Journal Pre-proof

Common Sense Model of self-regulation for understanding adherence and quality of life in type 2 diabetes with structural equation modeling

Estelle Fall<ce:contributor-role>Conceptualisation) (Formal analysis) (Investigation) (Writing - original draft), Nadia Chakroun-Baggioni<ce:contributor-role>Conceptualisation) (Methodology) (Writing - original draft), Philip Böhme (Writing - review and editing) (Visualization), Salwan Maqdasy (Writing - review and editing), Marie Izaute (Conceptualization) (Supervision) (Project administration), Igor Tauveron (Writing - review and editing) (Visualization)

PII: S0738-3991(20)30341-4

DOI: <https://doi.org/10.1016/j.pec.2020.06.023>

Reference: PEC 6666

To appear in: *Patient Education and Counseling*

Received Date: 7 February 2020

Revised Date: 19 June 2020

Accepted Date: 20 June 2020

Please cite this article as: Fall E, Chakroun-Baggioni N, Böhme P, Maqdasy S, Izaute M, Tauveron I, Common Sense Model of self-regulation for understanding adherence and quality of life in type 2 diabetes with structural equation modeling, *Patient Education and Counseling* (2020), doi: <https://doi.org/10.1016/j.pec.2020.06.023>

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2020 Published by Elsevier.

Common Sense Model of self-regulation for understanding adherence and quality of life in type 2 diabetes with structural equation modeling

Running title: Common sense model in type 2 diabetes

Estelle Fall^{1*}estelle.fall@univ-lorraine.fr, Nadia Chakroun-Baggioni^{2*}, Philip Böhme^{3,4}, Salwan Maqdasy^{5,6}, Marie Izaute², Igor Tauveron^{5,6}.

¹ Université de Lorraine, APEMAC, F-57000 Metz, France

² Université Clermont Auvergne, CNRS, LAPSCO, F-63000 Clermont-Ferrand, France.

³ CHRU-Nancy, Department of Endocrinology, Diabetology and Nutrition, F-54000 Nancy, France

⁴ Regional network LORDIAMN, Faculty of medicine of Nancy, F-54500 Vandœuvre les Nancy

⁵ CHU Clermont-Ferrand, diabetes dpt, Clermont-Ferrand, France

⁶ Université Clermont Auvergne, CNRS, Inserm, GReD, F-63000 Clermont-Ferrand, France

*** Corresponding author at:**

Estelle Fall: Université de Lorraine, Département SHS, Île du Saulcy, 57006 Metz, France
+ 33659447247

Words: 4998 (excluding abstract, bibliography, acknowledgment; tables and figures, and appendices)

1 table and 2 figures

Abstract:

Highlights:

- Illness perceptions are linked to adherence via treatment necessity-concerns.
- Perceived threat is linked to avoidant coping, and negative health outcomes.
- Perceived control is linked to vigilant coping, and positive health outcomes.
- Control and threat perceptions are potential levers for action (self-care; adherence).
- Acceptance influences diabetes management and should be addressed by interventions.

OBJECTIVES — The objective of the present study was to test the Common Sense Model of self-regulation (CSM) for its relevance for improving adherence and quality of life in type 2 diabetes.

METHODS — A sample of 253 patients with type 2 diabetes was recruited. They completed questionnaires about their perceptions regarding diabetes, coping strategies, therapeutic adherence and quality of life. Their HbA1c levels were also collected. Structural equation modeling (SEM) was used to check the adequacy of our theoretical model (CSM) with the patient data.

RESULTS — The final model indicated that perceptions were directly and indirectly related to health outcomes through coping strategies and adequately matched the data ($\chi^2 / df = 561 / 220 = 2.55$; RMSEA = .08; PCFI = .66; PGFI = .70). Moreover, the model appeared to be identical for both types of treatment (oral and injectable).

CONCLUSIONS — Illness perceptions and coping strategies, or, more specifically, how patients accept disease and think they are able to manage it, significantly affect therapeutic adherence and quality of life in type 2 diabetes.

PRACTICE IMPLICATIONS: These results pave the way for developing psychological treatments aimed at improving patient acceptance and internal resources (e.g. use of autobiographical memory, Acceptance and Commitment Therapy).

Keywords: Illness perceptions; treatment perceptions; coping; adherence; quality of life

1. Introduction

Type 2 diabetes is recognized as a major public-health problem owing to its prevalence and the severity of complications (1). The WHO predicts that by 2030 diabetes will be the world's 7th

leading cause of death (2). Accordingly, the need to identify factors capable of improving healthcare and quality of life for people with type 2 diabetes presents a real challenge. Patients can improve their glycemic control and avoid complications through self-care activities, such as physical exercise, diet and self-monitoring of glucose levels, and by taking medication (3). There is evidence, however, that low adherence rates are problematic among type 2 diabetes patients (4) and lead to poor quality of life (5).

Understanding and improving patient adherence and quality of life is therefore a key concern in health psychology. Several psychological health models aim to identify variables affecting adherence and quality of life. One of them is the Common Sense Model of self-regulation (CSM) (6), which considers both perceptions about illness and coping mechanisms. According to the CSM, illness perceptions affect coping strategies which, in turn, impact health outcomes, such as glycemic control and quality of life (6).

Among coping strategies, health models distinguish avoidant coping (e.g., denial, self-blame) and vigilant coping (e.g., planning; acceptance) (7). Vigilant coping has been linked to better health outcomes with chronic diseases, although avoidant coping can be adaptive when there is little possibility of controlling the situation (7). Among vigilant strategies, adherence to health behaviors prescribed by health professionals can be regarded as specific coping (8). According to the CSM, coping strategies are impacted by the meaning patients give their illness by creating illness and treatment perceptions (6).

Patients' cognitive and emotional perceptions of their illness appear to be the main factors determining their strategies for dealing with it. Cognitive perceptions include beliefs about the identity of the illness (labels and symptoms), its causes, consequences, nature, duration, and possibility of controlling it (expectations about personal self-efficacy and treatment). Emotional perceptions are negative reactions, such as fear or anger. Errors of judgment may occur,

triggering a perception which does not fully correspond to the reality of the illness (9). Treatment perceptions have also been shown to impact adherence behaviors in chronic illness, and specifically in diabetes (10).

Literature reviews and meta-analyses show that coping strategies mediate the relationship between perceptions and health outcomes, such as glycemic control (11, 12), and emotional outcomes, such as diabetes distress (13), or quality of life (14). Some chronic disease studies suggest there is a direct link between illness perceptions and outcomes (15).

In the literature, empirical studies have focused on parts of the CSM, such as illness perceptions (16), general coping strategies (14), or a specific strategy (e.g., adherence or health behavior) (8), in order to predict health outcomes in diabetes. However, few studies have analyzed all aspects of the CSM at once (15). Such an approach should reflect the complexity of what life is really like for patients in a more global way. The aim of the present study is to understand the reality of how diabetic patients face their illness and to describe it in greater detail by using both general and specific strategies of the CSM simultaneously, and by examining the direct and indirect links between perceptions and outcomes (Figure 1). More specifically, drivers of health outcomes (glycemic control, and quality of life) will be identified among perceptions (illness and treatment perceptions) and action strategies (coping and adherence).

- Insert Figure 1 here -

2. Methods

2.1 Survey design and population

French-speaking patients with type 2 diabetes were recruited via postal questionnaires sent out by two local offshoots (associations) of the French Federation of Diabetics, an advocacy group that attracts members throughout France. The aims of the Federation are prevention and to provide patients with support and information. The local associations taking part in the study gave their agreement for the research project, and the study was approved by a French ethics committee (*Commission Nationale de l'Informatique et des Libertés*). Before signing the consent form, patients were informed of the content of the study and assured that they would not be identifiable. They were included in the study if they had been prescribed regular medication for their diabetes for at least two months prior to the study, and providing they were neither psychotic nor demented. Out of 651 members of the associations, 299 answered the invitation. 253 (38.9%) patients filled in the questionnaire, and 46 declined to participate.

The patients' demographic characteristics are set out in Table 1. Compared to the large French cohort of the ENTRED survey (17), patients in the present study were older ($t_{228}=10$; $p<.001$) and had been living with their diabetes for longer ($t_{223}=8.75$; $p<.001$). There was no significant difference, however, in terms of HbA1c, BMI, or gender distribution.

- Insert Table 1 here -

2.2 Questionnaires

Brief-Illness Perception Questionnaire

The Brief-Illness Perception Questionnaire (B-IPQ) (18) is a self-administered questionnaire about diabetes beliefs. It includes 8 items measuring cognitive and emotional illness perceptions (i.e., consequences, timeline, personal control, treatment control, symptoms,

coherence, illness concern and negative emotions) on an 11-point scale. It has been used successfully to identify the link between adherence and illness perceptions in type 2 diabetes patients (19). In the present sample, Cronbach alpha was .64.

Beliefs about Medicines Questionnaire

The Beliefs about Medicines Questionnaire (BMQ, (10) consists of 18 items (see Appendix A). This tool has been used successfully to link adherence and medicines beliefs among chronic disease patients, including diabetic patients (10, 20). Each of the subscales was found to demonstrate good internal consistency with all Cronbach's alphas ranging from .79 to .85 in the present sample.

Brief-COPE

The Brief-COPE (21) contains 28 items assessing the following coping dimensions: active coping, planning, use of instrumental support, use of emotional support, venting, behavioral disengagement, self-distraction, self-blame, positive reframing, humor, denial, acceptance, religion, and substance use. Each item is scored on a 4-point scale, ranging from "not at all" to "always". Depending on the instruction, coping can be assessed with a dispositional format (such as personality style) or a situational format (specific to a situation). In this study, the dispositional format was used to assess how patients cope during stressful events. This tool has been used successfully to link coping and self-management among diabetic patients (22). In the present sample, Cronbach alpha was .78.

Therapeutic adherence

We used a French scale to measure specific adherence with chronic diseases (23). Respondents

indicate to what extent they agree with 6 statements describing how they take their treatment (e.g., “I comply with all medical prescriptions”) using a 5-point Likert scale ranging from 1 (“never”) to 5 (“always”). A total score was calculated by adding together the scores for each of the 6 items. A high total score denoted high adherence. This scale has been used with satisfactory psychometrical proprieties in a previous study to identify adherence in respect of diabetes medication (10). In the present sample, Cronbach alpha was .63.

SF-12 Health Survey

Quality of life was measured in terms of general and specific quality of life. The SF-12 Health Survey is the short version of the SF-36 health survey (24) and measures general physical and mental quality of life using 12 questions in different formats. A French-specific scoring algorithm was applied to obtain two scores for mental quality of life and physical quality of life, with a mean of 50, standard deviation of 10, and maximum of 100 denoting good quality of life. This tool has been used successfully with adherence as an outcome in a study using structural equation modelling among type 2 diabetic patients (25).

Diabetic Quality of Life

Diabetic Quality of Life (DQOL) (26) measures quality of life specific to diabetes by exploring the following dimensions: satisfaction, impact, concerns about professional and social work, concerns about diabetes, and wellbeing. As the tool was originally developed for type 1 diabetes, only questions suited to adults were used in this study. The 36 6-point scale items included were divided into two dimensions: satisfaction, ranging from “very satisfied” to “very dissatisfied”; and impact, ranging from “never” to “always”. This tool has been used successfully as an outcome in a previous study among type 2 diabetic patients which demonstrated a different impact depending on treatment type (27). For each dimension Cronbach alpha were .76 and .86,

indicating good reliability.

HbA1c

Last HbA1c level was reported by patients.

2.3. Statistical procedures

We used structural equation modeling (SEM) with factor analysis. Inter-correlated variables or items are grouped together as a single factor (“latent variable”). In a first step, we compared two models. In Model 1, perceptions were indirectly related to health outcomes through coping strategies. In Model 2, they were related to health outcomes both directly and indirectly. For both models, observed variables were used for treatment perceptions (i.e., differential between perceived necessity and perceived concerns), adherence, and glycemic control (i.e., HbA1C). Three latent variables were defined for illness perceptions, coping strategies, and quality of life. For each model, non-significant paths were removed for the purpose of identifying the best predictive model.

In a second step, we checked the invariance of the chosen model irrespective of the type of treatment (oral vs injectable) via Models 3 and 4.

The probability level for statistical significance was set at $p \leq .05$ for all statistical analyses. For SEM, the estimation method, i.e., the Maximum Likelihood (ML) method, was the one most frequently used with continuous variables (28). The models were Fit-assessed on the basis of multiple indicators: (adjusted) Comparative Fit Index (P)CFI, Root Mean Square Error Approximation (RMSEA), Tucker-Lewis coefficient (TLI), (Standardized) Root Mean Square Residual (SRMR), and Akaike’s Information Criterion (AIC). This SEM was performed in accordance with the procedure and criteria described in detail by Kline (29). A

model was considered a good fit if the χ^2/df was <3 . Moreover, values greater than .90 for CFI and .60 for PCFI (adjusted to take account of the parsimony of the model) are considered indicative of adequate model fit. TLI values close to 1 indicate a very good fit, with values greater than .90 deemed an acceptable fit. RMR values close to 0 indicate an acceptable model fit, with $SRMR \leq .08$ the threshold for concluding an acceptable fit. RMSEA values below .08 indicate an acceptable fit, with .05 the optimal critical value (30). We also reported the lower and upper boundaries of the 90% confidence interval for RMSEA, with an upper boundary of more than .10 indicating that the model should be rejected (31). AIC is not scaled on a zero-to-one range and is used for assessment relative to other models. The smaller the AIC values, the better and more parsimoniously the model fits.

Analyses were performed with the SPSS version 18 software for descriptive analyses and AMOS version 18 software for SEM.

3. Results

3.1. Latent variables

For illness perceptions, a model was created with two latent variables: control perception and threat perception ($\chi^2_8 = 10.18$ (NS); RMSEA = .03; CFI = .99; GFI = .99). For coping strategies, a model was created in line with coping style as usually described in the literature, with three latent variables: vigilant coping, avoidant coping, and seeking social support coping ($\chi^2_{74} = 210$; $\chi^2/df = 2.84$; RMSEA = .85; CFI = .66; GFI = .63). Seeking social support coping was not included because it was only weakly predicted by perceptions and not significantly related to quality of life or HbA1c. Moreover, the participants reported they do not often use this coping strategy ($M = 1.90$; $SD = .83$ on a 4 point-scale). For quality of life, a latent variable was created based on general and specific quality of life ($\chi^2_2 = 3.52$ (NS); RMSEA = .055; CFI = .99; GFI

= .99).

3.2. Retained model

Model 1, where perceptions were indirectly related to health outcomes through action strategies, fitted the data adequately ($\chi^2 / df = 586 / 222 = 2.64$; RMSEA = .08; PCFI = .66; PGFI = .70), indicating that the data in the present study are consistent with the theoretical model (CSM).

However, it fitted the data significantly less well than Model 2 ($\chi^2_{diff} = 25$; $p < 0.001$ and $AIC_2 (673) < AIC_1 (694)$), where perceptions related to health outcomes both directly and indirectly ($\chi^2 / df = 561 / 220 = 2.55$; RMSEA = .08; PCFI = .66; PGFI = .70).

Figure 2 is a graph showing retained Model 2 with all significant direct and indirect paths between perceptions, coping and health outcomes.

- Insert Figure 2 here -

For this final model, the configural invariance – Model 3 - (i.e., identical configuration of factors, number and direction of paths between the variables in respect of both groups) was proved between oral treatment and insulin treatment ($\chi^2 / df = 994,14 / 440 = 2,26$; RMSEA = 0,057; PGFI = 0,65; PCFI = 0,69; AIC = 1218,14), as well as the construct-level metric invariance - Model 4 - (i.e., identical strength of the links for each path, in other words the value of the regression coefficients) ($\chi^2 / df = 999,16 / 452 = 2,21$; RMSEA = 0,055; PGFI = 0,66; PCFI = 0,71; AIC = 1199,16). The chi-2 difference between the two models (Models 3 and 4) is also insignificant ($\chi^2_{12} = 5,02$, ns). We can therefore consider this model to be identical for both types of treatment.

4. Discussion and conclusion

4.1. Discussion

The objective of this study was to gain a better understanding of predictors of health and emotional outcomes in type 2 diabetes by considering all parts of the CSM and simultaneously measuring perceptions (illness and treatment) and coping strategies (general and specific).

According to structural equation modelling, perceived threat and perceived control are essential components of the diabetes experience because they influence treatment perceptions and coping strategies, as well as health and emotional outcomes, in a direct and indirect manner. The result obtained is congruent with recent meta-analysis on CSM (15). Threat perception and control perception are also indirectly linked to adherence, through treatment perceptions, which is congruent with other chronic disease studies which found adherence to be higher when perceived necessity overtakes perceived concern (32). The more threatened patients feel by diabetes, the more worried they are about their treatment (e.g., side effects, toxicity, risk of dependence), and, as a result, the less likely they are to adhere to their doctor's recommendations. Patients who perceive diabetes as a major threat also tend to use avoidant coping strategies (e.g., refusing to consider the disease; hiding diabetes from others; not going to see their doctor regularly), which have a negative impact on their health. The perceived threat from diabetes also has consequences for quality of life (e.g., feelings of discouragement, sadness or depression). Conversely, the more in control they feel of their diabetes, the more likely patients are to perceive the need to take their medication and follow their doctor's recommendations. Patients who feel strong in their control over their diabetes also tend to use appropriate coping strategies (e.g., seeking information; engaging in physical activity; participating in focus groups), which then have a positive impact on their health. Patients' feeling of being in control also improves their quality of life. For example, they feel stronger when it comes to coping with the disease, less depressed, more serene.

Control and threat perceptions are therefore potential levers for action. These findings are congruent with the literature on diabetes, which has shown the link between control perception and the use of active coping strategies (15), stronger adherence (30), and more caring behaviors (29; 33). In the present study, the perception of control is also related directly to better quality of life and indirectly to better glycemic control. This is consistent with the results of numerous studies showing the relationship between this perception, better quality of life (31) and lower glycated hemoglobin levels (33; 34; 11).

The threat perception appears to have the opposite effects to the control perception. In the literature, a number of studies have already highlighted the negative effect of strong patient identity on diabetes emotional impact (13) and glycemic control (11). Yet, other studies report a positive association between belief in the severity of diabetes and therapeutic adherence (30) or care behaviors (35). Thus, the arguments in the literature differ regarding the effects of threat perception on diabetes. A cross-national survey found discordance between patients' and physicians' ratings for perceptions of seriousness and the emotional impact of diabetes, with physicians underestimating the perceived seriousness of the disease and overestimating its emotional impact (36). In the present study, perceived threat is represented by a latent variable with three indicators, namely symptoms, consequences, and negative emotions. The negative effect of threat perception can be understood as an inhibitory effect of a negative emotion combined with negative cognitions on diabetes. Thus, it would appear that negative perceptions (symptoms, consequences, and negative emotions) hamper actions and are detrimental to quality of life because the overall meaning attributed to the disease is one of threat and disturbance. Conversely, positive perceptions such as control see the disease as a challenge and act therefore as a driver, rather than an obstacle (37).

These results confirm the adaptive aspect of positive illness perceptions (personal control, treatment effectiveness, and understanding of the disease) and the dysfunctional aspect of negative perceptions (consequences and perceived symptoms, negative emotions) in patients with type 2 diabetes. They are consistent with the "cognitive adaptation theory", according to which positive beliefs, however unrealistic (e.g. positive illusions in the case of serious diseases, such as HIV or cancer), are preferable to pessimistic beliefs (38). Although illusory, positive optimistic thoughts (e.g. comparative optimism, exaggerated perceived control) are psychological resources associated with mental and physical health, whereas a realistic and pessimistic assessment is linked to a more rapid progression of the disease.

The results also invite us to consider patients not only through their diabetes diagnosis, which is consistent with what some patient education programs already do. (39). They will all experience their disease differently depending on their own idiosyncratic perceptions, and in particular how they regard the seriousness of their disease and how they think they can manage it. A study involving patients with 10 different diagnoses without vital prognosis showed that, regardless of their diagnosis, patients could be divided into clusters according to the degree of perceived control over the disease (through medical care and personal behavior) and perceived consequences (level of disability due to the disease) (40). Almost 50% of diabetic patients were in the cluster that perceived their disease as highly controllable and not very disabling, a set of beliefs that resulted in fewer dysfunctional strategies (40).

The SEM also describes how patients engage in vigilant or avoidance strategies based on how they perceive their illness cognitively and emotionally. Vigilant strategies are considered to be

more adaptive when the situation is controllable (7), as is almost always the case with diabetes, with several treatment options available (3). In the present study, vigilant coping mediates the link between control perception and positive diabetes outcomes, whereas avoidant coping mediates the link between threat perception and negative diabetes outcomes. These results are in line with the literature showing that vigilant strategies are functional in type 2 diabetes while avoidance strategies are dysfunctional (41).

Among vigilant strategies, behavioral strategies (i.e., active coping and planning) are actions performed by patients to deal with the disease, and cognitive strategies (i.e., humor, acceptance) are mental efforts made in order to face the disease more easily. Acceptance, not to be confused with “resignation”, is a vigilant strategy consisting in limiting avoidance of (diabetes-related) thoughts and emotions (42). It has been linked to better glycemic control, and more care behaviors in type 2 diabetes (42). The present results suggest acceptance also influences diabetes management and should be addressed by specific interventions, such as Acceptance and Commitment Therapy (ACT, 42).

Among coping strategies, adherence is a specific vigilant strategy. It can be conceptualized as a key variable of the CSM, as an action both influenced by patients’ perception and in turn influencing their physical and mental health. Patients create their own model of their disease and useful actions for managing it, and then this personal model influences their strategies. The influence of personal models of diabetes on adherence has already been shown in the literature (30). It is interesting to note that the SEM model does not vary according to treatment type. Type 2 diabetes is a progressive illness with several treatment stages (5). The transition from oral treatment to insulin is challenging, requiring potential adjustments to diabetes-related perceptions and actions to deal with the disease and how it is treated (43). The invariance of the SEM with respect to different medical treatments is somewhat reassuring, underlining patients’

ability to adapt as they go through these two different stages of diabetes, so that they can self-manage their disease in congruence with their own personal model.

This study has a number of limitations that may point the way for future research. First, the patients were recruited from diabetes federations. Therefore, the sample consisted of patients most committed to their care and may not be representative of all diabetics. Second, given the cross-sectional study approach, it is impossible to draw conclusions about the causal effect of the link between variables, or to capture dynamic aspects of the CSM, which are often not evaluated or utilized in contemporary CSM-based research (44). Finally, assessments were based on Patient-Reported Outcomes. These can be biased by social desirability and lead to overestimations of some evaluations, such as adherence. However, a review of the available literature has highlighted a good match between self-reported adherence and objective adherence measures (45).

4.2 Conclusion:

Despite these shortcomings, the present study draws attention to potential predictors of quality of life, glycemic control, and adherence among illness and treatment perceptions and coping strategies. It also points to important possible interventions with type 2 diabetic patients that could be developed in patient education (39). Its originality lies in the way it takes account of both specific strategies (adherence) as well as other general strategies (coping) using SEM, which more accurately reflects the complexity of any patient's reality. To be effective, care behavior must be part of a set of strategies put in place to deal with diabetes or to manage the emotions triggered by the disease.

4.3 Practice implications:

The implication from the results of this study is that diabetes patients should be seen as active agents of their own health. They are influenced by both their cognitive and emotional experiences with the disease, all the more so because it is an asymptomatic illness, requiring a certain degree of expertise on their part (15). The results reinforce the importance of establishing a partnership between health professionals and patients (*patient-care partner approach*) (46, 47) and pave the way for the development of psychological treatments designed to enhance patient acceptance and internal resources (e.g. use of autobiographical memory, ACT). Vigilant coping strategies should be addressed by therapies focusing on illness and treatment perceptions, especially threat and control perceptions. Cognitive Behavioural Therapies can help patients modify their perceptions, thanks to techniques such as cognitive restructuring. Nevertheless, ACT presents an alternative, consistent with the CSM (45), for helping patients engage in valued actions. For example, it encourages them to take care of their health by devising a new way of considering thoughts and emotions without having to change them (“thoughts are not fact”). This is done by increasing acceptance, as an alternative to avoidance, and therefore their commitment to valued actions (48). This study shows that CSM is a good framework for conceptualizing interventions for type 2 diabetic patients, for example with the help of ACT processes to work on patients' representations. Finally, a previous study, based on CSM concepts, has shown the effectiveness of a brief intervention based on autobiographical recall (threat vs. control), with a change in perceptions, acceptance, and adherence reported after a 15-minute induction course. These new, brief intervention could be a promising way of addressing patients' personal beliefs about their diabetes, even in a short space of time, such as during a visit to the doctor (49).

Conflict of interest:

The authors declare that they have no conflicts of interest concerning this article.

Author contribution:

Fall Estelle: conceptualisation; formal analysis; investigation; writing original draft; Chakroun Nadia: conceptualisation; methodology; writing original draft; Bohme Philip: Writing – review and editing; visualization; Salwan Maqdasy: Writing – review and editing; Izaute Marie: conceptualization; supervision; project administration; Tauveron Igor: Writing – review and editing, validation. All authors approved the final version of the manuscript.

Acknowledgments

This study would not have been possible without the considerable involvement of the patients, and the associations AFD 63-03 and FFD which gave so generously of their time.

This work benefited from support from the French National Centre for Scientific Research (CNRS), and the University of Clermont Auvergne. The University receives funding from several companies, including Becton Dickinson Medical–Pharmaceutical Systems, France.

References:

- 1- Detournay B, Cros S, Charbonnel B, Grimaldi, A, Liard F, Cogneau J, Fagnani F, Eschwege E. (2000). Managing type 2 diabetes in France: The ECODIA survey 2000. *Diabetes Metab* 2000;26:363-9.
- 2- WHO 2016. Rapport mondial sur le diabète <https://www.who.int/diabetes/global-report/fr/>
- 3- Grant RW, Wexler DJ, Watson AJ, Lester WT, Cagliero E, Campbell EG, Nathan DM. How doctors choose medications to treat type 2 diabetes. *Diabetes Care* 2007;30(6):1448-53.
- 4- Bailey CJ, Kodack M. Patient adherence to medication requirements for therapy of type 2 diabetes. *International journal of clinical practice* 2011;65(3):314-22.

- 5- Stuckey HL, Mullan-Jensen CB, Reach G, Kovacs Burns K, Piana N, Vallis M, Wens J, Willaing I, Skovlund SE, Peyrot M. Personal accounts of the negative and adaptive psychosocial experiences of people with diabetes in the second Diabetes Attitudes, Wishes and Needs (DAWN2) study. *Diabetes Care*. 2014;37(9): 2466–74.
- 6- Leventhal H, Diefenach M, Leventhal EA. Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. *Cognit Ther Res* 1992;16:143-63.
- 7- Carver CS. You want to measure coping but your protocol's too long: Consider the Brief COPE. *Int J Behav Med* 1997;4(1):92–100.
- 8- Brandes K, Mullan B. Can the common-sense model predict adherence in chronically ill patients? A meta-analysis. *Health Psychol Rev* 2014;8(2):129-53.
- 9- Coutu MF, Marchand A, Dupuis G, O'Connor K, Turgeon L, Nielsen T. Une piste pour favoriser l'adhésion au plan de soins? How to improve compliance ? [One way to encourage adherence to care plan? How to Improve Compliance?] *Revue Francophone de Clinique Comportementale et Cognitive* 2004;9(4):17-24.
- 10- Fall E, Gauchet A, Izaute M, Horne R, Chakroun N. Validation of the French version of the Beliefs about Medicines Questionnaire (BMQ) among diabetes and HIV patients. *Eur Rev Appl Psychol* 2014;64(6):335-43.
- 11- Mc Sharry R, Moss-Morris T, Kendric T. Illness perceptions and glycaemic control in diabetes: a systematic review with meta-analysis. *Diabet Med* 2011;28(11):1300–10.
- 12- Breland JY, McAndrew LM, Burns E, Leventhal EA, Leventhal H. Using the common sense model of self-regulation to review the effects of self-monitoring of blood glucose on glycemic control for non-insulin-treated adults with type 2 diabetes. *Diabetes Educ* 2013;39(4):541-59. doi:10.1177/0145721713490079.
- 13- Paddison CAM, Alpass FM, Stephens CV. Using the common sense model of illness self-regulation to understand diabetes-related distress: The importance of being able to 'make sense' of diabetes. *NZ J Psychol* 2010;39(1):45–50.
- 14- Dempster M, Howell D, McCorry NK. Illness perceptions and coping in physical health conditions: A meta-analysis. *J Psychosom Res* 2015;79(6):506-513...
- 15- Hagger MS, Koch S, Chatzisarantis NLD, Orbell S. The common sense model of self-regulation: Meta-analysis and test of a process model. *Psychol Bull* 2017;143(11):1117-54.
- 16- Lawson VL, Bundy C, Belcher J, Harvey JN. Mediation by illness perceptions of the effect of personality and health threat communication on coping with the diagnosis of diabetes. *Br J Health Psychol* 2010;15(3):623–42.
- 17- Tiv, M, Viel JF, Mauny F, Eschwège E, Weill A, Fournier C, Fagot-Campagna A, Penfornis A. « Medication Adherence in Type 2 Diabetes: The ENTRED Study 2007, a French Population-Based Study ». *PloS One* 2012;7(3): e32412.
- 18- Broadbent E, Petrie KJ, Main J, Weinman J. The Brief Illness Perception Questionnaire. *J Psychosom Res* 2006;60:631-37.
- 19- Broadbent E, Donkin L, Stroh J. Illness and treatment perceptions are associated with adherence to medication, diet and exercise in diabetic patients. *Diabetes Care* 2011;34(2):338-40.
- 20- Horne R, Weinman J. (1999). Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *J psychosom Res* 1999;47(6):555-7
- 21- Muller L, Spitz E. Évaluation multidimensionnelle du coping: Validation du Brief COPE sur une population française [Multidimensional assessment of coping : validation of the Brief COPE among french population]. *Encephale* 2003;29(6):507–18.

- 22- Miles SR, Khambaty T, Petersen NJ, Naik AD, Cully JA. The role of affect and coping in diabetes self-management in rural adults with uncontrolled diabetes and depressive symptoms. *J Clin Psychol Med S.* 2018;25(1):55-65.
- 23- Tarquinio C, Fischer GN, Grégoire A. La compliance chez des patients atteints par le VIH: Validation d'une échelle française et mesure de variables psychosociales [Compliance in HIV-positive patients: Validation of a French scale and measurement of psychosocial variables]. *Int Rev Soc Psychol* 2000;13(2):61-91.
- 24- Gandek JE, Ware NK, Aaronson G, Apolone JB, Bjorner JE, Brazier M, Bullinger S, Kaasa A, Leplege L, Prieto et al. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. *International Quality of Life Assessment. B J Clin Epidemiol* 1998;51(11):1171-8.
- 25- Lee YY, Lin JL. The effects of trust in physician on self-efficacy, adherence and diabetes outcomes. *Soc Sci Med.* 2009;68(6):1060-8.
- 26- Renard E, Apostol D, Lauton D, Boulet F, Bringer J. Quality of life in diabetic patients treated by insulin pumps. *QoL Newsletter* 2002; 28:11-3.
- 27- Aikens E, Perkins DW, Piette JD, Lipton B. Association between depression and concurrent Type 2 diabetes outcomes varies by diabetes regimen. *Diabet Med.* 2008; 25(11): 1324-9.
- 28- Jackson DL, Gillaspay JA, Purc-Stephenson R. Reporting practices in confirmatory factor analysis: An overview and some recommendations. *Psychol Methods* 2009;14(1):6-23.
- 29- Kline R. Principle and practice of equation structural modeling. The Guilford Press, New York, 2011
- 30- Mann DM, Ponieman D, Leventhal H, Halm EA. Predictors of adherence to diabetes medications: The role of disease and medication beliefs. *J Behav Med* 2009;32(3):278-84
- 31- Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self-regulation of diabetes on quality-of-life outcomes. *Diabetes Care* 2000;23(10):1511-5.
- 32- Foot H, La Caze A, Gujral G, Cottrell N. The necessity-concerns framework predicts adherence to medication in multiple illness conditions: A meta-analysis. *Patient Educ Couns.* 2016;99(5):706-17.
- 33- Lee Y-J, Shin S-J, Wang R-H, Lin K-D, Lee Y-L, Wang Y-H. Pathways of empowerment perceptions, health literacy, self-efficacy, and self-care behaviors to glycemic control in patients with type 2 diabetes mellitus. *Patient Educ Couns.* 2016;99(2):287-94.
- 34- Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-2.
- 35- Glasgow RE, Hampson SE, Strycker LA, Ruggiero L. Personal-model beliefs and social-environmental barriers related to diabetes self-management. *Diabetes Care,* 1997;20(4):556-61.
- 36- Hajos TRS, Polonsky WH, Twisk JWR, Dain M-P, Snoek FJ. Do physicians understand Type 2 diabetes patients' perceptions of seriousness; the emotional impact and needs for care improvement? A cross-national survey. *Patient Educ Couns.* 2011;85(2):258-63.
- 37- Blascovich J, Mendes WB, Tomaka J, Salomon K, Seery M. The robust nature of the biopsychosocial model challenge and threat: A reply to Wright and Kirby. *Pers Soc Psychol Rev,* 2003;7(3):234-43.
- 38- Taylor SE, Kemeny ME, Reed GM, Bower JE, Gruenewald TL. Psychological resources, positive illusions, and health. *Am Psychol* 2000;55(1):99-109.

- 39- Lehrer HM, Dubois SK, Brown SA, Steinhardt MA. Resilience-based Diabetes Self-management Education: Perspectives From African American Participants, Community Leaders, and Healthcare Providers. *Diabetes Educ.* 2017;43(4):367–77.
- 40- Heijmans M, Rijken M, Foets M, de Ridder D, Schreurs K, Bensing J. The stress of being chronically ill: From disease-specific to task-specific aspects. *J Behav Med* 2004;27(3):255–271.
- 41- Macrodimitris SD, Endler NS. Coping, control, and adjustment in Type 2 diabetes. *Health Psychol* 2001;20(3):208-16.
- 42- Gregg JA, Callaghan GM, Hayes SC, Glenn-Lawson JL. Improving diabetes selfmanagement through acceptance, mindfulness, and values: a randomized controlled trial. *J Consult Clin Psychol* 2007;75(2):336-43.
- 43- Bradley C, de Pablos-Velasco P, Parhofer KG, Eschwège E, Gönder-Frederick L, Simon D. PANORAMA: A European study to evaluate quality of life and treatment satisfaction in patients with type-2 diabetes mellitus—study design. *Prim Care Diabetes* 2011;5(4):231-9.
- 44- Leventhal H, Phillips LA, Burns E. The Common-Sense Model of Self-Regulation (CSM): A dynamic framework for understanding illness self-management. *J Behav Med* 2016;39(6):935-46.
- 45- Garber MC, Nau DP, Erickson SR, Aikens JE, Lawrence JB. The concordance of self-report with other measures of medication adherence: a summary of the literature. *Med Care* 2004;42:649–2.
- 46- Halabi IO, Scholtes B, Voz B, et al. "Patient participation" and related concepts: A scoping review on their dimensional composition [published online ahead of print, 2019 Aug 8]. *Patient Educ Couns.* 2019; S0738-3991(19)30317-9.
- 47- Scollan-Koliopoulos M, Bleich D, Rapp KJ, Wong P, Hofmann CJ, Raghuwanshi M. Health-related quality of life, disease severity, and anticipated trajectory of diabetes. *Diabetes Educ.* 2013;39(1):83–91.
- 48- Karekla M, Karademas EC, Gloster AT. The Common Sense Model of Self-regulation and Acceptance and Commitment Therapy : integrating strategies to Guide Interventions for Chronic Illness. *Health Psychol Rev* 2019 ;13(4):490.
- 49- Fall E, Roche B, Izaute M, Batisse M, Tauveron I, Chakroun N. A brief psychological intervention to improve adherence in type 2 diabetes. *Diabetes Metab* 2013;39(5):432–8.

Figures

Figure 1- Research Framework: Common Sense Model of the experience of living with type 2 diabetes.

straight line with arrowhead denotes direct effect; dashed line with arrowhead denotes indirect effect

Figure 2 - Final model of the experience of living with type 2 diabetes.

Ellipse indicates latent, unobservable constructs; box indicates observed variable; straight line with arrowhead denotes direct and indirect effects; dashed line with arrowhead denotes factor loadings

Table

Table 1- Socio-demographic and diabetes-related characteristics of responders

	Type 2 diabetic patients
n	253
Socio-demographic characteristics	
Age (years)	68.6 ± 10.3
Men (%)	57
Living alone/with partner (%)	42.3/53.4*

Diabetes-related characteristics

Diabetes duration (years)	19 ± 12
BMI (kg/m ²)	28.9 ± 5.7
HbA1c (%) mmol HbA1c/mol Hb	7.22 ± 1.02
Oral Treatment/insulin** (%)	45.5/50.6*

Data are means ± SD unless otherwise indicated.

*Missing data were removed.

**Patients with both oral and insulin treatment were included in “insulin” count.

Appendix A:

Beliefs about Medicines Questionnaires (Horne et al 1999 ; Fall et al., 2014)

A- Specific Beliefs :

Nous nous intéressons à votre point de vue personnel sur les traitements qui vous sont prescrits pour votre diabète. Veuillez s'il vous plait indiquer à quel point vous êtes d'accord ou en désaccord avec les propositions suivantes. Il n'y a ni de bonnes, ni de mauvaises réponses. Vos réponses seront toujours bonnes si vous dites vraiment ce que vous pensez :

We would like to ask you about your personal views about medicines prescribed for you.

These are statements other people have made about their medicines.

Please indicate the extent to which you agree or disagree with them by ticking the appropriate box. There are no right or wrong answers. We are interested in your personal views.

1	2	3	4	5
Tout à fait d'accord <i>strongly agree</i>	D'accord <i>agree</i>	Incertain <i>uncertain</i>	En désaccord <i>disagree</i>	Fortement en désaccord <i>strongly disagree</i>

1- Ma santé, aujourd'hui, dépend de mon traitement. <i>My health, at present, depends on my medicines.</i>	1	2	3	4	5
2- Avoir à prendre un traitement m'inquiète. <i>Having to take medicines worries me</i>	1	2	3	4	5
3- Ma vie serait impossible sans mon traitement. <i>My life would be impossible without my medicines.</i>	1	2	3	4	5
4- Sans mon traitement, je serais très malade. <i>Without my medicines I would be very ill.</i>	1	2	3	4	5

5- Je m'inquiète parfois à propos des effets à long terme de mon traitement. <i>I sometimes worry about long-term effects of my medicines</i>	1	2	3	4	5
6- Mon traitement est un mystère pour moi. <i>My medicines are a mystery to me</i>	1	2	3	4	5
7- Ma santé future dépend de mon traitement. <i>My health in the future will depends on my medicines.</i>	1	2	3	4	5
8- Mon traitement perturbe ma vie. <i>My medicines disrupt my life</i>	1	2	3	4	5
9- Je suis parfois inquiet(e) de devenir trop dépendant(e) de mon traitement. <i>I sometimes worry about becoming too dependent on my medicines</i>	1	2	3	4	5
10- Mon traitement empêche mon état d'empirer. <i>My medicines protect me from becoming worse</i>	1	2	3	4	5

B – General beliefs

Nous nous intéressons à votre point de vue personnel sur la médecine en générale. Veuillez s'il vous plait indiquer à quel point vous êtes d'accord ou en désaccord avec les propositions suivantes. Il n'y a ni de bonnes, ni de mauvaises réponses. Vos réponses seront toujours bonnes si vous dites vraiment ce que vous pensez :

*We would like to ask you about your personal views about medicines in general.
These are statements other people have made about medicines in general.
Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.
There are no right or wrong answers. We are interested in your personal views.*

1	2	3	4	5
Tout à fait d'accord <i>strongly agree</i>	D'accord <i>agree</i>	Incertain <i>uncertain</i>	En désaccord <i>disagree</i>	Fortement en désaccord <i>strongly disagree</i>

11- Les médecins utilisent trop de traitements. <i>Doctors use too many medicines.</i>	1	2	3	4	5
12- Les personnes qui prennent des médicaments devraient arrêter leur traitement de temps en temps. <i>People who take medicines should stop their treatment for a while every now and again.</i>	1	2	3	4	5
13- La plupart des traitements provoquent une dépendance. <i>Most medicines are addictive.</i>	1	2	3	4	5
14- Les remèdes naturels sont plus sûrs que les traitements médicaux. <i>Natural remedies are safer than medicines.</i>	1	2	3	4	5
15- Les traitements font plus de mal que de bien. <i>Medicines do more harm than good.</i>	1	2	3	4	5
16- Tous les traitements sont des poisons.	1	2	3	4	5

<i>All medicines are poisons.</i>					
17 - Les médecins accordent trop de confiance aux traitements. <i>Doctors place too much trust on medicines.</i>	1	2	3	4	5
18- Si les médecins passaient plus de temps avec les patients, ils prescriraient moins de traitements. <i>If doctors had more time with patients, they would prescribe fewer medicines.</i>	1	2	3	4	5

Scoring instruction: All items have to be reversed before summing the items for each subscale.

- Specific beliefs: Necessity: items 1,3,4,7,10; Concerns : items 2,5,6,8,9
- General Beliefs: Overuse: items 11, 14, 17, 18 ; Harm : items 13,12,15,16