous les ans (Institut National d'Assurance Maladie-Invalidité, 2016), et un patient en trajet de soins tous les 18 mois (Institut National d'Assurance Maladie-Invalidité, 2009). L'hyperglycémie chronique engendrant des lésions dans les micro-vaisseaux, le patient atteint de diabète doit veiller à consulter régulièrement son ophtalmologue afin de repérer les signes de rétinopathie. L'hyperglycémie a également pour effet de réduire la résistance aux infections bucco-dentaires. Des visites régulières chez le dentiste permettent d'identifier et traiter avant aggravation les gingivites et les caries dentaires.

Le soin quotidien des pieds est primordial car ceux-ci se trouvent au carrefour d'une série de complications associées au diabète dont la neuropathie périphérique est la principale responsable. En effet, la neuropathie va engendrer une perte de sensibilité du pied, une diminution de l'hydratation naturelle et donc une sécheresse du pied avec fissures et callosités, ainsi qu'une déformation osseuse avec l'apparition de points de pression. A cela peuvent s'ajouter des complications vasculaires, ou artérite. Le rétrécissement des artères diminue alors la circulation du sang dans les membres inférieurs, avec pour possible conséquence des ulcères ou gangrène. Finalement, l'hyperglycémie augmente encore les risques d'infection de ces plaies ainsi que de mycose (Buysschaert, 2011).

1.2.7 Les stratégies de coping

Cette troisième stratégies considérée par l'AADE souligne l'importance des facteurs sociaux, psychologiques et émotionnels dans l'autogestion du diabète. La détresse influence ainsi directement la santé, mais également indirectement via la motivation à maintenir le diabète sous contrôle. Le *healthy coping* se définit comme *« des réponses à des défis physiques et psychologiques qui utilisent les ressources disponibles pour augmenter la probabilité d'une résolution favorable de ces défis à l'avenir »* (Kent et al., 2010, p. 229). Ces stratégies de coping plus favorables peuvent se manifester chez les personnes atteintes de diabète sous forme d'attitudes, de capacités ou de comportements tels que l'expression de ses émotions, la recherche d'aide et de réponses, l'adoption d'une activité physique, la motivation, le sentiment d'auto-efficacité, l'optimisme, etc. Pour favoriser ces stratégies de coping, les intervenants doivent veiller à reconnaître les besoins des patients, renforcer les comportements positifs en évitant de se focaliser sur le négatif, et renforcer l'atteinte de sous-objectifs. Un faible soutien social, un locus de contrôle externe, des événements stressants, l'apparition de complications, un faible niveau d'éducation ou de littératie en santé sont autant de barrières aux stratégies de coping plus favorables (Kent et al., 2010).

1.3 Autogestion, adhésion, compliance et observance

De par le rôle des recommandations de l'équipe médicale dans l'établissement des comportements d'autogestion à réaliser, la mesure de l'autogestion du diabète peut s'apparenter à une mesure d'adhésion, de compliance ou d'observance du traitement. Autrefois fortement utilisés dans la littérature, les termes compliance et observance indiquent toutefois une forme de soumission du patient à l'expertise médicale, ils renvoient également à une vision et une mesure dichotomiques de la gestion du diabète (R. E. Glasgow & Anderson, 1999) : le patient suit-il, ou ne suit-il pas les comportements tels que strictement établis par son médecin/diététicien/etc. ? Cette conception est de moins en moins partagée par les instances internationales telles que l'Organisation Mondiale de la Santé ou l'Institut National de la Santé qui proposent que le patient prenne une place de « co-décideur » dans la mise en place de son traitement. Le terme « autogestion » autorise dès lors plus de nuances dans la mesure où il envisage la fréquence, la précision et la régularité avec lesquelles le patient se conforme aux comportements d'autogestion « idéaux » dans son cas particulier.

1.4 Mesures

L'autogestion peut se mesurer de façon indirecte, via l'hémoglobine glyquée ou l'évaluation du médecin, ou par voie plus directe. Dans les mesures directes de l'autogestion, nous pouvons considérer l'observation, et les mesures auto-rapportées par entretien ou questionnaire.

1.4.1 Mesures par observation

L'autogestion désignant un ensemble de comportements que le patient effectue dans sa vie quotidienne, une évaluation par observation directe peut sembler difficile à mettre en place. Certains comportements, comme le contrôle de la glycémie sanguine, peuvent néanmoins être observés de façon indirecte. Il est ainsi possible d'observer le nombre de fois où le patient a contrôlé sa glycémie au moyen d'un carnet de glycémie ou des résultats mis en mémoire du lecteur.

1.4.2 Mesures auto-rapportées

Les mesures auto-rapportées offrent plusieurs avantages parmi lesquels un moindre coût et une plus grande facilité à mettre en place. On peut reprocher à ces mesures d'être soumises au biais de désirabilité sociale, bien qu'il semblerait que le niveau des comportements d'autogestion rapporté corrèle significativement avec des indicateurs objectifs tels que l'hémoglobine glyquée (Heisler, Smith, Hayward, Krein, & Kerr, 2003; Schmitt et al., 2013; Weinger, Butler, Welch, & Greca, 2005).

Les entretiens

En dehors du contexte de recherche, l'équipe médicale se renseigne sur la façon dont le patient gère sa maladie au quotidien et sur les éventuels obstacles à l'autogestion. Il existe également des canevas d'entretien plus ou moins structurés afin d'évaluer plus systématiquement les différents comportements d'autogestion. Hanson, Henggeler et Burghen (1987) ont par exemple développé un entretien structuré, le *Diabetes Self-Mangement Profile* (DSMP), de 23 questions en vue d'évaluer l'alimentation, l'ajustement du traitement à l'insuline, la gestion des hypoglycémies, le contrôle de la glycémie et les soins des pieds. Les versions plus récentes incluent désormais l'exercice physique et ont retiré le domaine des soins des pieds (Harris et al., 2000). Certaines questions ont également été adaptées afin de saisir l'adaptation des doses d'insuline en fonction des résultats du test de contrôle de la glycémie (Wysocki, Buckloh, Antal, Lochrie, & Taylor, 2012). Plusieurs études menées sur des enfants et adolescents atteints de diabète de type 1 ont démontré les qualités psychométriques du DSMP, avec un indice de cohérence interne allant de 0.67 à 0.79, et des corrélations modérées à élevées avec le taux d'hémoglobine glyquée (r entre 0.27 et 0.60) (Wysocki et al., 2012). Même hautement structurés, les entretiens nécessitent un entrainement préalable des interviewers en vue d'adopter une attitude de non-jugement des comportements du patient.

Les questionnaires

Les premiers questionnaires de mesure de l'autogestion du diabète sont apparus sous le label de questionnaire d'adhésion ou de compliance : telle que la mesure de compliance développée par Cerkoney et Hart (1980), le *Diabetes Regimen Adherence Questionnaire* (DRAQ, Brownlee-Duffeck et al., 1987), ou le *Diabetic Adherence Questionnaire* (Marquis & Ware, 1979). En 1994, Toobert & Glasgow développe le Summary of Diabetes Self-Care Questionnaire (SDSCA, Toobert & Glasgow, 1994). Contrairement aux questionnaires antérieurs, le SDSCA n'évalue pas l'adhésion à un traitement, car ce traitement est spécifique au patient, mais évalue le niveau d'autogestion du patient au cours des 7 jours précédents (Toobert, Hampson, & Glasgow, 2000). Le patient doit évaluer le nombre de jours au cours de la semaine écoulée durant lesquels il a suivi les recommandations de son médecin concernant son alimentation, son activité physique, sa médication, le contrôle de sa glycémie, ses soins des pieds et sa consommation tabagique (Toobert et al., 2000). L'étude publiée en 2000 par Toobert et al. indiquait que, sur 7 études ayant utilisé le SDSCA, ce questionnaire disposait d'un bon indice de cohérence interne en général, ainsi qu'une bonne validité et sensibilité au changement.

Un autre questionnaire utilisé pour mesurer l'autogestion est le *Self-care Inventory* (SDI, La Greca, Swales, Klemp, & Madigan, 1988). Ce questionnaire fut d'abord testé et validé auprès d'enfants et adolescents atteints de diabète (e.g. Wysocki et al., 1996), et plus récemment révisé et validé auprès de patients adultes (Weinger et al., 2005). Sur une échelle à 5 points, les répondants doivent répondre à 15 items afin d'évaluer la mesure dans laquelle ils ont suivi les recommandations d'autogestion en matière de contrôle glycémique, de prise d'insuline, d'alimentation, d'exercice physique et de conduites d'urgence au cours du mois précédent (1 = « ne l'ai jamais fait » et 5 « l'ai toujours fait comme recommandé, sans jamais faillir »).

Le *Diabetes Self-Management Questionnaire* (DSMQ) fut développé ultérieurement afin de mesurer les comportements les plus susceptibles d'influencer le contrôle glycémique (Schmitt et al., 2013). Sur une échelle à 4 points, les répondants doivent évaluer la mesure dans laquelle 16 descriptions de comportements d'autogestion s'appliquent à eux ou pas. Les comportements décrits sont relatifs à la gestion de la glycémie, le contrôle de l'alimentation, l'activité physique et le recours aux services de soin de santé. Un item général mesure également l'autogestion dans sa globalité. Le DSMQ et ses comportements présentent de bons indices de cohérence interne (Schmitt et al., 2013) ainsi qu'une forte corrélation avec le taux d'hémoglobine glyquée (Schmitt, Reimer, Hermanns, et al., 2016).

Des indices de corrélations modérés à élevés ont été trouvés entre les scores du SDSCA et du SCI-R (Weinger et al., 2005) et élevés entre le SDSCA et le DSMQ (Schmitt et al., 2013). Bien que ces trois mesures corrèlent toutes significativement avec le contrôle glycémique, des corrélations plus élevées ont été trouvées avec le DSMQ (Schmitt et al., 2013) (r entre -0.15 et 0.40) et le SCI-R ($r = -0.37$) (Weinger et al., 2005).

Dans le domaine pratique, le Diabetes Self-Management Assessment Report Tool (D-SMART) fut développé afin de permettre aux intervenants d'évaluer les sept comportements d'autogestion définis par l'AADE et fournir des pistes pour l'amélioration de l'éducation (Charron-Prochownik et al., 2007; Peyrot et al., 2007). Bien qu'encore peu utilisé dans le domaine de la recherche, le D-SMART montre de bonnes qualités psychométriques (Peyrot et al., 2007) et une bonne validité apparente auprès de la population de personnes diabétiques (Charron-Prochownik et al., 2007).

Outre les échelles évaluant les comportements d'autogestion, d'autres questionnaires mesurent le sentiment d'efficacité du patient vis-à-vis de ses capacités à gérer sa maladie et son traitement au quotidien. Ce sentiment d'efficacité spécifique est fortement associé aux comportements d'autogestion rapportés par les patients atteints de diabète (articles). Parmi ces questionnaires, on trouve la Diabetes Empowerment Scale (DES, R. M. Anderson, Funnell, Fitzgerald, & Marrero, 2000) et la Diabetes Management Self-Efficacy Scale (DMSES; Bijl, Poelgeest-Eeltink, & Shortridge-Baggett, 1999). La DES est composée de 28 items répartis en trois sous-échelles : la gestion des aspects psychosociaux du diabète (obtenir du support social, gérer le stress, s'auto-motiver, etc.), l'évaluation de la dissatisfaction et de la propension à changer, l'établissement et l'atteinte des objectifs en rapport avec le diabète. Sur une échelle de 1 à 5, les répondants doivent évaluer leur croyance en leur capacité à performer dans ces trois domaines. La DMSES se compose de 20 items. Le répondant doit évaluer sur une échelle de 1 à 5 sa capacité à s'engager dans quatre types d'activité d'autogestion : la nutrition spécifique en lien avec le maintien du poids, la nutrition générale et le traitement, les exercices physiques, et le contrôle de la glycémie.

2. L’éducation à l’autogestion du diabète

2.1 Définition

Pour renforcer les capacités des patients à autogérer leur maladie, l'éducation à l’autogestion du diabète est largement recommandée. L’éducation à l’autogestion du diabète se réfère au processus par lequel on facilite les connaissances et les compétences nécessaires à l’autogestion du diabète. Ce processus doit tenir compte des besoins, des objectifs et des expériences de vie de la personne vivant avec le diabète et être défini par des normes basées sur des preuves empiriques (Haas et al., 2012). Les objectifs généraux de l’éducation à l’autogestion du diabète sont dès lors, selon l’ADA, de (a) donner les informations nécessaires à la prise de décision éclairée, (b) soutenir les comportements d’autogestion, (c) aider à la résolution de problèmes, (d) promouvoir une collaboration active entre le patient et l’équipe de soin, et (e) améliorer les résultats cliniques, la santé et la qualité de vie (Haas et al., 2012).

2.2 Standards d’éducation

L’ADA et l’AADE reconnaissent les standards nationaux d’éducation à l’autogestion (*National Standards for Diabetes Self-Management Education*). Aux USA, ces standards permettent la reconnaissance de certaines interventions et leur remboursement (Powers et al., 2015). Environ tous les 5 ans, des experts de l’éducation au diabète se réunissent pour redéfinir ces standards d’éducation (Haas et al., 2012). Lors la dernière de ces réunions, il fut décidé d’étendre ces standards aux *supports* à l’autogestion du diabète. Soulignant de cette façon qu’au-delà de l’éducation initiale, le patient doit être continuellement soutenu dans son autogestion (Haas et al., 2012). Ces standards sont résumés dans le tableau suivant :

Table 5 : Standards nationaux d'éducation et de soutien à l'autogestion (Haas et al., 2012)

Standard 1 : La structure interne

Présence d'informations concernant la structure organisationnelle ou le système qui supporte l'éducation à l'autogestion.

Standard 2 : L'évaluation extérieure

Sollicitation d'avis extérieurs, d'évaluations d'experts afin de promouvoir la qualité de l'intervention.

Standard 3 : L'accessibilité

Présence d'un système évaluant régulièrement la population ou communauté recevant l'éducation afin de s'assurer que les barrières à l'éducation soient bien dépassées.

Standard 4 : La coordination

Présence d'un coordinateur responsable de la planification, l'implémentation et l'évaluation de l'éducation.

Standard 5 : L'équipe d'éducation

Au moins un des intervenants responsables du design et de la planification de l'intervention doit avoir suivi une formation d'infirmier, de diététicien ou de pharmacien, avec une expérience dans l'éducation à l'autogestion du diabète, ou une autre certification dans le domaine des soins au diabète. Les autres intervenants doivent suivre une formation au diabète avec suivi.

Standard 6 : Le curriculum

Présence d'un curriculum écrit reprenant les lignes directrices de l'éducation et les résultats qui seront évalués. Les éléments d'éducation repris dans ce curriculum doivent être basés sur des preuves empiriques. Le choix des parties du curriculum qui seront implémentées doit être définies en fonction des besoins spécifiques des participants à l'éduction.

Standard 7 : L'individualisation

Les besoins du patient en termes d'éducation et de support à l'autogestion doivent être évalués par au moins un intervenant. Le patient et le(s) intervenant(s) s'accorde(nt) ensuite ensemble sur le développement d'un plan d'éducation et de soutien personnalisé et focalisé sur le changement de comportement.

Standard 8 : Le soutien continu

Développement d'un plan personnalisé de suivi avec le patient pour soutenir l'autogestion. Les résultats et objectifs du patient, ainsi que son plan de suivi, seront communiqués aux autres membres de l'équipe.

Standard 9 : Les progrès du participant

Via l'utilisation de mesures appropriées, les intervenants veilleront à évaluer la progression du patient sur l'atteinte de ses objectifs personnels et d'autres indicateurs.

Standard 10 : L'amélioration de la qualité

Une revue systématique du processus et des résultats de l'éducation et du soutien devra régulièrement être effectuée par les intervenants impliqués afin d'améliorer la qualité de l'éducation et du soutien, et identifier les lacunes du service.

2.3 Efficacité de l'éducation à l'autogestion

L'éducation à l'autogestion a montré son efficacité pour l'amélioration : (1) de **déterminants comportementaux** tels que le sentiment d'efficacité et l'empowerment des personnes atteintes de diabète (Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012), (2) **de comportements** par l'adoption de stratégies de coping plus saines (Thorpe et al., 2013) et la réduction des risques de complications (Mehravar et al., 2016; Nicolucci et al., 2013a), (3) **d'indicateurs subjectifs de la santé** comme la qualité de vie (Cochran & Conn, 2008; Cooke et al., 2013; Deakin, McShane, Cade, & Williams, 2005) et (4) **d'indicateurs objectifs de la santé** tels que l'amélioration du taux d'hémoglobine glyquée (Deakin et al., 2005; Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003; Norris, Lau, Smith, Schmid, & Engelgau, 2002; Steinsbekk et al., 2012; Tshiananga et al., 2012), et la réduction de la fréquence des hospitalisations (Healy, Black, Harris, Lorenz, & Dungan, 2013) et des coûts qui en découlent (H. S. Brown et al., 2012).

Des études se sont penchées sur les caractéristiques des programmes d'éducation à l'autogestion les plus efficaces en considérant notamment : le mode de délivrance de l'intervention, la durée de l'intervention et les stratégies éducatives utilisées.

2.3.1 Le mode de délivrance

L'éducation peut être délivrée de façon individuelle, en groupe, en groupe de discussion (sans qu'il y ait une personne attitrée pour délivrer l'intervention), ou via l'utilisation de nouvelles technologies (smartphone, internet, etc.). Plusieurs études indiquent que l'efficacité de l'intervention ne varie pas significativement entre un mode de délivrance individuel et une délivrance en groupe (Chodosh, 2005; Norris et al., 2002). Ce même constat a été fait dans une étude récente effectuée dans le cadre du projet européen Diabetes Literacy. Dans cette étude, les auteurs ont vérifié la mesure dans laquelle les interventions comprenant une part d'éducation individuelle étaient plus efficaces que les programmes recourant uniquement à de l'éducation en groupe ou à des nouvelles technologies (Peer et al., Submitted). Une comparaison avant-après évaluant les comportements d'autogestion et des indicateurs de santé, tels que le BMI, la santé générale et le bien-être, a été réalisée auprès de 366 patients atteints de diabète de type 2 ayant suivi une intervention d'éducation à l'autogestion de leur maladie. Parmi eux, 65 avaient reçu une partie de leur éducation en entretien individuel. Les résultats montrent une amélioration générale des différents comportements d'autogestion et des résultats de santé pour tous les différents types d'intervention. Les interventions comprenant une part d'éducation en individuel n'étaient cependant pas associées à une plus grande efficacité, excepté pour l'examen des pieds et la résolution de problèmes (Peer et al., Submitted). Ces résultats rejoignent ceux de précédentes méta-analyses qui montrent que l'éducation donnée en groupe semble au moins aussi efficace que celle donnée en individuel (Deakin et al., 2005; Duke, Colagiuri, & Colagiuri, 2009a).

2.3.2 La durée de l'éducation

Si le type d'intervention semble peu déterminer l'efficacité de l'éducation, la durée de l'éducation semble quant à elle jouer un rôle. La méta-analyse réalisée par Norris et al. (2002) indiquait que, parmi les différentes caractéristiques des interventions considérées (le type d'intervention, la qualification de l'intervenant, le focus de l'intervention, etc.), seule la durée de l'intervention avait un impact sur l'hémoglobine glyquée. Près de 24 heures d'éducation semblent nécessaires pour voir apparaitre une amélioration de 1% de l'hémoglobine glyquée (Norris et al., 2002). Cette conclusion est rapportée par d'autres méta-analyses qui montrent que les interventions comprenant plus de 19h/24h d'éducation sont plus efficaces pour l'amélioration des connaissances, des compétences d'autogestion et de l'hémoglobine glyquée (Fan & Sidani, 2009; Steinsbekk et al., 2012). Ces résultats renforcent les standards de l'ADA et de l'AADE en faveur d'un *soutien continu* à l'autogestion, au-delà de la simple éducation initiale.

2.3.3 Les stratégies éducatives

Les standards actuels d'éducation à l'autogestion du diabète encouragent les interventions qui impliquent activement le patient. Dans leur méta-analyse, Norris, Engelgau et Narayan (2001) indiquent que les interventions impliquant une participation active des patients (discussions en groupe, interactions, empowerment, etc.) sont plus efficaces que les interventions strictement didactiques (simple transmission d'informations) pour l'amélioration de l'hémoglobine glyquée. Des résultats similaires sont trouvés dans la méta-analyse de Fan et Sidani (2009) qui montrent que les stratégies interactives sont plus efficaces pour améliorer les comportements d'autogestion. Cependant, ce sont les interventions qui combinent des méthodes didactiques et des méthodes interactives qui apparaissaient les plus efficaces pour améliorer les connaissances et le contrôle glycémique (Fan & Sidani, 2009).

2.3.4 Education à l'autogestion et éducation (thérapeutique) du patient

Un concept jumeau de l'éducation à l'autogestion, de par sa définition, est l'éducation thérapeutique du patient (ETP).

L'ETP apparait en Europe dans les années 70, avec le souci de considérer le patient dans sa globalité et de collaborer avec lui dans les soins (Lacroix & Assal, 2011). L'ETP est ensuite officialisée par la création d'un service d'enseignement thérapeutique pour les malades chroniques à l'Université de Genève (Chambouleyron, Lasserre-Moutet, Lagger, & Golay, 2013). Fin des années 90, l'Organisation Mondiale de la Santé indique que l'objectif de l'ETP est de « *former les patients à l'autogestion, à l'adaptation du traitement à leur propre maladie chronique, et de leur permettre de faire face au suivi quotidien. Elle contribue également à réduire les coûts des soins de longue durée pour les patients et la société.* » (World Health Organization, 1998, p. 12). Elle se concrétise en France avec les recommandations mises en place par la Haute Autorité de Santé (2007) pour l'implémentation de l'éducation thérapeutique.

L'ETP recouvre trois domaines d'éducation, allant du plus large au plus restreint (Deccache, 2002) : **L'éducation à la santé du patient** qui concerne tous les comportements de santé, qu'ils soient liés ou non à la maladie ; **L'éducation du patient à la maladie** qui inclut tous les comportements associés à la maladie, qu'ils soient de l'ordre du traitement, de la prévention des risques de complications, ou à l'origine de la maladie, etc. ; Et **l'éducation thérapeutique du patient** à proprement parler qui touche uniquement au traitement de la maladie et doit être sous la responsabilité du personnel soignant (Collignon, 2002).

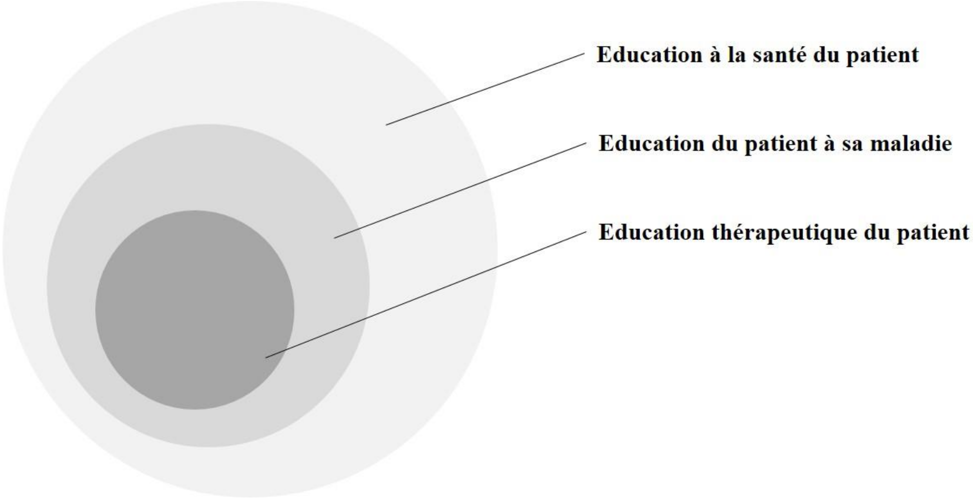

Figure 4 : L'éducation thérapeutique du patient (Collignon, 2002)

L'ETP vise par conséquent l'amélioration de la santé et de la qualité de vie du patient et de ses proches via : (a) l'acquisition de compétences d'autogestion et leur maintien, et (b) l'acquisition de compétences d'adaptation (Haute Autorité de la Santé, 2007). L'ETP se planifie en quatre étapes :

- L'élaboration d'un diagnostic éducatif, ou bilan éducatif partagé

  Via un entretien individuel, cette première étape consiste à identifier les connaissances, les besoins et attentes spécifiques du patient, ainsi que ses ressources et les possibilités de les mobiliser. Outre l'identification des compétences que le patient devrait acquérir, cet entretien permet de développer la relation entre le patient et le(les) intervenant(s) et de favoriser la collaboration au cours des prochaines étapes (Sandrin-Berthon, 2010).

- Le développement d'un programme d'ETP

  Sur base du bilan éducatif, le patient et l'intervenant définissent ensemble les objectifs de l'éducation et les compétences à acquérir. Ce programme doit identifier des priorités d’apprentissage et peut être revu à tout moment en fonction de l’évolution des besoins du patient et de sa maladie (Haute Autorité de la Santé, 2007).

- La planification des séances d’ETP

Il s’agit à cette étape de définir le contenu de chaque séance d’ETP. Le patient peut généralement choisir de participer à des séances individuelles ou des séances collectives, ou une alternance des deux méthodes (Haute Autorité de la Santé, 2007).

- L’évaluation des compétences acquises et de l’application du programme

Une évaluation de l’atteinte des objectifs du programme d’ETP est mise en place tout au long de l’intervention. Accompagné de son(ses) intervenant(s), le patient fera le point sur les compétences qu’il a acquises et, éventuellement, sur celles qu’il lui reste à acquérir. Cette évaluation peut donner lieu à une modification du programme ou à une nouvelle période éducative (Haute Autorité de la Santé, 2007).

3. La situation en Belgique

En Belgique, le domaine de la santé relève au départ des compétences des communautés linguistiques, bien que le système d’assurance maladie ainsi que les règles de financement des structures hospitalières et maisons de soins et de repos relèvent du gouvernement fédéral. En février 2016, un décret a été adopté pour le transfert de certaines des compétences de la fédération Wallonie-Bruxelles vers les régions wallonne et bruxelloise. En raison de ces différences de responsabilités régionales, il n’existe actuellement aucun plan national pour le diabète (Richardson, Zaletel, & Nolte, 2016).

3.1 Recommandations de bonne pratique et rapport sur la qualité et l’organisation des soins

La société scientifique de médecine générale (SSMG) a établi des recommandations de bonnes pratiques en matière de prise en charge des personnes atteintes de diabète de type 2 (Bastiaens et al., 2015). Parmi ces recommandations destinées aux médecins généralistes figurent les conseils à prodiguer aux patients en matière d’alimentation, d’activité physique, de tabagisme et de consommation d’alcool. Ces recommandations se basent notamment sur les standards d’éducation énoncés par l’ADA, ainsi que sur ceux du National Institute for Health and Clinical Excellence (NICE) et du Scottish Intercollegiate Guidelines Network (SIGN).

En 2006, le Centre Fédéral d’expertise des soins de santé (KCE, Federaal Kenniscentrum voor de gezondheidszorg, 2006) publiait un rapport sur la qualité et l’organisation des soins pour les personnes atteintes de diabète de type 2 en vue de formuler des recommandations pour le système de soins en Belgique. Pour ce faire, une série de guides internationaux de prise en charge du diabète ont été identifiés afin d’extraire des indicateurs de qualité en termes de processus et de résultats. A l’issue de ces investigations, le rapport considère 29 indicateurs potentiels de qualité répartis en cinq domaines : le contrôle de la glycémie, la détection des complications, le traitement des complications, les maladies cardiovasculaires et la qualité de vie. L'accès continu à l'éducation figure parmi les indicateurs de qualité pour le contrôle de la glycémie :

Table 6 : Indicateurs de qualité de la prise en charge du diabète de type 2 (KCE, 2006)

Control of glycemia	**Treatment of complications**	**Cardiovascular disease**
Patients should have a target HbA1c concentration Patients should have a regular measurement of their HbA1c concentration P Patients should receive lifestyle advice Patients should receive diabetes education on an ongoing basis Efforts to avoid severe hypoglycaemia should be made Patients should have (at least) annual disease review Patients on insulin therapy should receive education on blood glucose monitoring and self-management Patients should receive regular lifestyle control / assessment Insulin therapy should be considered in certain circumstances **Detection of complications** Patients should have a regular diabetic foot exam (interval depending on foot risk/problem) Patients should have an eye risk (factor) classification	Patients with (at least) microalbuminuria should receive appropriate medical treatment Patients who don't reach their target HbA1c under non-pharmacological treatment, should receive OAD mono-therapy Patients who don't reach their target HbA1c under optimal OAD combination therapy, should receive (combined OAD and) insulin treatment Patients with diabetic retinopathy should receive appropriate treatment (depending on eye risk - problem: conservative treatment, laser coagulation, vitrectomy, cataract extraction) Patients should receive foot care education Patients with diabetic foot / Charcot foot should receive appropriate treatment (pressure release, revascularisation, antibiotics, resection of necrotic tissue, amputation, …) Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy	Patients should have a target blood pressure Patients should receive smoke cessation counselling Patients with hypertension should receive appropriate antihypertensive treatment Patients should have a regular screening for cardiovascular risk factors and disease (+/- risk classification) patients with certain cardiovascular risk should receive appropriate (medical) treatment Patients with CVD should receive appropriate treatment Patients should receive intensive insulin treatment following an acute MI Long term treatment should be considered after an AMI (such as beta-blocking agents, ACEI, lipid lowering drugs, and anticoagulation therapy) Patients with cardiovascular disease should be on lipid lowering therapy Patients' smoking status should be monitored **Quality of life** Health care professionals should be aware of potential effects of life events on stress and self-care behaviour

3.2 Les réseaux impliqués dans l’éducation au diabète

L’éducation du patient diabétique se fait via divers réseaux. Une partie de l’éducation est dispensée par les infirmières éducatrices en diabétologie (dans le cas du trajet de soins et de la convention d’autogestion) ou par le médecin généraliste (programme restreint d’éducation à l’autogestion) et est fortement intégrée aux systèmes de prise en charge de la personne atteinte de diabète. Ces différents systèmes sont synthétisés sur le schéma ci-dessous (Réseau Multidisciplinaire Local Bruxelles, 2016) :

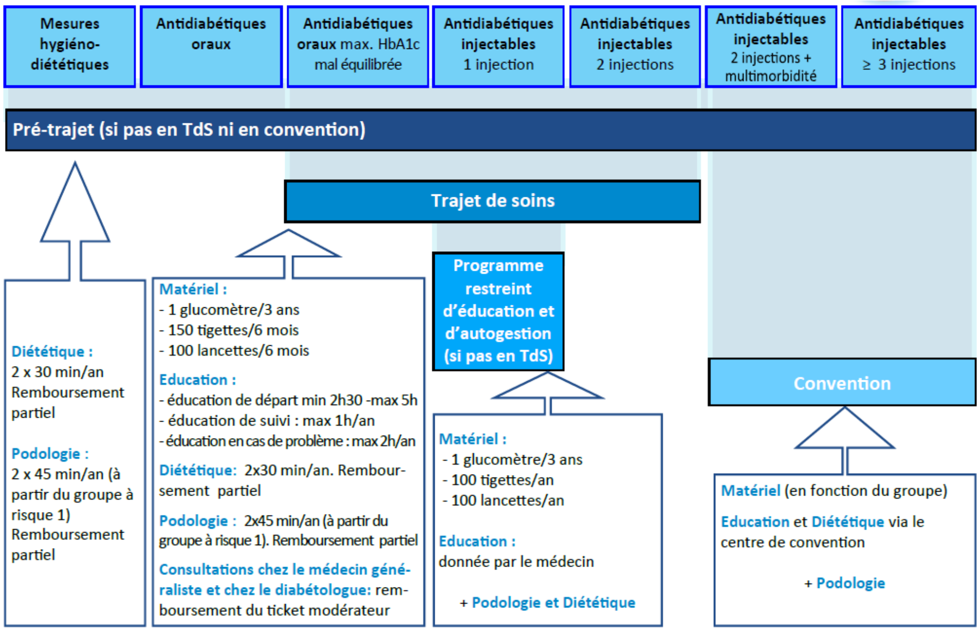

Figure 5 : Systèmes de prise en charge de la personne diabétique en Belgique (RML-B, 2016)

3.2.1 La convention autogestion

Depuis 1988, les centres multidisciplinaires de diabétologie belges (plus d’une centaine) peuvent conclure une « convention diabète » avec l’Institut National d’Assurance Maladie-Invalidité (INAMI). En outre, la convention diabète propose à certains groupes de patients diabétiques un programme d'autogestion de leur maladie et de leur traitement. Initialement, la convention diabète ne s’adressait qu’aux diabétiques de type 1. Par la suite, la convention a également intégré les diabétiques de type 2 réalisant au moins 2 injections d’insuline par jour. Les patients intégrés en convention sont suivis par une équipe multidisciplinaire, sous la supervision d’un docteur endocrinologue, et comprenant au moins un infirmier éducateur en diabétologie et un diététicien également spécialisé en diabétologie. Les patients conventionnés bénéficient d’un remboursement de l’éducation au diabète, et du matériel d’autocontrôle. La convention diabète est composée de différents sous-groupes selon le nombre d’injections réalisées par le patient :

Groupe A : Diabète type 1 et les patients avec une perte totale de la fonction endocrine du pancréas (pancréatectomie).

Groupe B : Diabète de type 2 et qui ont besoin d'un traitement complexe (≥ 3 injections d'insuline et/ou autres antidiabétiques injectables), diabète de grossesse traité avec de l'insuline, diabétiques après une transplantation d'organe ou traités au moyen d'une dialyse rénale, s'ils sont traités avec de l'insuline.

Groupe C : Diabète de type 2 avec > 2 injections d'insuline et/ou avec d'autres antidiabétiques injectables. Diabète de type 2 avec 1 injection par 24h, si cette injection est complétée – pour certains jours – par une injection d'un antidiabétique dont le fonctionnement couvre plusieurs nycthémères et avec situation médicale grave à côté du diabète (affection oncologique, BPCO avec des corticoïdes changeant fréquemment, nouveau diagnostic de diabète après un infarctus aigu du myocarde, un AVC). Il s'agira d'une prise en charge temporaire par l'établissement, généralement pas plus de 6 mois, faisant suite à une concertation entre le médecin généraliste et le médecin de l'établissement au sujet de cette prise en charge temporaire. Les patients qui répondent à une des situations suivantes : après transplantation, hypoglycémies organiques, diabète de grossesse sans insuline, femmes diabétiques sans insuline en désir de grossesse

A noter que depuis le 1er juillet 2016, les patients diabétiques de type 2 à 2 injections et sans multi-morbidités (autrefois labélisés groupe 3a) ne sont plus intégrés en convention, mais rejoignent le système de trajet de soins.

3.2.2 Les trajets de soins

Suite au nombre croissant de patients diabétiques de type 2, y compris ceux traités par insuline, les conventions sont submergées par les nouvelles arrivées de patients. Une autre limite des conventions est que celles-ci n'incluent pas les patients diabétiques traités à une injection par jour ou les patients sous antidiabétiques oraux. Or, selon l'Enquête de Santé de 2013 (Van der Heyden & Charafeddine, 2013), ces patients non inclus dans les conventions représentent environ 72% de la population diabétique. C'est pour décharger les conventions diabète que les trajets de soins voient le jour à partir de 2009. Le trajet de soins (TDS) organise le traitement et la gestion des patients souffrant de diabète de type 2 ou d'insuffisance rénale (RIZIV/INAMI, 2009). Il s'agit principalement d'une collaboration entre trois parties : le patient, le médecin généraliste et l'endocrinologue. Le trajet de soins débute lorsqu'un accord est signé entre ces trois parties.

Afin de bénéficier d'un TDS, le patient diabétique de type 2 doit être traité par insuline (1 ou 2 injections) ou doit être sur le point de commencer le traitement à l'insuline (antidiabétiques oraux insuffisants). Depuis le 1er juillet 2016, tous les patients diabétiques de type 2 sans multimorbidité (ancien groupe 3a des conventions diabète) rejoignent le système de trajet de soins.

Le patient en TDS reçoit son matériel d'autocontrôle en pharmacie. Le médecin généraliste prescrit un certain nombre d'heures d'éducation données par un infirmier éducateur en diabétologie. Une « éducation de départ » (minimum 2h30 et maximum 5h) est donnée dès que le patient commence son traitement à l’insuline. Une « éducation de suivi » est ensuite donnée chaque année (< 1h/an). Lorsque les glycémies ne sont pas suffisamment équilibrées (HbA1c > 7,5%), une « éducation supplémentaire » peut être donnée (1 à 2h/an).

Une étude réalisée lors de la mise en place des trajets de soins, entre 2009 et 2011, sur base des données de l’Agence InterMutualiste (AIM), a montré une implémentation efficace du système de trajets de soins en ce qui concerne les consultations avec le médecin généraliste, l’endocrinologue, et le remboursement du matériel d’autocontrôle. Cependant, les consultations avec l’éducateur en diabétologie n’étaient pas délivrées aussi fréquemment que souhaité (Van Casteren et al., 2015). Les raisons possibles de ce manque d’implémentation de l’éducation au début du lancement du système de TDS étaient la charge administrative que le médecin généraliste devait remplir pour référer à l’éducateur en diabétologie, les faibles compensations financières pour l’éducateur, la durée d’éducation insuffisante ainsi que le manque d’un système d’accréditation pour les éducateurs en diabétologie (Van Casteren et al., 2015). Une nouvelle étude investiguant la situation actuelle en matière d’implémentation des trajets de soins et des interventions des éducateurs en diabétologue devrait être entreprise.

3.2.3 Le suivi diabétique ou pré-trajet de soins

Depuis le 2 février 2016, le pré-trajet de soins, appelé officiellement le “Suivi diabétique”, remplace définitivement l’ancien passeport diabète. L’objectif du pré-trajet de soins est de mieux encadrer les patients diabétiques de type 2 qui ne rentrent pas dans les critères d’inclusion du trajet de soins, ni de la convention diabète. Comme pour le passeport diabète, les patients en pré-trajet de soins peuvent bénéficier de consultations podologiques (2 X 45 minutes par an pour les groupes à risque) et diététiques (minimum 2 X 30 minutes par an) sous prescription de leur médecin généraliste. A cette phase, il n’y a pas d’intervention obligatoire de l’endocrinologue, et une éducation à l’autogestion n’est pas encore prévue actuellement.

3.2.4 Le programme restreint d’éducation à l’autogestion

Les patients diabétiques de type 2 traités à une injection d’insuline peuvent bénéficier du programme restreint d’éducation à l’autogestion. Le médecin généraliste est alors chargé de donner les informations et les conseils directement au patient. Le matériel d’autogestion octroyé est moins important qu’en trajet de soins et ce système a été principalement établi pour éviter la surcharge des trajets de soins.

En dehors des systèmes de prise en charge médicale, une part de l’éducation et de l’information du patient diabétique se fait via d’autres structures telles que l’Association Belge du Diabète et différentes autres associations :

3.3 Les structures impliquées dans l’éducation au diabète

3.3.1 L’Association Belge du Diabète et maisons de l’ABD

Créée durant la seconde guerre mondiale afin d’assurer l’approvisionnement d’insuline auprès de la population diabétique, l’Association Belge du Diabète (ABD), ou Diabetes Liga dans la région flamande, a pour objectif principal de défendre les droits et intérêts des personnes atteintes du diabète (Association Belge du Diabète, n.d.).

A cette fin, elle **informe** les patients et leurs proches via une revue bimestrielle, un guide régulièrement actualisé, et l’organisation de conférences et de séances d’information. Outre l’information, l’ABD participe également à des actions de **sensibilisation** et de **prévention** du diabète, et se charge de représenter et d’améliorer l’image de la personne diabétique auprès du grand public. L’ABD organise également des séjours de **vacances sportifs** à destination des enfants et adolescents diabétiques en collaboration avec l’ADEPS. Finalement, l’ABD propose des **séminaires** et des **formations** à destination des professionnels impliqués dans la prise en charge de la maladie, et soutient la **recherche scientifique** via le Fonds Suzanne et Jean Pirart.

Les maisons ABD sont les antennes régionales de l’association. Ce sont elles qui se chargent de diffuser l’information via l’organisation de conférences pour les patients diabétiques. Dans la province francophone, ces antennes principales sont : Le Groupe des Personnes diabétiques de Bruxelles, Maison ABD de Namur, Maison ABD Wallonie picarde, Maison ABD Brabant wallon, Association des Parents de Jeunes Diabétiques soignés à l’UCL - 3D "Diabète -Défi -Dialogue", Association du Diabète de la Province de Luxembourg, Maisons du Diabète en Province de Luxembourg. Les provinces néerlandophones comptent 26 maisons de l’ABD.

3.3.2 Les associations sans but lucratif

Plusieurs asbl se sont construites autour du projet de l’éducation et de l’accompagnement des personnes atteintes de diabète. L’objectif ici n’est pas de lister l’ensemble de ces associations impliquées dans l’éducation au diabète, mais de donner quelques exemples d’initiatives dans le domaine. Le Centre d’Education du Patient (CEP) à Namur propose notamment des formations aux professionnels et un support à la création de programmes éducatifs à destination des patients. Le centre sensibilise également les politiques aux enjeux de l’éducation du patient. La formation de base à *l’éducation du patient et à l’accompagnement des patients chroniques* mise en place par le CEP propose aux professionnels en contact avec des malades chroniques, selon une approche d’éducation thérapeutique, des outils et techniques pour mettre en place une intervention éducative. En 2015, une formation présentant des outils spécifiques à l’éducation des patients atteints de diabète avait également été organisée.

L’asbl « Les Pissenlits » est, quant à elle, directement en lien avec les personnes souffrant de diabète. Située depuis 1996 à Curreghem, un quartier dit « fragilisé » de

Bruxelles, elle rassemble depuis 2003 un groupe de personnes atteintes de diabète autour de sujets variés. En respectant ainsi les cultures et cadres de référence de chacun, le personnel de l’asbl invite des professionnels (endocrinologues, diététiciens, etc.) à présenter et discuter d’une thématique particulière en rapport avec le diabète. Des projets communautaires sont également entrepris comme par exemple, la sensibilisation des boulangeries du quartier à la préparation de pains plus adaptés aux personnes diabétiques ou la distribution de flyers au marché local pour informer sur la problématique du diabète.

Le réseau santé diabète des Marolles est une association créée au début des années 2000 initialement afin de soutenir les activités réalisées au sein des maisons médicales, puis rapidement afin de consolider et accroître les collaborations, y compris avec les hôpitaux Bruxellois. Le réseau s’axe donc sur le principe de partenariat, organise des groupes de réflexion autour du diabète (alimentation, activité physique), communique aux personnes diabétiques un « agenda santé » reprenant les activités organisées autour du diabète et de la santé de façon générale. Il propose également des consultations de diététique ainsi que diverses activités physiques (sport ballon, vélo, marche nordique), et un coaching individualisé.

Depuis 2009, des réseaux multidisciplinaires locaux (RML) sont mis en place pour coordonner et promouvoir les collaborations entre le patient, le médecin généraliste et le médecin spécialiste dans le cadre du traitement de maladies chroniques via les trajets de soins (cfr. point 3.2.2), c’est-à-dire, les personnes atteintes de diabète de type 2 ou d’insuffisance rénale. Ces réseaux sont définis et financés par les cercles de médecine générale. Le budget alloué à chaque RML est fonction du nombre d’habitants au sein des cercles impliqués par province. Le nombre de « promoteurs » par RML est donc fort variable d’une province à l’autre et conditionne les activités organisées par le RML. Ces promoteurs sont chargés de favoriser la communication entre les prestataires de soins et les patients, d’aider les médecins généralistes à la mise en place d’un trajet de soins, organiser des formations à destination des éducateurs, des actions d’information et de sensibilisation auprès des patients, etc.

4. Conclusion

Les maladies chroniques ne se soignent pas, elles se gèrent au quotidien. Cette gestion quotidienne met le patient au centre même de sa prise en charge. Cette évidence a conduit les associations à définir quels étaient les comportements d’autogestion essentiels à mettre en place pour améliorer le contrôle glycémique et éviter ainsi les risques de complications et la mortalité liés à un diabète mal équilibré. Ces comportements ne relèvent pas uniquement de l’alimentation, de l’activité physique, de l’autocontrôle de la glycémie, ou de l’adhésion à la médication, mais ils concernent également les capacités de résolution de problèmes (tels que les situations d’hypoglycémie), de la réduction des risques de complications et des stratégies de coping.

Considérant l’importance de ces comportements, l’éducation à l’autogestion du diabète prend désormais une part essentielle dans la prise en charge du patient. Elle consiste à apprendre au patient à mieux gérer sa maladie et son traitement. Au-delà de l'enseignement des connaissances et compétences nécessaires, le soutien continu est désormais reconnu parmi les standards de l'éducation à l'autogestion. En effet, les interventions présentant un nombre d'heures élevé d'éducation semblent être plus efficaces pour améliorer le contrôle de la glycémie.

Bien que la Belgique ne dispose pas de programme d'éducation thérapeutique reconnu comme en France, l'éducation du patient s'est insérée dans le système de prise en charge du diabète via les conventions diabète, les trajets de soins, ou encore les programmes restreints d'éducation à l'autogestion donnés par le médecin généraliste. En dehors de cette prise en charge médicale, plusieurs associations proposent des formations en éducation du patient telles que les Réseaux Multidisciplinaires Locaux ou le Centre d'Education du Patient. D'autres associations offrent des activités et un soutien aux personnes atteintes de diabète, c'est le cas par exemple du groupe des diabétiques des « Pissenlits » ou du Réseau Santé Diabète à Bruxelles.

Les chapitres suivants aborderont deux variables pouvant impacter les capacités d'autogestion des personnes atteintes de diabète. La première variable concerne la délivrance des interventions, la fidélité de l'implémentation de l'éducation à l'autogestion. Nous inviterons le lecteur à prendre connaissance de la façon avec laquelle la fidélité au protocole d'éducation et les adaptations réalisée vis-à-vis de ce protocole influencent l'efficacité de l'intervention. La seconde série de variables envisagées concerne les variables psychologiques telles que la dépression, l'anxiété ou la détresse. Nous envisagerons d'abord le processus par lequel ces variables peuvent entraver la bonne autogestion du diabète. Nous considérerons ensuite l'intelligence émotionnelle comme facteur dispositionnel pouvant jouer un rôle protecteur contre l'apparition de ces troubles parmi les personnes atteintes de diabète.

Chapter 3

Assessment of implementation fidelity in diabetes self-management education programs

A systematic review

As diabetes requires extensive self-care, self-management education is widely recommended to enhance the effectiveness and reduce the costs of treatment. While a variety of diabetes self-management (DSM) programs are available, the conditions for their effective implementation are not well documented. This paper reviews the literature on implementation fidelity (IF), the degree to which programs are delivered as intended, as a factor influencing the effectiveness of diabetes education. Medical, psychological and educational research databases were searched to identify published studies on diabetes education describing the implementation process. Studies detailing the intervention adherence/fidelity/integrity were included to assess the way key elements of IF were addressed. More specifically, this review investigated: (a) how implementation fidelity is conceptualized; (b) how implementation fidelity is measured; (c) how the different components of implementation fidelity are assessed; (d) what is the level of implementation fidelity in diabetes education; and (e) if there is a relationship between implementation fidelity and intervention outcomes.

Reference

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Assessment of implementation fidelity in diabetes self-management education programs

A systematic review

Abstract

Objective: As diabetes requires extensive self-care, self-management education is widely recommended to enhance the effectiveness and reduce the costs of treatment. While a variety of diabetes self-management (DSM) programs are available, the conditions for their effective implementation are not well documented. This paper reviews the literature on implementation fidelity (IF), the degree to which programs are delivered as intended, as a factor influencing the effectiveness of diabetes education.

Methods: Medical, psychological and educational research databases were searched to identify published studies on diabetes education describing the implementation process. Studies detailing the intervention adherence/fidelity/integrity were included to assess the way key elements of IF were addressed.

Results: From an initial 418 abstracts, 20 published papers were retained for an in-depth analysis focusing on the components of IF. Intervention content was mainly assessed through observation, whereas intervention dose was more often assessed through self-report measures. Only one study addressed the relationship between IF and intervention effectiveness.

Conclusion: Despite the importance of IF to achieve program outcomes, IF of DSM programs remains largely under-investigated.

Practice implications: The results of this review suggest that reports on DSM education should systematically describe how the program was implemented. The impact of IF on program outcomes needs further investigation.

1. Introduction

Diabetes mellitus (DM) is one of the most challenging health problems of our time. As one of the most common noncommunicable diseases globally, it is the fourth or fifth leading cause of death in high-income countries, and is rapidly becoming epidemic in many developing and newly industrialized countries. In 2011, the number of persons suffering from diabetes was estimated at 366 million worldwide, almost 50% of whom are unaware of their condition (International Diabetes Federation, 2012). By 2030 this number is expected to rise to 552 million. As treatment and complications are costly, diabetes care takes up between 5 and 15% of total health expenditure, depending on the country (Health Service Executive, 2011).

Of the three main types of DM (type 1 diabetes caused by the body's failure to produce insulin, afflicting mainly children and teens; type 2 diabetes resulting from insulin resistance related to aging, sedentary lifestyle, poor, diet, genetic influence, and obesity; and gestational diabetes occurring in pregnant women without a previous diagnosis of diabetes), type 2 diabetes is by far the most common, making up approximately 95% of all DM cases. Its prevalence is rising rapidly and is expected to increase in the coming years as a result of aging populations, increasing urbanization, obesity, dietary changes, reduced physical activity, and other unhealthy behaviors (Hjartåker, Langseth, & Weiderpass, 2008). As early diagnosis and appropriate management of type 2 diabetes significantly increases the chances of preventing harmful and costly complications, the care for patients with this type of diabetes focuses strongly on the disease management, and especially on self-management by patients.

1.1 Diabetes self-management programs

Because diabetes requires extensive self-care, the capacities of patients to manage their own illness and care process are considered as a key determinant of treatment outcomes (Bartlett, 1986). To enhance these capacities, education of diabetes patients is widely recommended and carried out (Fond-Harmant, 2011). Diabetes self-management (DSM) education is defined as the process of teaching persons with diabetes to manage their illness and treatment by providing them with the knowledge and skills that are needed to perform self-care behaviors, manage crises, and make lifestyle changes (Clement, 1995; Norris et al., 2001).

The above definition allows for a variety of educational approaches to DSM. Educational interventions range from brief instructions by physicians, nurses, or dieticians to more formal and comprehensive programs (Clement, 1995). A meta-analysis by Brown (1999) showed a significant shift in the types of education programs over time. In the 1960s and 1970s, DSM interventions were brief, individually oriented, and mostly delivered in the hospital setting by a nurse or a dietician. From 1980 onwards, more specific programs have been set up for diabetes patients and their relatives, whereby health care professionals with different disciplinary backgrounds educate patients in their own domain of expertise. In addition to individual education of patients, more cost-effective alternatives such as group-based education (Duke, Colagiuri, & Colagiuri, 2009b), information technology (IT)-based education (Pal et al., 2013) and self-help programs or support groups have been developed (Simmons et al., 2013).

1.2 Implementation fidelity

The success of a diabetes education program not only depends on the strategy and methodology that is used, but also on the quality with which it is implemented. Given the demonstrated efficacy of existing strategies to improve glycemic control, increase physical activity and improve diet, the main public health challenge is not to find new efficacious treatments, but to implement the proven programs with consistency and efficiency (Engelgau, 2003).

A key element of the quality of implementation is its fidelity, or the degree to which the intervention is delivered as intended (Carroll et al., 2007). There are several reasons why implementation fidelity (IF) merits attention (Dusenbury, Brannigan, Falco, & Hansen, 2003). (a) Without information about the program delivery, the absence of significant effects may lead to a false attribution of the lack of an intervention's effectiveness to the shortcomings of the intervention itself, when it could have resulted from poor implementation. This phenomenon has been dubbed the ‘‘type III error’’ (Dobson & Cook, 1980). (b) Information about IF can help one understand why an intervention succeeded or failed. (c) Assessing IF can help to identify which components have been adapted to meet the specific needs of the health system and its patients, and how these adaptations influenced the outcomes. (d) Information on IF can help to assess the future feasibility of implementing the intervention, thus serving formative in addition to summative evaluation purposes.

There are different approaches to assess the IF (Century, Rudnick, & Freeman, 2010): (a) According to the critical components approach, a program is composed of several critical components, and the outcomes of the program depend on their presence or absence. To assess IF, researchers need to verify whether all the critical components have correctly been implemented. In this perspective, tools to assess IF look like a ‘‘fidelity index’’ that are very specific to a particular program (e.g. L. G. Hill & Owens, 2013). (b) The structure and process approach follows the logic of critical components and tries to characterize each component as ‘‘structure’’ or ‘‘process’’. Structural components can be related to resources and framework for service delivery, whereas procedural components can be related to roles and behaviors, or to the way in which services are delivered. According to this approach, IF depends on both the composition (structure) and the human interaction that occurs during the delivery (process) (e.g. Mowbray, Holter, Teague, & Bybee, 2003). (c) The dimensional approach considers IF as a multidimensional concept whereby each dimension can be assessed separately. Although certain dimensions such as adherence, exposure and quality are commonly mentioned (e.g. Dane & Schneider, 1998; Schoenwald et al., 2011), other dimensions vary between authors. These three different approaches may lead to very different IF measurements. As such, the critical components approach makes it possible to assess very specific aspects of the intervention, whereas the dimensional approach may allow researchers to compare the IF of different kinds of interventions.

Of the various theoretical models proposed to consider IF, the model developed by Carroll et al. (2007) is the most comprehensive (Hasson, 2010). This model has a dimensional approach but integrates the notion of critical components in one of its dimensions, notably the content of the intervention. The principal concept in this model is the adherence, which refers to the degree to which the active ingredients of the intervention have been delivered to the participants with the planned frequency, duration and intensity. Adherence is operationally defined by four components: (a) the content of the intervention (was the full content delivered to the participants?), (b) its frequency and (c) duration (was the intervention delivered with the frequency and duration prescribed by the developers?), and (d) coverage (have all the persons who should have participated in the intervention actually done so?). The combination of the frequency, duration and coverage of the intervention are referred to as the intervention dose. The level of IF may be moderated by four interrelated variables: (a) Intervention complexity refers to the nature and comprehensiveness of the intervention, whereby an intervention is more complex if several providers are involved, if it comprises several sessions, and if there are several groups of participants (Horner, Rew, & Torres, 2006; Santacroce, Maccarelli, & Grey, 2004); (b) Facilitation strategies such as a manual, training and feedback help to optimize and standardize the fidelity of the implementation; (c) The quality of delivery refers to the dedication of the individuals who are responsible for delivering the intervention. Durlak and DuPre (2008) suggested that provider characteristics such as perception of the need and the benefits of the intervention, self-efficacy, and skills may affect the fidelity of a program’s implementation. (d) Participant responsiveness refers to the fact that higher IF is achieved when the participants are more enthusiastic about the intervention. Hasson (2010) suggested two additional moderators, notably (e) Recruitment, which involves the procedure for selecting and recruiting participants, the reasons for non-participation, and the presence or absence of specific participant subgroups; and (f) Context, which refers to the culture and the organizational structure in which the intervention takes place (e.g. positive working climate, norms to change, share decisions, communication).

In recent years, efforts have been undertaken to measure and optimize IF in terms of the above dimensions or similar ones for a range of educational programs. Existing reviews of studies of DSM using these measures indicate that program guidelines are often poorly implemented (Norris et al., 2001), and that studies of self-management interventions seldom provide sufficient detail of the implementation to consider replication or application to other clinical settings (S. A. Brown, 1999). However, a systematic review of IF applied to self-management education programs for patients with diabetes has thus far not yet been reported. The present paper reports on the results of a systematic literature review of this subject, with a view to clarify how the IF is operationalized and assessed in existing DSM education programs and how it affects program outcomes. The results of such a review have important bearings for public health practice and policy.

2. Method

2.1 Literature search and selection

A search of the electronic databases PsycInfo, PsycArticle, MEDLINE, PubMed, and Google Scholar was undertaken in January and February 2013, using the search terms ‘‘self-management’’ AND ‘‘diabetes’’ in the title and the abstract, AND (‘‘intervention adherence’’ OR ‘‘implementation fidelity’’ OR ‘‘intervention integrity’’ OR ‘‘intervention fidelity’’) in full text. Preliminary searches showed that other search terms such as ‘‘intervention compliance’’ did not lead to identifying relevant articles. To select relevant publications, the following inclusion criteria were used: (1) The primary focus of the study had to be on self-management education for diabetes; and (2) The issue of implementation quality or fidelity had to be raised. As the number of empirical studies meeting these criteria was very low, theoretical articles and interventions for people at risk of type 2 diabetes (i.e., pre-diabetes) were also included. To be included in the review, interventions for people at risk had to focus on at least one of the seven self-care behaviors recommended by the AADE (American Association of Diabetes Educators, 2011) for DSM education, and raise the issue of IF. Study protocols were excluded from the review as they did not report any results. For practical reasons, only articles written in English were retained. No restriction was used concerning the publication date. The oldest article was a theoretical article by Glasgow published in 1995. All the empirical studies were published between 2003 and 2013. References from relevant studies were also examined to find additional titles.

When applying the above search procedure, and after elimination of duplicate articles, a total of 418 articles were identified. Twenty articles met the inclusion criteria and were selected for further analysis. Of these, 5 were literature reviews or theoretical articles, and 15 concerned empirical studies. The search process is summarized in the flow chart shown in figure 6.

2.2 Analysis

Articles that met the inclusion criteria were first separated into two groups: existing literature reviews and theoretical papers, and empirical studies. One protocol was also included in the review as it had been used to collect data and some results about IF were presented in the article concerned (Huizinga et al., 2006). Empirical studies were evaluated for completeness of information by assessing whether the following information was provided: (a) description of one or more self-management intervention(s); (b) indication of type 2 diabetes patients as the target group for the intervention(s); (c) reference to the concept of IF; (d) presentation of at least one approach to assess IF; (e) presentation of results related to IF. Two reviewers assessed independently whether this information content was provided in each article. Inter-reviewer agreement for each item was assessed using Cohen’s kappa, yielding a perfect agreement (k = 1) for the identification of the target group, and a substantial agreement (k = 0.68) for the identification of a self-management intervention. For the three items related to IF conceptualization, assessment approach and results, the agreement was fair (k = 0.40). Consequently, for these variables a consensus procedure between both reviewers was used to determine if the information was available.

In a second step, in-depth reviews of the full text were performed on all selected articles, performing separate analyses for existing literature reviews and theoretical papers and for empirical studies. For the first, the content analysis focused on the extent to which IF was addressed. For the empirical studies, the analysis focused on five specific questions: (a) How was IF conceptualized? (b) How was IF measured? (c) How were the different components of IF assessed? (d) What was the level of IF? And (e) was there a relationship between IF and intervention outcomes? For the first question, the model of Carroll et al. (2007) was used as a reference to check if the provider's adherence to the content, duration, frequency, and coverage of the intervention were included. For the second and third questions, Schoenwald et al. (2011) categorization of measures of IF was applied, distinguishing between (a) observation (direct or by audio/video tape), (b) self-report measures by the provider (through questionnaires or interviews), and (c) self-report measures by participants (through questionnaires or interviews).

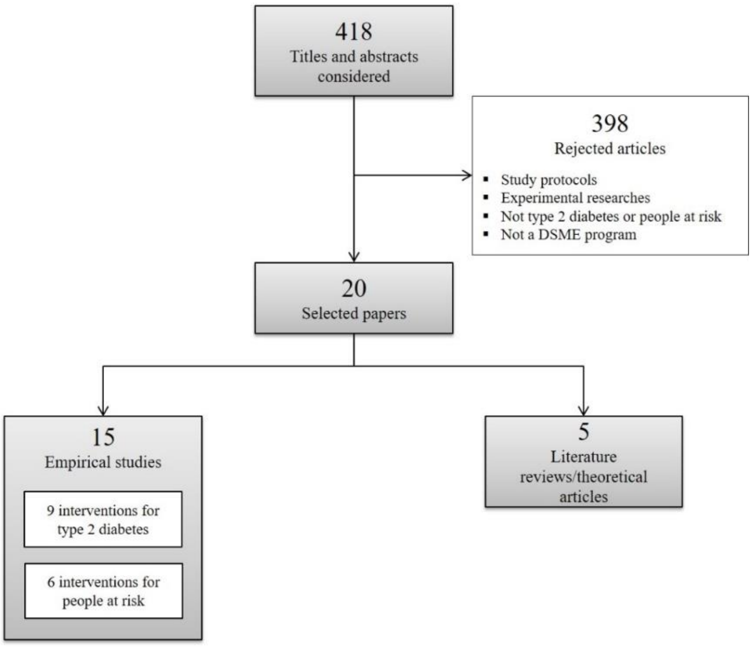

Figure 6: Flow chart of selection process for the review

3. Results

3.1 Existing reviews and theoretical papers

Five literature reviews and theoretical papers focused on self-management interventions for diabetes patients and mentioned IF (Russell E. Glasgow, 1995; Hayes, McCahon, Panahi, Hamre, & Pohlman, 2008; Hunt, 2011; Leeman, Jackson, & Sandelowski, 2006; McAndrew et al., 2008). In the theoretical articles, IF is often considered in a general way. Glasgow (1995) mentions IF in his conceptual model for DSM education, which in addition to the social environment, contextual factors, self-management behavior, and health and quality of life outcomes also focuses on the interaction between the patient and health care providers. The inclusion of this interaction component is expected to increase providers' adherence to recommended guidelines for diabetes care. In a similar way, Hayes et al. (2008) propose coaching by nurse practitioners as a means to overcome poor adherence to guideline recommendations: providers who receive direct feedback in a coaching relationship are expected to stay motivated and committed to the coaching relationship. McAndrew et al. (2008) discuss how a common sense model of self-regulation can be used to design interventions for chronic illness management, giving DSM as an example, and mention IF as a factor that needs to be considered before planning and implementing the intervention.

While these examples show that theoretical models of DSM pay attention to the providers' adherence to guideline recommendations, IF is only mentioned explicitly in two reviews of DSM interventions. Hunt (2011) presents two behavioral coding systems to evaluate treatment fidelity to motivational interviewing principles applied to diabetes. The first (Motivational Interviewing Skill Code) considers patients' and providers' behaviors, and the second (Motivational Interview Treatment Integrity) focuses on the providers' performance only. Leeman, Jackson (2006) look at barriers to implementation in the way intervention studies are reported in journal publications, and conclude that most published studies do not provide enough information on essential aspects such as the frequency and duration of patient contacts or the training of providers to allow potential users to adopt and implement an intervention in practice. Moreover, in only two out of the 46 studies included in their review, more intervention material was made available upon request.

If IF is only sparsely addressed in existing reviews and theoretical papers, there are even fewer attempts to operationally define the concept. Only two reviews and one theoretical article present an operationalization of IF. The scales described by Hunt (2011) include content, as well as participant responsiveness, and quality of delivery as indicators of the IF. Leeman et al. (2006) operationalize IF by considering the frequency and the duration of interventions. McAndrew et al. (2008) distinguish between the assessment of IF in terms of how treatment is delivered, how it is received, and how it is enacted. In all these cases, the operationalization of IF is limited to a small number of dimensions, and pays no attention to moderating factors as proposed in the model of Carroll et al. (2007).

3.2 Empirical studies

Fifteen empirical papers addressing IF in the context of DSM were identified in the literature. Of these, 9 concern type 2 diabetes patients as the main target group, and 6 focus on prediabetes patients and/or people at risk. Table 7 summarizes the information about these 15 studies, which are all included in this review. In the next sections, we will present (a) the description of each intervention, (b) the way in which IF and its potential moderators were conceptualized, (c) the way in which IF and its components were operationalized, (d) the level of IF achieved, and (e) the relationship between IF results and intervention outcomes.

3.2.1 Description of the interventions

Nine of the 15 studies (C. M. Castro, Pruitt, Buman, & King, 2011; Di Loreto et al., 2003; Griffin et al., 2010; Huizinga et al., 2006; Lakerveld et al., 2012; Perrin et al., 2006; Rothschild et al., 2012; Taub, 2006; Whittemore et al., 2010) provide complete information about the program, the conceptualization and assessment of IF, and the results of the intervention. Two studies describe the program and offer a conceptualization of IF, but do not provide any information on the way in which the concept was assessed (Haltiwanger & Galindo, 2013; Siminerio, 2005). Another study, describing a quality improvement intervention to improve providers' adherence to diabetes standards (Schouten et al., 2010), has assessed IF and report the results, but does not detail the conceptualization of IF on which the assessment was based. Finally, three publications describe studies involving IF of DSM interventions, but do not provide information about either the conceptualization or the assessment of the concept (Cherrington et al., 2008; Kramer et al., 2009; Pagoto, Kantor, Bodenlos, Gitkind, & Ma, 2008).

The self-management programs considered in these 15 studies all focus on a range of self-management behaviors, including glycemic control, medication adherence, maintaining a healthy diet, physical activity, smoking cessation, reducing alcohol consumption, or, more generally, increasing self-care behaviors or improving knowledge concerning diabetes and its complications. The approaches for enhancing these behaviors include: (a) individual approaches, such as face-to-face counseling sessions (Whittemore et al., 2010), therapy sessions (Haltiwanger & Galindo, 2013), face-to-face counseling sessions followed by phone contacts (Di Loreto et al., 2003; Griffin et al., 2010; Lakerveld et al., 2012), and phone contacts assessing the patients' adherence to treatment and providing assistance to overcome barriers to self-management (C. M. Castro et al., 2011; Huizinga et al., 2006); (b) group interventions supervised by trained educators (Griffin et al., 2010; Kramer et al., 2009; Pagoto et al., 2008; Perrin et al., 2006; Siminerio, 2005); and (c) peer support interventions with a community-based approach involving persons from the target group as providers (Cherrington et al., 2008; Rothschild et al., 2012). Two articles (Schouten et al., 2010; Taub, 2006) do not specify whether counseling has been given individually or in groups. The providers involved in these 15 studies were nurse practitioners (Lakerveld et al., 2012; Whittemore et al., 2010), nurses and dieticians (Huizinga et al., 2006), dieticians, exercise physiologists and psychologists (Pagoto et al., 2008), physicians (Di Loreto et al., 2003), trained health educators (Griffin et al., 2010), certified diabetes educators (Siminerio, 2005), clinic staff (Perrin et al., 2006; Schouten et al., 2010), unspecified health professionals (C. M. Castro et al., 2011; Haltiwanger & Galindo, 2013; Kramer et al., 2009; Taub, 2006) or members from the target population (C. M. Castro et al., 2011; Cherrington et al., 2008; Rothschild et al., 2012). The duration of the intervention is mentioned for 11 studies (C. M. Castro et al., 2011; Di Loreto et al., 2003; Griffin et al., 2010; Haltiwanger & Galindo, 2013; Huizinga et al., 2006; Kramer et al., 2009; Lakerveld et al., 2012; Pagoto et al., 2008; Perrin et al., 2006; Rothschild et al., 2012; Siminerio, 2005) and varies between 8 weeks (Haltiwanger & Galindo, 2013) to 24 months (Di Loreto et al., 2003; Huizinga et al., 2006; Rothschild et al., 2012). Sample sizes vary between n = 1 (Haltiwanger & Galindo, 2013) for a case study and n = 8159 (Griffin et al., 2010). Five of the studies involved randomized controlled trials (C. M. Castro et al., 2011; Di Loreto et al., 2003; Huizinga et al., 2006; Lakerveld et al., 2012; Rothschild et al., 2012), and for three others (Perrin et al., 2006; Schouten et al., 2010; Whittemore et al., 2010), randomization was done at the level of health centers. Intervention effects were assessed through self-monitoring of blood glucose, HbA1c, medication adherence, diet and physical activity, body mass index, blood pressure, and average energy expenditure.

Table 7: Information provided in selected empirical studies

	N (participants)	Self-management	Diabetes Type II	IF operationalization	IF measure	IF results	RCT
Di Loreto et al.	340	✓	✓	✓	✓	✓	✓
Perrin et al.	14 health centers	✓	✓	✓	✓	✓	Randomized control trial of health centers
Taub	2 287	✓	✓	✓	✓	✓	Subsample analyses
Huizinga et al.	164	✓	✓	✓	✓	✓	✓
Griffin et al.	8 159 participants spread over 12 sites	✓	At risk	✓	✓	✓	Program assessment
Whittemore et al.	58	✓	At risk	✓	✓	✓	Randomized controlled trial of 4 sites
Castro et al.	181	✓	At risk	✓	✓	✓	✓
Lakerveld et al.	490	✓	At risk	✓	✓	✓	✓
Rothschild et al.	144	✓	✓	✓	✓	✓	✓
Siminerio et al.	104	✓ Chronic Care Model	✓	✓		✓	Non randomized controlled trial
Haltiwanger et Galindo	1 (case study)	✓	✓	✓			Case study
Schouten et al.	1 125	✓	✓		✓	✓	Non randomized trial
Cherrington et al.	16 programs	✓	✓		Interviews with intervention developers		Program identification and assessment
Pagoto et al.	118	✓	21% type II and 79% at risk				Non controlled trial
Kramer et al.	93	✓	At risk				Non randomized trial
n		**15**	**9**	**11**	**10**	**11**	**5**

3.2.2 Conceptualization of implementation fidelity

Among the 15 selected empirical articles, 12 provide specific information about the conceptualization of IF. A content analysis of these articles yield the information summarized in Table 8.

As this table shows, the most commonly used indicator of IF is adherence, most often defined operationally in terms of the content of the intervention (C. M. Castro et al., 2011; Di Loreto et al., 2003; Griffin et al., 2010; Haltiwanger & Galindo, 2013; Huizinga et al., 2006; Lakerveld et al., 2012; Perrin et al., 2006; Rothschild et al., 2012; Siminerio, 2005; Taub, 2006; Whittemore et al., 2010). This is followed by frequency (Di Loreto et al., 2003; Griffin et al., 2010; Haltiwanger & Galindo, 2013; Whittemore et al., 2010), duration (C. M. Castro et al., 2011; Griffin et al., 2010; Whittemore et al., 2010) and coverage (Griffin et al., 2010; Taub, 2006; Whittemore et al., 2010). In three studies, the quality of the program delivery was used as an indicator of IF (C. M. Castro et al., 2011; Lakerveld et al., 2012; Rothschild et al., 2012), rather than as a potential moderator. Four articles do not specify how IF have been conceptualized (Kramer et al., 2009; Pagoto et al., 2008; Schouten et al., 2010). Some articles introduce components that are not considered in Carroll et al.'s model (2007), such as the number of adaptations (amount of changes introduced to the original protocol) (Griffin et al., 2010), and program differentiation (implementing the unique features of the intervention to distinguish it from other interventions) (Haltiwanger & Galindo, 2013).

In terms of the potential moderators of IF, several studies refer to facilitating strategies to enhance the implementation quality: (a) providers' trainings were set up in the studies described in 11 articles (C. M. Castro et al., 2011; Griffin et al., 2010; Kramer et al., 2009; Perrin et al., 2006; Rothschild et al., 2012; Schouten et al., 2010; Whittemore et al., 2010); and (b) intervention protocols and/or technical assistance were available to support providers during the intervention delivery in 9 studies (C. M. Castro et al., 2011; Di Loreto et al., 2003; Griffin et al., 2010; Huizinga et al., 2006; Kramer et al., 2009; Perrin et al., 2006; Rothschild et al., 2012; Schouten et al., 2010; Whittemore et al., 2010). One article reported on the positive impact of regular control with audiotaping of IF (Rothschild et al., 2012). Six studies explored participants' engagement through their satisfaction of the intervention (Griffin et al., 2010; Haltiwanger & Galindo, 2013; Lakerveld et al., 2012; Pagoto et al., 2008; Perrin et al., 2006; Whittemore et al., 2010). The quality of delivery was mentioned in three articles (C. M. Castro et al., 2011; Lakerveld et al., 2012; Rothschild et al., 2012), but was considered as an indicator of IF rather than as a moderator. A number of articles also provided information about the recruitment of participants. These included patients from the center where the study took place (Di Loreto et al., 2003; Pagoto et al., 2008; Perrin et al., 2006; Schouten et al., 2010), a subsample of a national health survey (Taub, 2006), people with diabetes living close to the study center (Huizinga et al., 2006), as well as persons recruited through mailing and advertisements (C. M. Castro et al., 2011; Griffin et al., 2010; Lakerveld et al., 2012), through a regional practice-based research network (Whittemore et al., 2010), a specific insurance plan (Rothschild et al., 2012), letters of invitation (Siminerio, 2005), and via screening (Haltiwanger & Galindo, 2013; Kramer et al., 2009). One article only provided information on the recruitment of the providers (Cherrington et al., 2008). No conceptualization was found of the context or of the intervention complexity. However, some authors suggested in their discussion that the context could impact the IF (Perrin et al., 2006; Taub, 2006).

3.2.3 Assessment of implementation fidelity

Ten studies report on the way in which IF was assessed (C. M. Castro et al., 2011; Di Loreto et al., 2003; Huizinga et al., 2006; Lakerveld et al., 2012; Perrin et al., 2006; Rothschild et al., 2012; Taub, 2006; Whittemore et al., 2010), which includes observation as well as self-report measures completed by the providers or participants. Observation by researchers involved the recording of sessions (C. M. Castro et al., 2011; Huizinga et al., 2006; Lakerveld et al., 2012) as well as direct observation (Di Loreto et al., 2003; Perrin et al., 2006; Rothschild et al., 2012). Self-report assessment of IF by the participants was done through questionnaires or checklists (C. M. Castro et al., 2011; Lakerveld et al., 2012; Schouten et al., 2010; Taub, 2006; Whittemore et al., 2010) and interviews (Perrin et al., 2006). The same is found for self-report measures by the providers: 5 studies used questionnaires (C. M. Castro et al., 2011; Griffin et al., 2010; Lakerveld et al., 2012; Rothschild et al., 2012; Whittemore et al., 2010) and one study used interviews (Perrin et al., 2006). The assessment of IF was also considered for each component separately: The content of the education program was mainly assessed through observation (C. M. Castro et al., 2011; Di Loreto et al., 2003; Huizinga et al., 2006; Lakerveld et al., 2012; Perrin et al., 2006; Rothschild et al., 2012) or by checklists completed by the providers (C. M. Castro et al., 2011; Griffin et al., 2010; Lakerveld et al., 2012; Rothschild et al., 2012; Whittemore et al., 2010). Two studies used self-report measures (questionnaire or interviews) completed by the participants (Perrin et al., 2006; Taub, 2006). Overall, four studies combined observation and self-reported measures to assess the adherence to the program content. Two studies (Haltiwanger & Galindo, 2013; Siminerio, 2005) provide no information on how the content was assessed. Frequency was mainly assessed through provider self-reports (Griffin et al., 2010; Whittemore et al., 2010) and observation (Di Loreto et al., 2003), whereas one article provides no information on the way frequency has been measured (Haltiwanger & Galindo, 2013). Duration was assessed through provider self-reports in the three studies (C. M. Castro et al., 2011; Griffin et al., 2010; Whittemore et al., 2010), one of which combined this with an observational measure (C. M. Castro et al., 2011). Coverage was assessed trough self-reports completed by providers (Griffin et al., 2010; Whittemore et al., 2010) or participants (Taub, 2006). As for the moderators, participant responsiveness was primarily explored with self-report measures completed by the participants (Haltiwanger & Galindo, 2013; Lakerveld et al., 2012; Pagoto et al., 2008; Perrin et al., 2006; Whittemore et al., 2010) or providers (Griffin et al., 2010), and quality of delivery was assessed via observation (C. M. Castro et al., 2011; Lakerveld et al., 2012; Rothschild et al., 2012). Information about other moderators was reported but was not assessed through a specific measure.

Table 8: Conceptualization and assessment of IF for empirical studies on self-management programs for people with or at risk of type II diabetes

	Conceptualization of IF					**Moderators of IF**					**Assessment of IF**					
	Content	**Frequency**	**Duration**	**Coverage**	**Intervention complexity**	**Facilitating strategies**	**Quality of delivery**	**Participant responsiveness**	**Recruitment**	**Context**	**Direct observation**	**Audio/video tap**	**Provider questionnaire or checklist**	**Provider interview**	**Participants questionnaire**	**Participants interview**
Di Loreto et al. (33)	✓	✓				✓			✓		✓					
Perrin et al. (34)	✓					✓		✓	✓	✓	✓			✓		✓
Taub (35)	✓			✓					✓	✓					✓	
Huizinga et al. (27)	✓					✓			✓			✓				
Griffin et al. (36)	✓	✓	✓	✓		✓		✓	✓				✓			
Whittemore et al. (37)	✓	✓	✓	✓		✓		✓	✓				✓		✓	
Castro et al. (38)	✓		✓			✓	✓		✓			✓	✓		✓	
Lakerveld et al. (39)	✓					✓	✓	✓	✓			✓	✓		✓	
Rothschild et al. (40)	✓					✓	✓		✓		✓		✓			
Siminerio et al. (41)	✓					✓			✓							
Haltiwanger & Galindo (42)	✓	✓				✓		✓	✓						✓	
Schouten et al. (43)						✓			✓						✓	
Cherrington et al. (44)						✓										
Pagoto et al. (45)						✓		✓	✓						✓	
Kramer et al.(46)						✓			✓							
n	11	4	3	3	0	14	3	6	14	2	3	3	5	1	8	1

3.2.4 Level of implementation fidelity

Eleven studies report results regarding the levels of IF that were attained (C. M. Castro et al., 2011; Di Loreto et al., 2003; Griffin et al., 2010; Huizinga et al., 2006; Lakerveld et al., 2012; Perrin et al., 2006; Rothschild et al., 2012; Schouten et al., 2010; Siminerio, 2005; Taub, 2006; Whittemore et al., 2010). Four of these studies give a global appreciation (Di Loreto et al., 2003; Perrin et al., 2006; Rothschild et al., 2012; Siminerio, 2005), while 7 express the results obtained for IF in percentages. The latter includes the percentage of sessions where the component was implemented (C. M. Castro et al., 2011; Huizinga et al., 2006; Whittemore et al., 2010); the percentage of patients who received the intervention components (Schouten et al., 2010; Siminerio, 2005); the level of implementation of each component (Lakerveld et al., 2012); or the division of the number of components completed per session by the number of components of the protocol (Whittemore et al., 2010).

Three articles provide a global percentage for IF, which varies between 58.2% and 92%. This leads to the authors' overall conclusion that the interventions were delivered with a relatively high level of fidelity (Griffin et al., 2010; Huizinga et al., 2006; Whittemore et al., 2010). The percentage of IF that is reached also depends on the kind of component (C. M. Castro et al., 2011; Griffin et al., 2010; Huizinga et al., 2006; Schouten et al., 2010; Taub, 2006), with 94% of the patients receiving counseling to adopt a healthy diet, but only 52% receiving instructions to monitor blood glucose (Schouten et al., 2010). Two articles report an increase of IF as a result of monthly control reports (Rothschild et al., 2012) or provider education (Siminerio, 2005). Another factor of influencing the percentage of IF is the person who does the coding (Lakerveld et al., 2012). Finally, one study concludes that providers do not give enough information to the patients in accordance to the ADA recommendations (Taub, 2006).

3.2.5 Implementation fidelity and program outcomes

Although it is generally assumed that the fidelity of implementation affects the results of the intervention, only one of the eleven articles in this review addresses the relationship between IF and intervention outcomes explicitly (Griffin et al., 2010). The paper describes two DSM programs. For both programs, no significant relationship is found between the intervention dose across seven different sites and physical activity effect size. To explain this lack of effect, three possible factors are mentioned: the program may have been robust enough to not be affected by small to moderate adaptations; the variation in IF across sites may not have been sufficiently large to show a relationship with the outcomes; or the sample size across the sites may have been too small to detect a relationship.

4. Discussion and conclusion

4.1 Discussion

Despite the growing interest in the way health interventions are being implemented, only a very limited number of empirical studies have been published to date on efforts to conceptualize and assess IF and to study its impact on program outcomes. While this holds true for IF in general, it certainly also applies to DSM education. Although implementation is increasingly mentioned as an important topic in theoretical papers on DSM support, the notion of implementation remains a peripheral issue in existing systematic reviews of DSM education programs. Moreover, as appears from the review presented in this paper, few empirical studies of DSM education programs addressed the issue of IF, and when it is, the information provided is often incomplete. More specifically, information about the conceptualization and measurement of IF is often lacking, and the relationship between IF and program outcomes is hardly ever investigated. Despite this lack of information, some authors argue that they reached a high level of IF. This kind of affirmation may sometimes lead to confusion, as no information is provided about what IF then exactly entails.

Overall, the results of our review resemble those of literature reviews on IF with regard to interventions targeting other health conditions. Durlak and DuPre (2008) concluded from a review of more than 500 studies of health promotion and prevention programs that the level of implementation in terms of variables related to communities, providers, the delivery system and the support system affects the outcomes, but that the collection of implementation data as an essential feature of program evaluation leaves much room for improvement. O'Donnell (2008) reviewed 133 studies on IF and concluded that there are too few studies to guide researchers on how to measure the fidelity of the implementation of core curriculum interventions and relate the results to outcomes. This is particularly the case for efficacy and effectiveness studies, where the requirements for fidelity measures differ. Perepletchikova et al. (2009), in a study of psychotherapy research, concluded that only 3.5% of the interventions adequately addressed IF.

The reasons why IF is seldom addressed in published intervention studies are manifold. For instance, researchers may acknowledge the importance of IF, but think they do not have enough knowledge to measure it (Perepletchikova et al., 2009). Furthermore, journals do not require papers on intervention studies to report on IF, and the word limits may also be an obstacle to report on IF in the published literature. Finally, conducting an evaluation of IF is costly and time-consuming, and there are no agreed-upon procedures for its assessment.

Whereas theoretical models of IF have been developed and are increasingly used in the health education literature, the few articles that do provide information on IF in the context of DSM do not refer to these models to conceptualize the notion. Instead, they use isolated notions or related concepts to evaluate IF. The most commonly used indicator of IF in DSM education is adherence, evaluated through the correspondence of the program content with guidelines. This is again in keeping with reviews of IF in other areas. Durlak and DuPre

(2008) noted in their review of prevention programs for children and adolescents that IF was mainly assessed through adherence to content and dose, and Dane and Schneider (1998) concluded that researchers mainly focus on exposure and adherence to assess IF. Only a small number of studies on DSM education also consider frequency, coverage or duration to conceptualize adherence in terms of intervention dose, and a few studies focus on the quality of the delivery as an indicator of IF.

To measure IF of DSM programs, researchers resort to observation as well as self-report measures by either providers or participants, or both. Observation can yield information on specific aspects of the implementation (e.g. nonverbal interactions during the intervention), whereas self-report measures can provide more general information on aspects of the implementation (Schoenwald et al., 2011). However, neither one of these techniques is without problems. Direct observation requires much time, may influence the intervention delivery, and may not always be possible, while provider self-reports are likely to suffer from social desirability bias, and participant self-reports may be influenced by the participants’ lack of familiarity with evaluation procedures or by their unwillingness to evaluate the provider unfavorably. Consequently, the results of different types of measures are not necessarily correlated (Ellis, Naar-King, Templin, Frey, & Cunningham, 2007; Schoenwald et al., 2011).

Our review also shows that different aspects of IF are typically assessed through different kinds of measures, whereby the content of the intervention is usually assessed through observation, while the different components of the intervention dose (i.e., frequency, duration, and coverage) are more often assessed through provider self-reports, and participant responsiveness via self-report measures completed by the participants. However, the variety of methods that are used to assess the different components of IF is not necessarily the result of a well-informed, deliberated choice. According to Century et al. (2010), researchers do not have a shared conceptual understanding of what fidelity of implementation is and how it can be measured, which means that the choice of measures is typically a secondary focus and based on specific contexts and programs.

Finally, it is also important to consider the potential barriers and moderators to IF. Although certain moderators were mentioned in the studies included in our review, none of these studies assessed their effects on IF. This finding is congruent with that of Appiah et al. (2013), who also noted that factors affecting the implementation of DSM guidelines remain largely unstudied.

Measuring IF is not a goal in itself, but serves the purpose of improving the way programs are implemented and, thereby, enhancing their effectiveness. It seems reasonable to assume that IF can be significantly improved by using well-developed guidelines. Some authors have proposed guidelines to develop implementation protocols that pay explicit attention to IF and offer clear guidance to improve fidelity (e.g. Saunders, 2005). However, the indicators to measure IF according to these guidelines are specific to the programs concerned, and can therefore not be used to compare different programs in terms of their IF.

4.2 Study limitations

While this paper is the first systematic review of IF applied to DSM education programs, the limitations of this review should be acknowledged. A first limitation concerns the small sample of the review. This small sample size may be due to the restriction of the search terms. However, while additional terms such as ‘‘intervention compliance’’ or ‘‘implementation quality’’ could have been used to complement ‘‘implementation fidelity’’, preliminary research showed that these other terms did not lead to the identification of additional relevant articles. On the other hand, the addition of search terms like ‘‘self-care’’ in addition to self-management could have led to the identification of more interventions, but would have implied a different focus. Second, the limited number of articles that met all the inclusion criteria makes it difficult to draw far-reaching conclusions from the content analyses. This is further complicated by the moderate inter-reviewer agreement for the application of the content criteria, which again illustrates the difficulty of finding a common agreement regarding the conceptual definition of IF. On the other hand, our findings concur with those of others reporting that many implementation studies in the literature do not address sufficiently the IF (Perepletchikova, Treat, & Kazdin, 2007). Moreover, the fact that our conclusions concur with those from reviews on IF applied to other areas also attests to their validity.

Another limitation is that the articles included in this review may not fully represent the variety of existing DSM programs. For instance, no studies were found that used an IT-based intervention, which is an approach that is becoming increasingly popular on account of its benefits for patients with limited literacy and greater self-management support needs (Schillinger et al., 2008; Schillinger, Handley, Wang, & Hammer, 2009). As the role of providers is different in IT-based intervention, it would be interesting to see how IF would be assessed in such interventions.

Finally, as IF is a relatively new concept, a unanimously agreed-upon framework with regard to this concept is not yet available. Amongst the various approaches that have been proposed, the model proposed by Carroll et al. (2007) was chosen as a basis for this review, as this provides the most complete framework on IF currently available. As a result, all publications included in this review were content analyzed using his specific framework. It is possible that the use of another framework would have yielded somewhat different results and interpretations. However, this model has been selected for its completeness, and another approach to conceptualize IF, such as the critical components approach, would not have provided the possibility to identify the different dimensions assessed in this review.

4.3 Conclusion

Self-management education is currently a standard of medical care in diabetes (American Diabetes Association, 2013). In 2006, the American Association of Diabetes Educators, the American Diabetes Association, the American Dietetic Association, the Veteran’s Health Administration, and other organizations jointly defined new DSM education standards (Funnell et al., 2010). Of the ten standards that were defined, three are related to facilitating strategies to improve the IF: documenting organizational structure, mission statement and goals in order to provide a solid basis to deliver quality diabetes education (standard 1); the presence of a designated coordinator to ensure that diabetes education is delivered through a coordinated and systematic process (standard 4); and regular continuing education for the providers (standard 5). This fact alone illustrates the growing importance of IF for the practice of DSM education. Despite this development, however, there is a dearth of empirical studies investigating IF for DSM programs using well-defined, theory-based and valid measures. Perhaps even more surprisingly, only one study assessed the relationships between IF components, moderators and program outcomes.

4.4 Practice implications

The results of this review suggest that reports on self-management education programs for diabetes patients should systematically describe how the program was implemented, how IF was conceptualized, what components and moderators were considered and how they were assessed, and how the IF affected the program outcomes. To facilitate this type of data collection and reporting, we argue that it is essential to develop a shared understanding of what fidelity of implementation entails and how it can be measured. In addition to agreeing on a common conceptual framework to understand IF, it is essential to develop common, easy-to-use measures to assess the core components of IF across multiple programs. Apart from facilitating the monitoring of the implementation of a given education program, such tools would allow a comparison of different programs in terms of their IF.

Attempts to develop such tools have already been reported in the context of process evaluation of comprehensive health promotion interventions (Century et al., 2010; Saunders, 2005). Although some authors are skeptical about the relevance of generic assessment tools for IF of DSM programs and argue that specific programs need specific fidelity measures (O’Donnell, 2008), the exclusive use of program-specific measures to assess IF creates a barrier to IF assessment in practice. Most program providers and researchers do not have the time or resources to develop measures of IF themselves. As such, a generic, user-friendly tool based on a relevant conceptual model need not replace the level of detail that program-specific measures can provide, but could nevertheless enhance the capacities of program providers and researchers to assess core aspects of the quality with which DSM programs are implemented, and compare them to other programs.

I confirm that the patient/person(s) have read this manuscript and given their permission for it to be published in PEC.

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Chapter 4

The impact of implementation fidelity on diabetes self-management education programs effectiveness

Results from the *Diabetes Literacy* project

Self-management education (SME) is generally considered to be a key determinant of treatment outcomes and related costs for diabetes. While the way in which existing SME programs are implemented is likely to influence their effectiveness, the impact of implementation on the effectiveness of diabetes SME is not well documented. This paper aims (1) to evaluate the association between implementation fidelity of a selection of diabetes SME programs and program-related effectiveness; (2) to assess whether factors related to the participants, the provider, the intervention, or the context are associated with implementation fidelity. Data from 33 providers of diabetes SME programs and 166 Type 2 diabetes patients participating in these programs were collected in 8 countries. Providers completed a questionnaire assessing their adherence to the program protocol and the factors that influenced their implementation. Patients answered a pre-post questionnaire assessing their diabetes-related health literacy, self-care behavior, general health and well-being. The associations between providers' implementation fidelity and the patients' outcome variables were estimated through exploratory analysis with logistic regressions and repeated-measures MANOVA, controlling for potential confounders.

Reference

Schinckus, L., Van den Broucke, S., Levin-Zamir, D., Müller, G., Hayter, V., Schillinger, D., … Chang, P. (2016). To adapt or not to adapt: exploring associations between implementation fidelity and diabetes self-management education effectiveness. *Submitted to BMC Endocrine Disorders*

The impact of implementation fidelity on diabetes self-management education programs effectiveness

Results from the Diabetes Literacy project

Abstract

Background Self-management education (SME) is generally considered to be a key determinant of treatment outcomes and related costs for diabetes. While the way in which existing SME programs are implemented is likely to influence their effectiveness, the impact of implementation on the effectiveness of diabetes SME is not well documented. This paper aims (1) to evaluate the association between implementation fidelity of a selection of diabetes SME programs and program-related effectiveness; (2) to assess whether factors related to the participants, the provider, the intervention, or the context are associated with implementation fidelity.

Methods Data from 33 providers of diabetes SME programs and 166 Type 2 diabetes patients participating in these programs were collected in 8 countries. Providers completed a questionnaire assessing their adherence to the program protocol and the factors that influenced their implementation. Patients answered a pre-post questionnaire assessing their diabetes-related health literacy, self-care behavior, general health and well-being. The associations between providers' implementation fidelity and the patients' outcome variables were estimated through exploratory analysis with logistic regressions and repeated-measures MANOVA, controlling for potential confounders.

Results Adaptations to the program protocol were reported by a minority of health providers. None of the factors systematically influenced the providers' self-reported implementation fidelity. Adaptations of the program were associated with better, rather than worse, patient outcomes in comparison with total adherence.

Keywords Diabetes; Self-management education; Implementation fidelity; Adherence; Adaptation; Intervention effectiveness.

1. Background

Diabetes self-management education is defined as the ongoing process of facilitating the knowledge, skills, and abilities that are necessary for diabetes self-care. As diabetes requires daily self-care, the patient's capacity to manage his or her disease is a key determinant of treatment outcomes and health-related costs (Haas et al., 2012). While diabetes self-management education (DSME) is generally recommended as part of national diabetes strategies, its effectiveness depends on a number of factors, which can be related to the patient (e.g., motivation, level of distress, health literacy, etc.), the organizational context (e.g., embeddedness of the program in a larger organization, composition and competences of the team, etc.), the education program (e.g., content, format), or the way the program is implemented. With regard to the latter, despite the availability of a wide variety of DSME programs, there is a significant lack of research about implementation fidelity of these programs (Saha, Müller, Riemenschneider, Schwarz, & the Diabetes Literacy Consortium, 2015).

Implementation fidelity, or intervention integrity, can be defined as "the extent to which the intervention has been delivered as expected" (Engelgau, 2003). It implies a comparison between the implemented intervention and the original program (Mihalic, 2004). While this concept originally appeared in the literature in the 70s (Berman & McLaughlin, n.d.; Freeman, 1977; Sechrest, West, Phillips, Redner, & Yeaton, 1979), it has only recently gained traction as a research topic within the health and social interventions environment (Faulkner, 2012; L. G. Hill & Owens, 2013; Moullin, Sabater-Hernández, García-Corpas, Kenny, & Benrimoj, 2016; Patel et al., 2015). The idea behind the concept is that assessing the fidelity with which an intervention is implemented leads to a better understanding of what works or does not work during the program delivery (Dusenbury et al., 2003). Without this information, the absence of significant effects of an intervention may lead to a false attribution of the ineffectiveness to shortcomings of the intervention itself, when it may have resulted from a poor implementation. This phenomenon has been referred to as the ''type III error'' (Dobson & Cook, 1980). In a similar way, though much less often considered, the occurrence of significant results may be due to some positive adaptations of an intervention. Information about the fidelity of a program's implementation can thus help to understand why an intervention succeeded or was less effective. Moreover, evaluating implementation fidelity also makes it possible to identify which specific components of the intervention were adapted, and how these modifications affected the intervention outcomes. Finally, information regarding implementation fidelity can help to enhance the future feasibility of implementing the intervention in a formative approach.

Implementation fidelity can be measured in three different ways: through direct observation (either participating or non-participating); through indirect observation (audio or video recording); or via self-report measures (questionnaire or interview) with the participants or providers. Each method has its advantages and disadvantages (Breitenstein, Gross, et al., 2010). Observation tends to provide a more objective and accurate assessment of the program implementation, but is also cumbersome and costly, as it requires the observers to be trained and spend long periods of time in the field. In addition, observation by an outsider can influence implementation fidelity, due to the practitioners' reactivity to observation. Self-report measures, on the other hand, are less expensive and less time consuming, but are more prone to bias due to social desirability on behalf of the providers, whereas participants may be influenced by their feelings toward the provider.

Apart from the measures used, there are two main approaches to assess implementation fidelity (Century et al., 2010). The *critical component approach* considers that a program is made of several core components that are essential to reach effectiveness. Therefore, assessing the implementation fidelity consists of checking if each of these critical components has been correctly delivered to the participants. In contrast, the *dimensional approach* holds that implementation fidelity is a multidimensional concept, whereby each dimension can be assessed separately. The dimensions that are considered as important for implementation fidelity vary between authors, but three dimensions are generally mentioned: adherence, exposure and quality. While the critical component approach makes it possible to assess very specific aspects of the intervention, the dimensional approach may allow researchers to compare implementation fidelity of different kinds of interventions.

A commonly used conceptualization of implementation fidelity is that of Carroll et al. (Carroll et al., 2007). This model follows a dimensional approach but integrates the idea of critical components in one of its dimensions. It defines implementation fidelity as the provider's adherence to the initial program *content* (were all the core components delivered to the participants?), *duration* and *frequency* (was the intervention delivered with the frequency and duration required by the developers?), and *coverage* (have all the persons who should have participated in the intervention actually done so?). The model also considers that implementation fidelity – or the provider's adherence – may be influenced by different contextual and individual factors: the *intervention complexity*, which refers to the nature and comprehensiveness of the intervention; the presence of *facilitating strategies* such as a manual, training and feedback help to support and standardize the fidelity of the implementation; the *quality of delivery*, refers to the skills, attitudes, and dedication of the individuals who are responsible for delivering the intervention; and *participant responsiveness* refers to the fact that higher implementation is achieved when the participants are more enthusiastic about the intervention. Two additional influencing factors were later added by Hasson (Hasson, 2010): the *recruitment*, which concerns the procedure for selecting and recruiting participants, the reasons for non-participation, and the presence or absence of specific participant subgroups; and the *context*, which refers to the culture and the organizational structure in which the intervention takes place (e.g. positive working climate, norms to change, shared decisions, communication). The integration of the critical and the dimensional approaches, as well as the consideration of different potential influencing factors, offers a comprehensive framework to assess implementation fidelity.

While the above mentioned model assumes that maximum adherence to the initial protocol is the best guarantee to achieve the best outcomes, this assumption is increasingly being challenged (Bopp, Saunders, & Lattimore, 2013; Kemp, 2016; Stirman, Miller, Toder, & Calloway, 2013). In practice, 100% fidelity can never be reached and some researchers suggested that program adjustments can be linked to its effectiveness (Durlak &

DuPre, 2008). Although maximum adherence to the initial protocol can ensure that the main components of the intervention are actually delivered, certain adaptations to the intervention may better fit the participants' specific needs and increase its contextual and cultural relevance (F. G. Castro, Barrera, & Martinez, 2004), adaptations may also address provider's needs (Stirman et al., 2013). Some interventions are also designed intentionally to allow certain adaptations (Pérez, Van der Stuyft, Zabala, Castro, & Lefèvre, 2016). From that perspective, assessing the adaptations providers make to the program is of utmost importance to understand what parts of the intervention can be or should not be adapted, in order to achieve the highest level of effectiveness.

A literature review (Schinckus, Van den Broucke, & Housiaux, 2014) showed that implementation fidelity of diabetes self-management education programs remains largely under-investigated. Despite the growing importance of implementation fidelity for the practice of diabetes education, very few studies have considered the provider's fidelity to the original program upon its implementation, and even fewer studies have assessed the impact of the provider's adherence on the effectiveness of diabetes education. Drawing on the conceptual model of implementation fidelity proposed by Carroll et al. (Carroll et al., 2007), the present paper aims (1) to assess the association between implementation fidelity and the effectiveness of a sample of DSME programs, and examin whether adaptations may have a positive impact on the program outcomes ; and (2) to assess whether certain potential influencing factors (related to the participants, the provider, the delivery strategies, or the context) are associated with implementation fidelity. Based on this model, it is assumed that providers will better adhere to the program protocol when (1) participants are motivated and engaged in the program; (2) the provider has sufficient knowledge and positive attitude about the content of the program; (3) when manuals and feedback are available to help the provider in the implementation process; and (4) when the context for the intervention delivery is flexible and adequate.

2. Methods

2.1 Recruitment and data collection procedure

This study was part of a larger international study on factors that influence the effectiveness of diabetes self-management education (Van den Broucke et al., 2014). To assess relation between implementation fidelity and the effectiveness of DSME programs, a pre-post comparative study design was used. DSME programs were selected from a compendium of existing programs in Austria, Belgium, Germany, Ireland, the UK, Israel, Taiwan and the USA (Saha et al., 2015). To be selected for inclusion, programs had to: (1) target diagnosed type 2 diabetes patients; (2) be set up for the general (patient) population rather than tailored to the needs of a specific age cohort, needs or gender group; (3) be eligible for newly diagnosed patients as well as for patients with an existing diabetes; (4) be stand-alone rather than an add-on to another program or part of a wider curriculum with (multiple) parallel programs; (5) admit new patients during the time of the baseline data collection.

For each selected program, patients who joined the program between October 2014 and June 2015 were systematically asked to participate in the study. Program staff were asked to distribute questionnaires to the patients who agreed to participate. They first completed an informed consent form and then received the pre-assessment questionnaire in a stamped envelope. They were contacted by phone for the post-questionnaire three months after. This procedure was followed by all participating countries, except for Israel and Germany. In Israel, the baseline data was also collected through a telephone interview. In Germany, the baseline data and the post-questionnaire were both collected via an e-mail survey.

Towards the end of the program, providers of the selected programs were invited to participate in a (face-to-face or phone) structured interview to assess implementation fidelity. The provider data were linked to those of the patients by using a unique ID enabling to establish the relationship between the intervention outcomes (patient assessment level) and the implementer's adherence to the program (provider assessment level).

2.2 Participants

In total, 33 providers from 16 different programs completed the structured interview. Their records were related to the responses of 166 diabetes patients to the pre- and post-intervention questionnaire.

Among the 16 included programs, three were delivered individually, the others were delivered to groups of participants. The patient sample was composed of 85 men (51.2%) and 81 women (48.8%). The mean age was 61.34 (SD=11.562). On average, patients had 11 years of schooling (SD=4.66). 90.4% (150) had the citizenship of the associated participating country. On a scale from 1 to 10, participants positioned their social status as average (score of 5.59, SD=2.045).

2.3 Measures

To investigate the intervention outcomes, an integrated questionnaire (Röthlin, Ganahl, & Pelikan, 2013) was used measuring the following aspects: (a) self-care behaviors were measured by means of the Summary of Diabetes Self-Care Activities Measure (SDSCA) (Toobert et al., 2000), this eight-point scale (0-7) assesses diet (e.g. *"How many of the last SEVEN DAYS have you followed a healthful eating plan?"*), exercise (e.g. "*On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity?*"), medication (e.g. "*On how many of the last SEVEN DAYS did you take your recommended insulin injections/number of diabetes pills?*") and foot care (e.g. "*On how many of the last SEVEN DAYS did you check your feet?*") ; (b) health literacy (i.e., the patient's capacity to access, understand, assess and apply health information) (Sorensen et al., 2015) was measured by the 6 item version of the European Health Literacy Survey (HLS-EU-Q6) (Pelikan, Röthlin, & Ganahl, 2014) (e.g. "*On a scale from very easy to very difficult, how easy would you say it is to use information the doctor gives you to make decisions about your illness?*"), and the Diabetes Health Literacy survey was used to assess diabetes specific communicative (e.g. *“In reading instructions or leaflets from hospitals/pharmacies, you ... (never – seldom – sometimes – often) found characters and words that you did not know”*), functional (e.g. *“Since being diagnosed with diabetes, you have ... (never – seldom – sometimes – often) collected information from various sources”*) and critical (e.g. *“Since being diagnosed with diabetes, you have ... (never – seldom – sometimes – often) considered the credibility of the information”*) health literacy (Ishikawa, Takeuchi, & Yano, 2008); (c) the perception of diabetes as a problem was measured using the Problem Areas in Diabetes (PAID-5) (McGuire et al., 2009) (e.g. “*The next questions ask you which of the following diabetes issues are currently a problem for you: worrying about the future and the possibility of serious complications? (Not a problem – minor problem – moderate problem – somewhat serious problem – serious problem)*”); (d) healthy coping was assessed by the Appraisal of Diabetes Scale (ADS) (Carey et al., 1991) (e.g. *“How much uncertainty do you currently experience in your life as a result of being diabetic? (Not at all – Slight amount – moderate amount –large amount – extremely large amount)”*); (e) perceived health was measured using the “General Health Perception” subscale of the SF-36 (Ware & Sherbourne, 1992) (e.g. “*I seem to get sick a little easier than other people (definitely true – mostly true –don’t know – mostly false – definitely false)*”); and (f) well-being was estimated via the WHO-5 Well-Being Index (Primack, 2003) (e.g. “*I have felt cheerful and in good spirits (all of the time – most of the time – more than half of the time – less than half of the time – some of the time – at no time)*”).

Implementation fidelity was assessed by a structured interview using the format of a self-report questionnaire assessing the different dimensions and potential influencing factors of implementation fidelity as described by Carroll & al. (Carroll et al., 2007). A set of items was developed based on a literature search and following an assessment of the relevance of each item by a group of French speaking diabetes educators, translated into the different languages of the participating countries: English, German, Dutch, Hebrew, and Mandarin Chinese. All the items are available online. Respondents were asked to use a visual analogue scale to indicate the extent to which they had adhered to the content, duration, frequency, and coverage of the intervention compared to the original protocol. For each dimension, qualitative information was asked about what the program was like originally, what it was like after the adaptation, and why the program had been changed. In addition, a series of Likert-type items were presented to assess the different factors that may influence the intervention delivery: (a) factors related to the participants (participants’ responsiveness, satisfaction and perception that the intervention met their needs) (11 items); (b) intervention complexity (10 items); (c) the presence and the quality of facilitating strategies: i.e., training (3 items), protocol (3 items), feedback (3 items), and evaluation (2 items); (d) factors related to the provider (quality of delivery) (12 items); and (e) the favorability of the context (4 items).

2.4 Analyses

Descriptive analyses of the provider data were performed to describe their adherence to the program content, duration, frequency and coverage. A general adherence score was computed by calculating the mean of the four dimensions. The general score and each of the four dimensions were also dichotomized to differentiate between providers who had adapted the program from those who reported a total adherence.

Internal consistency was checked for the potential influencing factors using Cronbach alpha coefficients. Factors related to the participants (α= .80) and the favorability of the context (α= .72) showed adequate internal consistency. Factors related to the provider had a sufficient internal coefficient when one item concerning provider's attitude was removed (α= .80). No scale was constructed for intervention complexity on account of its poor internal consistency (α= .03).

Exploratory analyses were performed through logistic regressions to test whether the potential influencing factors (related to the participants, facilitating strategies, factors related to the provider and favorability of the context) were associated with the provider' self-reported adherence to the program, measured as a dichotomous variable for total adherence. Assumptions to perform logistic regressions (i.e., independence of the observations, exclusive and exhaustive categories of the dependent variable, a linear relationship between any continuous independent variables and the logit transformation of the dependent variable, and none perfect or high multicollinearity between predictors) were checked and confirmed. As it is also recommended to have at least 10 observations per independent variable (Cohen, 1992), which was not the case in our sample, a first logistic regression was performed to predict the providers' general adherence, and four other regressions were performed to predict providers' specific adherence to the content, duration, frequency and coverage of the intervention.

A second series of exploratory analyses were then performed with repeated-measures MANOVA to assess the association between the providers' adherence (versus adaptation) and the patient outcomes (diabetes health literacy, self-care behaviors, coping and perception of diabetes as a problem, general health and well-being). The assumptions to perform repeated measures MANOVA (i.e., a normal distribution for each dependent variable, a reasonable correlation between the dependent variable to avoid multicollinearity, homogeneity of variances when there is a between-group independent variable, homogeneity of the variance-covariance, and sphericity of the within-group variances (Mayers, 2013)) were verified. On that basis, it was decided to remove the items related to *self-care medication* as they did not meet the conditions. A first repeated-measures MANOVA was done with the providers' self-reported general adherence as independent variable and controlling for social status and years of education. A second MANOVA included the providers' adherence to the content, duration, frequency and coverage.

3. Results

3.1 Descriptive analyses

Among the 33 providers, 13 reported total adherence to the program protocol and 13 reported at least one adaptation (10 reported changes in the content, 5 changed the duration, 9 adapted the frequency and 7 reported changes in the coverage). Seven providers did not answer any of the questions on adherence.

As only one third providers reported to have made adaptations, it was decided to create a dichotomized variable: (1) At least one adaptation, (2) Total adherence/No adaptation. In the programs of the providers who reported at least one adaptation, 49 patients participated; the providers who reported total adherence were associated to 80 participants. The patient groups defined by whether or not the program they followed had been adapted do not significantly differ with regard to age (F(1, 127) = .077, *p* = .784), gender (χ2(1) = 0,006, p =.939), years of schooling (F(1, 127) = 1,225, *p* =.271) or social status (F(1, 115) = 3.600, *p* = .060). However, nationalities are not represented in the same way in the different group: Most participants in the "adaptation" group are Israeli (65%), while participants in the "adherence" group are mainly English, American or Austrian.

3.2 Prediction of provider adherence to the program

A first logistic regression analysis looking at the relation between the 4 potential influencing factors (participants and provider's characteristics, facilitating strategies and favorability of the context) and the likelihood that providers would adapt the intervention did not show statistically significant results (χ2(7) = 7.63, *p* = .367). None of the predictor variables predicted the providers' self-reported general adherence to the program (as opposed to adaptation).

Logistic regressions using the four dimensions of provider adherence separately as predicted variables did not show a statistically significant association with the provider' self-reported adherence to the content ($\chi^2(4) = 5.51$, *p* = .238), the duration ($\chi^2(4) = 5.99$, *p* = .200), frequency ($\chi^2(4) = 5.41$, *p* = .248) or coverage (χ2(4) = 9.27, *p* = .055) of the program.

Table 9: Logistic regressions to predict the likelihood of provider's adaptation with participants' engagement, provider's attitude and knowledge, the favorability of the context and the presence of facilitating strategies

	General adherence $N_{prov} = 26$				Adherence to the content $N_{prov} = 26$				Adherence to the duration $N_{prov} = 26$				Adherence to the frequency $N_{prov} = 24$				Adherence to the coverage $N_{prov} = 22$			
	% correct	R^2	X_2	p	% correct	R^2	X_2	p	% correct	R^2	X_2	p	% correct	R^2	X_2	p	% correct	R^2	X_2	p
Model	73%	.332	7.63	.367	62%	.264	5.5	.338	81%	.299	5.99	.20	71%	.275	5.41	.248	73%	.482	9.27	.055
			Exp (B)	p			Exp (B)	p			Exp (B)	p			Exp (B)	p			Exp (B)	p
Participants			.070	.054			.439	.545			.392	.485			.434	.176			1.51	.883
Provider			.795	.860			.041	.110			.240	.496			7.42	.548			2.77	.570
Context			6.01	.074			4.16	.124			.895	.919			.542	.062			9.57	.153
Strategies			1.23	.136			1.00	.988			1.31	.079			1.31	.531			1.81	.069

3.3 Impact of provider adherence on program outcomes

A first repeated-measure MANOVA comparing the effects of diabetes self-management education programs with and without the provider’ general adherence on diabetes health literacy (DHL), self-care behaviors, diabetes coping and perception of diabetes as a problem, general health and well-being controlling for the participants’ social status and years of education showed a mean effect of the intervention for diabetes coping and perception of diabetes as a problem. Patient scores on these variables significantly improved after the intervention (F(2, 108) = 3.814, $p \leq .05$). Changes for the other considered outcome variables were not significant. A multivariate interaction effect of time and adherence group was also observed, indicating that the effect over time was significantly different for the “adherence” and “adaptation” groups in terms of diabetes health literacy (F(3, 98) = 4.651, $p \leq .01$).

Univariate analyses indicated that the significant interaction effect was mainly due to critical diabetes health literacy (Table 10), whereby the improvement in critical diabetes health literacy was greater for participants of programs for which the provider had made adaptations than for those for which the provider had totally adhered to the original intervention (F(3, 89) = 13.397, $p \leq .001$). Table 11 also shows several simple effect of adherence, indicating that before the intervention, the adherence group initially scored significantly higher for critical DHL (F(3,89) = 4.068, $p \leq .05$), exercise (F(3,87) = 11.136, $p \leq .01$), coping (F(2,108) = 8.571, $p \leq .01$), general health (F(2,109) = 8.571, $p \leq .01$) and well-being (F(2,109) = 13.871, $p \leq .001$), and lower for the perception of diabetes as a problem (F(2,108) = 10.559, $p \leq .01$).

Table 10: Univariate analyses of repeated-measures MANOVA to predict change in patients' outcomes depending on provider's adherence (versus adaptation)

Dependent variable	Range	Adherence (Mean and SD)		Adaptation (Mean and SD)		F_{time}	$F_{adherence}$	$F_{interaction}$
		T_1	T_2	T_1	T_2			
DHL com.	1-4	2.91 (.827)	2.83 (.738)	2.99 (.927)	2.75 (.879)	.008	.018	1.063
DHL func.	1-4	3.18 (.684)	3.27 (.557)	2.78 (.828)	3.09 (.695)	2.053	1.171	3.467
DHL crit.	1-4	3.09 (.755)	3.06 (.725)	2.59 (.962)	2.89 (.901)	6.375*	4.068*	13.397***
Diet	0-7	4.51 (1.592)	4.73 (1.306)	3.86 (1.679)	4.55 (1.35)	2.060	2.618	2.417
Exercise	0-7	2.97 (2.494)	3.54 (2.369)	1.64 (1.963)	2.68 (2.331)	2.464	11.136**	2.336
Foot care	0-7	3.99 (1.647)	4.68 (1.285)	3.65 (1.848)	4.13 (1.653)	5.259*	2.904	.412
Problem	0-4	1.35 (1.092)	1.18 (1.068)	1.92 (1.231)	1.77 (1.311)	1.305	10.559**	.006
Coping	1-5	3.64 (.624)	3.85 (.675)	3.29 (.698)	3.60 (.789)	2.940	8.751**	1.312
General health	1-5	3.24 (.709)	3.41 (.827)	2.79 (.826)	3.10 (.809)	1.113	10.032**	3.931*
Well-being	0-5	3.17 (1.112)	3.44 (3.234)	2.56 (1.271)	2.83 (1.183)	.394	13.871***	.018

A series of repeated measures MANOVAs with each of the four self-reported adherence dimensions (content, duration, frequency and coverage) as independent variables showed significant multivariate effects of the intervention for all of the intervention outcomes. Several multivariate interaction effects were found: (a) an interaction effect of time and adherence to the content on diabetes coping and perceiving diabetes as a problem (F(2, 81) = 5.214, $p \leq .01$); (b) an effect of time and adherence to the duration on diabetes self-care behaviors (F(3, 63) = 3.300, $p \leq .001$) and on general health and well-being (F(2, 77) = 6.113, $p \leq .01$); (c) an effect of time and adherence to the frequency on diabetes coping and perceiving diabetes as a problem (F(2, 81)=12.116 , $p \leq .05$); and (d) an effect of time and adherence to the coverage on diabetes health literacy (F(3,58) = 3.080, $p \leq .05$).

Univariate analyses show that communicative diabetes health literacy decreased more when the provider reported adaptations to the program content (F(3, 58) = 4.372, $p \leq .05$) or frequency (F(3, 58) = 7.775, $p \leq .01$). On the other hand, an adaptation of the program content also led to a greater increase of critical diabetes health literacy (F(3, 58) = 4.900, $p \leq .05$), as did an adaptation of the coverage (F(3, 58) = 8.275, $p \leq .01$). In addition, adaptation of the program duration was associated with a greater improvement of dieting behavior (F(3, 63) = 10.089, $p \leq .005$). Again, several simple effects are observed of adherence (Table 11), indicating that before the intervention, the patients in the adherence groups scored significantly higher on outcomes like communicative diabetes health literacy, coping, diet, general health and well-being.

Table 11: Univariate analyses of repeated-measures MANOVA to predict change in patients' outcomes depending on provider's adherence (versus adaptation) to the content, the duration, the frequency and the coverage

		Adherence (Mean and SD)		Adaptation (Mean and SD)		F_{time}	$F_{adherence}$	$F_{interaction}$
		T_1	**T_2**	**T_1**	**T_2**			
Dimension: adherence to the content								
DHL com.	1-4	3.03 (.845)	2.87 (.778)	2.88 (.902)	2.66 (.811)	7.408**	5.063*	4.372*
DHL func.	1-4	3.07 (.761)	3.22 (.567)	2.85 (.837)	3.08 (.765)	3.824	.006	.964
DHL crit.	1-4	3.00 (.869)	3.03 (.788)	2.54 (.894)	2.91 (.925)	13.855***	.135	4.900*
Diet	0-7	4.43 (1.724)	4.71 (1.405)	3.92 (1.555)	4.64 (1.609)	10.859***	.636	1.694
Exercise	0-7	2.59 (2.600)	3.15 (2.519)	2.03 (1.683)	3.11 (2.194)	11.567***	.536	.931
Foot care	0-7	4.07 (1.676)	4.68 (1.426)	3.39 (1.859)	3.79 (1.468)	8.926**	7.313**	.204
Problem	0-4	1.46 (1.194)	1.35 (1.160)	1.76 (1.099)	1.61 (2.324)	7.148**	.456	1.796
Coping	1-5	3.60 (.680)	3.83 (.713)	3.29 (.654)	3.54 (.746)	8.077**	8.008**	.020
General health	1-5	3.10 (.793)	3.34 (.885)	2.97 (.818)	3.19 (.681)	1.81	.409	1.051
Well-being	0-5	2.84 (1.375)	3.12 (1.254)	2.78 (1.193)	2.87 (1.107)	.156	.401	.149
Dimension: adherence to the duration								
DHL com.	1-4	2.99 (.858)	2.84 (.786)	2.74 (.838)	2.65 (.779)	7.408**	5.709*	.744
DHL func.	1-4	3.05 (.761)	3.21 (.614)	2.93 (.788)	3.18 (.629)	3.824	.141	1.854
DHL crit.	1-4	2.92 (.865)	3.02 (.784)	2.85 (.905)	2.92 (.849)	13.855***	.016	.451
Diet	0-7	4.45 (1.620)	4.66 (1.416)	3.53 (1.576)	4.68 (1.539)	10.859***	1.963	10.089**
Exercise	0-7	2.69 (2.471)	3.42 (2.439)	1.61 (1.847)	2.44 (2.011)	11.567***	3.365	.064
Foot care	0-7	3.91 (1.794)	4.54 (1.421)	3.67 (1.456)	4.20 (1.572)	8.926**	.139	.305
Problem	0-4	1.49 (1.164)	1.35 (1.206)	1.84 (1.197)	1.57 (1.152)	7.148**	.475	7.888
Coping	1-5	3.55 (.678)	3.79 (.735)	3.36 (.641)	3.64 (.692)	8.077**	.296	.079
General health	1-5	3.13 (.777)	3.35 (.855)	2.81 (.779)	3.11 (.724)	1.81	.419	.146
Well-being	0-5	2.99 (1.291)	3.17 (1.242)	2.42 (1.307)	2.76 (1.101)	.156	.196	1.062

		Adherence (Mean and SD)		**Adaptation (Mean and SD)**		F_{time}	$F_{adherence}$	$F_{interaction}$
		T_1	**T_2**	**T_1**	**T_2**			
Dimension: adherence to the frequency								
DHL com.	1-4	2.93 (.860)	2.80 (.774)	3.00 (.862)	2.84 (.831)	7.408**	4.221*	7.775**
DHL func.	1-4	3.11 (.701)	3.25 (.550)	2.79 (.911)	3.05 (.777)	3.824	.001	.552
DHL crit.	1-4	3.04 (.763)	3,07 (.739)	2,47 (1.049)	2.78 (.937)	13.855***	.900	.302
Diet	0-7	4.31 (1.656)	4.67 (1.338)	4.13 (1.672)	4.60 (1.717)	10.859***	.750	2.086
Exercise	0-7	2.56 (2.496)	3.26 (2.352)	2.22 (2.09)	3.02 (2.516)	11.567***	2.417	.325
Foot care	0-7	3.87 (1.642)	4.60 (1.398)	3.87 (.644)	4.11 (1.582)	8.926**	2.681	1.962
Problem	0-4	1.55 (1.219)	1.28 (1.134)	1.62 (1.068)	1.77 (1.329)	7.148**	.036	2.996
Coping	1-5	3.55 (.682)	3.79 (.743)	3.37 (.644)	3.65 (.682)	8.077**	1.545	1.247
General health	1-5	3.10 (.792)	3.35 (.831)	2.94 (.759)	3.12 (.835)	1.81	.453	2.953
Well-being	0-5	2.85 (1.351)	3.13 (1.221)	2.76 (1.262)	2.88 (1.190)	.156	.632	1.247
Dimension: adherence to the coverage								
DHL com.	1-4	2.91 (.821)	2.75 (.751)	3.34 (.916)	2.99 (.968)	7.408**	3.691	2.059
DHL func.	1-4	3.21 (.658)	3.25 (.586)	2.57 (.861)	2.98 (.736)	3.824	3.390	2.391
DHL crit.	1-4	2.98 (.769)	2.97 (.750)	2.50 (1.042)	2.72 (.981)	13.855***	.859	8.275**
Diet	0-7	4.32 (1.549)	4.63 (1.396)	3.86 (1.806)	4.39 (1.732)	10.859***	1.235	.587
Exercise	0-7	2.97 (2.223)	3.74 (2.245)	1.08 (1.893)	2.03 (2.324)	11.567***	16.108***	.551
Foot care	0-7	3.79 (1.593)	4.34 (1.286)	3.61 (2.052)	4.31 (1.906)	8.926**	.147	.293
Problem	0-4	1.44 (1.009)	0.99 (.947)	2.16 (1.338)	2.23 (1.360)	7.148**	.1626	.334
Coping	1-5	3.53 (.608)	3.84 (.675)	3.24 (.759)	3.49 (.887)	8.077**	.000	.967
General health	1-5	3.20 (.726)	3.43 (.769)	2.61 (.829)	2.91 (.844)	1.81	12.833***	2.057
Well-being	0-5	3.07 (1.129)	3.28 (1.097)	2.28 (1.526)	2.55 (1.305)	.156	7.510**	.071

4. Discussion

This study combined provider and patient level data of diabetes self-management programs implemented in eight different countries to assess the level of self-reported implementation fidelity in existing diabetes self-management programs, and its association with program effectiveness. Implementation fidelity was defined as provider' self-reported adherence to the content, duration, frequency and coverage of the intervention, while program effectiveness was operationalized in terms of the participants' improvement in diabetes health literacy, self-care behaviors, diabetes coping, perception of diabetes as a problem, general health, and well-being. Factors related to the participants, to the provider, the presence of facilitating strategies or the favorability of the context were considered as potential factors which determined the providers' adherence to the program original protocol.

The results showed that more than a third of the providers of diabetes self-management programs reported to have totally adhered to the intervention protocol. This proportion is surprisingly high, as the tool that was used to assess implementation fidelity was designed to capture even small program adjustments. A possible explanation for this finding is the providers' tendency to overrate the adherence to the program and their desire to provide a favorable evaluation of their program delivery (Breitenstein, Fogg, et al., 2010; Breitenstein, Gross, et al., 2010; Perepletchikova et al., 2007). The use of a self-report method to measure implementation fidelity, which is more prone to this type of distortions, may have exacerbated this tendency, despite the fact that the instructions explicitly referred to potential positive effects of adaptations as a strategy to overcome social desirability bias. Another explanation could be that the providers are not familiar with the intended content and scope of the intervention. Indeed, in the absence of consistent facilitating - or implementation - strategies (Proctor, Powell, & McMillen, 2013) in the form of an intervention protocol, the provider cannot assess his/her adherence to the intended intervention. While observational measures could be used to overcome these limitations, they could not be used in this study as the number of programs implemented in different countries would have made it very cumbersome to train enough observers to assess the implementation of all the programs. On the other hand, the fact that the providers making up the groups of "adapters" and "total adherers" came from different countries may reflect cultural differences in the way the instruction were given and/or the way adherence or adaptation is considered.

The second purpose of this study was to identify the reasons for adapting diabetes self-management programs. Based on the model proposed by Carroll et al. (Carroll et al., 2007), we assumed that the providers' likelihood to adhere to a program would depend on factors related to the participants and the provider, the presence of facilitating strategies (i.e. protocol, feedback, evaluation) or the favorable context. The results of logistic regressions did not confirm this hypothesis. A possible reason for this finding is the small number of providers that were involved in the study. Ideally, logistic regression requires a sample size of at least 10 observations per predictor (Cohen, 1992). To test our model, a minimum of 40 providers would have been more suitable. On the other hand, there is very little empirical research thus far that has tested the influence of the determinants of implementation fidelity. As such, the model we tested was hypothetical. To the effect that we could not find support for the effect of these dimensions on program adherence, our findings suggest that the model needs to be further refined.

Finally, the results of a comparison between programs of which the implementation had totally adhered to or adapted the program protocol in terms of program outcomes showed that some adaptations have a positive impact on some program outcomes. More specifically, adaptations of the content or coverage of the intervention were associated with a greater improvement of critical diabetes health literacy, and adaptation of the program duration with greater improvement of the participants' dieting behavior and general health.

While it is not possible to fully ascertain if these differences can be attributed to the adaptation, due to the different composition of the groups in terms of nationality, these findings suggest that adaptations may be positive. As such, they support the relevance of distinguishing between different kinds of program adaptations. In this regard, Wiltsey Stirman et al. (Stirman et al., 2015) make a distinction between *fidelity-consistent* and *fidelity-inconsistent* adaptations (Stirman et al., 2015). Fidelity-consistent modifications are those that do not significantly alter the core components of the intervention, while fidelity-inconsistent modifications reduce or cancel the delivery of intervention core components. It is likely that some of the reported adaptations, such as those with regard to the coverage (e.g., the number of participants required), are not associated with a decrease of program effectiveness, or even are associated with an increase of the intervention outcomes, as it is easier to engage the participants in a smaller group. The latter is corroborated by findings of qualitative studies suggesting that providers achieve better implementation when they are allow to adjust the program (Durlak & DuPre, 2008). This is also the conclusion of a recent meta-analysis which shows that benefits from chronic disease self-management were greater when fidelity requirements were unmet (Brady, Murphy, O'Colmain, & Hobson, 2016). Considering the potential positive effect of adaptations, some researchers have recently proposed an extended version of Carroll et al's framework that assesses both fidelity and adaptation (Pérez et al., 2016). They argued that adaptations, as the adherence, can be assessed through several dimensions. Adherence as well as adaptation should be evaluated to identify the core ingredients that contribute to intervention effectiveness. Other authors (Van Daele, Van Audenhove, Hermans, Van den Bergh, & Van den Broucke, 2012) argue that fidelity and adaptation can be combined by involving the providers more actively in the program implementation and fidelity monitoring. This would imply that program developers consider providers as equal partners and provide them with the concepts and tools to identify the main components of the program, and coach them in the process of adapting the intervention to local needs while maintaining the quality of the implementation. Similar to the more familiar empowerment evaluation approach, such an "empowerment implementation" would have the additional benefit that providers can enhance their skills and capacities to implement programs in the future.

4.1 Conclusions

Although this study has a number of limitations, namely the small number of providers, the likely overestimation of program adherence, and the different composition of provider groups in terms of nationalities, it is the first study to assess the level of implementation fidelity of DSME programs in different countries using a generic instrument. Furthermore, adding to the debate between proponents of a strict implementation fidelity versus the need to adapt programs to the needs of participants and the local context, our results tend to be in favor of fidelity-consistent modifications. While thus far, studies in the field of implementation science have mainly focused on fidelity, there is increasing evidence of the need to clarify the conditions for effective adaptations. The questionnaire used in our study, which was developed to assess provider' self-reported adherence, offers the opportunity to capture the nature and the reasons for adaptations. A combined use of this tool with observational measures can highlight which type of health programs can benefit from adaptations and under which conditions.

Chapitre 5

Les troubles émotionnels pouvant interagir avec l'autogestion du diabète

Prévalences, causes et conséquences de la dépression, de l'anxiété et de la détresse émotionnelle parmi les personnes atteintes de diabète

Le chapitre 5 sera consacré à la présentation des différents troubles émotionnels étudiés dans la littérature du diabète, à savoir la dépression, l'anxiété et la détresse associée au diabète. Pour chacun de ces troubles, nous présenterons leur prévalence parmi les personnes atteintes de diabète, leur impact pour la prise en charge de la maladie ainsi que les différences d'opérationnalisation et de mesure. L'efficacité des traitements par antidépresseurs et par psychothérapie sera alors considérée. Nous aborderons ensuite les liens possibles entre diabète et émotions, plus particulièrement les relations entre le déséquilibre glycémique et les émotions ressenties. Finalement, nous considérerons l'impact de l'alexithymie et plus largement de l'intelligence émotionnelle sur la prise en charge du diabète.

Les troubles émotionnels pouvant interagir avec l'autogestion du diabète

Prévalences, causes et conséquences de la dépression, de l'anxiété et de la détresse émotionnelle parmi les personnes atteintes de diabète

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La bonne gestion du diabète implique une attention quotidienne de la part du patient en vue d'atteindre un contrôle glycémique optimal et éviter le risque de complications. Les comportements attendus de la part du patient et sa perception des risques de complications en cas de contrôle glycémique insuffisant peuvent être sources de souffrances psychologiques. Depuis le début des années 2000, l'intérêt pour les troubles émotionnels associés au diabète a fortement augmenté. Dans les années 90, PubMed recensait moins d'une dizaine d'articles publiés chaque année sur la thématique diabète et dépression. Aujourd'hui, c'est plus de 100 nouveaux articles qui apparaissent chaque année sur cette base de données. Ce gain d'intérêt se justifie de deux façons par (1) la prévalence plus importante des troubles d'ordre émotionnel au sein de la population diabétique, due aux risques de complications et exigences du traitement, et (2) les conséquences de ces troubles sur la gestion du diabète et l'équilibre glycémique.

Nous utilisons ici le terme « trouble d'ordre émotionnel » pour désigner à la fois une expérience de peur (stress, anxiété) ou de désespoir intense (dépression) ou un entre-deux (détresse émotionnelle) que peuvent vivre les personnes atteintes de diabète. Parmi eux, la dépression a reçu le plus d'attention dans la littérature. Cependant, des inconsistances au sein de cette littérature peuvent être relevées, comme les différences de prévalence rapportées et les différences d'association entre la dépression, l'autogestion du diabète et le contrôle glycémique. Dans de nombreux cas, ces symptômes dépressifs doivent être considérés dans le contexte du diabète (Fisher, Gonzalez, & Polonsky, 2014). Ainsi, la charge émotionnelle associée au traitement et aux menaces de complications peut entrainer une détresse émotionnelle associée à la maladie. Dans ce contexte, la détresse est définie comme « le sentiment de submersion face au diabète et aux charges de son traitement » (Polonsky et al., 1995). La dépression majeure est un trouble psychiatrique non spécifique au diabète et se définit par la présence de symptômes. La détresse, quant à elle, est associée à une source spécifique et se définit par son contenu et son intensité. Les incohérences de la littérature de la dépression peuvent donc s'expliquer par le fait que des individus diabétiques sont considérés comme cliniquement dépressifs du fait de la présence de signes de dépression inhérente à leur détresse. Pour ces auteurs (Fisher et al., 2014), une détresse d'intensité sévère peut conduire à des troubles psychiatriques tels qu'une dépression majeure ou un trouble de l'anxiété. L'anxiété parmi les sujets diabétiques a reçu moins d'attention dans la littérature que la dépression, bien que plusieurs études suggèrent que sa prévalence et ses conséquences pour l'autogestion sont au moins aussi importantes (Khambaty, Callahan, Perkins, & Stewart, 2016; Smith et al., 2013). La peur associée aux hypoglycémies, les craintes de s'injecter de l'insuline ou de se piquer pour l'autocontrôle sont de possibles sources d'anxiété. Les sections suivantes détailleront la littérature concernant la prévalence, les causes et conséquences de la dépression, de l'anxiété et de la détresse associée au diabète.

1. La dépression et symptômes dépressifs parmi les personnes atteintes de diabète

Les critères de diagnostic de la dépression, tels que définis par l'American Psychiatric Association dans le DSM-V (American Psychiatric Association, 2013) sont la présence d'une humeur dépressive et/ou une perte de plaisir ET la présence supplémentaire d'au moins quatre des symptômes suivants : perte ou gain de poids significatif (5%) en l'absence de régime, diminution ou augmentation de l'appétit, insomnie ou hypersomnie, agitation ou ralentissement psychomoteur, fatigue ou perte d'énergie, sentiment de dévalorisation ou de culpabilité excessive ou inappropriée (qui peut être délirante), diminution de l'aptitude à penser ou à se concentrer ou indécision (signalée par le sujet ou observée par les autres), pensées de mort récurrentes, idées suicidaires récurrentes sans plan précis ou tentative de suicide ou plan précis pour se suicider. Et cela presque tous les jours durant au moins 2 semaines.

La dépression parmi les personnes atteintes de diabète a reçu énormément d'attention au cours de ces dernières années. Plusieurs études se sont penchées sur sa prévalence et ses conséquences en termes d'autogestion, de contrôle glycémique et de risque de complications. Toutefois, toutes ces études ne s'accordent pas sur les mesures de la dépression ainsi que sur la direction du lien entre diabète et dépression.

1.1 Prévalence de la dépression

Plusieurs méta-analyses rapportent une augmentation de la prévalence de la dépression parmi la population diabétique. Toutefois, ces méta-analyses ne s'accordent pas sur la taille de cette augmentation, allant de 60% de risque en plus (Fisher, Skaff, et al., 2008) à 300% de risque en plus (Anderson, Freedland, Clouse, & Lustman, 2001; Roy & Lloyd, 2012). Ces pourcentages varient notamment en fonction de la qualité de l'étude menée (transversale ou longitudinale) et du type de mesure employé (entretien clinique ou questionnaire auto-rapporté). Ces chiffres seront approfondis au sein de la section abordant les différentes mesures de la dépression (point 1.3.).

1.2 Conséquences de la dépression pour l'autogestion, le contrôle glycémique et les risques de complications

La dépression constitue un obstacle important à la prise en charge du diabète. Des méta-analyses indiquent que la dépression présente un effet délétère sur une série de comportements d'autogestion (alimentation, activité physique, médication et contrôle de la glycémie) (Gonzalez et al., 2008; Sumlin et al., 2014), l'impact le plus important étant sur la non-présentation aux rendez-vous médicaux (Gonzalez et al., 2008). Par conséquent, la dépression a également un effet néfaste sur l'équilibre glycémique (Lustman et al., 2000) et accroit le risque de complications et de mortalité. Une étude longitudinale de 7 ans menée auprès de 2 830 personnes diabétiques de type 2 de plus de 65 ans au Mexique a ainsi montré un effet d'interaction du diabète et de la dépression sur le développement de complications macro (maladies cardiovasculaires, arrêts cardiaques) et microvasculaires (nephropathie, neuropathie, rétinopathie et amputations) et de mortalité (Black, Markides, & Ray, 2003). En contrôlant des variables telles que le genre, l'âge, l'éducation ou le statut marital, les personnes cumulant un diabète et une dépression sont dès lors plus à risque de développer des complications et de façon plus précoce que les personnes atteintes de diabète et ne présentant pas de dépression. Outre les aspects humains, la coexistence du diabète et de la dépression représente un coût important en termes de soins de santé. Une étude menée aux USA sur les données médicales de 147 095 adultes entre 2004 et 2011 a ainsi montré que le coût total des soins de santé d'une dépression s'élevait en moyenne à 2 654 dollars et celui d'un diabète à 2 692 dollars. Cependant, les deux cumulés présentent un coût de 6 037 dollars (Egede, Bishu, Walker, & Dismuke, 2016). L'augmentation des coûts associés à la coexistence de ces deux pathologies peut s'expliquer par les frais plus élevés associés aux hospitalisations et aux prescriptions médicales ainsi qu'aux soins de santé à domicile.

Toutes les études ne s'accordent, cependant, pas sur la prévalence plus élevée de la dépression parmi les personnes atteintes de diabète ainsi que sur ses conséquences pour la prise en charge.

1.3 Les différentes mesures de dépression

La plupart des études menées sur la dépression parmi les personnes atteintes de diabète utilisent des mesures de dépression autorapportées (C. E. Lloyd & Roy, 2013). Les cinq outils d'évaluation les plus communément utilisés dans la littérature sur le diabète ainsi que leurs détails sont listés dans le tableau 12.

Cependant, selon Fisher et al. (2007), ces mesures autorapportées reflètent davantage la présence de symptômes dépressifs que celle d'un réel trouble de dépression majeure. Le patient rapporte généralement une perte d'énergie, une diminution de sa concentration mais ne remplit pas suffisamment de critères pour diagnostiquer une dépression. Lorsque mesurée au moyen d'un entretien clinique, la prévalence de la dépression n'est plus de 200 à 300% supérieure, telle qu'indiquée dans les méta-analyses (R. J. Anderson, Freedland, Clouse, & Lustman, 2001; Roy & Lloyd, 2012) mais de 60% supérieure à la population générale (Fisher, Skaff, et al., 2008). De plus, ces épisodes de dépression majeure apparaissent de façon épisodique, comparés aux symptômes dépressifs qui perdurent davantage dans le temps (Fisher, Skaff, et al., 2008). Par conséquent, les études évaluant la dépression à l'aide de mesures autorapportées surévaluent le nombre de patients réellement atteints de dépression. 70% des patients atteints de diabète rapportant des symptômes dépressifs élevés ne rencontreraient pas les critères diagnostiques de trouble de dépression majeure en entretien clinique (Fisher et al., 2007). Un autre élément qu'il convient de souligner est que certaines de ces mesures autorapportées, tel que le Patient Health Questionnaire, utilisent des items somatiques pour évaluer les symptômes dépressifs qui pourraient être confondus avec des symptômes associés au diabète. Un changement d'appétit ou un sentiment de fatigue pourrait en effet être attribuable à une fluctuation de la glycémie plutôt qu'à des indicateurs de dépression (Lloyd & Roy, 2013). Il importe cependant de souligner que, **bien que ne souffrant pas de dépression majeure, ces patients qui rapportent des symptômes dépressifs élevés présentent également des résultats moins favorables en termes d'équilibre glycémique et de risques de complications** (Fisher et al., 2007).

Table 12: Most often used Questionnaires to screen depression in the diabetes literature (Lloyd & Roy, 2013)

Instrument	Authors	N items	Item example	Advantages (+) and disadvantages (-)
Beck Depression Inventory BDI (I et II)	Beck, Ward, Mendelson, Mock, & Erbaugh, (1961) Beck, Steer, & Brown (1996)	21	*“**Item 2 :*** ** I am not discouraged about my future* ** I feel more discouraged about my future than I used to be* ** I do not expect things to work out for me* ** I feel my future is hopeless and will only get worse”*	+ Most commonly used self-report instrument to assess depression among diabetes population + Good sensitivity (87%) and specificity (81%) Based on cognitive and somatic items (like change in appetite or sleep). These can be confused with the symptoms of a poor glycemic control
Centre for Epidemiologic Studies Depression Scale CES-D	Radloff (1977)	20 10	***During the past week:*** ** I was bothered by things that usually don’t bother me* ** I felt that everything I did was an effort* ** I enjoyed life* ** I felt sad*	+ Do not containt a lot of somatic items that could be confused with a poor glycemic control + Good sensitivity and specificity + Identify as the best tool to screen depression among type 2 diabetes patients
Problem Areas in Diabetes PAID	Welch, Jacobson, & Polonsky (1997)	20	*Feeling constantly burned-out by the constant effort to manage diabetes*	- assesses diabetes-related distress and not clinical depression
Patient Health Questionnaire PHQ	Spitzer & Kroenke (1999)	9 8 2	***Over the last 2 weeks how often have you been bothered by any of the following problems?*** ** Little interest or pleasure in doing things* ** Feeling down, depressed, or hopeless* ** Trouble falling or staying asleep* ** Feeling tired or having little energy* ** Poor appetite or overeating*	+ Good sensitivity and specificity for the 9-item version + Considered as a powerful instrument to screen major depression - Some somatic items could be confused with the symptoms related to a poor glycemic control
Hospital Anxiety and Depression Scale HADS	Zigmond & Snaith (1983)	14	***I can laugh at the funny side of things*** ** As much as I always could* ** Not quite so much now* ** Definitely not so much now* ** Not at all*	+ Measure of depression (7 items) and anxiety(7 items) + Good sensitivity and specificity + Do not contain somatic items that could be confused with poor glycemic control

1.4 Le double lien entre diabète et dépression

Si plusieurs études ont pu mettre en évidence que les prévalences de symptômes dépressifs et de dépression majeure étaient plus élevées parmi les personnes souffrant de diabète que dans la population générale (R. J. Anderson et al., 2001; Fisher, Skaff, et al., 2008; Roy & Lloyd, 2012), d'autres recherches ont montré que le risque de développer un diabète était de 38 à 60% supérieur parmi les personnes atteintes de dépression (Mezuk, Eaton, Albrecht, & Golden, 2008; Rotella & Mannucci, 2013). N'ayant pu définir l'orientation exacte de la relation entre diabète et dépression, on s'accorde pour parler de double lien ou relation bidirectionnelle (Golden et al., 2008; Semenkovich, Brown, Svrakic, & Lustman, 2015). Le diabète augmente le risque de développer des symptômes dépressifs ou une dépression , et la dépression représente un facteur de risque de diabète de type 2 (Carnethon, Kinder, Fair, Stafford, & Fortmann, 2003). Une troisième possibilité est que le diabète et la dépression partageraient des facteurs communs d'apparition (Bădescu et al., 2016). Ces trois possibilités ont été développées dans les sections ci-dessous.

1.4.1 Le diabète comme stresseur et facteur de risque de dépression

Au même titre que pour la détresse, le diabète, de par les exigences du traitement et les risques de graves complications, peut être source de souffrance et de dépression clinique. Une méta-analyse des études *longitudinales* réalisées sur l'apparition de dépression parmi les personnes atteintes de diabète indique que ces personnes, par rapport à la population générale, ont 21% de risque en plus de développer des symptômes dépressifs et 29% de risque en plus de développer un trouble de dépression majeure (Nouwen et al., 2010). En outre, une étude longitudinale a récemment révélé que le diagnostic du diabète de type 2 s'accompagnait d'un appauvrissement de la qualité de vie et des relations sociales (temps passé avec les amis et la famille, contacts téléphoniques, temps de loisirs passé dans un groupe/club/paroisse) (Feng & Astell-Burt, 2017). Cet isolement social pourrait alors rendre compte d'une détérioration de la santé mentale et d'un risque accru de dépression.

Cependant, la prévalence plus importante de dépression chez les personnes prédiabétiques ou diabétiques encore non diagnostiquées (Chen et al., 2016) pourrait laisser entendre que les préoccupations issues de la maladie ne seraient pas l'unique explication de la dépression. Des études ayant induit des hyperglycémies chez des sujets sains (Ravona-Springer et al., 2012; Sanz et al., 2013) ou ayant réduit la résistance à l'insuline de personnes souffrant de diabète (Ng et al., 2014) ont montré que la glycémie pouvait avoir une influence sur les fonctions cognitives. En outre, l'hyperglycémie serait associée à un déclin des performances à différents tests cognitifs (Ravona-Springer et al., 2012; Sanz et al., 2013). Indépendamment de l'âge, du BMI, et de la santé physique, le diabète s'accompagne d'une augmentation de l'atrophie cérébrale (Kumar, Anstey, Cherbuin, Wen, & Sachdev, 2008). L'induction d'hyperglycémie auprès de sujets sains a également été associée à une moindre réactivité de l'hypothalamus, impliqué dans les émotions. Un mauvais équilibre glycémique réduirait le volume de l'hippocampe (Gold et al., 2007) et un processus neurodégénératif similaire est retrouvé dans le cas de la dépression (Sapolsky, 2001).

1.4.2 La dépression comme facteur de risque de diabète de type 2

Les hypothèses concernant l'existence d'un lien causal entre troubles émotionnels et apparition du diabète ne sont pas neuves. En 1679, Thomas Willis, le premier médecin ayant associé la présence de sucre dans les urines comme un signe de diabète, avait déjà suggéré que l'apparition du diabète pouvait découler d'un « malheur prolongé » (tristesse ou deuil) (Knol et al., 2006; C. Lloyd, Smith, & Weinger, 2005). Cette suggestion n'a cependant pas été retenue et, pendant longtemps, la prévalence plus élevée de dépression parmi les personnes diabétiques a conduit à considérer la dépression comme une conséquence, plutôt que comme une cause du diabète. Ce n'est qu'à partir de la fin des années de 90 que des chercheurs ont tenté d'investiguer l'hypothèse de Willis par des études longitudinales. Eaton et al. (1996) et Kawakami, Takatsuka, Shimizu, & Ishibashi (1999) ont ainsi montré que la présence de dépression en baseline doublait les risques de développer un diabète et ce, en contrôlant des variables telles que l'obésité, le niveau d'activité physique, le tabagisme, la consommation d'alcool et l'histoire familiale. Une série de méta-analyses ont récemment indiqué que les personnes souffrant de dépression avaient de 37% à 60% plus de risque de développer un diabète de type 2 (Knol et al., 2006; Mezuk et al., 2008; Rotella & Mannucci, 2013).

L'explication actuellement considérée pour rendre compte du lien causal entre dépression et apparition du diabète de type 2 relève du traitement par antidépresseurs (Semenkovich et al., 2015). En effet, de nombreux antidépresseurs ont un impact sur l'équilibre glycémique via la prise de poids et l'augmentation de la résistance à l'insuline (Kammer, Hosler, Leckman-Westin, DiRienzo, & Osborn, 2016; Rubin et al., 2010). Les patients souffrant de dépression sous antidépresseurs ont 25% de risque en plus de développer un diabète de type 2 que ceux ne prenant pas d'antidépresseurs (Mezuk et al., 2008). La prise de poids résultant de la consommation d'antidépresseurs ainsi que de mauvais comportements de santé adoptés par les personnes souffrant de dépression (Strine et al., 2008) peuvent conduire à une obésité, pouvant elle-même amener une résistance à l'insuline et au développement du diabète de type 2. Une étude longitudinale a ainsi montré que les personnes atteintes de dépression avaient 58% de risque de développer une obésité (Luppino et al., 2010).

1.4.3 L'étiologie commune

Une troisième façon d'expliquer le lien entre diabète et dépression est celle de l'étiologie commune. Rassemblant les résultats de plusieurs études, Bădescu et al. (2016) proposent un modèle où des facteurs de stress, tels qu'un faible statut socioéconomique ou une pauvre hygiène de vie, augmenteraient simultanément les probabilités de développer un diabète de type 2 et une dépression et cela, via l'activation de l'axe hypothalamo-hypophyso-surrénalien (axe HHS), le système nerveux sympathique (SNS) ainsi que la réponse inflammatoire. Leur raisonnement est illustré par la figure 7. En cas de stress prolongé, l'hypercortisolémie chronique et l'activation du SNS vont engendrer une résistance à l'insuline. Parallèlement, la noradrénaline et le cortisol vont activer le système de peur déterminant l'anxiété. Cette activation prolongée du système de peur va dérégler le système de la récompense ainsi que l'hypothalamus pour engendrer finalement de la dépression. L'activation de l'axe HHS et le SNS va également susciter une réponse inflammatoire en augmentant la production de cytokines inflammatoires. Ces cytokines interagissent avec les cellules β du pancréas et peuvent accroître la résistance à l'insuline et, par conséquent, engendrer un diabète de type 2. Finalement, ces cytokines vont également interagir avec plusieurs éléments physiopathologiques de la dépression (métabolisme des neurotransmetteurs, fonction neuroendocrine, plasticité synaptique). Le diabète de type 1 différant du diabète de type 2 en termes d'étiologie, d'âge d'apparition et de traitement, les liens entre ce premier et la dépression ne sont pas identiques. Dans ce cas également, Bădescu et al. (2016) ont rassemblé différentes études pour proposer un modèle de liens possibles (figure 8). La réaction auto-immune dans le cas du diabète de type 1 engendre un manque d'insuline, lui-même responsable d'une hyperglycémie chronique. Ces différentes caractéristiques du diabète de type 1 peuvent contribuer à l'apparition de la dépression. Ainsi, la réaction auto-immune est associée à une augmentation de la proportion de cytokines inflammatoires ; le manque d'insuline va influencer la neurogénèse ainsi que le métabolisme des neurotransmetteurs ; finalement, l'hyperglycémie chronique, ainsi que les hypoglycémies consécutives au traitement vont suractiver l'axe HHS.

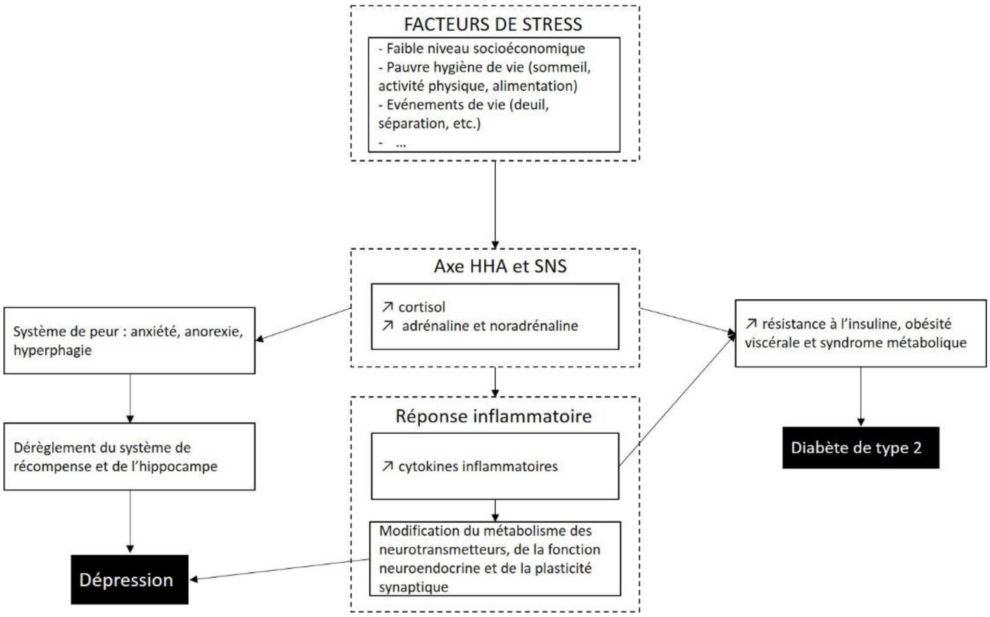

Figure 7 : Effet du stress chronique sur l'apparition du diabète de type 2 et de la dépression (Badescu et al., 2016)

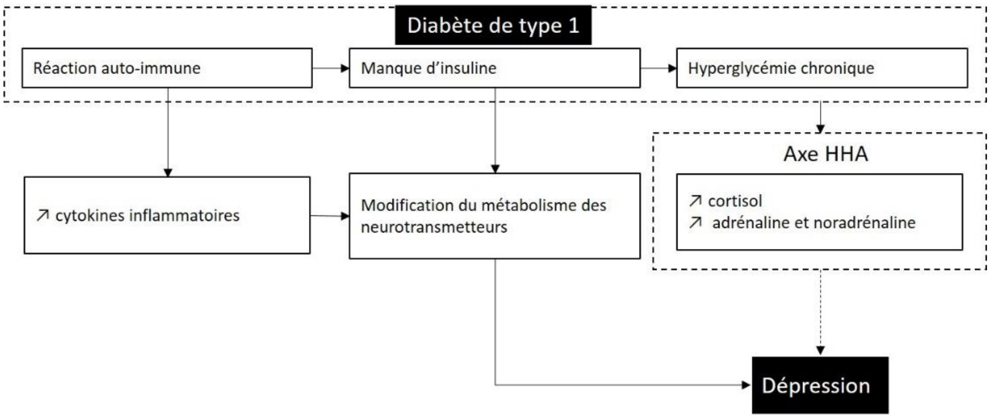

Figure 8 : Lien entre diabète de type 1 et dépression (Badescu, 2016)

2. L’anxiété et symptômes d’anxiété parmi les personnes atteintes de diabète

Bien qu’ayant reçu moins d’attention dans la littérature sur le diabète que la dépression, plusieurs études suggèrent que la prévalence et les conséquences de l’anxiété pour l’autogestion du diabète sont au moins aussi importantes (Khambaty, Callahan, Perkins, & Stewart, 2016; Smith et al., 2013). Le modèle présenté par Bădescu et al. (2016), dans le cadre du développement simultané de la dépression et du diabète de type 2, indique que la dépression apparait, entre autres, suite à une anxiété et une activation du système de peur trop prolongée.

Le trouble d’anxiété généralisé se caractérise par un souci excessif concernant un certain nombre d’événements ou d’activités, survenant la plupart du temps durant au moins 6 mois. La personne éprouve des difficultés à contrôler ses préoccupations. Le diagnostic d'un trouble d’anxiété généralisée, selon les critères du DSM V (American Psychiatric Association, 2013), requiert la présence d’au moins 3 des 6 symptômes suivants : une agitation ou sensation d’être survolté ou à bout, la fatigabilité, difficulté de concentration ou de mémoire, irritabilité, tension musculaire ou perturbation du sommeil.

Tout comme pour la dépression, une distinction peut être faite entre mesure du trouble psychiatrique de l’anxiété généralisée et mesure de symptômes d’anxiété.

2.1 Prévalence de l’anxiété et des symptômes d’anxiété

La prévalence des troubles liés à l’anxiété dans la population générale est estimée à 21%, l’anxiété généralisée étant la plus fréquente (12%) (Leray et al., 2011). Une méta-analyse menée par Smith et al. (2013) a révélé que la prévalence de trouble anxieux généralisé était 1.20 fois plus élevée parmi les personnes atteintes de diabète et près de 1.49 fois supérieure en ce qui concerne les symptômes d’anxiété. L’étude longitudinale menée par Fisher et al. (2008) a, quant à elle, montré que les personnes atteintes de diabète étaient au moins deux fois plus à risque de souffrir ponctuellement d’un trouble d’anxiété généralisé et 1.8 fois plus de trouble panique. Cependant, comme pour la dépression majeure, les troubles psychiatriques associés à l’anxiété ne semblent pas persister dans le temps (Fisher, Skaff, et al., 2008).

2.2 Conséquences de l’anxiété pour la prise en charge du diabète

Dans le cadre du diabète, l’anxiété a été associée à un plus faible contrôle glycémique, un risque accru de développer une complication liée au diabète et une moins bonne santé en général (R. J. Anderson et al., 2002; Collins, Corcoran, & Perry, 2009; Ludman et al., 2006).

Plusieurs études se sont intéressées à l’anxiété dans le cadre de deux aspects spécifiques du traitement du diabète : l’autocontrôle par lecteur de glycémie et l’injection d’insuline. La peur du sang et des blessures a été associée à moins d'autocontrôles et à un moins bon équilibre glycémique (Berlin et al., 1997). La peur des injections d'insuline a, toutefois, reçu plus d'attention dans la littérature (Mollema, Snoek, Pouwer, Heine, & van der Ploeg, 2000). Parmi les patients diabétiques insulinodépendants, 28% seraient concernés par la peur des injections. Pour 45% de ces patients, la peur aurait pour conséquence des comportements d'évitement des injections (Zambanini, Newson, Maisey, & Feher, 1999). Une méta-analyse réalisée sur 6 études portant sur l'impact de la peur des injections a montré que ces craintes étaient associées à un moins bon contrôle glycémique, ainsi qu'à un risque accru de complications et de mortalité (Fu, Qiu, & Radican, 2009).

3. La détresse émotionnelle associée au diabète

Les deux premiers points de ce chapitre abordaient deux troubles psychiatriques que sont la dépression et l'anxiété, ainsi que leurs symptômes sub-cliniques. La détresse émotionnelle associée au diabète, abordée dans ce troisième point, identifie, quant à elle, la source de cette surcharge émotionnelle dans les exigences liées au traitement et les risques associés à la maladie (Fisher, Gonzalez, & Polonsky, 2014a). Elle ne se restreint pas au domaine de la peur des injections ou de l'autocontrôle. Elle englobe divers domaines associés au traitement tels que les relations avec le médecin (et le sentiment de n'être pas suffisamment compris, écouté ou correctement aidé), avec les proches (le manque de soutien perçu) ou le régime alimentaire (se sentir dépassé par des restrictions alimentaires) (W. H. Polonsky et al., 2005).

Le concept de détresse émotionnelle provient de deux cadres théoriques, le premier étant les recherches sur le stress et les stratégies de coping et le second la régulation émotionnelle en réponse à un stresseur chronique (Fisher et al., 2014a). Elle ne s'évalue donc pas suivant l'absence ou la présence de certains symptômes mais sur l'expérience subjective d'émotions de peur, d'inquiétude **dans le contexte du diabète et de sa prise en charge**.

3.1 Mesures de la détresse émotionnelle associée au diabète

Les mesures de détresse relative au diabète les plus communément utilisées dans la littérature sont la Problem Areas in Diabetes (PAID; McGuire et al., 2009; W. H. Polonsky et al., 1995; Welch et al., 1997) et la Diabetes Distress Scale (DDS; W. H. Polonsky et al., 2005).

La PAID fut développée afin d'évaluer l'intensité des réponses émotionnelles associées à différents domaines du traitement du diabète. L'analyse de l'intensité de cette détresse relative à certains domaines de traitement devait permettre aux professionnels de concentrer leurs interventions sur les sources de détresse les plus importantes (W. H. Polonsky et al., 1995). Les patients doivent répondre à 20 items sur une échelle à 6 points afin d'évaluer dans quelle mesure les situations listées représentent un problème pour eux. Les expériences émotionnelles listées dans le questionnaire varient entre la colère (« Être énervé par le fait de devoir vivre avec un diabète»), la détresse interpersonnelle (« Avoir l'impression que ses amis et sa famille ne soutiennent pas assez ses efforts ») et la frustration associée au traitement (« La sensation de privation de nourriture pendant ou entre les repas »). La PAID fut traduite dans plus de 20 langues différentes et validées auprès de diverses populations (M.-F. Huang, Courtney, Edwards, & McDowell, 2010; Huis In 'T Veld et al., 2011; Sigurdardottir & Benediktsson, 2008; Snoek, Pouwer, Welch, & Polonsky, 2000). Des versions à 1 et 5 items ont également été développées et validées (McGuire et al., 2009).

En 2005, Polonsky et al. développent une nouvelle échelle de 17 items, la DDS, pour évaluer la détresse relative au diabète en réponse à plusieurs limites de la PAID. Les auteurs reprochaient à la PAID de ne pas investiguer suffisamment, voire pas du tout, certains domaines tels que le ressenti par rapport au médecin. En outre, bien qu'abordant différents aspects de la gestion du diabète, la PAID ne présente pas de sous-échelles. La DDS fut donc développée en réponse à ces limites afin d'inclure quatre sous-échelles évaluant la surcharge émotionnelle (« Avoir le sentiment que le diabète me prend trop de mon énergie mentale et physique chaque jour »), la détresse relative au médecin (« Avoir le sentiment que mon médecin ne considère pas mes inquiétudes assez sérieusement »), la détresse relative au régime alimentaire et au traitement (« Avoir le sentiment que je ne respecte pas assez mon régime alimentaire ») et la détresse interpersonnelle (« Avoir le sentiment que mes amis ou ma famille ne réalise pas à quel point cela peut être difficile de vivre avec le diabète ») (W. H. Polonsky et al., 2005). Une version à 2 items a également été développée et validée par les auteurs (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008a).

La PAID et la DDS présentant toutes deux de bonnes qualités psychométriques, une récente étude comparative a tenté d'évaluer dans quelle mesure ces échelles étaient interchangeables. Cette étude, menée par Schmitt et al. (2016), portait sur un échantillon de 422 patients souffrant de diabète de type 1 et 206 atteints de diabète de type 2. Les auteurs ont conclu que les deux échelles étaient fortement congruentes pour certains domaines tels que la surcharge émotionnelle, le manque de soutien social et les inquiétudes relatives aux complications. Elles présentaient de bons indices de cohérence interne et les analyses factorielles révélaient les dimensions attendues pour chacune des deux échelles. Cependant, des variations en termes de contenu et de prédiction ont toutefois été relevées. Les items de la PAID se focalisent principalement sur des soucis d'ordre émotionnel et des complications associées au diabète et, sont davantage associés aux symptômes dépressifs et aux copings dysfonctionnels ainsi qu'à la qualité de vie. La DDS, qui se focalise, quant à elle, sur la détresse associée au médecin et les préoccupations d'autogestion, prédit davantage l'adhésion au traitement et à l'équilibre glycémique.

Deux autres mesures plus anciennes de la détresse associée au diabète sont le questionnaire de *Measure of Emotional Adjustment to Diabetes* (ATT39, Dunn, Smartt, Beeney, & Turtle, 1986) et le *Questionnaire on Stress in Patients with Diabetes-Revised* (QSD-R, Herschbach et al., 1997). L'ATT39 est une mesure de l'ajustement émotionnel du patient de 39 items qui constituent 6 dimensions : le stress (« Le diagnostic du diabète est comme la sentence d'une vie de maladie »), l'adaptation (« Je pense m'être ajusté(e) au fait d'avoir le diabète »), la honte/culpabilité (« Je n'aime pas être référé comme « diabétique » »), le sentiment de distanciation du personnel médical (« La plupart des médecins ne savent pas ce qu'implique d'avoir le diabète »), les convictions par rapport à la sévérité de la maladie (« Avoir le diabète signifie accepter la responsabilité de son propre traitement ») et la tolérance à l'ambiguïté (« Je me sens capable de gérer mon diabète avec un minimum d'aide extérieur »). Le QSD-R est une révision du QSD (Duran, Herschbach, Waadt, Strian, & Zettler, 1995) et évalue le stress que peuvent ressentir des personnes diabétiques dans 45 situations relatives aux loisirs (« Je dois planifier mes temps libres en tenant compte de mon diabète »), à la dépression et la peur pour l'avenir (« Je m'inquiète souvent de l'assistance dont j'aurai besoin en fin de vie »), l'hypoglycémie (« Je crains de perdre conscience lorsque ma glycémie est trop basse »), la médication et l'alimentation (« Je ne me sens souvent pas assez rassasié(e) par la nourriture indiquée dans mon régime alimentaire »), les problèmes physiques (« Je souffre de moment de faiblesse/perte d'énergie »), le travail (« certaines perspectives de promotion sont limitées dans mon travail actuel à cause de mon diabète »), la relation avec le partenaire (« Je me sens moins attirant(e) depuis que j'ai développé un diabète »), et la relation avec le médecin (« j'ai reçu des informations différentes de plusieurs médecins concernant mon diabète »). Ces deux mesures couvrent un large champ de situations potentiellement problématiques pour les personnes atteintes de diabète. En raison de la longueur de l'ATT39 et du QSD-R et du manque de clarté de certains de leurs items (par exemple, pour le QSD-R : « Je souffre d'irritabilité »), ces questionnaires sont désormais rarement employés dans la recherche et la pratique. Les items de l'ATT39 et du QSD-R ont toutefois servi de base pour la constitution de la DDS (W. H. Polonsky et al., 2005).

3.2 Prévalence de la détresse associée au diabète

Une étude menée sur un échantillon de 8 596 personnes souffrant de diabète au sein de 17 pays différents a indiqué qu'en moyenne 44.6% d'entre eux rapportaient une détresse associée à leur diabète (Nicolucci et al., 2013b). Ce pourcentage était cependant fort variable d'un pays à l'autre : la proportion minimum étant trouvé au Pays-Bas où 20% rapportaient un niveau significatif de détresse et le maximum en Algérie où plus de 60% des participants rapportaient une détresse importante par rapport à leur diabète. Il semblerait, dès lors, que la détresse associée au diabète dépende fortement du pays et des conditions de soin de santé. En France, près de 40% des participants rapportaient un niveau de détresse élevé par rapport à leur diabète. Un score total à la PAID supérieur à 40 était utilisé pour identifier les personnes souffrant de détresse dans cette étude. Ce même critère était utilisé au sein d'une autre étude menée auprès de 3 338 participants diabétiques en Australie. Environ 25% des participants de cet échantillon rapportaient un niveau élevé de détresse associée à leur diabète. Un jeune âge, la présence d'un diabète de type 1, le traitement et l'existence de complications étaient les facteurs associés à une plus grande détresse (Speight, Browne, Holmes-Truscott, Hendrieckx, & Pouwer, 2012). Plusieurs auteurs ont dénoncé la confusion qu'il existait dans la littérature entre dépression, symptômes dépressifs et détresse associée au diabète (Fisher et al., 2014a). Bien que liés, ces concepts demeurent distincts et 71% des patients rapportant un niveau élevé de détresse ne remplissent pas les critères de dépression majeure, alors que 67% des patients souffrant de dépression majeure rapportent également un niveau de détresse élevé par rapport à leur diabète (Fisher et al., 2007).

3.3 Conséquence de la détresse associée au diabète pour la prise en charge du diabète

Un niveau élevé de détresse associée au diabète a été associé à une moins bonne gestion de la maladie et un plus faible contrôle glycémique (Pintaudi et al., 2015; W. H. Polonsky et al., 1995, 2005; Snoek et al., 2000). Plus encore, certaines études ont investi l'apport prédictif de la détresse associée au diabète par rapport à la dépression et l'anxiété dans l'autogestion du diabète et le contrôle de la glycémie. Ainsi, la dépression ne prédit plus significativement l'équilibre glycémique lorsque la détresse est contrôlée (van Bastelaar, Cuijpers, Pouwer, Riper, & Snoek, 2011), suggérant que la détresse prédit l'équilibre glycémique au-delà de l'effet prédicteur de la dépression (voir également Aghili et al., 2016; Schmitt et al., 2015).

4. Interventions visant les troubles d'ordre émotionnel parmi les diabétiques

Considérant l'impact des symptômes dépressifs, d'anxiété et de la détresse spécifique au diabète sur le contrôle glycémique et les risques de complications associées au diabète, on pourrait s'attendre à ce que de nombreuses études soient menées en vue d'évaluer l'efficacité d'une prise en charge adaptée pour les patients par ces troubles émotionnels. Deux grandes catégories d'intervention ont été investiguées dans le cadre du traitement des troubles émotionnels parmi les personnes atteintes de diabète : les interventions pharmacologiques par antidépresseurs et les interventions psychologiques.

4.1 Traitement pharmacologique

Comme exposé précédemment, le traitement par antidépresseurs semble associé à une augmentation des risques de développer un diabète de type 2 (Mezuk et al., 2008). Pour les personnes déjà concernées par le diabète, ces antidépresseurs peuvent également entraver les efforts de régulation de la glycémie : les antipsychotiques atypiques, de plus en plus utilisés dans le traitement de la dépression (Gerhard et al., 2014), sont en effet associés à une série de changements métaboliques parmi lesquels l'augmentation du sentiment de faim, de la prise de poids et de la résistance à l'insuline (Stahl & Muntner, 2013). Cependant, l'amélioration des symptômes dépressifs suite au traitement peut également avoir un impact positif sur l'équilibre glycémique et les comportements d'autogestion mis en place par le patient. Une revue de la littérature a noté une amélioration du contrôle glycémique à court terme dans les groupes sous antidépresseurs, comparés à des groupes placebo (Baumeister, Hutter, & Bengel, 2012). Une attention particulière doit dès lors être accordée quant au choix du type d'antidépresseur pour les personnes à risque ou souffrant de diabète. Les antidépresseurs ne devraient pas être systématiquement écartés du traitement des phases aiguës de dépression chez les personnes atteintes de diabète.

4.2 Traitement psychologique

Parmi les interventions psychologiques proposées aux personnes souffrant de diabète, les thérapies cognitivo-comportementales sont celles qui ont été le plus largement investiguées dans la littérature (Harkness et al., 2010; Ismail, Winkley, & Rabe-Hesketh, 2004). Leur objectif est de réduire les symptômes dépressifs en amenant le patient à identifier et réévaluer ses pensées dysfonctionnelles qui ont un effet négatif sur ses sentiments et comportements (Aaron T. Beck, 1979).

Plusieurs méta-analyses révèlent que ces interventions ont un effet favorable sur le contrôle glycémique des personnes atteintes de diabète (Alam, Sturt, Lall, & Winkley, 2009; Chapman et al., 2015; Harkness et al., 2010; Ismail et al., 2004). Selon les méta-analyses, l’amélioration de l’hémoglobine glyquée[1] des individus bénéficiant d’une intervention psychologique variait entre 0.29 (Harkness et al., 2010) et 1,56% (Chapman et al., 2015). Ces résultats sont encourageants puisqu’une réduction de 1% de l’hémoglobine glyquée est associée à une diminution des risques de 14% d’infarctus du myocarde, de 37% pour les complications miscrovasculaires (rétinopathie, nephropathie, etc.) et de 21% de mortalité (Stratton et al., 2000). Cependant, cet effet n’a pas pu être démontré dans toutes les méta-analyses (Li et al., 2017). Ces interventions apparaissent également efficaces pour réduire les symptômes de dépression et d’anxiété. Cette efficacité ne s’étend toutefois pas à la détresse spécifique au diabète (Li et al., 2017; Uchendu & Blake, 2017).

5. Facteurs émotionnels dispositionnels de la dépression, de l’anxiété et de la détresse associée au diabète

Bien qu’améliorant les symptômes généraux de dépression et d’anxiété, les interventions cognitivo-comportementales semblent toutefois peu efficaces dans l’amélioration de la détresse spécifique au diabète (Li et al., 2017; Uchendu & Blake, 2017). Or, cette détresse prédit l’équilibre glycémique au-delà des mesures de la dépression (Aghili et al., 2016; Schmitt et al., 2015; van Bastelaar et al., 2011). Une meilleure connaissance des antécédents et facteurs dispositionnels influençant la détresse associée au diabète pourrait permettre le développement d’interventions psychologiques plus efficaces. Cependant, peu d’études ont investigué les facteurs dispositionnels pouvant réduire ou exacerber le risque de détresse associée au diabète. Parallèlement, l’intelligence émotionnelle est un facteur dispositionnel dont on a montré qu’il prédisait des réponses subjectives et objectives au stress au-delà d’autres facteurs tels que la personnalité,

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[1] L’hémoglobine glyquée est un indicateur du niveau moyen de la glycémie au cours des deux à trois derniers mois. Il s’exprime en pourcentage. Pour éviter les risques de complications, les personnes atteintes de diabète doivent généralement veiller à maintenir le niveau de leur hémoglobine glyquée en-dessous du seuil des 7%

l’alexithymie ou l’optimisme (Andrei, Siegling, Aloe, Baldaro, & Petrides, 2016; Mikolajczak, Luminet, Leroy, & Roy, 2007; Mikolajczak, Luminet, & Menil, 2006; Mikolajczak, Petrides, Coumans, Luminet, & others, 2009). La section suivante présentera l’intelligence émotionnelle et son cadre théorique ainsi que sa considération dans la littérature sur le diabète. L’alexithymie partageant l’une de ces dimensions avec l’intelligence émotionnelle, nous commencerons par brièvement présenter les recherches menées à ce sujet chez les personnes atteintes de diabète.

5.1 Bref détour par l’alexithymie

L’alexithymie est une pathologie présentant un versant émotionnel et cognitif. Elle se caractérise par des difficultés à identifier et exprimer ses émotions et à les différencier d’autres sensations corporelles, ainsi que par un mode de raisonnement concret et peu introspectif. Des recherches ont montré que cette pathologie était fort présente parmi les personnes atteintes de diabète (Topsever et al., 2006) et était associée à un moins bon contrôle glycémique (Bastin, Luminet, Buysschaert, & Luts, 2004; Housiaux, Luminet, & Dorchy, 2016; Housiaux, Luminet, Van Broeck, & Dorchy, 2010; Luca et al., 2015; Luminet, de Timary, Buysschaert, & Luts, 2006). L’alexithymie a également été associée à une plus grande anxiété et dépression parmi les personnes atteintes de diabète (Avci & Kelleci, 2016; Sapozhnikova, Tarlovskaia, Madianov, & Vedenskaia, 2012). L’étude de Luminet, de Timary, Buysschaert, & Luts et al. (2006) montre que, chez les diabétiques de type 1, c’est cependant la dimension « difficulté à exprimer ses émotions » qui est le plus associée à un faible contrôle de la glycémie. Cette facette de l’alexithymie est également partagée avec le concept d’intelligence émotionnelle (Parker, Taylor, & Bagby, 2001).

5.2 Définition de l’intelligence émotionnelle et le modèle tripartite

De façon plus large, l’intelligence émotionnelle désigne la capacité à identifier, comprendre, écouter/exprimer, réguler et utiliser ses propres émotions et celles d’autrui (Mikolajczak, 2010). Elle est considérée par certains comme une forme d’intelligence à part entière (Mayer & Salovey, 1997) et par d’autres comme une disposition individuelle, un trait de personnalité (Petrides & Furnham, 2003). Le modèle tripartite proposé par Mikolajczak et al. (2009) intègre ces deux conceptualisations en considérant que l’intelligence émotionnelle présente trois niveaux : le niveau des connaissances, le niveau des capacités et celui des traits. Le niveau des connaissances désigne le savoir dont les individus disposent sur les émotions et les différentes compétences émotionnelles (par exemple : « exprimer de la colère envers un collègue lors d’une réunion de travail n’est pas approprié »). Le niveau des capacités se réfère aux habiletés nécessaires pour la mise en application de ces connaissances (par exemple, « serais-je capable de réguler ma colère et de ne pas exploser contre mon collègue en réunion ? »). Le dernier niveau, les traits, fait référence aux dispositions personnelles des individus, leur tendance à réagir d’une certaine façon dans une situation émotionnelle spécifique (par exemple, « ai-je tendance à m’emporter en réunion ? »). En résumé, selon le modèle tripartite, l’intelligence émotionnelle se réfère à la fois à (1) ce que les personnes **savent** concernant leurs émotions, (2) ce qu’elles **sont capables** de faire en termes de gestion des émotions, (3) ce qu’elles **font réellement** lorsqu’elles sont confrontées à une certaine situation. Ces différents niveaux ne sont toutefois que peu corrélés entre eux. Ainsi, les connaissances ne se traduisent pas toujours en habilités, et la capacité d’une personne à gérer son émotion ne détermine pas nécessairement son comportement.

5.3 Les différentes mesures de l’intelligence émotionnelle

Les différents outils présents dans la littérature pour évaluer l’intelligence émotionnelle (IE) reflètent les deux opérationnalisations de celle-ci en termes de trait ou d’habilité. De ce fait, l’intelligence émotionnelle, en tant qu’habilité, s’évalue au moyen de tests de performance et l’intelligence émotionnelle comme trait avec des questionnaires auto-rapportés. Différents instruments de mesure pour évaluer l’IE habilité et l’IE trait sont indiqués dans le tableau suivant :

Table 13: Examples of questionnaires to assess the emotional intelligence

	Scale	Item example
HAbility	Mayer Salovey Caruso Emotional Intelligence Test (MSCEIT, Mayer, Salovey, & Caruso, 2002)	What mood(s) might be helpful to feel when metting in-laws for the very first time ? (Not useful 1-2-3-4-5 Useful) - Tension – Surprise - Joy
	Levels of Emotional Awareness Scale (LEAS, Lane, Quinlan, Schwartz, Walker, & Zeitlin, 1990)	You and your best friend are in the same line of work. There is a prize given annually to the best performance of the year. The two of you work hard to win the prize. One night the winner is announced: your friend. How would you feel? How would you friend feel? 0. I don’t work hard to win “prizes”. My friend would probably feel that the judges knew what they were doing. 1. I’d feel sick about it. It’s hard for me to say what my friend whould feel – it would all depend on our relationship was like and what the prize meant to her. 2. I’d probably feel bad about it for a few days, and try to figure out what went wrong. I’m sure my friend would be feeling really good. 3. We would both feel happy. Hey, you can’t win ‘em all! 4. I would feel depressed) the friend in this light is just like any other competitor. I would also begrudgingly fee happy for my friend, and rationalize that the judges had erred. My friend would feel very gratified, but would take the prize in stride ti save the friendship. 5. I’d feel disappointed that I didn’t win but glad that if someone else did, that person was my friend. My friend probably deserved it! My friend would be happy and proud but slightly worried that my feelings might be hurt
	Situational Test Emotional Understanding (STEU, MacCann & Roberts, 2008)	Clara receives a gift. Clara is most likely to feel? A. Happy B. Angry C. Frightened D. Bored E. Hungry
	Geneva Emotion Recognition Test (GERT, Schlegel, Grandjean, & Scherer, 2014)	Présentation de 83 vidéos de courte durée au cours desquelles 10 acteurs expriment 14 émotions différentes. Les participants doivent indiquer après chaque vidéo laquelle des 14 émotions était exprimée par l’acteur.
Trait	Trait Emotional Intelligence Questionnaire (TEIQue, Petrides, 2009)	I normally find it difficult to calm angry people down
	Emotional Quotient Inventory (Bar-On, 2004)	I do not become jealous over other people’s achievements
	Profile Emotional Competence (Brasseur, Grégoire, Bourdu & Mikolajczak, 2013)	As my emotions arise, I don't understand where they come from.

Bien que les conceptions de l'intelligence émotionnelle en tant qu'habilité et en tant que trait soient conciliables au sein d'un même modèle à plusieurs niveaux, une méta-analyse a révélé que les mesures développées sur base de ces deux opérationnalisations ne corrélaient que très peu, voire pas du tout, entre elles (Van Rooy, Viswesvaran, & Pluta, 2005).

5.4 Influence de l'intelligence émotionnelle sur la santé physique et mentale

Au sein de la population générale, l'intelligence émotionnelle a été associée à une meilleure santé physique et mentale. Les personnes présentant un niveau plus élevé d'intelligence émotionnelle adoptent des comportements plus sains concernant leur alimentation, la pratique d'une activité physique, la prévention des risques d'accident (Fernández-Abascal & Martín-Díaz, 2015; Saklofske, Austin, Galloway, & Davidson, 2007; Saklofske, Austin, Rohr, & Andrews, 2007; Sygit-Kowalkowska, Sygit, & Sygit, 2015). L'intelligence émotionnelle constitue un facteur de protection envers la consommation d'alcool (Peterson, Malouff, & Thorsteinsson, 2011) et le tabagisme (E. M. Hill & Maggi, 2011). Elle a également été associée à de meilleurs indicateurs de santé tels qu'une moindre consommation de médicaments et moins de consultations et hospitalisations médicales (Mikolajczak et al., 2015). La direction de causalité de cette relation a pu être établie suite à l'amélioration de ces indicateurs de santé après augmentation de l'intelligence émotionnelle (Kotsou, Nelis, Grégoire, & Mikolajczak, 2011; Miliche et al., In submission; Nelis et al., 2011). En termes de santé mentale, des plus faibles niveaux d'anxiété (Killgore, Sonis, Rosso, & Rauch, 2016), de dépression (Gomez-Baya, Mendoza, Paino, & de Matos, 2017; S. J. Lloyd, Malek-Ahmadi, Barclay, Fernandez, & Chartrand, 2012) et une meilleure résilience face aux événements de vie difficiles ont été constatés (Armstrong, Galligan, & Critchley, 2011). Dans le cadre des maladies chroniques, l'intelligence émotionnelle a été associée à une meilleure autogestion, notamment pour les bronchopneumopathies chroniques obstructives (Benzo, Kirsch, Dulohery, & Abascal-Bolado, 2015).

5.5 Diabète et émotions

Avant de nous intéresser à l'intelligence émotionnelle dans la prise en charge du diabète, il convient de s'intéresser aux différents liens possibles entre le diabète et les émotions et, notamment à la relation de double causalité qui existe entre le diabète et les émotions.

5.5.1 Hypo/hyperglycémie et fluctuation de l'humeur

Il y a près de 30 ans, Gonder-Frederick, Cox, Bobbitt, & Pennebaker (1989) avaient déjà relevé un lien entre la fluctuation de la glycémie et les émotions ressenties parmi des patients insulino-dépendants. Grâce à un design de mesures répétées réalisé sur 34 sujets, ils avaient montré que des émotions telles que la colère et la tristesse étaient davantage associées à un épisode d'hyperglycémie, alors que la nervosité et l'absence d'émotions positives étaient davantage associées à un épisode d'hypoglycémie. Les auteurs insistaient sur l'aspect idiosyncrasique de ces fluctuations, le ressenti et la réponse subjective au niveau de glycémie variant fortement d'un sujet à l'autre. Bien que propre à chaque patient, ces « sautes d'humeur » sont suffisamment répandues que pour figurer parmi la liste des signes d'hypoglycémie (cfr. Figure 9 de NovolinCare).

Toutefois, si l'irritabilité et la nervosité peuvent être signes d'hypoglycémie, le stress, par l'activation du système nerveux orthosympathique et de l'axe hypothalamo-hypophyso-corticosurrénalien, va conduire à la production de cortisol afin de maintenir l'homéostasie et préparer l'organisme à faire face au stresseur. Or, ce surplus de cortisol a un effet hyperglycémiant immédiat (permettant de fournir de l'énergie au corps). Au niveau du fonctionnement cérébral, l'hyperglycémie parmi un échantillon de jeunes participants sains a été associée à une moindre réponse de l'hypothalamus aux stimuli émotionnels (Schöpf et al., 2013). Les liens entre émotions et équilibre glycémiques sont donc multiples et complexes.

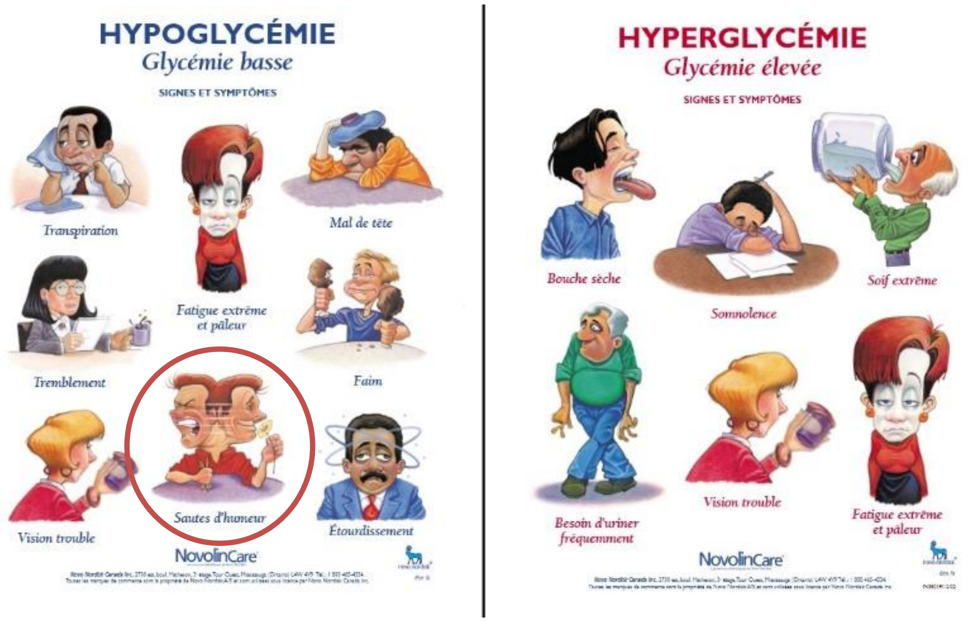

Figure 9 : Signes de l'hypoglycémie (à gauche) et de l'hyperglycémie (à droite)

5.5.2 Impact de l'intelligence émotionnelle pour la prise en charge du diabète

Peu d'études se sont penchées sur l'intelligence émotionnelle dans la prise en charge du diabète. Deux récentes recherches ont toutefois montré qu'un plus haut niveau d'intelligence émotionnelle s'accompagnait d'un meilleur contrôle glycémique parmi les diabétiques de type 1 (Zysberg, Bar Yoseph, & Goldman, 2017) et de type 2 (Coccaro, Drossos, & Phillipson, 2016). En outre, l'intelligence émotionnelle prédit 12% de la variance d'hémoglobine glyquée au-delà de ce que peuvent expliquer les covariables de type de traitement et de litératie en santé (Coccaro et al., 2016).

Même si ces deux études ne permettent pas d'établir la direction de causalité entre intelligence émotionnelle et contrôle glycémique, cette direction fut démontrée préalablement par Karahan & Yalcin (2009) qui ont développé et implémenté une formation d'intelligence émotionnelle auprès de personnes atteintes de diabète de type 2 en Turquie. Cette formation consistait en 12 séances d'une heure et demie délivrées durant 12 semaines. L'objet de chaque séance est indiqué dans le tableau 14. Les séances se composaient d'échanges en groupe, de présentation de la théorie, d'exercices à faire chez soi, de jeux de rôle et d'exercices corporels.

Table 14: Structure du programme d'entrainement des capacités d'intelligence émotionnelle de Karahan & Yalcin (2009)

Séance 1 : Rencontre des participants, information concernant le programme, les règles du groupe et les questions de présence
Séance 2 : Améliorer la perception des émotions
Séances 3 et 4 : Différencier les émotions
Séance 5 : Conscientiser sur les méthodes d'expression des émotions
Séance 6 : Gérer les émotions
Séances 7 et 8 : Améliorer les capacités à établir des liens empathiques avec les autres, exposer les réactions empathiques et introduire aux capacités d'écoute empathique
Séance 9 : Acquérir des capacités d'auto-motivation, la détermination d'objectifs et des moyens pour y parvenir
Séances 10 et 11 : L'utilisation des émotions dans la vie quotidienne
Séance 12 : Partage de l'expérience du programme en groupe, évaluation du processus, échange des pensées et émotions et exercice de relaxation

Par rapport au groupe contrôle dont les sujets étaient mis sous liste d'attente, les participants de la formation ont expérimenté une plus grande amélioration de leur bien-être ainsi que de leur qualité de vie (Yalcin, Karahan, Ozcelik, & Igde, 2008). À l'issue de la formation, leur score d'intelligence émotionnelle était significativement plus élevé que celui du groupe contrôle et ils rapportaient moins d'anxiété et de burnout. Leur hémoglobine glyquée fut réduite de près de 1% (Karahan & Yalcin, 2009) et s'est maintenue 3 et 6 mois après la formation (Karahan & Yalcin, 2009). Cette réduction est d'autant plus significative que l'objectif glycémique est généralement de 7% et qu'une diminution de 1% correspond à une réduction de 21% de risque de décès suite au diabète et de 37% de risque de complications microangiopathiques telles que la rétinopathie, la néphropathie ou la neuropathie (Stratton et al., 2000).

6. Conclusion

Le but de ce chapitre était de présenter les différents troubles d'ordre émotionnel rapportés par les personnes souffrant de diabète. La dépression a reçu le plus d'attention dans la littérature. Les recherches montrent que sa prévalence est plus importante que dans la population générale et qu'elle entrave l'autogestion du patient vis-à-vis de sa maladie et de son traitement. Diabète et dépression semblent associer par divers liens et les études s'accordent désormais pour parler de double directionnalité et d'étiologie commune : le diabète accroit les risques de développer une dépression, la dépression augmente les risques de développer un diabète de type 2 et le stress semble prédire à la fois l'apparition du diabète et de la dépression. Les troubles anxieux ont été moins examinés dans la littérature sur le diabète, bien que leur prévalence et leur conséquence sur le contrôle glycémique soient aussi importantes que celles de la dépression. Quelques rares études envisagent l'anxiété vis-à-vis des injections d'insuline et de l'autocontrôle de la glycémie. Contrairement à la dépression et à l'anxiété qui sont principalement des mesures non spécifiques, la détresse associée au diabète considère la souffrance du patient dans le contexte de sa maladie. Selon les pays, la proportion des patients atteints de diabète rapportant de la détresse par rapport à leur condition varie entre 20% (Pays-Bas) et 60% (Algérie). En France, 40% des patients présentent un niveau important de détresse associée au diabète. Cette détresse a été associée à un moins bon contrôle glycémique et des risques accrus de complications. Les études considérant simultanément ces trois troubles indiquent que la détresse spécifique au diabète a un effet plus important et plus direct sur le contrôle glycémique que l'anxiété ou la dépression. Dans le cas de la dépression majeure, la plupart des interventions rapportées en vue de réduire ces troubles sont pharmacologiques ou de type cognitivo-comportementales. Si les méta-analyses s'accordent sur l'efficacité des interventions cognivo-comportementales pour la réduction des symptômes dépressifs, elles varient en matière d'efficacité sur le contrôle glycémique et la détresse associée au diabète. L'intelligence émotionnelle, bien qu'ayant été associée à de nombreux indicateurs de santé subjectifs et objectifs dans la population générale, n'a été que peu investiguée dans le cadre des maladies chroniques et, en particulier, dans le diabète. Les quelques études menées dans ce domaine laissent, toutefois, entrevoir un effet très favorable de l'intelligence émotionnelle sur le contrôle glycémique et le bien-être des personnes atteintes de diabète

Chapter 6

When knowing is not enough

Emotional distress and depression reduce the positive effects of health literacy on diabetes self-management

Adequate self-management activities are important predictors of diabetes outcomes. As newly diagnosed diabetes patients often have difficulty to adopt these behaviors, leading to an exacerbation of the disease and complications. As diabetes literacy and self-efficacy are strong predictors of diabetes self-care, self-management education programs focus essentially on these factors. However, potential moderators of their effects on education outcomes have largely been neglected. This study investigated whether emotional distress or depression moderates the relation between health literacy, self-efficacy and diabetes self-care behaviors. 128 people with type 2 diabetes were recruited in hospitals, through general practitioners and via a diabetes website, and completed a questionnaire assessing health literacy, self-efficacy, diabetes-related distress, depression and self-care behaviors.

Reference

Schinckus, L., Van den Broucke, S., & Housiaux, M. When knowing is not enough: Emotional distress and depression reduce the positive effects of health literacy on diabetes self-management. (2017). *Patient Education and Counseling,* In Press.

When knowing is not enough

Emotional distress and depression reduce the positive effects of health literacy on diabetes self-management

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Abstract

Objectives Adequate self-management activities are important predictors of diabetes outcomes. As newly diagnosed diabetes patients often have difficulty to adopt these behaviors, leading to an exacerbation of the disease and complications. As diabetes literacy and self-efficacy are strong predictors of diabetes self-care, self-management education programs focus essentially on these factors. However, potential moderators of their effects on education outcomes have largely been neglected. This study investigated whether emotional distress or depression moderates the relation between health literacy, self-efficacy and diabetes self-care behaviors.

Methods 128 people with type 2 diabetes were recruited in hospitals, through general practitioners and via a diabetes website, and completed a questionnaire assessing health literacy, self-efficacy, diabetes-related distress, depression and self-care behaviors.

Results Multiple regression analysis confirms that health literacy and self-efficacy significantly predict reported self-care behaviors. Additional regression analyses reveal that distress or depression do not predict self-care behaviors directly, but moderate the effect of health literacy, which has a weaker impact in patients experiencing distress or depression. In contrast, distress and depression do not moderate the effect of self-efficacy on diabetes self-care behaviors.

Conclusion Emotional distress, whether related to diabetes or not, prevents patients from acting on their competence to perform adequate self-management behaviors.

Practice implications Diabetes Professionals should pay more attention to the patients' affective state and its influence on self-care. Psychological support should be integrated in the care for people suffering from type 2 diabetes.

Keywords Diabetes; Health literacy; Self-efficacy; Depression; Distress.

1. Introduction

Early diagnosis and appropriate management of type 2 diabetes significantly increase the chances of preventing harmful and costly complications. Therefore, the care for patients with diabetes focuses strongly on disease management. Because managing diabetes requires extensive self-care, the capacities of patients to manage their own illness and care process are considered to be a key determinant of treatment outcomes (Bartlett, 1986). The practice guide of the American Association of Diabetes Educators ("AADE: 7 self-care behaviors TM position statement," 2011) specifies seven self-care behaviors that are essential for people with diabetes: (a) healthy eating, (b) being active, (c) blood glucose monitoring, (d) taking medication, (e) problem solving (e.g. when there is an obstacle to dietary compliance), (f) healthy coping (e.g. speaking with friends or playing music to deal with stress), and (g) changing behaviors that increase the risk of developing diabetes complications (such as smoking or alcohol consumption).

The patient's adherence to the above-mentioned self-care behaviors is critical to achieve better glycemic control and, thereby, avoid complications associated to a poor diabetes control (Heisler et al., 2003; Rhee, 2005). Understanding the factors that influence adherence is therefore of utmost importance. As appears from the literature, a patient's adherence to the treatment is affected by several factors, both at the patient level (e.g. health literacy, self-efficacy) and at the provider or service level (e.g. organization of health services, communication skills). The current paper focuses on three individual factors that may impact on self-care behaviors for diabetes, i.e., health literacy, self-efficacy, and emotional distress. Recent studies have demonstrated the impact of these factors on self-care behaviors separately, but to our knowledge, none has examined the potential interactions between them. This study investigates whether emotional distress can moderate the relationship between health literacy or self-efficacy on diabetes self-care behaviors.

Health literacy is defined as "a person's knowledge and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."(DeWalt, Berkman, Sheridan, Lohr, & Pignone, 2004; Powell, Hill, & Clancy, 2007). It is well established that a low level of health literacy leads to poorer health outcomes, greater use of health care services, poorer adherence to medication, and poorer self-care behaviors (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). As the treatment of diabetes requires the patient to seek information, take health-related decisions, and understand medical instructions, health literacy is highly relevant for diabetes treatment (Millan-Ferro & Caballero, 2009). Lower levels of health literacy have indeed been associated with poorer knowledge about diabetes and poor glycemic control (DeWalt et al., 2004; Powell et al., 2007), which increases the risk of developing diabetes-related complications like retinopathy (Barnard & Lloyd, 2012; Baudrant-Boga, 2009; Schillinger et al., 2002).

Self-efficacy is defined as a person's beliefs about his or her capacities to complete tasks and reach goals. These beliefs, whether justified or not, influence a person's choices, goals, and motivation to engage in behavior to reach these goals (Bandura, 1982, 1991). The concept of self-efficacy has been integrated in several theoretical models that explain and predict health-related behaviors, such as the Protection Motivation Theory (Rogers, 1975) and the Theory of Planned Behavior (Ajzen, 1991). In the context of diabetes self-management, it was shown that a strong sense of self-efficacy is related to higher glycemic control and self-care behaviors (Cherrington, Wallston, & Rothman, 2010) and to a better adherence to the medical treatment (Mann, Ponieman, Leventhal, & Halm, 2009).

While health literacy and self-efficacy are cognitive constructs, the management of diabetes is also related to emotional factors. The fact of being diagnosed with diabetes can be a big challenge for the patient. In addition, the treatment of the illness requires a great adaptation, as the newly diagnosed patient has to learn to self-manage his(her) illness at all times and in all situations (Barnard & Lloyd, 2012). Therefore, patients with diabetes are likely to experience a range of emotions regarding their treatment and the possible risk of complications, such as feeling stressed or defeated by the disease, feeling it controls their life, worrying about their capacity to self-manage their diabetes, losing their motivation, avoiding tasks that could give negative feedback of their self-management capacity, and feeling alone to face the disease (Barnard & Lloyd, 2012). This range of emotions is referred to as “diabetes-related distress” (Fisher, Skaff, et al., 2008)(Barnard & Lloyd, 2012)(Barnard & Lloyd, 2012). The prevalence of distress is higher among patients who are treated with insulin injections (Delahanty et al., 2007) and among younger patients (Paddison, Alpass, & Stephens, 2007). It has been demonstrated that emotional distress in diabetes is related to poorer adherence and poorer self-management (J. S. Gonzalez, Delahanty, Safren, Meigs, & Grant, 2008), but it remains unclear whether distress is the cause or consequence of these outcomes. Patient who feel distressed are also less willing to perform self-care activities, which can lead to higher levels of glycated hemoglobin (J. Gonzalez, Shreck, Psaros, & Safren, 2015) and higher risk of mortality (Black et al., 2003).

In addition to distress, diabetes patients are also vulnerable to develop clinical depression. Based on a meta-analysis, Anderson and co-workers (R. J. Anderson et al., 2001) estimated that 31% of patients with diabetes had symptoms of depression and 11% major depression. In controlled studies indicated by these authors, the proportion of people who reported depression was twice as high in the diabetes group compared to the comparison group (R. J. Anderson et al., 2001). Three reasons may underlie this high prevalence: firstly, diabetes entails a number of restrictions and constraints, which may be a source of depression. Secondly, depressive people are more at risk for developing diabetes because of poor lifestyle habits (e.g., physical inactivity, high-fat diet, smoking, alcohol consumption, …) or metabolic disturbances (Engum, 2007). Finally, the depression and diabetes may both be the effect of a third variable, notably overweight, as overweight people are more at risk to develop both depression and diabetes (Thompson, Syddall, Rodin, Osmond, & Barker, 2001).

Whereas the impact of health literacy, self-efficacy, emotional distress and depression on adherence to diabetes treatment have been demonstrated independently, no studies have been performed to date which considered these factors simultaneously. As a result, it is not known to what extent these cognitive and emotional processes interact. The present study attempts to fill this gap by investigating whether the impact of patients' health literacy and self-efficacy beliefs on their self-care behaviors is moderated by diabetes-related distress and depression. Specifically, we hypothesized that distress and/or depression would attenuate/eliminate the positive effect of health literacy and self-efficacy on diabetes self-care behavior by preventing the patient from using his (her) cognitive resources to manage the disease and treatment.

2. Methods

2.1 Recruitment and data collection procedure

Participants were patients with Type 2 diabetes mellitus who were recruited from 7 different sources: two hospitals, two diabetes centers, two general practices, and the Belgian Diabetes Association. Only patients with Type 2 diabetes (80% of diabetes cases (27)) were included in the study.

Data collection was performed between August 2014 and March 2015 and involved the distribution of a questionnaire in two ways: (1) a paper version of the questionnaire was handed to the patients from the collaborating hospitals, diabetes centers, and general practices, to be completed at home and returned to the researchers in a pre-stamped envelope; (2) an online version of the questionnaire was made available via a web-link placed on the website of the Belgian Diabetes Association ("Association Belge du Diabète," 2014). In total, 409 paper questionnaires were distributed: 197 in the two hospitals; 160 in the diabetes centers, and 52 in the general practices.

Ethical approval was obtained from the ethical committees of the participating hospitals (P2014/256). Each participant provided informed consent in writing.

2.2 Evaluation Instruments

Self-care behaviors were assessed by means of the Diabetes Self-Management Questionnaire (DSMQ) (Schmitt et al., 2013), which contains 16 items in the form of self-management activities (e.g. *I do regular physical activity to achieve optimal blood sugar levels*; *I keep all doctors' appointments recommended for my diabetes treatment*; etc.) to be scored on a 4-point Likert scale ranging between "does not apply to me" to "strongly applies to me". The questionnaire yields scores on 4 sub-scales: "glucose management" (GM), "dietary control" (DC), "physical activity" (PA), and "health-care use" (HU), as well as a "sum scale" (SS). In this study, the questionnaire shows an acceptable level of internal consistency ($\alpha = 0.719$).

Two questionnaires were used to assess health literacy. General health literacy was measured via the 6-item version of the European Health Literacy Survey Questionnaire (HLS-EU-Q6) (Sorensen et al., 2015), which produces a mean score ranging from 1 to 4. Participants who score less than 2 are considered to have an insufficient level of health literacy; those who score between 2 and 3 have a limited level of health literacy; and those who score more than 3 are considered to be sufficiently health literate. The HLS-EU-Q6 shows very strong correlations with both the full version HLS-EU-Q47 and the 16-item shorter version HLS-EU-Q16 (Pelikan et al., 2014). The internal consistency of this scale in our sample is adequate ($\alpha = 0.797$). Diabetes-specific health literacy was assessed by the questionnaire developed by Ishikawa and colleagues (Ishikawa et al., 2008), which measures functional (difficulties in reading the instructions or leaflets from hospitals and pharmacies), communicative (patients' extraction and communication of diabetes-related information since they were diagnosed with the disease) and critical (critical analysis of the information and used it to make decisions) health literacy related to diabetes via 11 items. The internal consistency of this scale ($\alpha = 0.852$) and of its sub-scales ($\alpha = 0.860$; $\alpha = 0.797$; $\alpha = 0.744$) in our sample is adequate. For the purpose of our study, and based on the PCA results (see supplementary online material), the combined score of general health literacy and diabetes-specific health literacy was used, which will be referred to as "health and diabetes literacy".

Self-efficacy beliefs were assessed using the 15-item version of the Diabetes Management Self-Efficacy Scale (DMSES) (33,34), which measures people's beliefs concerning their efficacy to perform self-care activities in 4 areas: specific nutrition and weight, general nutrition and medical treatment, physical exercise, and blood sugar control. An item related to general practitioner visits was added from the initial 20-item version. The final questionnaire is thus composed of 16 items. The internal consistency of the scale in the current sample was 0.864.

Diabetes-related distress was assessed by means of the Diabetes Distress Scale (DDS) (W. H. Polonsky et al., 2005), which measures patients' distress in four domains: emotional burden, physician-related distress, regimen-related distress, diabetes-related interpersonal distress. The 17 items of the questionnaire are rated on 6-point scale ranging from "not a problem", "mild problem" and "serious problem". The internal consistency coefficient for this scale in the current sample was very good ($\alpha = 0.933$) and good to very good for its sub-scales ($\alpha = 0.873$; $\alpha = 0.973$; $\alpha = 0.824$; $\alpha = 0.873$).

Depression was measured by the 13 item version of the Beck Depression Inventory (BDI), which is known to be a good instrument to detect major depression among people with diabetes (C. E. Lloyd & Roy, 2013). The total score can vary between 0 and 39 and discriminates between minimal depression, mild depression, moderate depression, and severe depression. The internal consistency of the scale in the current sample was 0.864.

With the exception of the BDI, none of the selected questionnaires was available and validated in French. The DSMQ, the HLS-EU-Q6, the diabetes specific health literacy questionnaire, the DMSES, and the DDS were translated into French by a native speaker, using the back-translation method to validate and ensure the quality of the translation.

2.3 Statistical Analyses

Principal component analyses (PCA) with Varimax rotation were performed to confirm the factorial construct validity of each of the translated questionnaires. The influence of health literacy, self-efficacy beliefs, diabetes-related distress and depression on diabetes self-care was tested via multiple linear regressions. A first multiple linear regression assessed the impact of health literacy and self-efficacy on diabetes self-care behaviors. To consider the moderating impact of distress on the relation between health literacy, self-efficacy and diabetes self-care behaviors, a second multiple regression analysis was performed. Additional multiple regression analyses, with the sub-scales of diabetes-related distress as moderators, are detailed in the supplementary online material. The independent variables were first centered in other to calculate the interaction terms. These interactions terms were then introduced in the regression as independent variables. All statistical analyses were performed with the IBM SPSS 22 software.

3. Results

3.1 Sample

In total, 128 patients participated in the study: 67 (52.3%) returned the paper questionnaire (16.4% of the questionnaires that had been distributed), and 61 (47.7%) completed the online questionnaire. Among those who completed the paper version, 38 (29.7%) were treated in one of the two hospitals, 12 (9.4%) in a diabetes center, and 17 (13.3%) by a general practitioner. Participants' characteristics are summarized in Table 15.

Table 15 : Participants' characteristics

Sociodemographic variables	
Mean age	61.87 (SD = 12.27)
Gender	F: 47.6% / M: 52.4%
Number of years of schooling achieved	12.25 (SD = 3.08)
Education status	
No diploma	0.8%
Primary education	5.6%
Lower secondary education	15.3%
Upper secondary education	42.7%
Higher education (3 years)	20.2%
Higher education (≥5 years)	10.5%
Other	4.8%
Professional status	
Employed or self-employed	26%
Unemployed	36.2%
Retired	35.4%
Student	2.4%
Marital status	
Married	57.9%
Divorced	18.3%
Widowed	14.3%
Single	9.5%
Number of years with diabetes	12.64 (SD = 9.87)
Age of diagnosis	
After 40	65.6%
Between 30 and 39	13.3%
Between 20 and 29	3.9%
Before 20	6.2%
Missing	10.9%
Diabetes treatment	
Healthy lifestyle exclusively	3.2%
Oral medication	61.6%
Insulin injection	53.6%
Concerned by diabetes-related complications	30.6%

The means, standard deviations and internal consistency coefficient of the different scales and subscales resulting from the PCA are summarized in Table 16.

Table 16: Means, standard deviations and internal consistency coefficient of the different scales and subscales

Scale	Mean	SD	α
Diabetes Self-Management Questionnaire (DSMQ)	2.09	0.420	0.719
Glucose management	2.26	0.78	0.706
Dietary control	1.92	0.76	0.587
Physical activity	1.63	0.82	0.568
Health-care use	2.58	0.58	0.441
Health Literacy	2.96	0.48	0.852
European Health Literacy Questionnaire (HLS-EU-Q6)	2.85 9.8% inadequate HL (<2) 42.2% limited HL ([2;3[) 48% sufficient HL (≥3)	0.64	0.797
Diabetes-related health literacy (Ishikawa, 2008)	3.01	0.52	0.824
Diabetes Management Self-efficacy Scale (DMSES)	2.75	0.75	0.915
Nutrition and physical activity	2.37	0.88	0.877
Medical treatment	3.25	0.73	0.734
Blood sugar	3.02	1.03	0.884
Diabetes-related distress (DDS)	2.48	1.14	0.933
Emotional burden	2.79	1.34	0.873
Physician-related distress	1.97	1.40	0.923
Regimen-related distress	2.44	1.17	0.824
Diabetes-related interpersonal distress	2.69	1.61	0.873
Depression (BDI)	6.63 36.5% minimal dep (0-3) 29.8% mild dep (4-7) 20.2% moderate dep (8-15) 13.5% severe dep (16-39)	5.766	0.864

3.2 Impact of health literacy and self-efficacy on self-care behaviors

A first multiple regression analysis shows that, as predicted, the level of health and diabetes literacy combined and the patients' self-efficacy beliefs predict the reported self-care behaviors (Model 1, Table 17).

Table 17: Regression and interaction analysis to predict reported diabetes self-care behaviors

	R^2	β	t	p
Model 1	0.317			≤0.001
Health literacy (HLS-EU-Q6 + Diabetes specific HL)		0.301	3.018	≤0.005
Self-efficacy		0.350	3.509	≤0.001
Model 2	0.380			≤0.001
Health literacy (HLS-EU-Q6 + Diabetes specific HL)		0.321	3.030	≤0.005
Self-efficacy		0.415	3.642	≤0.001
Distress		0.092	0.987	0.326
Health literacy*Distress		-0.256	-2.490	≤0.05
Self-efficacy*Distress		0.137	1.334	0.185
Model 3	0.402			≤0.001
Health literacy (HLS-EU-Q6 + Diabetes specific HL)		0.300	2.987	≤0.005
Self-efficacy		0.346	3.335	≤0.001
Depression		-0.089	-1.003	0.319
Health literacy*Depression		-0.322	-3.260	≤0.005
Self-efficacy*Depression		0.151	1.515	0.133

3.3 Moderating effect of diabetes-related distress and depression

3.3.1 Diabetes-related distress as a moderator

Model 2 in Table 17 shows the results of the multiple regression analysis with diabetes-related distress as a moderator of the effects of health and diabetes literacy and self-efficacy beliefs on self-care behaviors. The model is significant. As for Model 1, both health and diabetes literacy and self-efficacy predict diabetes self-care activities directly. Diabetes-related distress does not predict the self-care activities directly, but the interaction of distress and health and diabetes literacy does: When the patient reports diabetes-related distress, the positive impact of health & diabetes literacy on self-care activities is significantly less important (Figure 10). This moderating effect remains stable after controlling for professional and education status. It is also noted that diabetes-related distress does not significantly moderate the impact of self-efficacy on self-care (Figure 11).

distress does not significantly moderate the impact of self-efficacy on self-care (Figure 11).

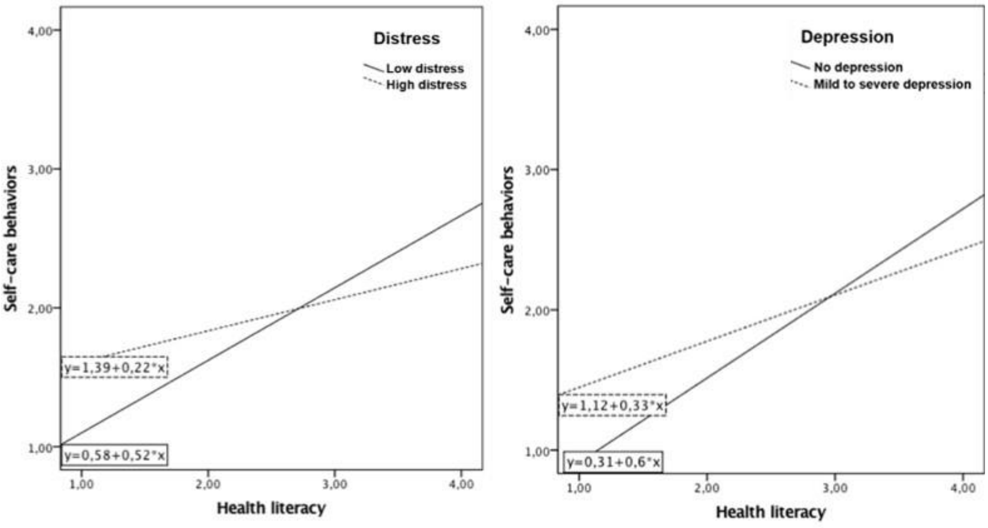

Figure 10: Impact of health literacy on self-care behaviors depending on diabetes-related distress or depression

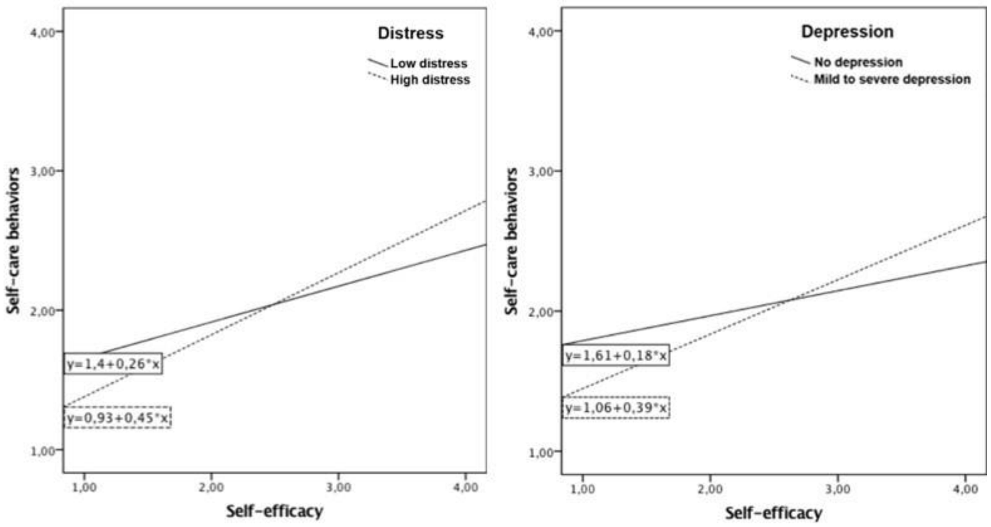

Figure 11: Impact of self-efficacy on self-care behaviors depending on diabetes-related distress or depression

3.3.2 Depression as a moderator

Model 3 in Table 17 shows the results of the multiple regression analysis with depression as a moderator of the effect of health literacy and self-efficacy on self-care behaviors. The model is again significant. Similar to Models 1 and 2, health and diabetes literacy and self-efficacy both predict diabetes self-care activities, while depression does not predict these activities directly, but influences the effect of health literacy. When a patient with diabetes reports depression, the impact of health and diabetes literacy on self-care behaviors is significantly less important (Figure 10). This moderating effect remains stable after controlling for professional and education status. Again, the moderating impact of depression is only found for health literacy but not for the impact of self-efficacy on diabetes self-care (Figure 11).

4. Discussion and Conclusion

4.1 Discussion

This study investigated the moderating effect of diabetes-related distress and depression on the relationship between health literacy, self-efficacy and diabetes self-care behaviors. Diabetes-related distress and depression were shown to reduce the positive effect of health and diabetes literacy on self-care behaviors.

In our sample of 128 Type 2 diabetes patients, 44.1% presented limited to insufficient health literacy. This result is very similar to what is observed in the general Belgian population (Sorensen et al., 2015). Among our participants, 17.5% and 11.7% reported moderate (≥8) and severe (≥14) depression respectively. These proportions do not differ much from what is usually found for adults with diabetes using the BDI (R. J. Anderson et al., 2001). In accordance with the literature (Cherrington et al., 2010; DeWalt et al., 2004; Mann et al., 2009; Powell et al., 2007), health literacy and self-efficacy significantly predicted the self-care behaviors reported by the patients, in the sense that patients with higher levels of health literacy and higher efficacy beliefs regarding diabetes self-management more often reported appropriate self-care behaviors. In our data, health literacy appears to be the strongest predictors of self-care behaviors.

Contrary to previous studies (J. S. Gonzalez et al., 2008; J. Gonzalez et al., 2015), diabetes-related distress and depression were not directly associated with poorer self-care behaviors in our sample. However, the interactions between diabetes-related distress and health literacy, as well as between depression and health literacy, significantly predicted self-care behaviors. When patients reported being depressed, their self-care activities were less influenced by the level of health literacy. The same was found for diabetes-related distress, whereby an interaction with health literacy was found for the emotional burden, physician-related distress and interpersonal distress. So, without having a direct impact, emotional distress (whether clinical or subclinical) seems to reduce the positive effects of health literacy on self-care activities. For patients with severe depression, the general reduction of energy and loss of interest may prevent the use of health literacy resources to self-manage the disease correctly. With regard to the moderating impact of distress, the emotional burden and distress related to a lack of support by the doctor or relatives may also restrain the patient in the utilization of his/her health and diabetes literacy to perform adequate self-care behaviors.

It should be noted that a similar moderating effect of depression and diabetes-related distress was not found for self-efficacy. One explanation for this could be that self-efficacy is already more associated with emotional distress than the level of health literacy. According to Gonzalez (2014), the link between diabetes-related distress and poor medication adherence can be explained by the lower level of self-efficacy. In this case, self-efficacy is represented as a mediator of the relationship between distress and self-care behaviors. In addition, Bandura (1991) underlined that a low self-efficacy can increase the vulnerability to depression. As a consequence of these potential links between self-efficacy, emotional distress and self-care behaviors, it is understandable that in our study the interaction was not significant.

While this study has produced important findings regarding the interaction between cognitive and emotional factors that influence self-care behavior of patients with diabetes, some limitations need to be recognized.

A first limitation concerns the representativeness of the sample. Among the 409 paper questionnaires distributed, only 67 were returned (16.4%). As the patients were invited to participate in a study on diabetes and emotional distress, it could be that those suffering from distress related to their diabetes were more willing to participate. In addition, the majority of type 2 diabetes included in this study were on medication, either by taking oral medication or by insulin injections. Only 3.2% were treating their diabetes exclusively through a healthy lifestyle. Therefore, the results may not entirely reflect the reality of Type 2 diabetes patients who are not treated with medication.

A second limitation refers to the self-report nature of the collected data. As the participants estimated the quality of their own self-care behaviors, this measure may have been subject to social desirability bias. A further limitation concerns the cross-sectional design of our study. Due to this design it is not possible to determine the direction of the observed relationships. Prospective studies are necessary to further illuminate the direction of these relationships.

4.2 Conclusion

As diabetes treatment requires extensive self-care activities, the patient's capacities to manage his/her own illness is a key determinant of treatment outcomes. These capacities can be influenced by cognitive and affective factors. This study showed that the levels of health literacy (i.e. the person's capacity to access, understand, assess and apply health-related information) and self-efficacy have a positive impact on reported diabetes self-care behaviors. However, for health literacy, this positive effect disappears when the patient suffers from depression or diabetes-related distress. These results offer new evidence of the role of cognitive and emotional factors in diabetes self-management. Further research involving longitudinal designs should be conducted to learn more about the links between these variables and identify the main causes of depression and distress among diabetes patients, such as repeated frustration toward the treatment, lack of diabetes self-efficacy, coping strategies, exhaustion of personal resources to deal with the disease, fear of complications, etc.

4.3 Practice Implications

Patients with sufficient health literacy tend to adhere better to their treatment. However, when patients are experiencing depression and/or diabetes-related distress, the positive impact of health literacy is reduced. This suggests that the emotional burden interferes with the cognitive resources that are required for adequate diabetes self-management. In view of the high prevalence of depressive symptoms amongst patients with diabetes – depression is twice as prevalent among diabetes patients than in the overall population – health professionals should acknowledge the debilitating impact of this condition on cognitive capacities, and realize that patients who have enough knowledge to self-manage their diabetes but who suffer from emotional distress are less able to put this knowledge into practice. A cross-sectional study of Hajos, Polonsky, Twisk, Dain, & Snoek (2011) indicated that the physicians do not always appreciate properly patients' perceptions of the disease and their emotional status. In the light of these elements, diabetes services should focus on depression and distress screening and integrate more psychological support to diabetes self-management education. A systematic literature review (Harkness et al., 2010) showed that, currently, very few diabetes interventions focus on both physical and mental health improvement. It seems reasonable to suggest that an emotional intelligence training, in addition to classical diabetes education, could help patients to deal with diabetes-related distress. Emotional intelligence trainings aim to improve people capacities to identify, understand, express, regulate and use their own emotions and emotions from the others (Brasseur, Grégoire, Bourdu, & Mikolajczak, 2013a). These trainings have proved their effectiveness in improving psychological well-being (such as stress and distress) and self-reported physical health in general population (Kotsou et al., 2011; Nelis et al., 2011) and also among type 2 diabetes patients (Karahan & Yalcin, 2009; Yalcin et al., 2008). Teaching patients to deal with difficult emotions such as diabetes-related distress may help them to preserve their cognitive resources to self-manage their disease and treatment.

Chapter 7

The role of emotional intelligence in diabetes self-management

The mediating effect of diabetes-related distress

The purposes of the two presented studies in this seventh chapter are (1) to investigate whether the level of emotional intelligence of people suffering from diabetes differs from the non-diabetes population, and (2) to explore the impact of emotional intelligence on diabetes-related distress and diabetes self-management behaviors. In study 1, an existing database of 8 532 members of a health insurance fund (333 with diabetes and 8 199 without diabetes) was analyzed through group comparisons to investigate whether the level of emotional intelligence of people suffering from diabetes differs from the non-diabetes people sharing the same gender, age, education level and body mass index (BMI). Study 2 consisted of a survey among 146 persons with type 1, type 2 or gestational diabetes to investigate the relations between emotional intelligence, distress and diabetes self-management behaviors through regressions and mediation analyses.

Reference

Schinckus, L., Avalosse, H., Van den Broucke, S., & Mikolajczak, M. (2017). The role of emotional intelligence in diabetes self-management behaviors: the mediating effect of diabetes-related distress. *Submitted to Personality and Individual Differences.*

The role of emotional intelligence in diabetes self-management

The mediating effect of diabetes-related distress

Abstract

Purpose The purposes of the two presented studies are (1) to investigate whether the level of emotional intelligence of people suffering from diabetes differs from the non-diabetes population, and (2) to explore the impact of emotional intelligence on diabetes-related distress and diabetes self-management behaviors.

Methods In study 1, an existing database of 8 532 members of a health insurance fund (333 with diabetes and 8 199 without diabetes) was analyzed through group comparisons to investigate whether the level of emotional intelligence of people suffering from diabetes differs from the non-diabetes people sharing the same gender, age, education level and body mass index (BMI). Study 2 consisted of a survey among 146 persons with type 1, type 2 or gestational diabetes to investigate the relations between emotional intelligence, distress and diabetes self-management behaviors through regressions and mediation analyses.

Results The first study showed that people suffering from diabetes had significantly lower levels of emotional intelligence than controls, but that this difference was essentially due to differences in gender, age, educational level and BMI. When people with diabetes were matched with participants without diabetes of the same gender, age, educational level and BMI, this difference disappeared. The second study showed that emotional intelligence influences diabetes self-management behaviors, and that this relationship is mediated by diabetes-related distress, which proved to be a better predictor of self-management behaviors than depression or anxiety.

Conclusion These findings suggest that enhancing emotional intelligence can be an appropriate way to reduce the distress associated with diabetes management and the risk of complications.

1. Introduction

Affective issues associated with diabetes, such as depression, anxiety, and diabetes-related distress, are increasingly gaining interest over the last years. This attention can be explained by the growing prevalence of affective disorders among people with diabetes (R. J. Anderson et al., 2001; Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002; Nicolucci et al., 2013b) and by their impact on diabetes self-management, glycemic control, risk for complications, and mortality (Collins et al., 2009; Park, Katon, & Wolf, 2013; Schmitt et al., 2017). The term “affective disorder” is used here to refer to an intense fear (stress or anxiety) or despair (depression), or something in between (distress), that people with diabetes can experience when facing the reality of having to deal with extensive self-care demands and risks of serious complications for the rest of their life.

Among the psychological comorbidities of diabetes, depression is the one that has received the most attention in the literature. Meta-analyses have shown that the prevalence of depression is twice or three times as high among people with diabetes than in the general population (R. J. Anderson et al., 2001; Roy & Lloyd, 2012). While coping with a depression is a challenge in itself, it is even more problematic in people with diabetes, because it is associated with lower adherence to the diabetes treatment and with poorer glycemic control (Jeffrey S. Gonzalez et al., 2008; Lustman et al., 2000; Sumlin et al., 2014). As a consequence, it also increases the risk of diabetes complications and mortality (Black et al., 2003; de Groot, Anderson, Freedland, Clouse, & Lustman, 2001). Several authors point out that in many cases depressive symptoms originate in the context of the chronic disease (Fisher, Gonzalez, & Polonsky, 2014b). Both the practical constraints of the daily self-management of the disease (e.g., dietary restrictions regarding sugar intakes, insulin injections, glucose monitoring) and the important risks of serious complications hanging over patient’s head like a Damocles’ sword, such as cardiovascular problems, nephropathy, retinopathy, neuropathy, or amputations, are generally considered as sufficient to explain the apparition of distress (W. H. Polonsky et al., 1995). The emotional workload associated with diabetes treatment or with the risk of serious complications is considered as a *diabetes-related distress* (W. H. Polonsky et al., 1995), which has been associated with poorer self-management behaviors (diet, physical activity, medication adherence) and, consequently, with poorer glycemic control (Pintaudi et al., 2015). In some cases, intense distress related to diabetes can lead to a major depression or to an anxiety disorder. Anxiety among people with diabetes has received less attention in the literature than depression, but several studies suggest that its prevalence and its consequences on self-management may be at least as much important as those of depression (Khambaty et al., 2016; Smith et al., 2013).

This has prompted several researchers to investigate the *relative* prevalence and consequences of depression, distress and anxiety among people with diabetes. A longitudinal study by Fisher and colleagues (2008) has shown that the prevalence of general anxiety disorders and depression were respectively 123% and 60% higher in people with diabetes than in the general population, The same study also revealed that diabetes-related distress persisted over the 18 months of the study, whereas anxiety disorder and major depression were more episodic (one episode among the three assessed periods). While diabetes-related distress was significantly associated with higher glycated hemoglobin (HbA1c), no significant correlation was found between the HbA1c and general anxiety disorder or major depression. While some studies did not find a connection between depression and glycemic control, others did find a relationship that disappeared when diabetes distress was controlled for (van Bastelaar et al., 2011). Therefore, several authors suggest that diabetes-related distress may act as a mediator of the relationship between depressive symptoms and glycemic control (Aghili et al., 2016; Schmitt et al., 2015). Regardless of whether distress is a predictor(Fisher, Skaff, et al., 2008) or a mediator (Aghili et al., 2016; Schmitt et al., 2015; van Bastelaar et al., 2011), these studies converge in the sense that they lend support to the view that the relationship between diabetes-related distress and glycemic control is stronger than that of depression with glycemic control.

The detrimental effect of diabetes-related distress on diabetes self-management and glycemic control is even more serious when considering the prevalence of diabetes-related distress among people with diabetes. The Diabetes Attitudes, Wishes and Needs study (DAWN2) revealed that, among 8596 adults with diabetes, as much as 44.6% reported diabetes-related distress (Nicolucci et al., 2013b). However, surprisingly few published studies have tried to identify the dispositional factors that may reduce or exacerbate the risk of diabetes-related distress. Amongst the factor that have been named as related to greater diabetes-related distress are younger age, lower levels of self-efficacy and less perceived health care support (Wardian & Sun, 2014). However, emotional intelligence, a dispositional factor that has been found to predict subjective and objective responses to a number of acute or chronic adverse situations over and above personality traits such as the big five, alexithymia, optimism, etc. (Andrei et al., 2016; Mikolajczak, Luminet, et al., 2007; Mikolajczak et al., 2006, 2009; Mikolajczak, Roy, Luminet, Fillée, & de Timary, 2007), remains virtually unmentioned in the diabetes literature.

Emotional intelligence (EI) refers to the capacity to identify, understand, express or listen, regulate and use our own emotions and others’ emotions (Mayer & Salovey, 1997; Mikolajczak, 2010; Petrides & Furnham, 2003). In the general population, higher EI has been associated with healthier behaviors (Fernández-Abascal & Martín-Díaz, 2015; Saklofske, Austin, Rohr, et al., 2007; Sygit-Kowalkowska et al., 2015), better health (as evidenced by less drug consumption, fewer doctor visits and fewer hospitalizations (Mikolajczak et al., 2015); and lower negative affects such as anxiety (Killgore et al., 2016), depression (Gomez-Baya et al., 2017; S. J. Lloyd et al., 2012), or distress in the face of adversity (Armstrong et al., 2011). In clinical populations, EI was found to be significantly associated with self-management and well-being in chronic obstructive pulmonary disease (Benzo et al., 2015). These findings suggest that EI could also be important for people with diabetes, yet very few studies have investigated the concept in the context of diabetes treatment. To our knowledge, only three studies have investigated the role of EI in diabetes. Zysberg, Bar Yoseph, and Goldman (2017) showed that EI among young adults with type 1 diabetes was associated with better levels of HbA1c and of blood sugar during the last day. Similar results were found in the cross-sectional study of

Coccaro, Drossos, & Phillipson (2016), who found that EI and affect intensity accounted for 12% of the variance in HbA1c among participants with type 2 diabetes. The direction of causality between EI and glycemic control had previously been demonstrated by researchers who showed that, compared to a control group, a training program on EI skills significantly improves well-being and quality of life of patients with diabetes (Yalcin et al., 2008), and reduces their anxiety and improve glycemic control (Karahan & Yalcin, 2009). The glycated hemoglobin was reduced by nearly 1% after the intervention (from 8.66 ± 0.31 to 7.82 ± 0.26). This improvement is highly significant, as a reduction of 1% in the glycated hemoglobin is associated to a risk decrease of 21% for deaths related to diabetes and to a decrease of 37% for microvascular complications such as retinopathy, nephropathy, or neuropathy (Stratton et al., 2000).

Research on alexithymia, a construct closely related to EI with which it overlaps in its dimensions of identifying and expressing feelings (Parker et al., 2001), has already shown the relevance of investigating individual differences in emotional competences in relation to diabetes. Specifically, it has been demonstrated that the prevalence of alexithymia is greater among people with diabetes (Topsever et al., 2006), and that this condition, and more particularly the dimension “difficulty to express emotions”, affects glycemic control(Luminet et al., 2006). Alexithymia has also been related to depression and anxiety among people with diabetes (Avci & Kelleci, 2016; Sapozhnikova et al., 2012). In view of these findings and taking account of the positive impact of EI training on anxiety and glycemic control, it can be assumed that EI plays a key role in reducing diabetes-related distress and improving self-management.

This article reports on two studies that aimed to explore the role of emotional intelligence in diabetes self-management. The first study aimed to determine whether the level of EI of people with diabetes differs from that of controls. The second study aimed to examine the relationship between EI, diabetes-related distress and self-management behaviors, building on previous studies demonstrating the relative importance of depression, anxiety and distress in predicting diabetes self-management behaviors. We specifically tested the hypothesis that EI would increase self-management behaviors by reducing diabetes-related distress.

2. Study 1

This first study aimed to explore whether the levels of emotional intelligence of people with diabetes differs from the non-diabetes population. In doing so, we controlled for gender, age, educational levels and BMI.

2.1 Method

2.1.1 Participants and procedures

A stratified sample of 200,000 adults aged between 18 and 80 years old, drawn from the membership database of the largest health insurance fund in Belgium (Mutualité Chrétienne

- Christelijke Mutualiteit, abbreviated as MC-CM), was contacted by mail and invited to complete a survey on emotions and health. The sample was stratified for gender, age, and socio-economic status to be as representative as possible of the Belgian population. Of this sample, 16 999 respondents completed the entire questionnaire and gave their consent for coupling it with the health data of the MC-CM, which allowed to identify persons with diabetes through their record. People were considered as having diabetes if they received at least one medical delivery related to diabetes care over the last year. Participants who met some diabetes criteria (e.g., performing a fasting blood glucose test) but not the most restrictive one (i.e., receiving at least one medical delivery related to diabetes care) were removed from the study to avoid overlap between the two sub-groups. This resulted in a total of 8 532 remaining participants, of which 333 had diabetes.

2.1.2 Measures

Demographic and biometric information was collected by self-report questions about gender, age, education level, language, and height and weight allowing the calculation of the BMI.

Emotional intelligence was assessed with the *Profile of Emotional Competence* (PEC; Brasseur, Grégoire, Bourdu, & Mikolajczak, 2013). This measure, consisting of 50 items to be scored on a scale from 1 (strongly disagree) to 5 (strongly agree), provides separate sub-scores for 5 emotional competency dimensions (identification, understanding, expression, regulation and) in their intraindividual (one's emotions) and interindividual aspects (others' emotions), forming three global scores: an intrapersonal EC score ($\alpha = .86$), an interpersonal EC score ($\alpha = .89$), and a total EC score ($\alpha = .92$). Examples of items are *"during an argument, I can't identify if I am sad or angry"* and *"my emotions inform me of what is important to me".*

2.1.3 Analyses

Statistical analyses were performed using SPSS 24 (IBM SPSS Statistics). Group comparisons were performed by Student's *t*-test for continuous dependent variables, such as the PEC scales, and Pearson's Chi^2 test for categorical variables, such as gender. Using the case control matching process on SPSS, participants from the diabetes sub-group were matched with participants without diabetes with the same gender, age (+/- 2 years), educational level, and BMI (+/- 2). Student's *t*-test for paired samples were performed to test whether people with diabetes had different emotional intelligence scores than comparable non-diabetes people.

2.2 Results

The diabetes group differed significantly from the non-diabetes group in terms of gender, age, education level and BMI: Unlike the non-diabetes group, the diabetes group comprised more men than women ($Chi^2(1) = 52{,}656$, $p \leq 0.001$), and the men were twice as likely to suffer from diabetes than women (risk report = 2.148). Participants from the diabetes group were also significantly older (F(1,8532) = 85.421, $p \leq 0.001$, Cohen's *d* = 0.570), had a lower education level (*Chi*^{2}(5) = 56,476, $p \leq 0.001$), and a higher BMI (F(1,8532) = 172,705, $p \leq 0.001$, Cohen's *d* = 0.698). While the participants with diabetes tended to be overweight or moderately obese, the group without diabetes were only slightly overweight.

Without controlling for these variables, people with diabetes showed lower intrapersonal and interpersonal EI, which resulted in a lower global emotional intelligence score than that of people without diabetes (Table 18). When looking at the specific emotional competences, people with diabetes were less able to identify, understand, express and use their own emotions, and to identify, understand and listen to other peoples' emotions.

Table 18: Mean differences between diabetes and non-diabetes people on emotional intelligence and its sub-scales (before controlling for gender, age, education level and BMI)

	Diabetes group		**Non-diabetes group**		**N**	**F**	***P***
	M	**SD**	**M**	**SD**			
Emotional intelligence	3.37	0.42	3.47	0.43	8532	16.78	.000
Intrapersonal EI	3.37	0.44	3.46	0.48	8532	9.706	.002
Identification	3.64	0.56	3.74	0.59	8532	9.599	.002
Understanding	3.41	0.70	3.55	0.71	8532	12.233	.000
Expression	3.13	0.67	3.24	0.75	8532	7.770	.005
Regulation	3.34	0.72	3.32	0.75	8532	0.288	.592
Utilisation	3.35	0.55	3.43	0.58	8532	6.073	.014
Interpersonal EI	3.36	0.47	3.47	0.48	8532	18.856	.000
Identification	3.40	0.60	3.56	0.64	8532	21.963	.000
Understanding	3.36	0.59	3.56	0.61	8532	37.127	.000
Expression	3.61	0.70	3.76	0.65	8532	17.543	.000
Regulation	3.40	0.59	3.45	0.59	8532	2.806	.094
Utilisation	3.04	0.64	3.03	0.66	8532	0.011	.917

Pairing of the respondents with diabetes to those without diabetes who were comparable with regard to gender, age, education level and BMI resulted in 255 matched pairs. Although BMI was used as a matching criterion, it still differed significantly between the two matched groups (t(254, 1) = 19.456, $p \leq 0.001$). This observed difference can be assumed to reflect a true difference, as it has been repeatedly shown that people suffering from diabetes have on average a higher BMI than controls(Narayan, Boyle, Thompson, Gregg, & Williamson, 2007). However, despite this statistical significance, the mean difference of 0.3 after matching (BMI = 27.96 for diabetes and 27.67 for non-diabetes) was considered too small to be clinically important, as it represents a difference of less than 1 kg for a person measuring 1.75 meter.

Paired samples analyses did not show any significant differences between persons with and without diabetes for intrapersonal (t(254, 1) = -0.367, $p = 0.714$) or interpersonal EI (t(254, 1) = 0.442, $p = 0.659$) , or for global emotional intelligence (t(254, 1) = 0.040, $p = 0.968$). Follow-up analyses revealed that of the control variables, age (F(10,8516) = 41,279, $p \leq 0.001$), gender (10,8516) =21.751, $p \leq 0.001$), education level (F(10,8516) = 86.182, $p \leq 0.001$) and BMI (10,8516) = 2.915, $p \leq 0.001$) were responsible for the group differences in EI before matching.

2.3 Discussion

Our primary analyses suggest that people with diabetes have a significantly lower level of both intra- and interpersonal EI than the non-diabetes population, but that the two groups also differ significantly in terms of gender, age, educational levels and BMI. These differences are not surprising, since globally the number of men suffering from diabetes is greater than the number of women(International Diabetes Federation, 2015), and age and BMI are recognized as important risks factor for type 2 diabetes (Buysschaert, 2011). However, these variables are also known to influence EI (Brasseur, Grégoire, Bourdu, & Mikolajczak, 2013b; Fantini-Hauwel & Mikolajczak, 2014). When comparing people of the same age, gender, education level and BMI, there was no longer a difference in EI between respondents with diabetes and without. This suggests that the EI of people with diabetes does not differ from that of the general population when they are compared to biologically and demographically similar individuals. However, in reality, type 2 diabetes cannot be dissociated from its two most important risk factors: age and overweight/obesity. Therefore, the finding that diabetes is associated with lower levels of intra- and interpersonal EI should not be dismissed, especially not since EI training has been found to improve glycemic control in people with diabetes (Karahan & Yalcin, 2009). To further explore the relationship between EI and diabetes, and uncover why EI is an asset for diabetic people, study 2 was undertaken testing the hypothesis that EI would reduce diabetes-related distress and improve self-management behaviors.

3. Study 2

The second study pursued the following objectives: (i) investigate if diabetes-related distress is a better predictor of diabetes self-management behaviors than depression or anxiety; (ii) investigate if EI reduces diabetes-related distress and increases self-management behaviors; and (iii) investigate if diabetes-related distress mediates the relationship between EI and diabetes self-management behaviors.

3.1 Method

3.1.1 Participants and procedures

Data were collected from 19th October 2016 to 1st January 2017 through an online questionnaire circulated on French language diabetes forums. During this period, replies were initiated for a total of 263 questionnaires, 146 of which were fully completed and used for the study. Of the 146 respondents, 80.5% were women. The mean age was 40 ± 14 years. Slightly more than half (52.8%) of the sample had higher education qualifications, 53.1% were working, 22.8% were unemployed and 17.8% retired. 60.3% had type 1 diabetes, 26.7% had type 2 diabetes and 13% gestational diabetes. The mean number of years living with the condition was 13 ± 11. Diabetes was treated mainly by insulin injections only (61%) or combined with oral medication (14.4%); 10.3% took oral medication without insulin, and 14.4% had no medication for their diabetes but tried to reach/maintain a healthy lifestyle (diet and physical activities). Almost a third (28.3%) of the respondents reported diabetes complications (neuropathy, retinopathy, diabetic coma, episodes of acute ketoacidosis, hypertension and heart problems, nephropathy, daily discomfort).

3.1.2 Measures

Diabetes self-management behaviors were assessed with the *Diabetes Self-Management Questionnaire* (DSMQ)(Schmitt et al., 2013), a 16 items-scale which assesses glucose management (e.g. *I check my blood sugar levels with care and attention*), dietary control (e.g. *The food I choose to eat makes it easy to achieve optimal blood sugar levels*), physical activity (e.g. *I avoid physical activity, although it would improve my diabetes* - Invers) and health-care use (e.g. *I keep all doctors' appointments recommended for my diabetes treatment*) on 4 point Likert scales ranging between "does not apply to me" to "strongly applies to me." This scale showed an acceptable level of internal consistency (α = .746).

Emotional intelligence was assessed through the short version of the *Trait Emotional Intelligence Questionnaire* (TEIQue-SF)(Cooper & Petrides, 2010), which consists of 2 items, rated on a 7-point scale, for each of the 15 facets assessed by the TEIQue (Petrides & Furnham, 2003) (e.g. *Many times, I can't figure out what emotion I'm feeling*; *I'm normally able to "get into someone's shoes" and experience their emotions*). The short TEIQue was used here because we were looking for a shorter instrument than the full PEC (50 items) used in Study 1 and because we were not able replicate the original psychometric properties of the Short (20-item) version of the PEC (Mikolajczak, Schinckus and Fantini-Hauwel, in preparation). The internal consistency of the TEIQUE-SF scale in this study was good (α = .881).

The *Diabetes Distress Scale* (DDS)(W. H. Polonsky et al., 2005) is a 17-items questionnaire assessing diabetes-related emotional distress in four domains: emotional burden (e.g. *Feeling that diabetes is taking up too much of my mental and physical energy every day*), physician-related distress (e.g. *Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes*), regimen-related distress (e.g. *Feeling that I am often failing with my diabetes regimen*), diabetes-related interpersonal distress (e.g. *Feeling that friends or family don't appreciate how difficult living with diabetes can be*). The items are rated on 6-point scale ranging from "not a problem" to "serious problem". The internal consistency for this scale in the current sample was excellent (α = 0.910) and very good for its sub-scales (α = 0.851; α = 0.863; α = 0.866; α = 0.844). Based on previous studies (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008b; Fisher, Hessler, Polonsky, & Mullan, 2012) a mean score ≥ 3 was used as a cut-off point for high distress

Depression was measured by the 13-item version of the *Beck Depression Inventory* (BDI). The BDI is considered as a reliable instrument to detect major depression (C. E. Lloyd & Roy, 2013). The total score can vary between 0 and 39 and detects a range of depression severities (0-4 No depression, 4-7 Mild depression, 8-15 Moderate depression, ≤ 16 Severe depression). The internal consistency of the scale in the current sample was 0.893.

Anxiety was assessed using the A-Trait scale of the *State-Trait Anxiety Inventory* (STAI) (Lushene, Gorsuch, & Spielberger, 1970). The A-Trait scale comprises 20 items, scored on a 4-point Likert scale ranging from “almost never” to “almost always.” Contrary to the STAI State, which assesses how respondents feel “right now, at this moment,” the STAI Trait targets how respondents “generally feel” (e.g. *I lack self-confidence*). A cut score of 39-40 has been suggested to identify clinically anxious respondents (Knight, Waal-Manning, & Spears, 1983).

3.1.3 Statistical analyses

Group comparisons were performed using *Chi*^{2} test and analysis of variance (ANOVA) using SPSS 24 (IBM SPSS Statistics). The research questions were tested using linear regression analyses, controlling for the type of diabetes and treatment. The first research question (i.e. whether diabetes-related distress was a better predictor of diabetes self-management behaviors than depression or anxiety) was investigated by comparing regression models that included different combinations of depression, anxiety and diabetes-related distress, to predict diabetes self-management behaviors. The different models were compared to determine the respective parts of the variance of self-management behaviors explained by each of the predictors and reported with the ΔR^2 (indicator of the additional variance explained compared to the previous model).

The mediating effect of diabetes-related distress on the relationship between EI and the patients’ self-management behaviors was tested by means of Baron and Kenny’s model of mediation (Baron & Kenny, 1986). First, the following mediational conditions were tested: (i) EI is significantly related to diabetes self-management behaviors; (ii) EI is significantly related to diabetes-related distress; (iii) diabetes-related distress is significantly related to diabetes self-management behaviors. After verification of these conditions, the mediational hypothesis was verified, i.e.: (iv) the relationship between EI and self-management behaviors is significantly reduced when diabetes-related distress is included in the model. The significance of this difference was tested using the Sobel test (Baron & Kenny, 1986). All analyses were performed with and without the participants with gestational diabetes, yielding similar results. Only the analyses conducted on the full sample are presented in the following section.

3.2 Results

A very high proportion of the sample reported affective issues. Half the sample showed a significant level of diabetes-related distress (i.e., scored above the cut-off of 3) and 65.9%

had high levels of anxiety symptoms. With regard to depressive symptoms, 37.4% of the respondents had no depression, 25.9% experienced mild depression, 27.3% moderate and 9.4% severe depression. Distress, anxiety and depression did not differ between participants with different types of diabetes. However, the proportions of distressed ($Chi^2(1) = 5.234$, $p \leq .05$) and depressed ($Chi^2(3) = 8.071$, $p \leq .05$) participants were significantly higher among those who had reported diabetes complications.

3.2.1 Prediction of self-management behaviors

When considered separately (Table 19), depression (model 2: $R^2 = 0.093$, $F(3,140) = 4.812$, $p \leq 0.005$), anxiety (model 3: $R^2 = 0.166$, $F(3,140) = 9.301$, $p \leq 0.001$) and distress (model 4: $R^2 = 0.230$, $F(3,140) = 13.908$, $p \leq 0.001$) all significantly predicted the diabetes self-management behaviors. However, diabetes-related distress was the strongest predictor and depression the weakest. When added to depression, anxiety predicted 8.1% additional variance (ΔR^2 for model 5 versus model 2); whereas diabetes-related distress, if added to depression and anxiety, predicted 9.6% additional variance (ΔR^2 for model 6 versus model 5). This finding underlines the important shared variance between depression, anxiety and distress in predicting diabetes self-management behaviors. The fact that diabetes-related distress was the strongest predictor of self-management activities conforms findings of other studies.

Table 19: Regression models to predict diabetes self-management behaviors

	R^2	R^2_{adj}	F	Residual variance	Standardized coefficient (B)
Model 1	.027	.014	1.982	27.565	
Type of diabetes (0-1)					.158
Treatment (0-1)					-.011
Model 2	.093	.074	4.812**	25.691	
Type of diabetes					.217*
Treatment					.037
Depression					-.261**
Model 3	.166	.148	9.301***	23.630	
Type of diabetes					.221*
Treatment					.046
Anxiety					-.376***
Model 4	.230	.213	13.908***	21.833	
Type of diabetes					.195*
Treatment					.012
Distress					-.451***
Model 5	.167	.143	6.974***	23.603	
Type of diabetes					.216*
Treatment					.043
Depression					.047
Anxiety					-.411***
Model 6	.247	.220	9.075***	21.328	
Type of diabetes					.207*
Treatment					.027
Depression					.065
Anxiety					-.207
Distress					-.357***

* P-value ≤ .05; ** P-value ≤ .01; *** P-value ≤ .001

3.2.2 Mediating effect of diabetes-related distress

A test of the conditions of the Baron and Kenny model prior to testing the mediating impact of distress on the relationship between EI and diabetes self-management activities indicated that: (i) emotional intelligence was significantly associated with self-management behaviors (B = 0.391, $p \leq 0.001$, $R^2 = 0.168$); (ii) emotional intelligence was significantly related to diabetes-related distress (B = -0.468, $p \leq 0.001$, $R^2 = 0.213$); and (iii) diabetes-related distress was significantly associated with self-management behaviors (B = -0.450, $p \leq 0.001$, $R^2 = 0.219$). When diabetes-related distress was added to the model with EI as a predictor of self-management behaviors (iv), the coefficient for emotional intelligence decreased but remained significant (B = 0.230, $p \leq 0.01$, $R^2 = 0.255$), whereas diabetes-related distress was more predictive (B = -0.342, $p \leq 0.001$, $R^2 = 0.255$). The Sobel test revealed that this effect was significant (Z = 3.488, $p \leq 0.001$), thus confirming that distress partially mediated the relation between EI and self-management behaviors.

4. Discussion

The finding that half of the respondents reported diabetes-related distress confirms the results of the Diabetes Attitudes Wishes and Needs second study (DAWN2) on 8596 diabetes adults across 17 countries, finding that 44.6% reported diabetes-related distress (Nicolucci et al., 2013b). Consistent with previous studies (Fisher et al., 2010; Schmitt et al., 2015; van Bastelaar et al., 2011), diabetes-related distress appeared to be the best predictor of diabetes self-management, over and above depression and anxiety. As expected and confirming other studies (Coccaro et al., 2016; Karahan & Yalcin, 2009; Zysberg et al., 2017), EI significantly predicted diabetes self-management behaviors. Finally, as hypothesized, diabetes-related distress acted as a mediator between EI and diabetes self-management.

4.1 general discussion

This study adds to the large body of literature concerning diabetes management and emotional issues such as depression, anxiety and diabetes-related distress. Firstly, it confirms the findings from previous studies which showed that diabetes-related distress, or the feeling of being overwhelmed by the difficulty of facing extensive self-care demands and the risks of serious complications, is highly prevalent in people with diabetes (Nicolucci et al., 2013b) and impedes self-management behaviors(Franks et al., 2012). It also confirmed that diabetes-related distress is a better predictor of self-management behaviors than general symptoms of depression or anxiety (Fisher et al., 2010; Schmitt et al., 2015; van Bastelaar et al., 2011). Secondly, our study also gave a better understanding of the antecedents of diabetes-related distress by investigating the role of emotional intelligence as a possible predictor of diabetes-related distress, and thus, of diabetes self-management behaviors. Exploring this under-researched area can add to the improvement of practice, given the importance of diabetes-related distress in the control of diabetes (Franks et al., 2012) and the risk of complications of deregulated diabetes (Stratton et al., 2000). Previous studies already showed that EI is associated with better levels of HbA1c (Coccaro et al., 2016; Zysberg et al., 2017), and that EI training improves glycemic control and well-being among diabetes patients (Karahan & Yalcin, 2009; Yalcin et al., 2008). The results of our study add to this by showing that EI improves diabetes self-management behaviors by reducing diabetes-related distress. As such, these findings argue for the inclusion of EI training in the self-management education of patients with diabetes.

The need for such training is also corroborated by the finding of our first Study that people with diabetes have, on average, lower emotional intelligence levels than controls. Previous studies alexithymia and diabetes (Topsever et al., 2006) already showed that alexithymia was significantly more prevalent among people with diabetes than in the population. Our results confirm and refine these findings by showing that people with diabetes experience greater difficulties in identifying, understanding, expressing and utilizing their own emotions as well as in identifying, understanding and listening to the emotions of others. Although these differences are no longer present when people with diabetes are compared with non-diabetic persons of the same gender, age, education level and BMI, the EI of diabetes patients remains important as type 2 diabetes, which the most common type of diabetes, is strongly associated with age and BMI (Buysschaert, 2011) as well as with gender and education level.

4.2 Implications for diabetes educators

As such, the findings of the studies presented in this paper provide new suggestions for the care to be offered to diabetes patients: In addition to the self-management education that is currently provided, health professionals dealing with diabetes should also pay attention to the emotional distress that affects nearly half the patients with diabetes and that has a dramatic impact on the patients' self-management capacities and, thereby, on their glycemic control. For these patients, offering a training program that strengthens their emotional intelligence, like the one developed by Karan et Yalcin (2009), may be very beneficial, and should be more systematically integrated in care programs.

General discussion

This discussion section will first summarize the main results and their articulations to answer our four research questions. We also take the opportunity of this discussion to state some general limitations of the work undertaken in this thesis, which provide the possibility of considering new lines of researches. We would also like to present two personal reflection about the practical implications of this thesis for diabetes care in Belgium.

General discussion

Summary and integration of the main results and conclusions

Due to its prevalence and the associated risk of acute and chronic complications, diabetes has become one of the greatest health challenge for the 21st century. Its chronicity and the need for extended daily self-care activities put the patient at the center of the care process, with diabetes self-management being generally considered as a key pillar in diabetes care.

As shown by the model of Jack (2004, see figure 1, p. 4), many contextual and individual factors are likely to influence and interact with a patient's capacity to perform adequate diabetes self-management behavior. This thesis focused on two of these factors: the quality of the implementation of diabetes self-management education programs, and the patient's emotional experience of the disease and its treatment. The exploration of these two factors specifically involved four research questions: (1) How is implementation fidelity operationalized and measured in studies of diabetes self-management education? (2) How does implementation fidelity influence the effectiveness of diabetes self-management education interventions? (3) Do depressive symptoms and/or diabetes-related distress interfere with a patient's knowledge and competences to perform diabetes self-management behaviors, as expressed by the notion of health literacy? (4) Can emotional intelligence be considered as a protective factor against the development of diabetes-related distress and its consequences in terms of poorer diabetes self-management?

The first research question (*How is implementation fidelity operationalized and measured in studies of diabetes self-management education?)* was investigated through a literature review, the results of which were presented in Chapter 3. The review was carried out between January and February 2013, and aimed to determinate: (a) how implementation fidelity is conceptualized; (b) how implementation fidelity is measured; (c) how the different components of implementation fidelity are assessed; (d) what is the level of implementation fidelity in diabetes education; and (e) if there is a relationship between implementation fidelity and intervention outcomes. The literature review revealed that despite the growing theoretical interest in the concept of implementation fidelity, very few empirical studies have investigated this question with regard to diabetes education. Moreover, when implementation fidelity is addressed in diabetes education, little information is available concerning the way in which implementation fidelity was operationalized and measured, and even less concerning its impact on the effectiveness of the education program. Among the very few studies that paid attention to implementation fidelity, most assessed this concept through the providers' adherence to the program content, while disregarding the importance of adherence to the duration, frequency or coverage. We also found that implementation fidelity is assessed by program observers as well as by self-report measures completed by providers or participants, but that there is little reflection about the importance of the way implementation fidelity is operationalized. In terms of the impact of implementation fidelity, the only published study we are aware of that evaluated the impact of implementation fidelity on program effectiveness did not find a significant relationship between the two. These findings emphasized the need to use a common conceptualization of implementation fidelity and to develop a generic and easy-to-use tool in order to better investigate the link between implementation fidelity and diabetes education effectiveness.

The development and use of this tool were part of the second study of this thesis, which addressed the research question: *Does implementation fidelity influence the effectiveness of diabetes self-management education interventions?* The study, which was described in Chapter 4, was embedded within the European Diabetes Literacy study, which aimed to determine the (cost-)effectiveness of different educational approaches to diabetes education (individual in face to face, in groups, by self-help groups and IT based) controlling for various potential moderators such as the participants' level of health literacy, the organizational context in which the self-management education program is offered, and the fidelity with which the program is implemented. To investigate the impact of implementation fidelity on program effectiveness, a pre-post assessment was performed with the provider's adherence to the program protocol as the independent variable and the patients' behavioural and psychological outcomes as dependent variable (i.e., as proxys of program effectiveness). For the purpose of this study, an implementation fidelity questionnaire was developed, based on the model of Carroll et al. (see chapter 3, p. 57, 2007). For each component of the model a number of items were generated in accordance with the literature. They were then submitted to a group of diabetes educators to check for their practical relevance. The results of this study partly supported the conclusion deriving from the literature review that it is difficult to precisely estimate the level of implementation fidelity through self-report measures. Nearly one third of the providers reported a perfect adherence to the program protocol, which reduces the variability of the measure and precludes an assessment of the impact of implementation fidelity on program effectiveness. However, some effects were nevertheless found, and at odds with our expectations, these suggested that program effectiveness benefits from *adaptation*, rather than from fidelity to a program. As such, the study results highlight the necessity to focus the process of implementing diabetes self-management programs on adaptation and on the conditions under which program modifications can be made without threating its effectiveness.

The third research question was concerned with the second research axis, i.e., the emotional experience associated with diabetes, and raised the question if *depressive symptoms and/or diabetes-related distress interfere with a patient's capacity to use his or her knowledge and competences to perform diabetes self-management behaviors.* Indeed, the negative impact of depression and diabetes-related distress has been well documented in the literature, but the process in which this depression or distress interferes with diabetes self-care activities is not well known. The study presented in Chapter 6 aimed to answer that question by testing the assumption that diabetes distress or depression moderates the relation between health literacy, self-efficacy and diabetes self-care behaviors. The results of the study indicate distress or depression do not influence the outcomes of diabetes self-management education directly, but prevent the patient to use his or her knowledge and competencies to self-manage the disease. These results support the idea that in case of distress or depressive symptoms, the patient is less able to use the cognitive resources to cope with the burdens of the treatment. Health professionals should pay more attention to the signs of depression and distress in order to orient the patient towards a more adapted care.

The fourth research question was whether *emotional intelligence can be considered as a protective factor against diabetes-related distress and its consequence in terms of poorer diabetes self-management.* Emotional intelligence has been identified in the literature as a protective factor for the development of depression and anxiety in the general population. More recently, this concept is also beginning to be investigated in the field of diabetes. The two studies that are described in Chapter 7 found an association between higher level of emotional intelligence and better diabetes management, and via a mediation analysis we could document an effect of emotional intelligence on diabetes self-management through the reduction of diabetes-related distress. These results offer new insights for the development of psychological interventions that would focus on emotional intelligence development.

Limitations, elements of reflection and avenues for future research

While the studies outlined in the previous section add to the literature on diabetes self-management education, they are not without some limitations. The limitations of each study were mentioned and discussed in each chapter, but to obtain an overview we will detail them in the following paragraphs and discuss how they can be addressed in future research.

Other factors that can impact on diabetes self-management

One of the limitations of this thesis is that it focused only on some of the factors that can impact on diabetes self-management. As shown in the model of Jack (2004, see p. 4), the factors that are assumed to influence the quality and effectiveness if diabetes self-management are manifold, but out of these only the fidelity of the implementation of diabetes education interventions and the patients' emotional experience of diabetes were considered in this thesis. This does not mean, however, that other factors have been ignored. The Diabetes Literacy project, in which the first two research questions were embedded, looked at diabetes self-management education in a more comprehensive way and also investigated how the **delivery modes** of the self-management education (individual, in groups, self-help groups, IT based, or mixed), and the patients' **health**

literacy impact on diabetes self-management behaviors. With regard to the first, Peer et al.(Submitted), based on data of the 10 countries involved in the Diabetes Literacy project consortium, showed that diabetes education interventions were effective in improving participants' diabetes self-management behaviors regardless of the delivery mode. This suggests that providers have the opportunity to select the best way to deliver the education according to the participants' needs and the organizational context. Concerning the influence of health literacy, Vandenbosch et al. (Submitted) showed that a patient's higher level of health literacy is associated with better diabetes self-management behaviors, but that participation in a diabetes education intervention leads to better self-management behaviors regardless of the patient's health literacy level. These results support that diabetes education interventions are effective in improving patients' self-management behaviors. Consequently, beyond developing new educating interventions, the current challenge is to increase access to existing diabetes education.

Fidelity vs adaptation?

A second limitation of our work is the fact that in our literature review we paid little attention to the notion of adaptation (chapter 3). Indeed, whereas several studies have demonstrated the positive impact of a high level of implementation fidelity on the effectiveness of educational interventions (eg: Resnick, Neale, & Rosenheck, 2003; Thomas, Baker, Thomas, & Lorenzetti, 2015), other authors have argued for a more flexible approach to implementation with a view to better respond to participants' specific needs (eg: Card, Solomon, & Cunningham, 2011). The literature on implementation fidelity (Blakely et al., 1987; Boruch & Gomez, 1977; Calsyn, Tornatzky, & Dittmar, 1977) posits that adaptations, when they are not initially expected in the program, interfere with program effectiveness. This is also the case for the model of Carroll et al. (2007), which we used to determine the dimensions of implementation fidelity for our study. More specifically, the moderators that are presented in this model reflect the vision that certain external factors (such as the participants' engagement in the program or the organizational context) as well as internal factors (such as the complexity of the intervention or the presence of facilitating strategies) are likely to prevent or facilitate the intervention delivery, and that adaptations are potentially detrimental. However, the idea that fidelity and adaptation do not constitute the opposite pole of a same dimension is increasingly gaining ground. In the most recent literature, several authors have reconsidered this issue and proposed alternatives to reduce the tensions between the supporters of fidelity and those of adaptation. One solution that has been considered in the literature consists of identifying the principal components of the intervention (Backer, 2002), i.e., the elements that are necessary to reach the expected results of the intervention. Kemp (2016) referred to this option by making an analogy to the "*Cookery Book Basic Plain Cake with Variations"* recipe to represent the articulation between fidelity and adaptation: Some ingredients (like sugar), methods (beating the eggs), and equipment (oven) are crucial to bake a cake, but other components can be adapted (adding some vanilla) to better suit to one's taste, while certain components cannot be changed without altering the final preparation (reducing the cooking time). According to Kemp (2016), program developers should initially pay attention to the principal components (ingredients, methods and equipment), as well as to the possible variations, for the purpose of delivering the intervention with sufficient fidelity and but with room for adaptations to better suit the recipients' needs. Other authors have tried to classify the adaptations according to their nature. For example, Stirman et al. (2013) developed a framework to identify who performed the adaptation, what was adapted, at which level of implementation and what the nature was of this adaptation. In another publication (Stirman et al., 2015), these authors introduced the distinction between *fidelity consistent adaptation* and *fidelity inconsistent adaptation* : Consistent adaptations do not alter the delivery of the main components of the intervention, whereas inconsistent adaptations reduce or prevent the delivery of these components. Finally, some researchers consider that fidelity and adaptation can be reconciled by involving the providers in the development of the intervention protocol (Bopp et al., 2013; van Daele, van Audenhove, Hermans, van den Bergh, & van den Broucke, 2014). Van Daele et al. (2014) introduced the term "*empowerment fidelity*" to designate a hybrid approach in which providers are consulted in the definition and the evaluation of the implementation of the principal components.

As most of these views have been published recently, we have not considered them in our literature search and did not include the terms "adaptation", "modification" or "variation" in our search strategy. As such, there was a low probability to find studies reporting the impact of fidelity consistent program variations on program effectiveness. However, despite the fact of not paying specific attention to adaptation in our literature review, we have integrated comprehensive questions about adaptations in the questionnaire that we developed to assess implementation fidelity (in chapter 4). Future studies can take up this issue more explicitly by making a clearer distinction between fidelity consistent adaptation and fidelity inconsistent adaptation of diabetes self-management education programs.

Assessment of implementation fidelity

Three criticisms could be addressed concerning the measure of implementation fidelity presented in Chapter 4. The first one concerns the **generic** nature of the developed questionnaire. As the study demonstrated, the majority of respondents reported a very high level of implementation fidelity. As such, it could be argued that a generic self-report questionnaire, which can be used for any sort of intervention, does not sufficiently capture the specific components of implementation fidelity for the programs investigated. On the other hand, the decision to use a generic tool can be justified on account of the fact that very few studies have thus far investigated the issue of implementation fidelity upon delivering a diabetes self-management education program (Schinckus et al., 2014). Moreover, the use of a generic questionnaire also allowed a comparison with other types of programs, as in addition to its use in diabetes education, the questionnaire was also applied to a smoking prevention intervention (Remy, 2016) and as an interview guide to assess the implementation of cardiovascular education interventions in France (Magaux, 2015). In both these studies, a positive attitude of training providers toward implementation fidelity was noticed, which suggests that the tool can stimulate a reflection among the providers about the quality of delivering the intervention.

The second limitation we can underline concerning this measure of implementation fidelity is that it does not take account of the **interventions' characteristics** that must impact on interventions' effectiveness. Data analyzed in chapter 4 were related to 16 different interventions. As such, we cannot fully ascertain if differences in terms of interventions' effectiveness can be attributed to provider's adaptations or to specific interventions' characteristics. Without controlling for these intervention's characteristics, this questionnaire should rather be used when assessing intervention effectiveness related to several providers who deliver the same intervention, or, at best, with providers who deliver the same intervention several times.

The third issue related to the assessment of implementation fidelity is the **self-report** nature of the measure used. In this sense, the low number of providers in the study in Chapter 4 who reported having adapted the programs, and especially the large proportion of "positive" adaptations reported, suggests a social desirability bias. In addition, it is also possible that some of the providers did not know the exact content of the original program protocol. To prevent this kind of bias, providers were asked to carefully read the manual that accompanies the questionnaire (see Appendix B), which specifies the conditions under which the tool can be employed. These include: (a) a specific intervention should be identified; (b) a protocol specifying the content, duration, frequency and coverage of the intervention must be available; and (c) the respondent must have sufficient knowledge about the protocol and the actual delivery of the intervention. However, as the reading of this manual was not systematically controlled in each country that participated in the European project, it is possible that some providers have responded without meeting all these conditions. This would partially explain the low proportion of adaptations.

Future research should therefore make sure that when implementation fidelity is studied, the study protocol specifying the conditions for the investigation should be carefully followed so as to minimize a social desirability bias. In other words, the fidelity of the way in which the implementation fidelity study is carried out should also be maximized. If that can be accomplished, the questionnaire assessing the implementation fidelity of educational programs can provide useful information about any changes that were made to the program upon its implementation and link this to the program effectiveness, while also stimulating the reflection about which adaptations were made and how they impact on the program effects in a positive or negative way.

Measurement of self-management behaviors

Another limitation of this work concerns the absence of an "objective" indicator of diabetes self-management. In the three empirical studies reported in this thesis, self-management activities were assessed by means of the Summary of Diabetes Self-Care Questionnaire (chapter 4) or the Diabetes Self-Management Questionnaire (Chapters 6 and 7). These measures are self-report measures and therefore subject to self-report bias (memory, social desirability). A physiological indicator, such as the glycosylated hemoglobin (HbA1c) could have completed these self-report measures. That being said, the use of HbA1c is not without limitations either. Indeed, as this measure provides the mean of glycaemia for the last three months, it does not consider the intensity of glycaemia variability. As such, a patient who experienced intense episodes of hyper- and hypoglycemia can have the same level of HbA1c as one who had a better glycemic control. In addition, the use of physiological indicators of diabetes control creates a number of practical challenges. This is also the main reason why they were not used in the studies reported here: For the two studies presented in Chapters 6 and 7, data were mainly collected through an online version of a questionnaire made available via diabetes forums, which made it impossible to relate these data to medical records. While it would have been possible to ask participants to indicate their last result of HbA1c, this would also have been subject to self-report bias. Due to these practical reasons, and considering the good correlations previously reported between diabetes self-management questionnaires and the actual level of HbA1c (Schmitt et al., 2013), it was decided to not include this physiological indicator in the current studies. Further research could verify the results emerging from the present studies by adding a measure of HbA1c or by using the data from continuously glucose monitoring that is increasingly widespread among the patients.

Diabetes-related distress and self-management behaviors: direction and linearity of the link

The two studies that were undertaken to investigate the moderating impact (on the effect of health literacy, chapter 6) and the mediating impact (on the effect of emotional intelligence, chapter 7) of diabetes-related distress on self-management behaviors assumed a direction of causality that could not actually be confirmed through cross-sectional studies. While it was assumed that distress or depression had an impact on self-management behavior, it is also possible that poor self-management behavior leads to higher level of distress, or that an external factor (e.g., negative life events) impacts on both self-management activities and the patient’s sense of well-being. Furthermore, as outlined in Chapter 5, research seems to indicate that there is a bidirectional link between diabetes and depressive symptoms (Bădescu et al., 2016). As this is difficult to establish, there is a need for longitudinal studies that allow to investigate these directions of causality more in depth.

Apart from the direction of the relationship, one can also consider the linearity assumed for this association. The literature shows that diabetes-related distress is associated to poorer self-management and glycemic control and to higher risk of complications. However, one could also suspect that a lack of diabetes-related concern can interfere with self-care activities. The Diabetes Distress Scale that was used to assess diabetes-related distress in chapters 6 and 7 was not designed to capture the absence of diabetes-related concern. It could be interesting to expand the range of this and to consider diabetes-related distress and lack of concern as two ends of one continuum. In that case, the relation between diabetes concern/distress and diabetes self-management could be conceived of as curvilinear, whereby it could be hypothesized that both a lack of concern *and* an excess of distress would be associated to poorer self-management, whereas a moderate level of diabetes concerns would be linked to better self-management and glycemic control.

Different kind of Diabetes-related distress

While diabetes-related distress affects all diabetes patients, regardless of their diabetes type, it is possible that the source of this distress can vary depending on the type of diabetes. People suffering from type 1 diabetes have to self-control their blood glucose level and perform insulin injections several times per day from the very onset of the disease. As the disease can occur at an early age, children and (to an even larger extent) adolescents with diabetes therefore often have to deal with the feeling of “being different from others”. This increases the risk of denying the disease and its treatment, with serious effects in terms of poor self-management behavior, poor glycemic control and higher risk of complications. Among type 2 diabetes patients, on the other hand, the development of a complication (e.g., retinopathy, nephropathy) sometimes occurs before the discovery of the diabetes, and this can certainly be a source of distress. Newly diagnosed people with diabetes who display poor health habits must adjust their lifestyle dramatically. This can lead to treatment-related distress. For gestational diabetes, the distress also concerns insecurities about the development of the child and the risks of complications at childbirth. Further qualitative research should investigate whether and how the source of diabetes-related distress varies depending on the type of diabetes and the patient’s characteristics (gender, age, familial context, etc.). This will allow to customize psychological assistance to the patient’s specific concerns. Furthermore, diabetes-related distress can also concern the patient’s relatives. Whether they are parents, children or partners, close relatives may feel powerlessness, overwhelmed, or guilty toward the diabetes. How distress from the relatives impacts on a patient’s capacity to self-manage the disease is another question that is worthy of further investigation.

Measurement of emotional intelligence

As a final methodological consideration, one should also be aware of the limitations of the short TEIQue that was used to assess emotional intelligence in Chapter 7 on account of the heterogeneity of the items that make up this scale. The short version of the TEIQue is based on the full version of this tool, which is comprised of 15 dimensions. Some of these, like the *well-being* dimension, can be considered as a consequence of good emotions management (Matthews, Zeidner, & Roberts, 2004) or as a personality trait such as extraversion (Matthews, Zeidner, & Roberts, 2012). To overcome this limitation, it was originally considered to use the Profile of Emotional Competences (PEC) to assess emotional competences of diabetes patients. The PEC (Brasseur et al., 2013b) measures the level of emotional intelligence in terms of specific abilities to identify, understand, express, use and regulate one’s emotion (intrapersonal dimension) and others’ emotions (interpersonal dimension). The respondent is asked to what extent 50 propositions reflect his/her usual reaction on a scale ranging from 1 (*it does not describe me at all or I never respond like this*) to 5 (it *describes me very well or I experience this particular response* *very often*). Based on this questionnaire, a short version composed of 20 propositions was developed and validated (S-PEQ, Mikolajczak, Brasseur, & Fantini-Hauwel, 2014). For the study presented in Chapter 7, a first data collection was performed with the S-PEC to assess emotional intelligence, but for reasons that still have to be explored, a lack of internal consistency of both intra- and inter-personal dimensions of the S-PEC made it impossible to use these data to test our hypotheses on this sample. Consequently, it was necessary to perform a second data collection using the S-TEIQue as a measure of emotional intelligence. Further analyses are planned to better understand why the dimensions of the S-PEC showed weak internal consistency coefficients.

Practical implications for diabetes care in Belgium

This section will raise three points from a more personal reflection that has progressively emerged throughout our work within the field.

The delivery of diabetes education in Belgium, a structured and systematic process?

A fundamental issue that became apparent throughout the research project presented in this thesis concerns the structure of diabetes self-management education in Belgium. The question arises if there is in fact a well-structured diabetes education? This question became apparent when we tried to investigate the implementation fidelity of Belgian diabetes education interventions. It is indeed difficult to assess provider's adherence to a protocol that does not exist or is not used. Some structures, as the Scientific Society for General Practice, developed recommendations for diabetes care (Bastiaens et al., 2015), but they only addressed diabetes education in a general manner for general practitioners. Several of the diabetes nurses who operate within the framework of the Diabetes Convention or the Diabetes Care Trajectory and who have been interviewed about this issue within this research project reported that they developed their own education intervention protocol, but never communicated about their protocol outside their center. A diabetes nurse from the care trajectory reported that only a checklist was available to guide the educators with the different topics that should be raised during the education sessions. Several diabetes nurses reported feeling powerless when they wanted to provide diabetes education.

In this context, one can ask the question if a structured and shared protocol is necessary for diabetes education in Belgium? One the one hand, the absence of structured education should not be considered as an indicator of a lack of quality of the education that is provided within the Diabetes Convention or Care Trajectory, as diabetes education trainings for voluntary nurses, but also for dieticians, podiatrists and physiotherapists, provide substantial knowledge about the physiopathology, treatment methods and educational skills to help the patient to manage the disease and treatment. It is also recommended to use the specific knowledge, resources and skills of the patient and addressing the topics in order of priority. The “security goals”[1] must be prioritized to reduce the risk of complications. On the other hand, a more structured and shared protocol could provide more guidance in ensuring this education process and reduce the necessity to “reinvent the wheel”. Indeed, nearly all the Belgian diabetes nurses interviewed stated that a lack of time was the principal problem when implementing diabetes education.

More than the lack of structure in the offer of diabetes education, it is the non-systematic aspect of the education that seems to be problematic in Belgium. As pointed out in Chapter 2, to access to diabetes education in a formal system (either the Convention or the Care Trajectory), patients must follow a treatment with at least one insulin injection or with incretin mimetic. However, many type 2 diabetes do not meet these conditions at the moment of diagnostic. While these patients can access education through structures such as the Belgian Diabetes Association or several non-profit organizations, as outlined in Chapter 2, we believe that all diabetes patients should have easy access to basic education with a diabetes nurse, as it is the case in Convention and Care Trajectory.

A psychological intervention that targets emotional competences

The results of our two last studies (Chapters 6 and 7) support the previous literature about the negative impact of distress and lower level of emotional intelligence on diabetes self-care. The development of a targeted psychological assistance represents a major challenge in diabetes care. This necessity is now well recognized by the American Diabetes Association, who integrated emotional health in their care algorithm for diabetes patients. (figure 12: Powers et al., 2015).

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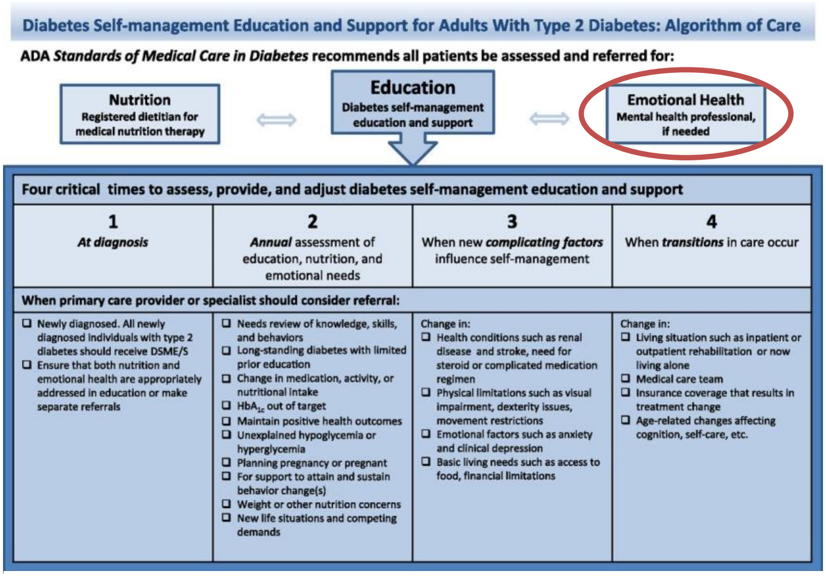
[1] For example, for a new diagnosed insiluno-dependent patient, the main security goals would be to be able to self-control blood sugar and inject insulin accordingly, and to know how to react in case of hypoglycemia



Diabetes Self-management Education and Support for Adults With Type 2 Diabetes: Algorithm of Care

ADA *Standards of Medical Care in Diabetes* recommends all patients be assessed and referred for:

Nutrition
Registered dietitian for medical nutrition therapy

Education
Diabetes self-management education and support

Emotional Health
Mental health professional, if needed

Four critical times to assess, provide, and adjust diabetes self-management education and support			
1 ***At diagnosis***	**2** ***Annual*** assessment of education, nutrition, and emotional needs	**3** When new ***complicating factors*** influence self-management	**4** When ***transitions*** in care occur
When primary care provider or specialist should consider referral:			
☐ Newly diagnosed. All newly diagnosed individuals with type 2 diabetes should receive DSME/S ☐ Ensure that both nutrition and emotional health are appropriately addressed in education or make separate referrals	☐ Needs review of knowledge, skills, and behaviors ☐ Long-standing diabetes with limited prior education ☐ Change in medication, activity, or nutritional intake ☐ HbA_{1c} out of target ☐ Maintain positive health outcomes ☐ Unexplained hypoglycemia or hyperglycemia ☐ Planning pregnancy or pregnant ☐ For support to attain and sustain behavior change(s) ☐ Weight or other nutrition concerns ☐ New life situations and competing demands	Change in: ☐ Health conditions such as renal disease and stroke, need for steroid or complicated medication regimen ☐ Physical limitations such as visual impairment, dexterity issues, movement restrictions ☐ Emotional factors such as anxiety and clinical depression ☐ Basic living needs such as access to food, financial limitations	Change in: ☐ Living situation such as inpatient or outpatient rehabilitation or now living alone ☐ Medical care team ☐ Insurance coverage that results in treatment change ☐ Age-related changes affecting cognition, self-care, etc.

Figure 12 : Algorithm of care developed by the ADA
(Powers et al., 2015)

In Belgium, some diabetes convention centers are assisted by a psychologist, but he/she mainly intervenes in extreme cases (like anorexia or after bariatric surgery). Furthermore, diabetes nurses who are in charge of patient education report to be more and more overloaded due to the increasing number of diabetes patients. As a result, emotional issues are not prioritized during education sessions.

On the other hand, an emotional intelligence program delivered in Turkey (Yalcin et al., 2008) has demonstrated its effectiveness in improving type 2 diabetes patients well-being and glycemic control (see chapter 5, p. 115). In Belgium, a similar intervention has been developed by Mikolajczak, Nelis, Quoidbach et Kotsou, with a view to improve five emotional competences of the participants (identify, understand, express, use and regulate the emotions). Several controlled trials with waiting list or active control groups have been performed to validate the intervention, with 6 months and one year of follow-ups, showing that this training is effective in improving emotional competences and psychological, social and physical well-being (Kotsou, Nelis, Grégoire, & Mikolajczak, 2011; Nelis et al., 2011). More specifically, compared to the control group, the participants who attended the training experienced a significant improvement of their emotional competences, happiness, social relationships and employability, as well as a reduction of their somatic complaints and mental problems.

These findings indicate that there is both a need and a possibility to adapt existing education programs for diabetes patients who suffer from distress or depressive symptoms and to include a component focusing on emotional competence training. Further research should be conducted to determine the desirability and the effectiveness of such a training for patients with diabetes. As type 2 diabetes is the more prevalent form of diabetes and is strongly associated to older age, we should be especially vigilant with eldest sensitivity to the question of emotions. Forthcoming investigations should investigate whether some vulnerable populations (e.g. older and/or less educated people) may not benefit as much as other non-vulnerable populations from an emotional intelligence training.

Toward an individualized and extended model of diabetes education

The results that emerged from this thesis have shed light on two important issues: the importance of adaptation in self-management education for patients with diabetes, and the role of emotional health in diabetes self-management. This section will further investigate these two points and introduce the reflection for an individualized and extended diabetes education.

The question of "fidelity vs adaptation" refers to an ongoing debate in patient education that is mainly ideological: Should health education be standardized according to well-defined standards to ensure that all patients receive all the necessary information and acquire the necessary competences, or should it be individualized and tailored to the patients' specific needs, resources, wishes and objectives? Our results presented in chapter 4 tend to support the view that adaptations are helpful and thus are more in the line of individual tailoring of education. However, both the structuration and the individualization of diabetes self-management education are standards stated by the American Diabetes Association and the American Association of Diabetes Educators (see standards 6 and 7, table 6, p.46). Educating patients with diabetes thus involves negotiating a balance between the standardized security goals that are vital to improve glycemic control and avoid the risks of diabetes complications, and the patients' individual goals, which are essential to motive the patient and integrate diabetes self-management into his or her patient's own life project. In this regard, the individualization of the diabetes self-management education is more than necessary for an empowerment-oriented view of patient education.

Individualization of diabetes education requires considering the patient in a holistic way, which means not only paying attention to his or her knowledge, understanding and competences, but also to his/her emotions. Throughout this thesis, we have referred to diabetes self-management education as the process through which the knowledge and competences are acquired that are needed to perform adequate self-management behavior. This definition mainly focuses on cognitive and behavioral aspects and corresponds to a vision of patient education as a linear transfer of content. Although this view does not formally exclude emotions, they are generally not part of diabetes self-management education interventions. However, an alternative conceptualization of education is proposed in the "allosteric learning model" (Giordan, Jacquemet, & Golay, 1999). According to this model, the learner's emotions, beliefs, self-esteem, reasoning, etc. are all legitimate components that can be targeted in the education. Applied to patient education, this model considers the patient as a whole with his/her knowledge (cognitive dimension), emotions and intention (affective dimension), reasoning and cognitive distortions (infra-cognitive dimension), self-perception and self-esteem (metacognition dimension).

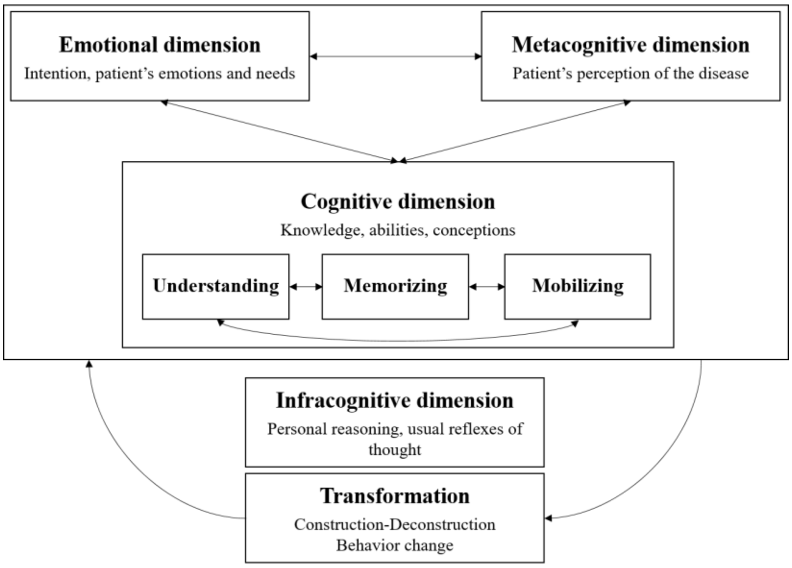


Figure 13: Patient's education in four dimensions (Golay, Lagger, & Giordan, 2007)

Adequate self-management behaviors can be facilitated if the patient can express and understand his or her own needs and emotions, give meaning to the treatment, identify his/her own dysfunctional reasoning, and confront his/her expertise to new knowledge to better understand the disease (Golay, Lagger, & Giordan, 2007). The term “allosteric” refers to the systemic functioning of this model: what is modified in one component can also affect other components of this system. When conceptualized as such, diabetes self-management education cannot be separated from patient’s emotions. It is important to note that the emotional dimension does not only focus on serious emotional difficulties, but also on positive emotions, such as the patient’s daily pleasure and self-confidence in performing adequate self-care behaviors. The metacognitive dimension also places diabetes self-management within the patient’s life course and considers how the patient makes sense of the disease and its treatment.

A high-quality diabetes self-management education should therefore be individualized and consider the patient in respect of all aspects of his or her personal dimensions. It should be included in the general care process and not separated from the patient’s own experience of the disease. On the other hand, education providers should also be aware of the current diabetes education standards.

Lastly, replacing the idea that diabetes education is only a matter of transferring knowledge and abilities to a more holistic approach that considers the patient as a person also highlights the potential role of psychologists in the multidisciplinary diabetes team. Unlike the widespread cliché that psychologists are needed to help patients who have “psychological problems”, the presence of a psychologist in a diabetes team is not limited to providing psychological assistance, but can also be useful to understand and act with the patient on multiple intra- and interpersonal dimensions.

Conclusion

Today, diabetes self-management is considered as a key pillar in diabetes care. To avoid the risk of serious complications, diabetes patients have to manage their blood glucose daily through a series of medical and lifestyle behaviors. Understanding how better improve and support these behaviors by diabetes education, and which are the contextual, social and individual determinants of these behaviors is of utmost importance. This thesis was initially part of the Diabetes Literacy project, which investigated individual (health literacy), contextual (organization of health services) and educational (delivery mode) factors that can impact on patients' self-management of diabetes.

One of these factors, the implementation fidelity of diabetes education interventions, was specifically examined in this thesis. The level of implementation fidelity was highly estimated by most of the providers leading to a lack of variability for this measure. Nevertheless, some significant results were found in favor of intervention adaptations rather than strict providers' adherence to the intervention protocol. These results support the necessity of investigating the conditions under which program modifications can be made without threating its effectiveness. Concerning the impact of the delivery mode and the participants' level of health literacy, it appeared that diabetes education was effective in improving self-management behaviors regardless of these two factors. This suggests that other factors may need to be considered to explain differences in effectiveness of diabetes self-management education. The presence of a regular and sustained diabetes self-management support, the involvement of patient's relatives in the education, the presence of a psychological assistance, … are other factors that can be investigated to better understand the conditions for effective diabetes education.

The second part of this thesis targeted one of these alternative factors, the emotional experiences of the disease, like depression, anxiety and diabetes-related distress, which can also impact on diabetes self-management. The results from this second research axis underlined that diabetes patients suffering from depressive symptoms or diabetes-related distress were less able to use their health literacy to perform their requested self-care activities. Emotional intelligence could act as a protective factor against the development of diabetes-related distress and its detrimental effect on self-management.

The results presented throughout this thesis sustain the major importance of diabetes education to support self-management behaviors to achieve good glucose control and avoid the risk of serious complications. From the Diabetes Literacy results, we can conclude that most existing diabetes education interventions are effective in improving self-management behaviors. However, patients experiencing difficult emotions, who represent a significant part of diabetes patients, seem to benefit less from this education. The two main current challenges highlighted in this thesis are then to increase the access to existing diabetes education and to offer a more systematic psychological assistance to patients who suffer from disease-related distress.

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Appendices

Appendix A – The implementation fidelity questionnaire

Appendix B – The manual for the implementation fidelity questionnaire

Appendix A. The implementation fidelity questionnaire

Questionnaire

Assessment of the adherence to and adaptation of a health education intervention

Diabetes Module

Dear Sir/Madam,

Thank you for taking the time to complete this survey by Diabetes Literacy. Your participation is very important to improve the understanding of how diabetes self-management education programs are delivered to the patients.

To help you answer the several questions, a manual resuming all the necessary information is available.

This survey should take about 30 minutes of your time. Your answer will be completely kept anonymous. All survey results will be communicated after data collection and analysis.

If you have any questions about the survey, please contact us at louise.schinckus@uclouvain.be

1. General information

Please provide the requested information regarding the intervention and your identity.

Name of the program English name Original name	
Author/publisher (if known)	
Is there a website available for this program?	☐ Yes: ______ ☐ No
Have you already answered to the wiki of the Global Diabetes Survey? *If yes, please go to the second part of this questionnaire (p. 6)*	☐ Yes ☐ No
Name of the person completing this questionnaire	
E-mail address	
Date	…/…/…

2. Adherence & adaptations

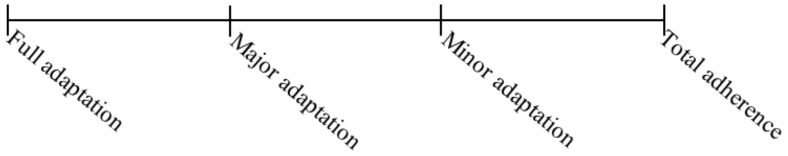
The questions below refer to the way the intervention is or has been implemented as planned. Please provide the requested information regarding the intervention by ticking the appropriate box(es) for each question. Please also provide additional information when requested.

2.1. Content

Was each of the intervention component implemented as planned?

Were changes made to the content of the intervention?	☐ Yes, changes were made ☐ No, no changes were made ☐ Does not apply

Please, indicate to what extent the content of the intervention was adapted or the original content was adhered to by putting a cross on the scale below:



If some changes were made, please complete the information below for each change during the reporting period:

Date of Change: …/…/…

Primary reason: ☐ Recipient Issues ☐ Program Provider Issues ☐ Community Issues – broader context

☐ Setting Issues – narrow context ☐ Sustainability Issues

Please describe the changes that were made to the content of the intervention and your reasons for making them. For each change made, please detail (1) what the program content was like originally, (2) what it is like now, and (3) why it was changed.

(1) What was the program content like originally? …

(2) What is it like now? …

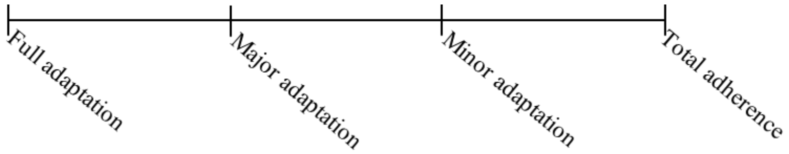
(3) Why was it changed? …

2.2. Duration

Where the intervention components implemented for as long as planned?

Were any changes made to the duration of the intervention?	☐ Yes, changes were made ☐ No, no changes were made ☐ Does not apply

Please, indicate to what extent the duration of the intervention was adapted or the duration that was originally foreseen was maintained by putting a cross on the scale below:



If some changes were made, please complete the information below for each change during the reporting period:

Date of Change: …/…/…

Primary reason: ☐ Recipient Issues ☐ Program Provider Issues ☐ Community Issues – broader context
☐ Setting Issues – narrow context ☐ Sustainability Issues

Please describe the changes that were made to the duration of the intervention and your reasons for making them. For each change made, please detail (1) what the program duration was like originally, (2) what it is like now, and (3) why it was changed.

(1) What was the program duration like originally? …

(2) What is it like now? …

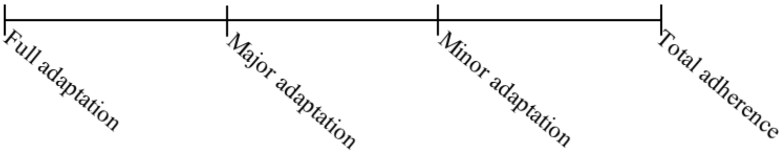
(3) Why was it changed? …

2.3. Frequency

Where the intervention components implemented as often as planned?

Were any changes made to the frequency with which intervention components were implemented?	☐ Yes, changes were made ☐ No, no changes were made ☐ Does not apply

Please, indicate to what extent the frequency with which intervention components were implemented was adapted or the frequency that was originally foreseen was maintained by putting a cross on the scale below:



If some changes were made, please complete the information below for each change during the reporting period:

Date of Change: …/…/…

Primary reason: ☐ Recipient Issues ☐ Program Provider Issues ☐ Community Issues – broader context
☐ Setting Issues – narrow context ☐ Sustainability Issues

Please describe the changes that were made to the frequency of the intervention and your reasons for making them. For each change made, please detail (1) what the program frequency was like originally, (2) what it is like now, and (3) why it was changed.

(1) What was the program frequency like originally? ...

(2) What is it like now? ...

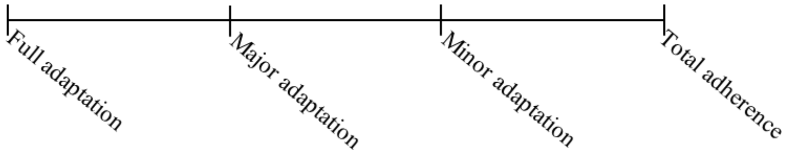
(3) Why was it changed…

2.4. Coverage

What proportion of the target group participated in the intervention?

Were any changes made to the expected number of participants?	☐ Yes, changes were made ☐ No, no changes were made ☐ Does not apply

Please, indicate to what extent the coverage foreseen for the intervention was adapted or maintained by putting a cross on the scale below:



If some changes were made, please complete the information below for each change during the reporting period:

Date of Change: …/…/…

Primary reason: ☐ Recipient Issues ☐ Program Provider Issues ☐ Community Issues – broader context ☐ Setting Issues – narrow context ☐ Sustainability Issues

Please describe the changes that were made with regard to the coverage of the intervention and your reasons for making them. For each change made, please detail (1) what the program coverage was like originally, (2) what it is like now, and (3) why it was changed.

(1) What was the program coverage like originally? …

(2) What is it like now? …

(3) Why was it changed? …

3. Potential moderators

The questions below refer to factors that may have influenced the way in which the intervention is or has been delivered. Please provide the requested information by indicating the degree with which you agree or disagree with each statement. If the statement is not relevant for your intervention, please choose the “does not apply” category.

3.1. Moderators related to the recipients

Please, indicate the extent to which you agree or disagree with the following statements concerning participants’ satisfaction and engagement

The participants were engaged in small group activities	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants were satisfied with the intervention content	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants thought that the intervention met their needs	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants were engaged in the discussions	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants took a proactive role as learners	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants were satisfied with the way in which the intervention was delivered	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants demonstrated autonomy	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants used the available resources	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants recognized the intervention’s benefits	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants	☐	☐	☐	☐	☐	☐

carried out the essential activities	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Does not apply
The participants were involved beyond what was expected	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply

3.2. Intervention complexity

Please, indicate to what extent you agree or disagree with the following statements concerning the intervention

The provider was familiar with the content of the intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants had to complete homework for the intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
There were many components to deliver during each session	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The description of the intervention was clear	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants were used to this kind of intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider had to deliver this intervention several times	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The description of the intervention was sufficiently detailed	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The participants had many difficult goals to reach	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider had to work with other professionals to deliver this intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The intervention required many efforts from the participants' side	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply

3.3. Facilitating strategies for the implementation

What strategies were used to support implementation? How were they perceived by staff involved in the project?

The provider participated in a training to deliver this intervention	☐ Yes* ☐ No
**If yes*	This training was **clear**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree This training was **useful**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree This training was **sufficient**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
An implementation protocol was available to deliver this intervention	☐ Yes* ☐ No
**If yes*	This protocol was **clear**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree This protocol was **useful**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree This protocol was **sufficient**: ☐ Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly agree
A monitoring system was in place to assess the intervention delivery	☐ Yes* ☐ No
***The implementation of the intervention was assessed trough** *Select all that apply*	☐ An external observer during the session ☐ A recording of the session (audio/video) ☐ A questionnaire completed by the provider ☐ An interview with the provider ☐ A questionnaire completed by the participants ☐ Interviews with the participants

***The frequency of this assessment was**	☐ Once ☐ Several times ☐ During/after each session
The provider received feedback concerning the way he/she delivered the intervention	☐ Yes* ☐ No

***If yes*	This feedback was **clear**:				
	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
	This feedback was **useful**:				
	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree
	This feedback was **detailed**:				
	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree

3.4. Moderators related to the provider (quality of delivery)

Please, indicate the extent to which you agree or disagree with the following statements concerning the provider's knowledge, skills and attitudes toward the intervention

The provider thought the intervention would be very useful for the patient	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider knew the subject of the intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider used simple words	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider was highly motivated to deliver the intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider repeated essential information	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider was able to answer the participants' questions	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider	☐	☐	☐	☐	☐	☐

encouraged the participants to reach their goals	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Does not apply
The provider lacked experience	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider asked open questions	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider had good knowledge about diabetes and its treatment	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider listened actively to the participants	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The provider was skeptical about the intervention outcomes	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply

3.5. Recruitment

What recruitment procedures were used to attract individuals to the intervention?

Please specify the percentage of participants for each proposal	☐ Via the provider's organization's network: ___% ☐ On the advice of a friend or relative: ___% ☐ On their own initiative: ___% ☐ Other (*Please specify :* ________________) ___% ------------- 100%

What barriers were present for maintaining the involvement of individuals?

What was the proportion of participants who dropped out before the end of the intervention?	________ %* ☐ I do not know
***What reasons were given for dropping out?** *Please rank the following options from the most relevant (1) to the less relevant (5)*	___ Reasons not related to the intervention (e.g. relocation, holidays, other commitments) ___ Reasons related to the content of the intervention (e.g. too difficult, already familiar, not adapted to the individual needs) ___ Reasons related to the provider (e.g. lack of empathy, lack of knowledge, too intrusive) ___ Reasons related to other participants (e.g. lack of interactivity, negative atmosphere) ___ Other reasons: _______

3.6. Context

What factors at political, economic, and organizational levels affected the implementation?

The intervention was supported by public policies	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The intervention received financial support	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The intervention was seen as valued and valuable by the organization where it took place	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply
The organization accepted to make internal changes to deliver this intervention	☐ Strongly disagree	☐ Disagree	☐ Neutral	☐ Agree	☐ Strongly agree	☐ Does not apply

Thank you for your participation.
Please feel free to send any comments or to ask for more information by e-mail:
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Appendix B. The manual for the implementation fidelity questionnaire

Manual

Report on provider's adherence and adaptation of health education/prevention interventions

Why assessing provider's adherence and adaptation?

Adhering to a health education/prevention program, as it was originally designed by its developers, may be challenging for the provider. Indeed, some contextual constraints as well as provider or participants' characteristics necessitate adapting the program in order to better fit the cultural and organizational needs. In addition, the participatory approach to health education promotes ownership and empowerment. However, these changes can lead to different results, sometimes less effective than expected. This lack of effectiveness may then be attributed to a weakness of the program, whereas it is due to a poor provider's adherence. This is called type III error. Assessing provider's adherence and adaptation makes it possible to avoid this misattribution.

What are the objectives of this tool?

The purpose of this tool is to assess provider's adherence to an identified health education/prevention programs, as well as any change during its implementation. This assessment will lead to a better understanding on what works or does not work in the health education/prevention program.

What health education/prevention programs?

There is no restriction concerning the topic of the program (physical, mental or social health) or the educational approach (individual, in groups, IT-based). The only required condition is the availability of a formal program protocol or guideline. The protocol or guideline have to be available in written form (i.e., protocol, guideline, website, PowerPoint presentation, etc.) and has to be easily available for the implementers. It should specify at least the content (was the full content delivered to the participants?), frequency and duration (was the intervention delivered with the frequency and the duration prescribed by the developers?) and coverage (have all the people who should have participated in the intervention actually do so?) of the program, with enough details to enable a comparison of the procedures outlined with the implementation practice.

Three versions of this tool are currently available: one is related to diabetes education interventions, the second is related to cardiovascular disease education interventions and the third is a general version that can be used for any kind of promotion and prevention intervention.

Who can answer to this tool?

This questionnaire has been designed for people who are responsible for a program implementation or have a sufficient understanding of the program and information on its implementation.

How using this tool?

This tool can be used as a self-report questionnaire or as an interview guide. In the first case, providers respond to the questions reporting to their own practice. In the second case, an outsider asks every question to the providers, makes sure they understand the items and completes the questionnaire by interview.

This questionnaire can be used during and/or after the program implementation. During the stage of implementation, it is helpful to identify any adaptation or barrier to the implementation and to ensure provider's adherence. Or it can be applied retrospectively to assess the level of implementation fidelity of the program.

Structure of the questionnaire

This questionnaire consists of three parts: (1) Program description (2) Adherence and adaptations assessment (3) Identification of potential moderators

1. Program description

As there are a wide variety of health education programs, the first part contains general information about the program. This information is essential to determine what exactly is assessed.

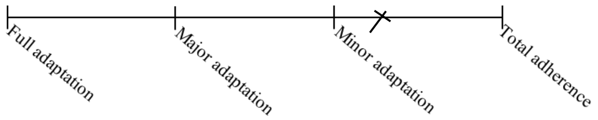
This first part is derived from the Diabetes Literacy Survey – Wiki Diabetes (Schwarz, Nebel, Lindner, Rothe and Muller, 2014). People who have already answered to this Wiki in the framework of the Diabetes Literacy project are exempted from this part.

1. Content of the program	**2. Form of the program**	**3. Program implementation**
○ Program topics ○ Objectives (improve knowledge, believes and attitudes change, etc.)	○ Educational approach (individual, in group, self-help group, IT-based) ○ Teaching methods (lectures, discussions, group work, etc.).	○ Time of implementation ○ Total duration ○ Frequency and session duration ○ Context
4. Recipients characteristics	**5. Provider characteristics**	**6. Program evaluation**
○ Gender ○ Age ○ Ethnic minority ○ Level of knowledge	○ Profession (physicians, nurses, educators, etc.) ○ Program specific training ○ Additional qualifications	○ Evaluation of the quality delivery ○ Publication of the results ○ Evaluation methods (observation, provider or participants questionnaires/interviews)

2. Adherence and adaptations assessment

The second part evaluates any changes in the content (was the whole program delivered to participants?), duration and frequency (did duration and frequency of sessions correspond to what was expected?) and coverage of the program (all persons who take part in the program they actually participated?). For each change, a visual estimation, the date, the nature and the purpose of these adaptations must be specified:

The estimation is a visual and quantifiable indicator of the provider adhesion versus adaptation of the content, frequency, duration and coverage of the program. The respondent has to put a cross on a scale:



A substantial adaptation can be represented by a cross on the left side of the scale, while a little significant change can be indicated by a cross on the right side of the scale.

Date that the change occurred. This information is used to (1) track adaptations over time during the course of a program, (2) examine how the timing of a change may affect program outcomes, (3) if a program has multiple cycles, determine during which cycle the change took place, (4) and identify when adaptations are likely to occur across various programs.

The primary reason for the change. This involves an appraisal of the primary reason for a program modification using five categories: (1) recipient reasons, (2) program provider reasons, (3) community reasons, (4) setting reasons, (5) and sustainability. The categories, along with some examples, are listed below:

(1) Recipient reasons (cultural norms, demographic characteristics, specific needs, etc.)
"We were able to recruit less diabetes than anticipated because local people were not used to this kind of intervention" (coverage)
"On participants demand, we decided to extend the second session on two periods as this topic corresponded to their demand" (duration)

(2) Program provider reasons (staff recruitment/retention issues, costs, etc.)
"We didn't have the required number of providers for the number of diabetes, so providers were unable to spend as much time with each patient as the program required." (duration)
" The provider was not very familiar with the topic of the third session so that the content was adapted to fit his own skills." (content)

(3) Community reasons *(broader context)* (political climate, traumatic incident, community norms, etc.)
"We had to eliminate two sessions because the community did not think the subject matter of this content was a priority." (content)

(4) Setting Issues *(narrow context)* (policies, scheduling, facilities, etc.)
"The location of the program was changed from a hospital to a community center. We felt that we would have better luck recruiting participants in the community than in the hospital because our agency has a very strong relationship with the center." (coverage)
" Program sessions were spaced because of the other institution activities." (frequency)

(5) Sustainability Issues (potential funding leverage, community buy-in, etc.)
"A key community stakeholder threatened to withdraw her support for the program unless the content of two sessions was modified." (content)
" Participants groups have been merged because of subsidies reduction."

- A description of the programmatic change and why it occurred. This narrative provides qualitative information on the cause and nature of adaptations and provides a valuable record for funders, researchers, and implementers.

3. Identification of potential moderators

Finally, the third part discusses the various factors that may affect the implementation of the program. This information could be useful for the design of new educational programs tailored to participants' needs and resources of the organization.

These factors are:

1. Moderators related to the recipients	2. Program complexity	3. Facilitating strategies for the implementation
○ Participants involvement ○ Participants satisfaction ○ Perceived benefits of the program	○ Complexity for the provider ○ Program description complexity ○ Complexity for the recipients	○ Training ○ Protocol ○ Monitoring system ○ Feedbacks
4. Moderators related to the provider	**5. Recruitment**	**6. Implementation context**
○ Attitudes toward the intervention ○ Knowledge related to the intervention ○ Communication skills	○ Recruitment methods ○ Percentage of premature termination ○ Reasons given by participants for premature termination	○ Narrow context (organization of the institution) ○ Broader context (political climate, economic support, etc.)

The questionnaire completion lasts about 30 minutes. In advance our thanks for the time you spend to answer to our questions.