The role of behavioral characteristics in disease-management of insulin-treated type 2 diabetes mellitus patients

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ABBREVIATIONS

HbA1c = hemoglobin A1C

BHLS = Brief Health Literacy Screen

COREQ = Consolidated Criteria for Reporting Qualitative Research

DNT-15 = Shortened version of Diabetes Numeracy Test

(F)HL = (Functional) Health Literacy

HSCO = Hungarian Central Statistical Office

MeSH = Medical Subject Heading

NVS = Newest Vital Sign

NEAK = Tasks of the National Health Insurance Fund of Hungary

OECD = Organisation for Economic Co-operation and Development

PIAAC = Programme for the International Assessment of Adult Competencies

PLS-SEM = Partial Least Squares Structural Equation Modeling

REALM = Rapid Estimate of Adult Literacy in Medicine

S-TOFHLA = Short Test of Functional Health Literacy

T2DM = Type 2 Diabetes Mellitus

WHO = World Health Organization

1. Introduction

Thanks to the rise of evidence-based medicine, there have been dramatic developments in the field of diabetology in the last twenty years. There have been major developments in the field of antidiabetic products, modern insulins have been introduced and insulin delivery devices became much more sophisticated. In addition, the emergence of non-insulin subcutaneous preparations and the expansion of blood glucose monitoring devices are a milestone in the field of diabetes management (Winkler & Barkai, 2013). Nevertheless, in the case of diabetes, knowing the options for preventing metabolic control complications and slowing down the progression of these complications and taking the pathophysiological basis of the disease into consideration often cannot provide clearly positive, risk-free patient care, despite the best medical knowledge, technology and care (Jermendy, 2013; White, 2014). This can be explained mainly by the complexity of the chronic disease involving the whole body and the specificity of individual responsibility and self-management which are essential for the management of the disease (Karádi et al., 2020).

It is well known that there can be basically two main reasons behind cases where the management of Type 2 Diabetes Mellitus (T2DM) is ineffective and an optimal metabolic status cannot be maintained in the long term: one is due to the healthcare system (e.g.: inaccurate estimation of patients' situation/condition, lack of education, etc.), the other is due to inadequate self-management of the person with diabetes, often associated with a low level of adherence (Winkler, Hosszúfalusi & Baranyi, 2015). The increasingly intensive and complex treatment regimes and the pressure on the health care system all require that diabetes patients possess adequate knowledge, psychological resources and self-management skills. Well informed and knowledgeable patients are able to participate as active decision-makers on health issues concerning them. However, scientific evidence suggests that nearly 48% of people with diabetes do not have the optimal metabolic levels needed to manage their diabetes (Ferguson et al., 2015; García-Pérez et al., 2013).

To find out what causes weak adherence, what factors influence, help and hinder patients' adherence to therapy and proper disease-management, an isolated examination of certain aspects or phenomena is not enough. In the current dissertation the question arises as to what extent successful treatment can be determined by the patient's health literacy (HL), competencies and at what point psychological and behavioral factors take over and can influence the therapeutic cooperation of diabetes patients and their successful adherence to

complex treatment. Therefore, exploring the above mentioned aspects and questions, inspecting this complex phenomenon through the patient lens was the main focus of our research.

1.1. Theoretical background

1.1.1. Type 2 diabetes mellitus as a chronic disease, its prevalence and treatment

T2DM is a complex metabolic disease, characterised by relative insulin deficiency caused by inadequate function of pancreatic β-cell and insulin resistance in target organs (Chatterjee et al., 2017). In addition, diabetes mellitus (DM) consequently affects lipid and protein metabolism of patients (Karádi et al., 2020). The disease is frequently undiagnosed for many years because hyperglycemia develops gradually and often DM symptoms caused by high blood glucose levels do not appear for a long time (Kong et al., 2016). Nevertheless, T2DM increases the risk of developing macrovascular and microvascular complications. Microvascular complications include retinopathy, nephropathy, and neuropathy, while macrovascular complications affect the large blood vessels and include strokes and cardiovascular diseases (Karádi et al., 2020; Rawlings et al., 2014).

According to International Diabetes Federation (IDF), there are currently 463 million people in the world who are suffering from some form of DM, and this number is projected to rise to 700 million by 2045. It is also important to note that T2DM accounts for approximately 90% of all diagnosed cases of diabetes (Goldenberg et al., 2021; Vandenbosch et al., 2018). Globally more than 1 million deaths per year are attributed to DM, and it is the ninth leading cause of mortality (Khan et al., 2020). According to VASCUNET collaboration which is a clinical and administrative vascular registry, the number of amputations performed per 100,000 population varied considerably between countries, being the highest in Hungary and lowest in New Zealand (Behrendt et al., 2018). The Hungarian Central Statistical Office (HCSO) stated that 48% of the Hungarian population reported some form of chronic illness, while 77% of them are aged 65 and older. It is also concerning that more than 80% of health care budget is spent on chronic diseases (Rivera et al., 2018). In Hungary the prevalence of DM is 8.8% and 55.5% of Hungarians are reported to be obese or overweight, which is considered as a risk factor in the onset of DM (Bácsné Bába et al., 2020).

It is important to note that the exponential increase of the disease is also explained by the development of medical technology, changes in diagnostic criteria, the prevalence of screening tests, so it is not only due to a sedentary lifestyle, unhealthy eating habits, and the phenomenon

of an aging society (Thibault et al., 2016; Zheng et al., 2018). Additionally, it has been stated that T2DM negatively affects patients' quality of life as well as life expectancy (Chew et al., 2017; Faselis et al., 2020; Trikkalinou et al., 2017) and it often puts serious economic burden on the society and its health care systems (Karl et al., 2020).

From the point of view of diabetes treatment, it can be stated that in order to regulate long-term metabolism parameters, it is not enough to follow and accept the treatment instructions advised by a physician, but it is also necessary to constantly monitor and keep blood glucose values within the appropriate targets (Marín-Peñalver et al., 2016). During the medical nutrition therapy individuals diagnosed with T2DM should pay attention to creating a proper diet plan, their exact energy requirements, as well as the frequency of meals. At the same time, it is important to incorporate regular and properly planned and performed physical activity into their lifestyle, which has to be customised and adapted the patient's endurance capacity, health status, age and other comorbidities (Karádi et al., 2020; Winkler, 2012). We must also emphasise that T2DM requires the target values of treatment to be customised for each individual. These should be determined and monitored by the physician and the patient in the form of a treatment target range (glycated hemoglobin A1C 6.0-8.0%) (Karádi et al., 2020). According to one study only 44-56% of T2DM patients have an acceptable hemoglobin A1C (HbA1c) level (7%) measured in primary care (Beneby et al., 2015). The basis of individualised therapy relies on the fact that these treatment guidelines should not only be formulated in theory, but patients have to be able to adapt to them in practice and integrate them into their daily routine. For this, an appropriate level of patient cooperation, also known as adherent behavior, is essential.

1.1.2. Determination of medication adherence

Initially, the research on patient cooperation paid little attention to patients' perspectives and focused mainly on the indicators of compliance with the prescribed medical recommendations. However, patients' views have become increasingly important over time in the choice of treatments and disease management on a daily basis. In addition, the term 'compliance' has been increasingly replaced by the term adherence, which no longer sees the patient as a passive participant but as an active partner in the doctor-patient relationship and in the therapeutic process (Aronson, 2007; Vrijens et al., 2012). In 1997, the American Heart Association described adherence as a behavioral process, which is influenced mainly by the patient's environment, including the health care system. They also pointed out that the key factors for adherence include the patient's individual level of knowledge, motivation, skills and

psychological resources. In 2005, the intentional and unconscious aspects and factors of medication adherence were recognised, and four years later, in 2009, the term medication adherence was added to the Medical Subject Heading (MeSH) dictionary. Nowadays, the most cited definition of compliance comes from a 1976 study by Sackett and Haynes, which was later replaced by the World Health Organization's (WHO) definition of adherence (Vrijens et al., 2012). According to this latter definition, adherence is '*the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider*' (WHO, 2003, p.3.).

In the study of adherence it is still not clear enough how researchers approach the phenomenon:

- Are they taking into account the extent to which patients seek help from the health care system?
- Are they considering whether the patient takes the medicines and prescriptions prescribed by their doctor?
- Or are they examining the behavior itself, whereby the person deviates from the instructions previously given to them by their doctor related to taking their medication? (Vrijens et al., 2012).

1.1.3. Importance of adherent behavior in Type 2 Diabetes Mellitus

Adherent behavior plays a central role in T2DM in terms of the development of the disease, the appearance of complications, and the aggravation of the disease. Earlier studies related to diabetes therapy adherence focused on patients' medication compliance (Hou et al., 2021; Khunti et al., 2017; L.-K. Lin et al., 2017; McGovern et al., 2018) probably because it is much more easier to monitor and quantify the results compared with other adherence types (Lam & Fresco, 2015; Rickles, 2008). Although taking medication regularly is unquestionably an important part of T2DM treatment, it is important to emphasize that neither medication nor insulin therapy alone can result in desired metabolic enhancement effect if the therapy is not supplemented by proper lifestyle management (medical nutrition therapy and physical exercise) and with adherent behavior related to regular blood glucose monitoring (Krzemińska et al., 2020). In addition, these individuals must concurrently keep their body weight at an optimal level and be able to change their previous unhealthy lifestyle (McSharry et al., 2020; Schlesinger et al., 2020). All these requirements are made more difficult by the fact that lifestyle

factors are strongly related to each other (Schlesinger et al., 2020) and more than 95% of diabetes care is done by the patients themselves (Lin & Wang, 2013; Snoek & Skinner, 2000).

Some researchers emphasize that non-adherence in T2DM patients can be attributed to the traditional approach to diabetes care. In other words, it means that a physician-directed, compliance-oriented approach to care itself promotes non-adherence (Funnell & Anderson, 2000). Due to the fact that diabetes treatment requires not only medical therapy, but also rigorous self-management, in most cases health care professionals and DM patients do not 'speak the same language' (Bruno et al., 2019; Shirazian et al., 2016). On the one hand, approximately half of patients' concerns are not discussed during visits, and nearly 50% of consultations between physicians and their patients do not focus on the same points of the therapy. More precisely, it means that professionals are trying to emphasize acceptable blood glucose levels while the primary goals of the patients are finding ways to accept and live with the disease (Bruno et al., 2019; Funnell & Anderson, 2000).

In Hungary one of the important studies which measured diabetes adherence was carried out by Hankó et al. (2007). The questionnaire study measured medication and lifestyle adherence among Hungarian DM patients and they found that nutrition therapy was followed by 76.8% of patients, physical activity by 33.8%, adherence to blood glucose monitoring by 81%, while adherence to medication by 52.1% (Hankó et al., 2007). Furthermore, in a survey conducted by the National Association of Diabetes Patients (Cukorbeteg Egyesületek Országos Szövetsége – CEOSZ) and Szinapszis Market Research and Consulting (2018) in which 1800 individuals diagnosed with diabetes were included, it was found that 80% of Hungarian DM patients fully follow the physcian's instructions for oral antidiabetics and insulin dosing, while complex lifestyle therapy is followed by only 35% of these persons (Füzesi & Rosta, 2019).

A research on adherence to insulin dosing among diabetes patients analysed U.S., Japanese and German databases, and it found that 18-26% of patients discontinue insulin treatment within one year, while an additonal 15-62% of them fails to administer the prescribed dose of insulin at least once within a year (Polonsky et al., 2017). Previous researches also show that every third person diagnosed with T2DM does not comply with medical instructions for medication, a half of them have an unhealthy diet and two-thirds of these patients live an inactive lifestyle (low physical activity) (Mogre et al., 2019; Sal et al., 2018; Schlesinger et al., 2020). According to a survey that sampled patients from Poland, the Czech Republic and Slovakia, factors associated with adapting to medical nutrition therapy and changes in eating habits induce a deterioration in quality of life (Krzemińska, Bąk, et al., 2020). The latter is also supported by

the results of the Hungarostudy Health Panel survey (2013), which emphasises that the quality of life indicators of DM patients are worse than those of the average population (Sal et al., 2013).

It is important to highlight that adherence to regular blood glucose monitoring is also increasingly challenging for DM patients. Primarily because it limits the patient's lifestyle, their meal times, and it also shows a strong correlation with adherence to nutrition and exercise therapies. On the other hand, inadequate blood glucose control may increase the frequency of hyper- and hypoglycemic conditions, as well as the possibility of late diabetes complications (Janapala et al., 2019.; Rubin, 2005; Sun & Lian, 2016). However, in Hungary instructions related to daily blood glucose monitoring is followed by only half of DM patients (CEOSZ, 2018). At the same time, the degree of adherent behavior related to blood glucose monitoring among various adherences is not sufficient in itself to successfully treat the disease because the control of blood sugar levels is affected by the duration of diabetes, the state of beta-cells, the presence of comorbidities and the age of the person (García-Pérez et al., 2013; Nowakowska et al., 2019).

1.1.4. Self-management types of DM patients in light of their adherent behavior

It has been stated that the nature of diabetes care is dynamic (Delamater, 2006), therefore, patients' self-management, the success of self-care in evaluating the process and adaptation to therapy is essential (Barnard et al., 2014; Boels et al., 2019). '*Self-management is defined as the ability of patients to adopt and maintain certain health promoting behaviors'* (Shirazian et al., 2016, p.19). Basically, self-management comprises three different sets of activities: one of them is medical management, (e.g. taking medication and adhering to nutrition therapy); the second one is behavioral management, (e.g. adopting new behaviors in the context of a chronic disease); and the third one is emotional management, (e.g. being able to cope with the negative feelings associated with chronic disease) (van Smoorenburg et al., 2019). Self-management is successful when T2DM patients themselves are able to control all these aspects. This is why self-management support must be developed from the perspective of patients, rather than health professionals and healthcare providers (van Smoorenburg et al., 2019). In other words, diabetes self-management is the main strategy for controlling DM, and patients' activation levels significantly improve it (Hosseinzadeh et al., 2021). Inadequate self-care behaviors put patients into a passive, vulnerable position during diabetes care, and they will be forced to endure

fluctuations of their metabolism; their quality of life will decline, life prospects will deteriorate and diabetes complications are more likely to develop (Hosseinzadeh et al., 2021).

Rivera et al. (2018) state that one of the reasons why self-care varies among T2DM patients is that these persons conceptualize their disease, its treatment and its significance very differently (Rivera et al., 2018). Fazio et al. (2019) examined types of successes experienced by T2DM individuals who participated in a randomized control trial. The findings of the study highlighted that patients experienced success in many ways such as changes in health behaviors, mindset or awareness, engagement with resources, physical or emotional health, and health indicators. Furthermore, they concluded that health technology paired with nurse coaching can help patients to achieve better results in diabetes management (Fazio et al., 2019). Vég et al. (2006) used three open-ended questions about self-perceived role in diabetes management and they identified three categories of self-management profiles: Disease Manager, Compliant and Disheartened. Moreover, they related these profiles with glycemic control of patients (Vég et al., 2006). In the DIABASIS study which measured T2DM patients' self-management, researchers identified five distinct patient types: 'committed' (25%); 'carefree' (23%); 'bitter' (19%); 'disheartened' (19%); and 'overwhelmed' (15%). According to this study, the most evident differences between categories were patients' commitment to lifestyle changes, especially exercise, and their support needs for diabetes management. During the exploratory multivariate analytical method of canonical typology it was concluded that the most problematic patients were the 'bitter' and 'overwhelmed' patient groups. Moreover, the study found that 'disheartened' and 'overwhelmed' patients are more overweight, while 'bitter' and 'overwhelmed' patients are more frequently treated with insulin. In addition, 'overwhelmed' patients appear to have feelings of depression more frequently and are overall less satisfied with their treatment. The only deficiency of the study was that only 19% of the sample consisted of insulin-treated patients and its results were based on a self-questionnaire survey study (Mosnier-Pudar et al., 2010). It could be stated that national surveys based on representative samples, studies using standardized scales and questionnaires cannot explore T2DM patients practices in depth. However, still few qualitative studies measure the complex T2DM management practices (Weller et al., 2017). Therefore, it is becoming evident that patient adherence can be described as a dynamic, constantly changing process influenced by a combined effect of several factors (WHO, 2003). As in the present dissertation we are making an attempt to understand and explore the complexity of treatment adherence through the lens of the patients, the effect

of a non-clinical factor, namely health literacy (HL), should not be ignored either since it is important not only in prevention but also in treatment of the disease.

1.1.5. Health literacy and diabetes-specific numeracy skills in the therapeutic effectiveness of insulin-treated T2DM patients

Based on the definition of the Institute of Medicine, HL is '*the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions*' (Ratzan and Parker, 2000, p.6). Another definition of HL is adopted by the WHO, which describes HL as cognitive and social skills which are needed for patients to gain access, understand, and use information and services to make decisions about their health (Nutbeam, 2015). In the literature, two types of HL can be identified: one is connected to individuals' performance and it is called performance-based HL, while the other one is self-assessed HL (van der Heide et al., 2016). Martensson and Hensing emphasise the point that HL shows fluctuation from situation to situation and many times depends on the environmental context (Sørensen & Pleasant, 2017). Because of this, professionals often devide HL into three different dimensions: functional, communicative and critical health literacy (Wångdahl & Mårtensson, 2015). One of the most widely studied dimensions is functional health literacy (FHL), which is connected to the communicative and critical HL dimensions and focuses on basic functional skills (reading comprehension, writing skills and numeracy) in addition to knowledge about disease and maintaining or improving health (Heijmans et al., 2015).

Besides basic reading and comprehension, numeracy skills are also essential. *Numeracy can be defined as the ability to understand and use numbers in daily life*' (Rothman et al., 2008, p. 584). In addition to reading skills, numeracy skills are required in many health-related tasks, such as understanding food labels, measuring medications, interpreting blood parameters, understanding health risks and symptoms (Bailey et al., 2014; K. Cavanaugh et al., 2009; Rothman et al., 2008). More precisely, in the context of healthcare, numeracy includes not only the ability to interpret risk, but also the ability to estimate time and measure, logical thinking and multistep math skills needed to solve problems and make appropriate health-related decisions (K. Cavanaugh et al., 2008). Golbeck et al. (2005) emphasized that numeracy may be operationalized in four functional categories: basic (identifying numbers), computational (e.g. determining net carbohydrates based on information on a nutritional label), analytical (including inference, estimation, proportions), and statistical (e.g. probability, risk) (Golbeck et al., 2005).

In addition, Huizinga et al. (2008) also emphasize that a higher numeracy level among DM patients helps understand medical graphic representations (Huizinga et al., 2008).

According to previous studies, inadequate HL is common among DM patients (Abdullah et al., 2019; Lavin-Tompkins, 2020; Osborn et al., 2010; Papp-Zipernovszky et al., 2016), which is a cause for concern, as it is a disease that requires adequate disease knowledge and skills. It has been also stated that limited HL shows significant association with age, education level, worse self-reported health, poorer health outcomes and shorter life expectancy (Lavin-Tompkins, 2020; Poureslami et al., 2017; Vogt et al., 2018). At present in most countries across the world educational information about diabetes treatment and healing is distribued to patients on paper. Lifestyle therapy and disease treatment related recommendations by the physicians are also handed out to patients on paper due to the overload of healthcare systems. This means that diabetes patients are able to interpret and follow disease related medical recommendations only if they understand what they read, i.e. they have the right FHL that comprises reading, comprehension and numeracy skills. Thereby it can be asserted that studying and understanding FHL has become a major topic in DM research (Al Sayah et al., 2013) since patients' limited HL presents significant risks to prevention and treatment (Chew et al., 2008). Taking into account that HL researches among chronic patients, including T2DM patients who are treated with insulin, are less common in Central and Eastern Europe countries, including Hungary, the study of the phenomenon becomes justified (Baccolini et al., 2021; Heijmans et al., 2014).

In order to interpret and evaluate the importance of HL in terms of its therapeutic effectiveness, it is essential to understand the role of FHL and numeracy skills in self-management of diabetes. Al Sayah et al. (2013) compiled areas within diabetes self-management where basic FHL and numeracy skills are essential:

- patients have to be able to read and understand medication labels, information on medication bottles, insulin bottles and pens, and apply this information in taking medication and/or insulin, and be able to properly interpret blood glucose values;
- these individuals have to read diabetes education materials and apply described instructions in their daily life activities;
- T2DM patients must understand how to follow nutrition therapy, why physical activity is an important element of diabetes therapy, and why frequent self-monitoring of blood glucose level is indespensable;
- these individuals have to be able to complete medical forms, glucose monitoring logs, and dietary logs;

- they have to communicate with health care providers, be able to explain their health concerns, ask adequate questions, and obtain needed information;
- as they have to undergo several types of medical examinations during diabetes management, they have to know how to successfully navigate through different health care systems, and make appropriate health-related decisions (Al Sayah et al., 2013)

All in all, it can be stated that self-management of T2DM requires advanced FHL and numeracy skills (Al Sayah et al., 2013; R. O. White et al., 2010; Yamashita & Kart, 2011). DM patients with limited skills in reading, comprehension, oral communication and in diabetes-specific numeracy will not be able to participate adequately in traditional health education, and they will also have less developed skills to act upon instructions they get from health-care providers (Nutbeam, 2015). According to previous research, only 50% of patients with inadequate FHL and numeracy skills recognise common symptoms of hypoglycemia and only 38% correctly respond to the need to eat when experiencing the symptoms (K. Cavanaugh et al., 2009). HL and numeracy skills are associated with numerous health outcomes, impact health status and health-related behaviors (Connor et al., 2013). FHL as a nonclinical factor is also associated with increased risk of diabetes complications (Bailey et al., 2014) and risk of hypoglycemia (Sarkar et al., 2010). It has also been observed that lower levels of FHL among patients may cause difficulties in naming their medications and describing their indications. Additionally, inadequate FHL levels independently associate with poor understanding of the disease (Schillinger et al., 2003), with lower self-rated health and with a range of poor health outcomes (Berkman et al., 2011; Nutbeam, 2000; Sørensen & Brand, 2014). Despite the fact that FHL not only influences but also affects patients' ability to function in a health care system (Kickbusch, 2001), this skillset could also help patients to cope with the consequences of a chronic illness, and increase their confidence during medical consultations (Heijmans et al., 2015).

Diabetes-specific numeracy skills impact patients' health behavior (K. Cavanaugh et al., 2008), associate with a higher HbA1c levels in T2DM patients (Juul et al., 2018), negatively affect adherence to recommendations, and also cause more complications (Speros, 2005; Wang et al., 2019). Individuals with significantly better mathematic skills are able to apply this knowledge to diabetes and they are more likely to have greater confidence in performing self-care tasks (K. Cavanaugh et al., 2009). Based on other research findings, lower levels of FHL were not necessarily associated with worse HbA1c levels (Kim et al., 2004; Morris et al., 2006),

nevertheless, it has been found that they correlated with the presence of more diabetes complications (Ishikawa et al., 2008; Vandenbosch et al., 2018).

One of the main barriers according to identifying patients' poor HL is that health care professionals often overestimate their patients' skills, due to persons' compensatory behavior. More precisely, these individuals often do not diclose their troubles, doubts about treatment or health information given by health care providers because they may feel shame and embarrassment due to their poor skills (Al Sayah et al., 2013; Andrus & Roth, 2002; Chew et al., 2008), and because of that most of these patients will not be able to adhere to various treatment regimens (Miller, 2016). It is important to keep in mind that FHL and diabetes-specific numeracy skills are critical components of diabetes self-management; however, these are not the only variables which influence patients' self-care skills. Both theoretical and empirical studies confirm that a person's level of self-efficacy, attitudes, motivation, degree of severity of illness, and social factors too impact self-management behavior (van der Heide et al., 2014). Moreover, Miller (2016) suggests that adherent behavior is based on the patient's ability to understand and organise health information, as well as on motivation to take care of their own health (Miller, 2016). However, it is important to mention that the connection between HL and diabetes self-management is not straightforward and depends on the type of self-management behavior followed by patients (Fransen et al., 2012; von Wagner et al., 2009). This is especially true for diabetes patients with poor FHL because these chronic patients must adhere to complex treatment regimens, manage visits to multiple clinicians, monitor themselves for changes in health status and initiate positive health behaviors (Schillinger et al., 2003). All in all, adequate FHL could enhance understanding and awareness about chronic disease and help facilitate patients' engagement in diabetes self-management (Poureslami et al., 2017).

1.1.6. Psychological aspects which could influencing diabetes self-management activities

The treatment of insulin dependent DM can create the experience of being in a 'constant present' as patients are required to self-monitor themselves and maintain their condition. The feeling of a never-ending present is infused with a number of fears and doubts related to their future and plans (for example: concerns about the course of the disease and the appearance of late complications). Therefore professionals need to recognise that even with advanced, innovative and effective diabetes technologies, a wide range of insulin preparations, excellent oral antidiabetic drugs and besides top medical expertise, the therapy of T2DM patients requires

a holistic approach that takes into account patients' ability to adapt, their mental and material opportunities, and their motivational pillars.

Nowadays, diabetes care rather focuses on biomedical aspects of patients' care and pays little attention to the psychological and social impacts of DM (Litterbach et al., 2020). To be a committed and cooperative patient is not easy at all. One of the main reasons is that there are multiple biological, psychological, social, behavioral and cultural factors that play a role in the development and progression of DM (Caballero, 2018; Dirik & Göcek-Yorulmaz, 2018; Hill-Briggs, 2003). Another reason is that patients' self-management activities are complex and they are embedded in their unique life situatitons (Hill-Briggs, 2003; Minet et al., 2011). Clinical practice therefore needs to address the challenge of putting patients' inviduality first and understanding their behavior and system of subjective experiences through an individual's personal history and context (Graffigna et al., 2014; Young-Hyman et al., 2016). Hendrieckx et al. (2020) emphasises that a truly patient-centred care and shared decision-making can result in greater treatment satisfaction among patients with DM (Hendrieckx et al., 2020). With this type of approach, we get the opportunity to understand why, despite appropriate health care and educational programmes for patients, absorbing information remains selective among patients. A possible explanation can be related to the fact that we usually store information which is in line with our disposition and attitudes. If we consider this as truly decisive, then we need to bring the individual into focus for a complex understanding of the phenomenon.

An illness confronts people with vulnerability, mortality and the question whether life is meaningful (Pintér, 2018). Thus, the internal processes taking place in an individual can only bring change in their adherence if their intellectual/cognitive and emotional levels are concurrent. Most patients have their own explanatory model of illness, why they think symptoms, a disease or health-related situation may be happening (Caballero, 2018). It is important to highlight that these individual representations of illness are closely linked with diabetes self-management activities and influence the way people act and cope with the disease (Dimova et al., 2019; Heijmans & De Ridder, 1998; Reinhardt, 2007). For example negative illness perceptions can increase emotional distress and depression (Skinner et al., 2014), and they can be associated with poorer adherence to diabetes treatment (Burns et al., 2016). However, adaptive coping strategies help improve HbA1c levels and dietary behavior (Knowles et al., 2020). In terms of coping with chronic disease, illness perceptions play a more significant role than disease severity (Látos et al., 2021). Leventhal et al. (1984) describe seven components of illness representations: identity (symptoms), consequences, timeline, cause,

controllability, emotional representations and illness coherence. Patients' motivations which impact self-management of T2DM could be examined with the aforementioned parameters (Dimova et al., 2019). Since enhancing self-management is a very complex and critical step (Rivera et al., 2020), one of the most important objectives is to understand patients' subjective perceptions, experiences of diabetes and to explore their motivations related to T2DM self-management. The meaning given to the illness is the relationship to the illness itself, which essentially determines the attitude to treatment and cooperation with health care professionals. Being ill is therefore never neutral: it has representations, languages and meanings, which include emotional and cognitive content (Pintér, 2018). According to Lipowski (1983), who drew attention to attitudinal components in illness representation, there are eight main meanings of the illness: 'illness as challenge', 'illness as enemy', 'illness as punishment', 'illness as weakness', 'illness as relief', 'illness as strategy', 'illness as irreparable loss or damage' and 'illness as value' (Schüssler, 1992). Besides these, we also need to take the symbolic associations of illness reports into account, as these can influence individuals in how they perceive their own disease and what attitudes they may experience from their environment (Reinhardt, 2007). Thus, in the process of healing the ill, individuals must be taken into account, with their own unique thoughts, feelings, fears and beliefs (Reinhardt, 2007).

Another important fact is that the overwhelming nature of self-management regimens and a constant fear of diabetes-related complications results in poor emotional well-being among T2DM patients (Bruno et al., 2019; Shirazian et al., 2016). This poor emotional well-being means that people diagnosed with T2DM may experience a wide range of negative emotions and feelings (Dimova et al., 2019). Furthermore, these different kinds of fears are usually interwoven with patients' values and health beliefs (Caballero, 2018). Additionally, T2DM patients who are using insulin report significantly more anxiety and more emotional distress during diabetes self-care (Gonder-Frederick et al., 2016; Holmes-Truscott et al., 2018) and they also have less confidence than patients who are not under insulin therapy (Tourkmani et al., 2018; Whittemore et al., 2005). Researchers explain these results with the fact that insulin therapy is different from most medication therapies, because the insulin need of human organism changes throughout the day and could be influenced by physiological and behavioral factors of patients, including their current blood sugar levels, metabolic demand, physical activity and daily food intake (Gonder-Frederick et al., 2016). Furthermore, it is also common that T2DM patients believe the physician's prescription of insulin therapy means that they have failed diabetes self-management and their condition is getting more severe (Ellis et al., 2018;

Stuckey & Peyrot, 2020). Others internalise blame for their diabetes (Dimova et al., 2019) and this diabetes-related anxiety and negative emotions have detrimental effects on their blood glucose levels and glycemic control (Esmaeilinasab et al., 2016).

It is important to note that becoming ill can be a traumatic experience for the subject, especially if it is an incurable disease (Pintér, 2018). This type of stress can directly and indirectly affect blood glucose levels of DM patients. When stress directly impacts blood sugar level, it happens through a physiological stress response. In this case, hormonal fluctuations could negatively impact patient's blood glucose levels. Indirect affects of stress on blood glucose levels are known for their negative influence on self-care behaviors (Serlachius et al., 2011). Stress can also affect food intake and may result in increased energy intake and fat accumulation (Czeglédi, 2012). It is also important to highlight that not every stressful event results in negative psychological effects on diabetes management, because some traumatic events can bring about positive changes alongside these special health problems. The latter is called post-traumatic growth (PTG), which could positively influence the individual's emotions, cognition and behavior. This kind of personal growth after a traumatic event depends on several different factors such as self-efficacy and coping strategies (Dirik & Göcek-Yorulmaz, 2018).

'*Self-efficacy is a person's belief of their ability to control, organize, and execute actions within a given domain of functioning, actions that are necessary to accomplish a goal that they believe to be important*' (Davis et al., 2006, p.61). In the development of self-efficacy, a person's previous successes and failures can be decisive. Moreover, model effects provided by others, the individual's own beliefs and a positive, supportive environment are also significant. These are especially important when the course of the illness becomes worse due to the nature of the chronic disease. If patients have a lower level of self-efficacy, they might experience more negative feelings and they may think their self-management is unsuccessful (van Smoorenburg et al., 2019).

As we have previously mentioned, there are many components which can affect how people develop and cope with stressful situations such as being diagnosed with T2DM, how successfully they can change their previous lifestyle and acquire new habits, gain adequate diabetes knowledge, following medical advice and perform diabetes self-management tasks. It is also well-known that coping difficulties are common among T2DM patients. One of the main reasons is that the DM regimen is demanding and unpleasant, and some factors outside patients' control can affect their blood glucose levels (e.g. weather conditions, seasonal diseases, etc.).

Furthermore, there is no definite way to avoid diabetes-related complications, which can also be very disappointing for individuals (Snoek & Skinner, 2000). Lazarus and Folkman (1984) define '*coping as the cognitive and behavioral tasks used to manage stressful situations*' (Serlachius et al., 2011, p.2). Coping processess are dynamic: they fluctuate over time and across different situations (Serlachius et al., 2011). According to classic coping theory there are two types of coping strategies: task-oriented and emotion-oriented. Emotion-oriented coping involves efforts to regulate negative emotions that emerge when confronted with a stressor, whereas task-oriented coping means that people believe that the stressor can be changed, and they make active steps to modify the problematic situations (Folkman & Lazarus, 1980). Avoidance-oriented coping has emerged as a third class of coping strategies and involves cognitive and behavioral efforts oriented toward denying, minimising or avoiding the problem or the stressor (Burns et al., 2016).

It is important to emphasize that all the above mentioned depends on how patients perceive their illness symptoms. Disease symptoms are not necessarily biological signs, but can be considered as the results of a complex biopsychosocial process in which sociodemographic factors, personality traits, emotions, expectations and disease-related assumptions also play an important role (Kolk et al., 2003). Diabetes could be asympthomatic for a long time and due to this patients often deny the existence of the condition (Dimova et al., 2019). Furthermore, if defense mechanisms, as psychological strategies, are not effective enough, the person tends to perform unfavorable actions like eating unhealthy, drinking, etc. In addition, regular use of defense mechanisms increases the possibility of a split in emotional and thought processing. According to Arthur Frank, – who is one of the most prominent representatives of the study of disease narratives, – disease involves some kind of self-loss. The feeling of self-loss is especially present in patients diagnosed with chronic diseases, like DM, where it manifests itself as a fundamental form of suffering. With the onset of the disease, patients' previous normal, everyday lives become more valued (Csabai, 2005). In addition, they have to learn to live with the multiple weekday roles and patient roles at the same time (Reinhardt, 2007). A further problem could be the fact that there is no visible trace of DM for a long time. Therefore, T2DM patients live with this diagnosis, and it becomes a part of their self, which can cause a major rupture in identity if their environment is unaware of it (Pintér, 2018).

All in all, it could be stated that T2DM patients need to be able to adapt to a very complex and complicated system during the management of their disease. They have to face the fact that T2DM is not curable, it can only be treated; they need to understand the risks of hyper- and

hypoglycemias; they have to accept the fact that their lives need to be adjusted to diabetes. In most cases, spontaneity disappears from their everydays and a constant self-control should be exercised (e.g. continuous blood glucose monitoring, following strict medical nutrition therapy, etc.). T2DM patients also need to learn to live with some self-harming behaviors (e.g. injecting insulin); they should attend a variety of screening examinations and visit different healthcare providers (e.g. nephrologists, hepatologists, eye or foot specialists, etc.). In other words, they have to develop new relationships with the whole healthcare system.

With the onset of the illness, a number of secondary processes becomes observable: the disease creates new life situations for patients, and forces them to adapt very quickly to the diabetes threapy. Therefore, it is not uncommon that the uncertainty of their own existence becomes a central theme for them. This rearrangement process is psychologically overwhelming for patients, and requires time and patience from both professionals and patients themselves. More precisely, in situations where T2DM patients feel that external expectations exceed their abilities or capabilities, their typical reaction will be rejection or avoidance. The above train of thought is supported by previous studies, which highlight that diabetes education programs can be effective only if professionals take into account patients' own expectations, focus on the long-term processes and give them continuous support and follow-up (Świątoniowska et al., 2019). Moreover, health care professionals should take into account that patients' disrupted emotional balance, changes in their well-being and body integrity, experiences of loss, insecurity in environmental and social situations, and handling traumatic experiences are all processess that require time and perseverance as well as external support. Therefore, to understand adherence problems in this population, researchers have to explore the subjective interpretations, needs and attitudes of these individuals (Chew et al., 2014; Conner & Norman, 2017; Minet et al., 2011; Mogre et al., 2019).

2. Aims

In this dissertation the following aims were set:

Aim 1:

Mapping the adherent behavior of patients with T2DM by examining the association between the various types of adherence.

Aim 2:

Mapping the level of FHL among insulin-treated, T2DM patients. Furthermore, we examined the role and the impact of these special competencies and skills during self-care and disease management.

Aim 3:

Assessing patients' experiences comprehensively related to treatment and types of medication: to explore and understand patients' relationship to treatment, the integration of these experiences into their daily lives, and their expectations related to diabetes mellitus therapy.

We also examined the therapeutic behavior of the patients, the psychological aspects and experiences behind their behavior, attitudes toward treatments and technologies, and the impact of these factors on quality of life.

One of our goals was to analyse the interviews from the qualitative research in a complex manner and to identify the most common patient types and their characteristics based on our results.

In line with the behavioral responses and disease-related coping strategies of the patient types, we tried to formulate psychological intervention recommendations that could help DM patients to adapt more easily to therapies and which could be beneficial for future diabetes care programs.

3. Methods

3.1. Associations of different adherences in patients with type 2 diabetes mellitus

3.1.1. Participants

The sample of the study consisted of patients diagnosed with T2DM receiving treatment at the Diabetes Unit, 1st Department of Internal Medicine, Szent-Györgyi Albert Health Centre, University of Szeged. It is important to note that the patients were in the process of switching from antidiabetics to insulin, or from one type of insulin to another. The final sample consisted of 113 T2DM patients on insulin therapy, including 38 men and 75 women. The mean age of the patients was 60.56 years (*SD* = 12.94, minimum: 20 years, maximum: 85 years), and the participants were diagnosed with DM for an average of 13 years (*SD* = 8.2). Two groups were created in terms of educational attainment: those with a lower level of education and those with a higher level of education. The group of individuals with a lower level of education included those who had finished less than 8 grades or completed primary and middle school or vocational school/technical education or secondary grammar school. The group of individuals with a higher level of education included those who had a higher educational qualification, college or university degree. The majority of participants (70.8%) were retirees (Table 1). The patients' average of HbA1c was 8.98 (*SD* = 3.167). At the moment of the research most of the participants were under intensive insulin therapy (40.7%). The most common comorbidity among participants was hypertension (67.3%) (Table 2).

Table 1 Sociodemographic characteristics of the sample and descriptive statistics for the study variables

Sociodemographic factors	n (%), mean, SD, range
Sex	
Male, n (%)	38 (33.6)
Female, n (%)	75 (66.4)
Age, mean (SD), range	60.56 (12.94), 20-85
20-63 years old n (%)	62 (54.9)
≥ 63 years old n (%)	51 (45.1)
Labor market status	
Employed, n (%)	33 (29.2)
Retired, n (n%)	80 (70.8)
Educational level	
Low level, n (%)	60 (53.1)
High level, n (%)	53 (46.9)

Table 2 Descriptive statistics of the diabetes and health-related factors

Health-related variables	mean, SD
Duration of diabetes	13 (8.230)
Hemoglobin A1C	8.98 (3.167)
Comorbidities	**N (%)**
Hypertension	76 (67.3)
Retinopathia	30 (26.5)
Neuropathia	28 (24.8)
Coronary artery disease	21 (18.6)
Lower extremity ulcers	11 (9.7)
Kidney disease	10 (8.8)
Stroke	9 (8)

3.1.2. Study measurements

We used the self-reported 4-item *Morisky Medication Adherence Scale* (*MMAS-4*), which is the most commonly used scale in the literature on the subject, to measure patients' adherence to medication. The four items on the scale consisted of questions about taking medication, particularly as prescribed. The questionnaire was of the forced choice type (yes or no), and patients who responded 'no' to three or more of the questions were considered to have high adherence (Morisky et al., 1986).

An adherence questionnaire conceptualized by the research group was used to explore different adherence types. Our questionnaire measures diverse types of adherence: adherence to medication, adherence to blood glucose monitoring, adherence to medical nutrition therapy, and adherence to physical exercise. The section about adherence to medication contains statements related to medication prescription and taking medication according to prescription (e.g.: *'I follow the prescribed treatment regimens for my illness with regard to getting all the prescribed medicine'* or *'I follow the prescribed treatment regimens for my illness with regard to take medication according to the prescription'*). Adherence to blood glucose monitoring was measured with a statement related to prescribed treatment regimens (e.g.: *'I follow the prescribed treatment regimens for my illness with regard to measuring blood glucose level'*). Lifestyle therapy adherences were measured with statements related to medical nutrition therapy and daily physical exercise (e.g.: *'I follow the prescribed treatment regimens for my illness with regard to medical nutrition therapy'* and *'I follow the prescribed treatment regimens for my illness with regard to daily physical exercise'*). The goal of our diabetes-specific adherence scale was to measure multiple adherence types and to allow for a more nuanced comparison on a five-point scale in contrast with the MMAS-4 scale, which measures with binary values. In addition, we collected demographic data of the participants.

3.1.3. Data analysis

Data were collected between February and November, 2016 by convenience sampling conducted by an interviewer who asked the participants to evaluate their adherence to DM therapy by filling out a questionnaire. When the data were processed, one patient's data had to be excluded as the person had been diagnosed with diabetes for 60 years, which was an outlier in our sample. In processing the data, we checked the distributions with participants'

sociodemographic data and statistics on the analysis of their scores (mean ± deviation) (Table 1). We examined the relationship between variables using Spearman's rank correlation and used multivariate regression analysis of predictive variables for adherent behavior. In addition, we attempted to examine factors with a negative effect on adherence using factor analysis. It is important to note that the MMAS-4 scale was excluded during the statistical analysis because of its low reliability level (Cronbach's alpha value = 0.544). Instead of the MMAS-4 results, the results of the adherence questionnaire conceptualized by the research group were taken into account. In addition, the study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Human Investigation Review Board of University of Szeged (Approval No. 3715).

3.2. Health literacy and diabetes-specific numeracy skills in the therapeutic effectiveness of insulin-treated T2DM patients

3.2.1. Participants

The present study included 102 insulin-treated T2DM patients, 42 men and 60 women, with a mean age of 64.75 years (*SD* = 9.180, range: 37–85 years) and an average diabetes duration of 10.76 years (*SD* = 6.702). Most of the participants had high school (*N* = 58) education, while 29 participants finished primary school and 15 of them had a university degree. The average duration of insulin treatment was 6.59 years (*SD* = 5.098), while the majority (45.1%) of the participants reported administering insulin four time per day. It is important to note that most of the patients (67.6%) measured their blood glucose levels more than twice per day, while 73.5% had diabetes complications. In terms of the latter, the distribution was as follows: vision impairment (retinopathy): 52% (*N* = 53); cardiovascular disease: 44.1% (*N* = 45); kidney failure (nephropathy): 7.8% (*N* = 8); nerve damage (neuropathy): 45.1% (*N* = 46); lower limb amputation: 6.9% (*N* = 7).

3.2.2. Study measurements

Brief Health Literacy Screen (BHLS)

Three health literacy screening questions were developed for rapid pre-screening at the clinic to identify adults with inadequate health literacy. These were the following questions: *'How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver)*

help you read hospital materials?' (Help Read), *'How often do you have problems learning about your medical condition because of difficulty understanding written information?'* (Problems Reading), and *'How confident are you filling out forms by yourself?'* (Confident with Forms). Responses were given on a Likert scale from 0 to 4 (0 = never, 1 = occasionally, 2 = sometimes, 3 = often, 4 = always). Administration time of the test is 3 minutes. The higher number of points scored after adding up points for each response, the more problematic the person's health literacy is. It is important to note that according to the original scoring the point value of the first item is calculated as reversed (Papp-Zipernovszky et al., 2016).

Short Test of Functional Health Literacy (S-TOFHLA)

Originally, the S-TOFHLA, which stands for Short Test of Functional Health Literacy, includes reading comprehension and numeracy tasks. As our goal was to examine diabetes-specific HL, we included a diabetes-specific numeracy test instead of the general calculation exercises of S-TOFHLA. It is important to note that the other reason why we did not use S-TOFHLA's computational tasks was because the numeracy section in the Hungarian version showed a low internal reliability value (Papp-Zipernovszky et al., 2016). During the reading comprehension exercise of S-TOFHLA, the subjects read medical information on abdominal x-rays (3^{rd} grade comprehension level, 16 questions) and a text related to health insurance contracts (9^{th} grade comprehension level, 20 questions), and they had to complete the sentences of the texts by choosing the right one out of four possible answers. The total time to complete the S-TOFHLA is 7 minutes. Respondents were not informed about the time constraint but were stopped after 7 minutes by the interviewer. Each correct answer is worth 1 point, and questions left blank, wrong answers and answers given after 7 minutes are worth 0 points. The maximum score of the S-TOFHLA reading comprehension test is 36 points. Based on the scores obtained on the test, scoring 0-16 points means an inadequate HL, 17-22 points marginal HL and 23-36 points adequate HL of the subjects (Baker et al., 1999).

A shortened version of Diabetes Numeracy Test (DNT-15)

In order to better understand numeracy in T2DM, a shortened version of Diabetes Numeracy Test (DNT-15) was used. The DNT-15 specifically evaluates numeracy skills used by patients diagnosed with DM. It consists of 15 questions in four domains: nutrition, exercise, blood glucose monitoring, and medication. DNT-15 includes three items on nutrition, one item about

exercise, three items regarding blood glucose monitoring, one item on oral medications and seven items about insulin administration. Estimated administration time of DNT-15 is between 15-20 minutes. The scale covers different types of math problems such as addition, multiplication or division, fractions, multistep mathematics, and numeration/number hierarchy (Huizinga et al., 2008).

To the best of the authors' knowledge, diabetes-specific numeracy skills have not been studied in Hungary among insulin-treated T2DM patients. Due to that fact the DNT-15 was translated from English into Hungarian by applying standardized translation methods, such as back-translation and cultural adaptations, which are essential steps before implementing an instrument in research (Brislin, 1970; McDermott, & Palchanes, 1992; John, Hirsch, Reiber, & Dworkin, 2006; Sechrest, Fay, & Hafeez Zaidi, 1972). Before using the translated version of the DNT-15 instrument on a larger sample, a pretest was conducted with 10 independent respondents, who completed the test in order to determine if the tasks were comprehensible and if there were any legitimate comments about the test questions.

3.2.3. Data analysis

The investigation was conducted between January and March, 2020. A cross-sectional quantitative research was conducted. Convenience sampling was used as a sampling method. Subjects were recruited with the help of three diabetes associations in Csongrád County. The inclusion criteria for the participants were as follows: 18 to 89 years of age; diagnosed with T2DM; use of insulin therapy; voluntary participation in the study. Regarding the exclusion criteria, cerebral stroke affecting cognitive processes or previous head injuries were listed. After the preparation and detailed analysis of statistical data, we detected missing values and screened the outliers in the sample. The Kolmogorov-Smirnov Goodness-of-Fit test was used to assess the distribution of data. In order to gain correct results from the statistical analysis, we had to take into account the fact that our complex analyses were made on a smaller sample, we had data with variables which include ordinal scales too, and also that conditions for normality deviation were not always met. Therefore we decided to use nonparametric tests. To describe the population's characteristics and providing basic information about variables in a dataset, we used descriptive statistics. Internal consistency and reliability value of the measurements were tested by Cronbach's Alpha and Kuder-Richardson reliability coefficient. We examined the associations between variables using Spearman's rank correlation. Differences between groups

were checked with the Mann-Whitney test, and in order to suppress type 1 error, the significance value of our tests was examined using Bonferroni correction, while for dependent variables with ordinal values the Kruskal-Wallis test was used. In addition, Partial Least Squares Structural Equation Modeling (PLS-SEM) path analysis was used to estimate a complex model of diabetes self-management components. The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Human Investigation Review Board of University of Szeged (Approval No. 4639).

3.3. Treatment attitudes of insulin-treated T2DM patients, integration of self-care into daily life and expectations related to diabetes therapies

3.3.1. Participants

Interview participants were selected with stratified convenience sampling and snowball sampling. The final sample consisted of 50 insulin-treated patients (24 men and 26 women), who were diagnosed with T2DM. The mean age of the patients was 64.82 years (SD = 9.735) and they all had been diagnosed with T2DM for an average of 18.77 years (SD = 12.303). In terms of education, there were 11 patients who had primary education, two of them had vocational education, 22 of them finished high school, one person had an academic secondary school degree, while 14 people had a university degree. The majority (N = 30) of the participants were married. Participants were asked to rate their financial situation on a scale of 1 to 10 on the basis of subjective judgment. According to the results, individuals gave an average value of 5.98 to their subjective financial situation. In the final sample, there were 41 (82%) patients who suffered from one or more comorbidities, while 9 (18%) patients reported having no, or at least do not know having other illness besides T2DM. The most common diabetes complications were hypertension (42%) and cardiovascular disease (38%). During the recruitment of patients, twenty people rejected the participation in the study. Five subjects dropped out of the sample because these individuals were so touched by their previous memories and facts about DM that they asked the interviewer if they could quit the interview. Exclusion criteria included documented mental retardation, decreased cognitive function, and severe psychiatric disorder.

3.3.2. Study measurements

A qualitative study using semi-structured interview techniques was carried out. The interview questions were organized along three main groups of questions focusing on the history of the illness, the current treatment regimen, and the ecological context of the treatment which is related to the environmental (social and situational) parameters that could affect treatment effectiveness. The elements related to the content were drafted following the recommendations of the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist. Qualitative results from semi-structured interviews related to insulin-treated T2DM patients' treatment experiences, diabetes-therapy expectations, adherence and quality of life were analyzed and evaluated by using thematic content analysis.

3.3.3. Data collection

Data were collected during semi-structured interviews between October 2018 and September 2019. During data collection, patients who appeared in the routine patient care at the 1st Department of Internal Medicine, Szent-Györgyi Albert Health Centre, University of Szeged were personally informed about the research by the interviewer. During snowball sampling followed by a telephone inquiry, the interviewer and the interviewee agreed on the date and details of the face-to-face interview study. All participants participated in the interview study on a voluntary basis. The patients were also informed about their right to discontinue the interview and that there would be no consequences whatsoever to their participation. The interviews were audio-recorded with the patients' consent and transcribed with the deletion of personal data to ensure confidentiality of the participants' data in accordance with ethical rules. The interviews were recorded privately in a closed and quiet room. The interviews lasted 1 hour 30 minutes on average. The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Human Investigation Review Board of University of Szeged (Approval No. 4324).

3.3.4. Data analysis

All the interviews were transcribed by verbatim transcriptions. After manual analysis of the qualitative data the final transcripts were uploaded into Analysis Software for Content in Qualitative Research – ATLAS.ti 8, a qualitative software program for coding and theme

generation. The texts of the transcripts were analyzed by AK, OP-Z and by an independent encoder, who was not a member of the research team. Before coding, the units of the texts in the sample were categorized, and in order to draw replicable and valid conclusions, they were recoded by two independent coders and differences between coders were also examined. The internal reliability of the resulting qualitative results was calculated using Krippendorff's internal reliability value, according to which the Alpha value = 0.920, i.e. strong inter-rater reliability was detected. Quotations from participants were presented to illustrate the main themes and findings. These quotations are provided in the results to illustrate the themes/findings with each quotation identified by gender and age of anonymised participants. To ensure that the examples are illustrative of the findings, we have provided the most salient quotations from the interview transcripts. The following main themes were detected in the interviews: 'representation of illness', 'emotional response to disease' 'living with the disease' and 'openness to new technologies', which included satisfaction with the current treatment regimen. The differences in responses determined the categories (e.g. self-illness relationship, successful long-term coping, etc.) within the main themes (e.g. representation of illness, living with the disease, etc.). It is important to note that the analysis also took into account the interviewer's self-reflections and the nonverbal, metacommunicative signs of the subjects (e.g. facial expressions, gestures, proxemics, etc.).

4. Results

4.1. Associations of different adherences in patients with type 2 diabetes mellitus

On the *Diabetes Adherence Questionnaire* which measured self-reported adherence level, 87.6% of the respondents stated that they get all the prescribed medicines, and 80.5% of respondents reported taking medications according to prescriptions. 78.8% of the patients stated being adherent to measuring blood glucose level, while adherence to diet was stated by only 13.3% of participants. From lifestyle therapies patients adhered to physical exercise the least, only 12.4%.

4.1.1. The association between the various types of adherence

Adherence to medication showed a weak, positive, significant correlation with adherence to glucose monitoring among T2DM patients (r_{106} = 0.322, p < 0.001); that is, the more adherent patients to drug treatment, the more likely they are to follow instructions on self-monitoring of blood glucose levels. However, adherence to medication showed a moderate-to-negative correlation with patients' medical nutrition therapy adherence (r_{109} = –0.575, p < 0.001). This finding suggests that the more patients adhere to taking antidiabetics regularly and properly, the less motivated they feel to adhere to carbohydrate intake and to meet the criteria for a proper diet. Furthermore, we found a moderate, significant, and inverse correlation between adherence to medication and adherence to physical exercise (r_{108} = –0.496, p < 0.001), suggesting that the more patients follow medication orders, the less they will adhere to physical exercise therapy. Adherence to medical nutritional therapy showed a correlation with adherence to blood glucose monitoring (r_{105} = 0.414, p < 0.001) as well as with adherence to physical exercise (r_{109} = 0.279, p = 0.003). Based on these findings, we can say that the subjects who attempted to integrate the diet prescribed for people with diabetes, were more likely to control their blood glucose levels, and found time to follow the prescribed physical exercise regimen (Table 3).

Table 3 The relationship between various types of adherence and Spearman's rank correlation values

	Adherence to medication	Adherence to blood glucose monitoring	Adherence to medical nutrition therapy	Adherence to physical exercise
Adherence to medication		0.322∗	– 0.575∗∗	– 0.496∗∗
Adherence to blood glucose monitoring	0.322∗		0.414∗∗	
Adherence to medical nutrition therapy	– 0.575∗∗	0.414∗∗		0.279∗
Adherence to physical exercise	– 0.496∗∗		0.279∗	

∗∗ p < .01; ∗ p < .05

4.2. Health literacy and diabetes-specific numeracy skills in the therapeutic effectiveness of insulin-treated T2DM patients

4.2.1. Average score of the correct responses and the internal consistency of the functional health literacy measurements

The internal consistency of the BHLS measurement was 0.412, which indicates a low reliability. Due to this, the self-reported health literacy test was excluded from the complex statistical analysis.

In the S-TOFHLA's reading comprehension task the average score of correct responses for task „A" (3rd grade comprehension level) was 78.5%, while the average score of correct responses for task „B" (9th grade comprehension level) was 56.4%. Because of the 7 - minute timeframe, the rate of correct responses for item 6 in task „B" was lower. The average score on the S-TOFHLA was 23.78 points (*SD* = 10.084), while the 36-item scale included a Cronbach's alpha of 0.957, indicating high reliability. Based on the results, 27.7% of the participants (*N* = 28) had inadequate FHL, 6.9% (*N* = 7) had marginal FHL, and 65.3% (*N* = 66) had adequate FHL (Table 4).

Table 4 The percentage distribution of the sample's FHL levels in the S-TOFHLA

S-TOFHLA scores (reading task)	N (%)
Inadequate Functional Health Literacy (0-16)	28 (27.7%)
Marginal Functional Health Literacy (17-22)	7 (6.9%)
Adequate Functional Health Literacy (23-36)	66 (65.3%)

DNT-15 test had good internal reliability (*KR-20* = 0.85). The average score on the DNT-15 test was 7.51 (*SD* = 3.509). Results show that problem areas for respondents mostly included food label interpretation and items that required multistep calculations, like calculating insulin dosage based on current blood glucose level and carbohydrate intake.

4.2.2. The role of functional health literacy and diabetes-numeracy in the PLS-SEM model of sociodemographic variables, subjective health status, HbA1c values, duration of insulin treatment and diabetes self-management behaviors

In the current thesis we tried to understand the relationship between measured variables with the help of Partial Least Squares Structural Equation Modeling (PLS-SEM), because with this method the regression equations and paths can be detected among the examined variables. More precisely, the PLS-SEM method enables us to estimate complex models with many constructs, indicator variables and structural paths without imposing distributional assumptions on the data. Furthermore, PLS-SEM can be successfully used in samples that do not follow a normal distribution, and its advantage is that it can be used for nominal, ordinal, and interval measurement level scales. Smaller sample sizes can also be measured reliably with PLS-SEM.

Taking into account the significant effects of variables, the final model included the following variables: sociodemographic latent variables as age, marital status and educational attainment. The model also included the results of the S-TOFHLA and DNT-15 tests, the subjectively assessed health status, HbA1c levels, which indicate three-month blood glucose levels, the duration of insulin treatment, the frequency of daily blood glucose monitoring and daily insulin administration, which all play an important role in the management of T2DM. Regarding direct effects, based on the standardized path coefficients indicated on the arrows in Figure 1, the pairings between latent variables can account for both positive and negative effects.

Based on the analysis, the results of S-TOFHLA are more strongly influenced by patients' age ($\beta = -0.417$), marital status ($\beta = 0.226$) and educational attainment ($\beta = 0.501$). The S-TOFHLA, which measures reading and comprehension competencies, effects the diabetes-specific numeracy DNT-15 test results ($\beta = 0.626$). In addition, the subjective health status of T2DM patients has a negative effect on the DNT-15 test scores ($\beta = -0.177$). Self-assessed health status also shows a positive impact on the outcome variable, i.e. the HbA1c level ($\beta = 0.079$), while it has an inverse effect on one of the self-management behaviors, namely, the frequency of daily insulin administration ($\beta = -0.028$), which impacts HbA1c values ($\beta = -0.180$) and it is also conditioned by the duration of insulin treatment ($\beta = 0.103$). At the same time, regular blood glucose monitoring, which plays a key role in the treatment of T2DM, is affected by patients' DNT-15 scores ($\beta = 0.304$) and the frequency of daily insulin administration ($\beta = 0.607$). The direct effect of subjective health status through the variable of

daily insulin dosage frequency on the HbA1c level is positive and smaller (–0.028 ∗ (–0.180)) than its indirect effect (β = 0.079). Among indirect effects, education level has a positive impact on DNT-15 scores (0.314), while S-TOFHLA has a positive impact on the frequency of daily blood glucose measurements (0.190).

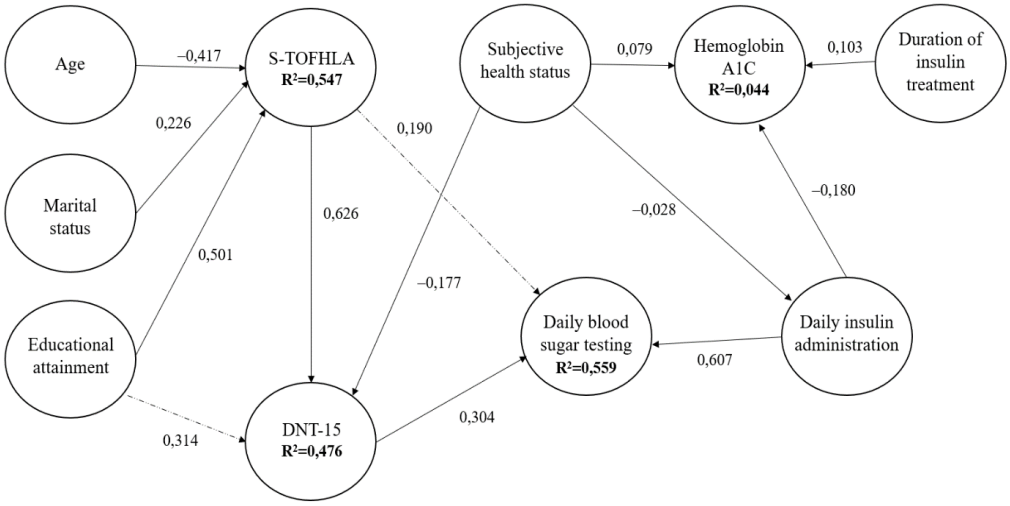
The partial and full mediation relationships were determined with the Cohen's f^2 effect size. It is important to note that values around 0.02 have low, values around 0.15 have medium, and values around 0.35 indicate a strong effect size (Cohen, 1988). The effect sizes between the variables are shown in Table 5.

Table 5 The effect sizes between the variables in the model

	S-TOFHLA	HbA1c	DNT-15	Duration of insulin use	Daily Blood Sugar Testing
Age	**0.377**				
Duration of insulin use		0.011			
Marital status	0.113				
Educational attainment	**0.544**				
Subjective health status		0.006	0.056	0.001	
S-TOFHLA			**0.705**		
DNT-15					**0.194**
Number of insulin injections		0.033			**0.775**

The value of the multiple coefficient of determination for the sociodemographic variables (age, marital status, educational attainment) and mean scores on the S-TOFHLA test showed R^2 = 54.7% explanatory power in the sample. Results obtained on the S-TOFHLA test predict R^2 = 47.6% of the total scores on the DNT-15 test. Diabetes-specific numeracy skills and the frequency of daily insulin administration showed R^2 = 55.9% prediction on the daily blood glucose monitoring behavior of diabetes patients. The frequency of insulin administration as a variable, the duration of insulin treatment and patients' self-rated health status showed only R^2 = 4.4% explanatory power on patients' self-assessed three-month HbA1c levels (Figure 1).

Figure 1 The role of FHL and diabetes-numeracy in the PLS-SEM model of sociodemographic variables, subjective health status, HbA1C values, duration of insulin treatment and diabetes self-management behaviors

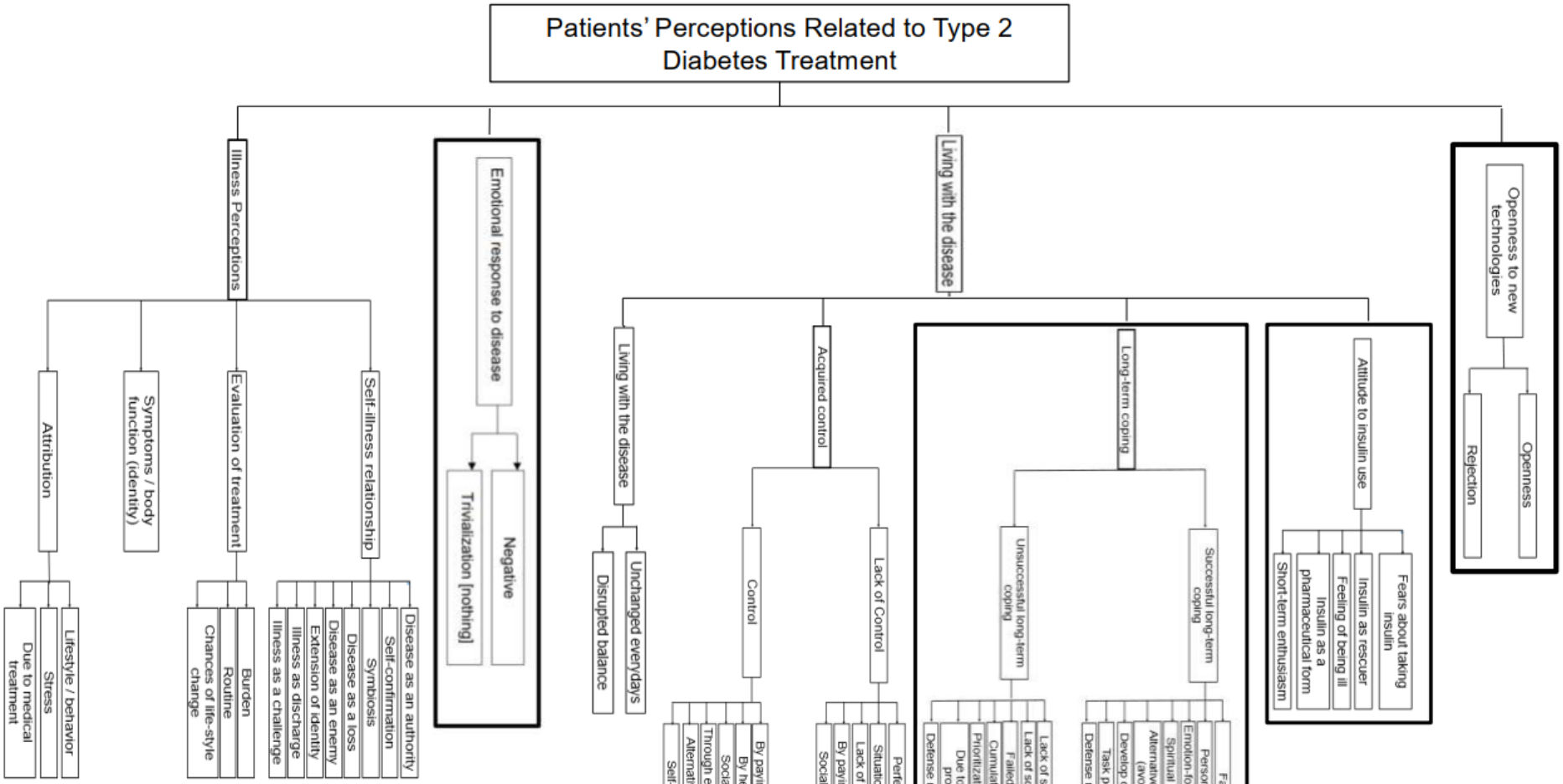


4.3. Treatment attitudes of insulin-treated T2DM patients, integration of self-care into daily life and expectations related to diabetes therapies

4.3.1. Themes, sub-themes and categories outlined during the qualitative study

In our qualitative study, we examined the content of semi-structured interviews with T2DM patients treated with insulin. The responses were typed and analysed with thematic content analysis. During the analysis the following main themes were identified: '**representation of illness**', '**emotional response to disease**' '**living with the disease**' and '**openness to new technologies**'. Within the main themes, differences in responses were further structured into sub-themes and categories. Taking into account the length constraints of the dissertation, we will only present those variables of the coding units that have shown significant response differences based on a cluster analysis detailed later in the thesis. These themes and sub-themes were the following: '**emotional response to disease**', '**long-term coping**', '**attitude to insulin use**' and '**openness to new technologies**' (Table 6).

Table 6 Code tree of thematic analysis and highlighted themes which have shown significant response differences based on cluster analysis



Emotional response to disease

During the qualitative analysis one of the main themes identified was the '**emotional response to disease**'. While coding, the topic was mainly implied by interview questions such as: *How did you feel when you were diagnosed with diabetes? /What does it mean for you to have diabetes? / Is there a life situation where your diabetes is a particular burden for you?* The topic comprises emotional responses related to experiences of learning about having DM, living with DM, and being introduced to related medical treatments. Emotional manifestations were often present throughout the interviews. From the perspective of attitude researches, this informs us that a significant proportion of responses is dominated by emotional correlates. Within the theme of '**emotional response to disease**', two fundamental emotional reactions emerged as sub-themes: '**trivialization**' and '**negative emotion**'.

T2DM patients whose emotional response is often trivialisation underestimate the symptoms of their diabetes, they often lack an awareness of their disease, they define chronic metabolic disorder mostly as a condition, they deny the existence of the disease, and they often emphasize the insignificance of diabetes. This type of emotional response was observed in 78% (N = 39) of the T2DM respondents.

Response examples
'Yes, it's like getting the electricity bill or going shopping. It's like this. This what I can compare it [diabetes] to. A whatsoever event, no, it has never meant any distress to me.' (woman, 70 years old)
'My son is a professional soldier, he's been to XY country, he was sent there. He's gone through all of it, it was such a bad place. People were dissected with a circular saw, and he saw this, and I see it with my mind, horrible! Then... Never mind, let's leave it, this is why I say, no, it [diabetes] is nothing.' (man, 68 years old)
'Well... I don't know (laugh). Well, it isn't a serious disease! Well, one must not bury oneself. Especially not because of diabetes. You have it, and that's it... Because, I, as I've said before, do not take my diabetes seriously. I firmly believe, it shouldn't be taken seriously.' (woman, 60 years old)

Negative emotional responses characterized 96% (N = 48) of the diabetes patients. Within this sub-theme, we coded statements, thoughts that expressed worry, doubt, dislike or disappointment about the diagnosis of diabetes, its current treatment, failures or difficulties in living with chronic disease, specifically those that hinder keeping to a prescribed treatment or accepting the disease.

Response examples
'This is like, you know, going and giving someone a slap every day, they can live with it, and what's more, they can be getting these slaps until the end of their lives, but it's not all the same if they like it or not. See what I mean?! Or we could say, what kind of a life is this?! See what I mean? Like OK, you can live with diabetes, but

it makes me angry when some degrade the disease by saying you can live with it. Well yes, it's like taking away someone's car and telling them they can live without it, but I'd really like to see these loudmouths when they get up at 4 am and go to work in the hospital, how happy they would be having to go on foot. Why?! Well, you can live without this! Then many often say, it's all about will power, yes, I do want things, a lot, but there's a price for it! So a more humane approach would be much better!' (man, 69 years old)

'It's most annoying at night, because no one will notice if you fall in a coma, and should I die then?' (woman, 60 years old)

'Because there were much more negative (experiences)! Much, much more! Even now I don't feel any advantages. Want me to say something positive? No, I can't.' (woman, 59 years old)

Long-term coping

DM and the conflicts caused by intense emotions accompanying the disease require high-level adaptibility and good problem-solving skills. In order to maintain their psychological well-being, protect their physical health and overcome threatening, stressful situations they experience during the treatment of diabetes and living with the disease, many patients use so-called coping strategies. These coping mechanisms can be conscious and unconscious, while their type is mainly determined by the controllability of stressful events and the existing internal resources of diabetes patients. Namely, the latter influence the evaluation processes in individuals. When identifying themes in the course of our thematic content analysis, the following interview questions were most helpful: (1) *How much can you keep your disease under control?* (2) *How is this treatment type helping you in your daily life?* (3) *How has the way you administer this treatment changed?* (4) *Based on your experience, how can you best control your condition?* (5) *What helps you not to forget taking/administering it? What helps you to persist in continuing the treatment?* (6) *How can you maintain your usual daily routines during administering this treatment?*

Within the sub-theme of '**long-term coping**' two aspects were considered: when long-term coping is successful and when the attempt to adapt is hindered, or fails. '**Personalization**' as a long-term coping strategy proved to be successful with 76% ($N = 38$) of diabetes patients. More precisely, a significant number of patients with diabetes have the appropriate parameters in their three-month glycemic control when it comes to evaluating the effectiveness of their efforts. Illustrated by the quotes below, the basis of long-term coping in these patients is their 'personal self-effectiveness'. Patients explore and control a variety of external impacts on their blood glucose level, well-being or they actually correct and modify medical prescriptions, treatment principles in order to make them more acceptable, and more adaptable in their usual routines.

Response examples
'Well..., how should I say?! What it means... it's difficult to put it into words, because especially recently it doesn't mean much, because I've realised that medical prescriptions, the ones physicians give, can only be recommendations, but we don't really have to keep to them as they are given, rather they should be adjusted to the way one lives.' (man, 74 years old)
'You can't keep to them! Not this rigorously. I've heard of a person who was so strict with themselves, that the food they are was measured out, and even then they had to have their eyes operated. I'm still at this stage, and I'm like I can only funtcion in this cowboy system.' (man, 60 years old)
'I don't keep to it rigorously, so I'm not on a diet. But I do a lot of excercise.' (man, 70 years old)

During the thematic content analysis the stress situations caused by diabetes and its treatment were associated with a number of negative or ambivalent emotional reactions that some diabetes patients did not cure by changing their circumstances (problem-focused coping) but by reducing the negative affective state from the critical situation. As higher-level stress and tensions accompanying the treatment of the disease can imply a kind pyschological regression, many patients deploy primitive defense mechanisms (e.g.: repression, denial, etc.). Defense mechanisms often help patients to cope with psychologically stressful situations; however, if they persist for a long time, they may reduce individuals' adherence during diabetes treatment. In addition to the '**lack of self-strength**' (66%) which was the most common code category among interviewees, the second most common response type was coded as '**defense mechanisms**' (58%).

Response examples for '*defense mechanisms'* coping style
'I've had diabetes since 2008, that's 11 years. There are some who had their limbs cut off in only 5-6 years! Limbs were cut off! I but my leg under the knee, we compressed it with a belt and went to the hospital, there they put three clips on it and it healed. If you're really a diabetic, then there's no chance it will heal!' (man, 55 years old)
'I have a lady acquaintance, who wants to give me advice, because she's a diabetic too, but she'd better not say a word (laughing). I'm extremely annoyed with this, so... And we don't really talk about this in our family, or about other things either. And no.' [silence for several seconds] (woman, 70 years old)
'That's one thing, and the other one is I have this what's-it-called, that I feel the crumbs on the floor under my feet. And so... I think, that's my opinion, that until I can feel those crumbs on the floor, I have no fear of my diabetes.' (man, 74 years old)

Attitude to insulin use

Within the main sub-themes, a significant difference in responses was stated in the '**attitude to insulin use**'. Within the sub-theme '**attitude to insulin use**', the research team detected patients' experiences, expectations and views toward insulin therapy. The interview questions that helped us define this theme were these: *How have the prescribed treatments helped your daily well-being? (positive experiences) How have the treatments spoiled or threatened your daily well-being? (negative experiences) / How do you feel about keeping to treatment directions? / How satisfied are your with your current treatment? If you need an injection: how does it impact your contentment?* What needs to be emphasised is the common feature of the categories defined in this theme: patients' perceived attitudes were mostly dominated by emotional responses, and not cognitive processes. The interviews outlined that patients' attitudes to insulin are mostly affected by their previously formed beliefs about insulin therapy (e.g.: insulin fatten, it can cause infertility, needlestick pain, etc.). The most common emotions related to insulin were fear, despair, anger and feelings of frustration. Besides the above, there were many responses that related the introduction of insulin therapy to the severity of the disease. In line with these experiences, we created several categories. The two most common attitudes toward insulin and the mode of insulin administration were '**fears about taking insulin**' and '**insulin as rescuer**'.

84% (N = 42) of the T2DM patients in the study primarily associated negative emotions related to insulin therapy, of which emotions fear was the predominant one. As control loss is experienced mostly in the body, attitudes toward taking insulin were described with physical experiences.

Response examples
'There's one more thing I'm always afraid of: what if the needle gets clogged?' (man, 65 years old)
'Yes, the first one wasn't scary, it didn't hurt, I didn't even feel it. These needles are good because one or two injections go without pain. It's not true that it' painless or you can't feel it. You inject it, and what-what, where-where did you inject it? Well, the second, fifth, sixth, tenth, especially if injected in the same place, is a different problem! Then it hurts. That's one thing, the other one is that if you have been injecting yourself for years, then you get these certain small bumps, lots of them, and if you hit one of them, then ouch-ouch-ouch... it hurts a lot!' (man, 74 years old)
'Because I feared insulin so much, because it's like the end is here, my diabetes is at that level.' (woman, 57 years old)

While many patients reported being frightened about insulin therapy and the use of a pen, a part of them had this reaction of fear only in the beginning. The category named '**insulin as rescuer**' characterised 70% of respondents (N = 35) and was identified based on three types of responses. First, thanks to insulin many reported about a better general health, and they believed that it helped them control the severity of their disease. Second, insulin helped them ease the rigorous limits of medical diet therapy as part of life-style therapy, and it also ensured a more relaxed attitude to the amount of food they were allowed to consume.

Response examples
'For example, not in my diet, no... Well I won't, why would I? Even less, should I limit eating even more? More? Should I not eat ham? No sausage? Well a diabetic is allowed to eat everything, everything is allowed but with measure. Even icream and cake! That's where you get insulin! Swoosh (imitates the sound of a rocket toy landing) and I swallow it! You just need to know how much.' (man, 60 years old)
'Well, it has good effects. Considering the condition of my eyes... well I could have become blind, an old lady with a white walking stick.' (woman, 59 years old)
'The only way to heal diabetes is insulin, nothing else! These jibber-jabber things are good supplementaries, a good „little substitute" pyschologically, but it means that if it was 20, then it would become 18. It takes away a little, it's a little pat, nothing else! (laughs)' (man, 74 years old)

Openness to new technologies

Adminstering insulin with ease and a flexible attitude to therapy are important factors because due to a progressive disease and decreased insulin secretion patients may need new therapy modifications. For patients it is indespensable to be able to properly use the technological tools required for insulin administration and to be satisfied with the individualised therapy of diabetes. Therefore, the fourth main theme was '**openness to new technologies**' which summarised patients' expectations and experiences related to new technologies (e.g. mucoadhesive film, oral insulin capsules). The questions that implied the theme were the following: *How satisfied are you with your current treatment? What experiences have influenced changing your treatment (if you have changed it)? / What would you like to change in your treatment? / How do you think your treatment influences the progression of your disease? (complications) / Are you familiar with other treatment methods? / Would you try them? What does this depend on?*

Based on our results, about 42% (N = 21) of the interviewed persons were satisfied with their current insulin administration technology, while 46% (N = 23) of them complained about needle use. At the same time, opennes to new technologies can be detected in 20% of patients (N = 10), who would expect new developments to be easier to use (e.g. the majority of patients find

taking insulin more time consuming than previously taking antidiabetics, many complain about the frequency of the treatment, the loss of spontaneity). Another expectation of theirs is to be able to inject insulin unnoticably in social environments and that there are fewer side effects. In addition, there were persons who complained that the current technological devices for blood glucose measurement and the needles and pens used for insulin administration are not environmentally friendly so when developing new insulin delivery devices these aspects should also be taken into account.

Response examples
Satisfaction with current insulin delivery device:
'Now I'm on insulin, but I'm satisfied with this pen because I can use it anytime, even at work, and even on the utility pole because I did it once when I forgot to take it, and then I carry it with me everywhere, so I could take up there too.' (man, 70 years old)
'...as a matter of fact, what matters to me is not the method, but the result of the treatment. And as long as it's somewhat effective, because obviously the results are not as perfect as those of a healthy person, but as long as I'm close, I haven't any. If, God forbid, things turn out that way, then it should be changed, but until then...' (woman, 62 years old)
Dissatisfaction with the current insulin delivery device due to needle use:
'...this injection, this is well, this, this... because until I was on medication only I just swallowed it in the morning, at noon and in the evening... but this... this procedure... Because take a look! Here's my hand (shows it and there are marks all over his hand, somewhere with bruises). See what I mean?! I simply don't know where else to inject it, I can't do it into my stomach... not there...' (man, 68 years old)
'Who's satisfied with this? (laugh uncomfortably) No one loves it. Well ok, if the tissue isn't damaged, then maybe you can inject it painlessly. The problem here is that those who need to inject it many times, those will feel that small needle painful too.' (woman, 44 years old)
'Not at all! Not at all, that's kind of logical. Because, even in my mother's time they talked about implants under the skin that automatically dose it, well this was in the 60's, you see? And it's funny that since then it hasn't changed much, only the needles have become smaller, they aren't that big, but that's something too. But umm, I can't see any major changes coming in this direction.' (man, 60 years old)
***Openness to new insulin delivery technologies**:*
'*If it was easier to use it and without so much mess, fiddling-faddling, then why not?! It would be great if it could measure and dose the insulin, then we wouldn't need that much time to measure and count. And that it's available soon, not something in the future that I may not live to see.'* (woman, 70 years old)
'The one I used at the beginning, its inside had to be changed, but the one I use now is not environmentally friendly.' (woman, 59 years old)
'Only to make one that isn't harmful for us. I'd be the first to try it. You bet! Anytime! If it could simplify our everyday life, then life would be much easier.' (man, 61 years old)

4.3.2. Cluster analysis and identification of patient types in the light of qualitative results

During the thematic content analysis, a wide range of grouping possibilities was considered, with each group being both exclusionary and inclusive. Such problems in research can be adequately addressed by clustering techniques. Since we wanted to get an idea of the

characteristics of the possible patient groups when interpreting the results of this research, we decided to use cluster analysis as a quantitative method. In such a case, it is possible to check the similarities between groups of texts. However, as a definitional step, we had to distinguish classical cluster analysis from clustering as a text mining technique. More specifically, the data sources are text-based in this case. Therefore, the text-based data sources first had to be transformed into quantitative data in order to perform mathematical operations, i.e. cluster analysis on them. However, it is important to highlight that cluster analysis was presented as a complementary procedure to data processing and evaluation, i.e. as an analytical strategy in the present research. We decided to apply this strategy because cluster analysis techniques help to summarise and organise the text corpora. The main patient groups were outlined based on the results of the qualitative analysis, but we wanted to verify these with the help of a quantitative procedure.

Data were analysed using hierarchical cluster analysis and Ward's method, as well as using squared Euclidean distances. The number of clusters used for further analyses was determined by taking the values of the coefficients, the dendrogram and the number of elements in the groups into account. On this basis, the four-cluster solution was used for further analyses, because the distribution of the numbers of patients appeared to be distributed most evenly in this case (Table 7).

Table 7 Determined cluster numbers during the use of Ward's method

Clusters	N	%
Cluster I	16	32%
Cluster II	18	36%
Cluster III	14	28%
Cluster IV	2	4%
Total	50	100%

The variables included in the analysis were 'acquired control', 'long-term coping', 'attitude to insulin use', 'openness to new technologies', 'evaluation of treatment', and 'emotional response'. In the next step, we checked which groups are homogeneous in terms of the variables by also considering the results of Ward's method. Where the homogeneity of the groups was found to be low, it was presumably due to the large distances between the values of the group members. In order to check whether there were significant differences between the groups in terms of the examined variables: a one-way analysis of variance was applied. To determine

which differences were observed between which clusters, the Games-Howell post-hoc test was performed.

The results showed significant differences along the four clusters in the variables '**emotional response to disease**', '**long-term coping'**, '**attitude to insulin use**' and '**openness to new technologies**'.

Based on the results of the variable '**negative emotional responses**' it is stated that there is a significant difference F (3,46) = 55.293, MSE = 3.785, $p < 0.001$. During the comparison of the clusters, it was outlined that the first group was significantly different from the second group $p < 0.001$ and the third group $p < 0.001$, and the second group was significantly different from the third group $p = 0.001$. By observing the means of these clusters, we can see that the 'negative emotional reaction' appears most often in the case of the first group, while it appears least often in the case of the third group.

For the variable '**trivialization**' as an emotional reaction variable, the variances were significantly different F (3,46) = 3.255, $p = 0.005$. Looking at the test scores, the occurrence of minimization differs significantly between the groups F (3,5.653) = 7.763, $p = 0.02$. When comparing the groups, it can be determined that the first group is significantly different from the second group $p < 0.001$, and the second group is significantly different from the third group $p = 0.001$, and the fourth group $p = 0.004$. When checking the means it can be seen that the second group showed the highest incidence of 'trivialization' as an emotional reaction.

Within the category of successful long-term coping, the results of the variable '**personalization**' showed a significant difference F (3,46) = 3.166, MSE = 6.162, $p = 0.033$. However, when comparing the groups, it was found that there was no significant difference between the groups. It is important, however, that a marginally significant difference was observed in the case of the second and third groups, $p = 0.057$. Looking at the means, it was outlined that the second group had a higher proportion of personalization as a successful long-term coping type than the third group.

Within the category of unsuccessful long-term coping, the variances for the variable '**defense mechanisms**' were significantly different F (3,46) = 3.333, $p = 0.027$. Looking at the test scores, there was a trend level difference in means F (3,4.720) = 4.447, $p = 0.076$. However, no significant difference was found between the groups during the comparison of the groups. In spite of this, there was a marginally significant difference between the first and second

groups, p = 0.066. The means showed that the second group had a higher proportion of avoidance mechanisms than the first group.

In Welch's t-test, a marginally significant difference was observed by only one. For the variable '**insulin as rescuer**', the variances were significantly different F (3,46) = 4.864, p = 0.005. For the test results, there was a marginally significant difference F (3,5.747) = 4.495, p = 0.059. When comparing the groups, the difference between the first and third groups was p = 0.01. When checking the means, it can be concluded that the first group is significantly more likely to have the 'insulin as rescuer' attitude than the third group, which is also the least likely to have this attitude.

For the variable '**rejection of new technologies**', there was a marginally significant difference F (3,46) = 2.760, MSE = 1.996, p = 0.053. Comparing the groups, there was a marginally significant difference between the first and third groups p = 0.052. Considering the means, we can say that the first group is more inclined to reject new technologies than the third group, which is the least inclined.

4.3.3. Characterization of patient types based on the semi-structured interviews with insulin-treated T2DM patients

During the cluster analysis four groups of patients were identified. These groups were comprehensively characterized along the measured variables, the codes, and they were also interpreted in accordance with the experiences of qualitative analysis. These four groups were named by the research team as the following: '*Vulnerable Personality*', '*Ambivalent*', '*Effective Self-Managers*' and the '*Somatising*' groups.

Vulnerable Personality

As mentioned earlier, the term Vulnerable Personality is mainly created based on the nature of the response patterns to chronic disease and the subsequent emotional and behavioral responses. The impairment of the self-esteem of the patients in the group, and thus the impairment of their sense of self-efficacy, makes the successful adaptation related to the disease and the treatment more difficult. It is important to pay attention to how long depressive emotional mood persists in individuals who living with the disease. Reactions triggered by a series of losses and negative life events can develop into chronic stress in the long term and make it difficult to do self-care in diabetes mellitus successfully. It may be worth clarifying the prevalence of depression in patients (e.g. by means of Beck's Depression Inventory). This is

also important because T2DM patients are at a more increased risk of depression as mood disorder. If depression can be excluded in the person, individual or group grief therapy should be offered. Furthermore, as professionals, we need to be able to consider whether the primary objectives should be reducing additional sources of stress, coping with stressful situations more effectively or influencing stress-related body reactions. The latter is important because the emotional and psychological capacities of patients may vary and the motivational bases closely depend on the degree to which someone becomes resilient. Psychoeducation, goal-setting, relaxation techniques, basic KIP methods, emotionally recharging activities (e.g. Nordic walking, listening to music, art psychology) can be used in line with these. For more open-minded individuals with higher cognitive abilities, even involvement in existential psychotherapy can be fruitful in coping and adapting to illness.

Ambivalent

For patients in the Ambivalent group, the perception of a serious health threat induces strong anxiety, which may be countered by defense mechanisms (e.g. denial, trivialization). For some of them, the defenses presumably aim to protect the ego; therefore, it is almost inconceivable from medical, health professionals' professionals point of view that a patient would not start to change their attitude towards diabetes management even if they are in a severe condition (e.g. after a foot amputation or severe hypoglycaemic crisis). On the other hand, patients, by whom defensive optimism (underestimation of their own vulnerability) is constantly dominant, do not change their behavior patterns in response to increased risk perception. Thus, as a professional, it is necessary to increase the emotional engagement of patients towards diabetes therapy and the sense of control, which can be achieved by doctors showing their patients that their relationship is not hierarchical, but that the key to their cooperation is the active involvement of the patient. The application of the latter would modify the manipulative and resistant attitude of patients with diabetes towards therapeutic prescriptions. In addition, the interview transcripts and the experience of the qualitative study outlined that this group of patients often experience isolation and social loneliness, which is essentially self-generated. Teaching them support-seeking strategies can be effective for them, for example, by organising educational and training programmes that the diabetes patient can visit with family members or close friends and where there is an opportunity to discuss and debate about the experiences during living with diabetes, thus strengthening the involvement of the social environment in the patient's life. Individuals can also benefit from the introduction of methods used in cognitive behavioral therapy and schema therapy (e.g.: restructuring cognitive distortions and irrational beliefs) and learning

more effective coping mechanisms. The use of imaginative personalization techniques can be a way forward in understanding and correcting behavior for diabetes patients with weight problems and binge eating.

Effective Self-Managers

Individuals in the Effective Self-Managers group are able to successfully manage diabetes self-management tasks, have higher levels of self-efficacy and some sort of dispositional optimism since they focus on the potential positive outcomes instead of the difficulties regarding diabetes management. In addition, several of them also show constructive thinking, i.e. some sort of sensitivity and openness to change, which may be an important aspect in facilitating adaptation when living with diabetes. Since they are conscientious and essentially task-oriented, one may wonder why this group of patients deserves special attention. The answer lies in the nature of insulin-dependent T2DM as a chronic disease. To give an example, it is a common experience of medical professionals that exactly those patients develop complications such as retinopathy, who are most committed to following treatment guidelines. This is because constant adjustments can cause blood sugar fluctuations to occur more frequently, which can affect the early development of eye problems. This can give rise to serious controversies on the part of the patient, which can make them more vulnerable, for example, to cognitive dissonance. The latter is a risk factor because, from a psychological point of view, when decisions need to be made on the basis of feelings and cognition, and the cognitive aspects are too contradictory, it is rather almost always the feelings that tend to project the behavior. Therefore, for these highly self-monitoring individuals, it may be beneficial to provide occasional reinforcement in the form of feedback on their therapeutic behavior and outcomes. In addition, it is worth paying attention to ensure that the individual does not experience a sense of excessive personal control while managing the disease, as this may reinforce the assumption of responsibility. The latter is risky because T2DM is a chronic disease, which can often lead to late complications and other health problems, even with adequate metabolic management, which patients may experience as a personal failure in spite of inadequate information.

Somatising

In the Somatising patient group, avoidant behavior can prevent them from facing change, loss and resolving crises with positive outcomes. This finding is also consistent with the earlier result that people in crisis also have a lower level of efficacy in their daily activities and that an integrated mature personality can only develop in old age through the appropriate experience

and resolution of crises. It is well known that psychosomatic illnesses tend to develop when the emotional stress is too intense or lasts longer than average, or when the individual response patterns (e.g. coping patterns) are at a lower level. In these cases, the patients' only tool is the somatising response. In my opinion, the solution in their case should primarily be organised around reducing anxiety, more specifically developing a safe, protective relationship with a health professional (e.g. doctor). The latter may have the effect of increasing the patient's level of stress tolerance. They may benefit from ventilation therapy, biofeedback therapy or, in cases of strong avoidance, the involvement of health psychologists who can help to uncover the factors behind the patient's behavior through imagination, symbol therapy or projective psychology techniques. However, one thing should not be overlooked: since this type of patient is the most likely to show negative emotional manifestations and the level of avoidance can be very high, a medical professional should not, by any means, demand changes and increased assumption of responsibility from patients. Instead, the aim should be to build trust and safe, unconditional acceptance, and to work only with the approach that best suits the patient and the particular structure of their disease. There is no doubt that the process must focus on emotional support rather than rational arguments (e.g. patient education), which can require a lot of patience and understanding.

5. Discussion

In our work, we sought to explore and understand therapeutic cooperation, disease-management related to complex treatment, and behavioral aspects of adherence to diabetes therapy in people diagnosed with T2DM who are treated with insulin, primarily from the patient perspective. The knowledge gained in this area may in the future contribute to a better understanding of the dynamic processes at work within individuals with diabetes and how these processes interact with each other and even could overwrite the intention to medical recommendations and considerations. Carefully and within the limits of our own professional competence, we aim to formulate recommendations, which can serve as guidelines for the preparation of prevention programmes regarding future behavior change as well as more effective patient care needed in daily clinical practice.

As highlighted earlier in the introduction, adherent behavior in T2DM patients plays a central role in the development of the disease and in the occurrence and possible worsening of complications. It has also been identified that nowadays a wide range of medical devices are

available, which are required for diabetes care (e.g. insulin preparations, insulin delivery technologies, blood glucose monitoring devices, etc.), yet, relatively few patients with T2DM can maintain an optimal metabolic control in the long term (Ferguson et al., 2015; García-Pérez et al., 2013). It is undeniable that in the background a number of environmental, socio-demographic, disease-specific and personality factors play a role in the latter phenomenon; however, considering the fact that it is the patient who is essentially responsible for a proper management of T2DM, we aimed to understand and explore the factors depending on the patient and their self-management more deeply in order to understand this phenomenon.

Based on the main hypothesis of our research on adherence behavior in T2DM, we presumed that a correlation between the different types of adherence would be detected and we managed to confirm this hypothesis. Namely, the different adherences in the management of diabetes showed a significant correlation with each other. Based on the obtained results, more cooperative behavior in medication management is presumably one of the factors which may reduce long-term adherence to lifestyle therapies. This statement can be supported from two points of view. The first one relates to the way how the health care system functions. The health care system in Hungary is based on a former socialist approach as in most Central and Eastern European countries. This traditional paternalistic approach to patient cooperation has been dominant in this region for a long time: the patient is a passive participant who follows medical instructions and expects their health to improve primarily through healthcare and medications. More specifically, doctor-centred communication and decision-making were predominant (Murgic et al., 2015). The other aspect is that T2DM requires lifelong specialist care, i.e. it is incurable after a certain progression, but it can be managed with adequate attention and effort. As mentioned in the introduction, some studies show that successful management of diabetes is more than 95% dependent on the patient's self-management abilities and skills. This phenomenon also highlights the fact that lifestyle therapies require a dynamic approach, taking into account a combination of variables that have an impact (e.g. socio-demographic parameters, psychological and behavioral characteristics, individual competencies, etc.).

The fact that these complex therapies are mostly individualised also plays a role. Patients who are properly educated and adherent to several elements of complex therapy are aware that their body delays the release of insulin after a meal, which can cause a sudden spike in blood glucose levels; therefore, an adherent approach related to nutritional therapy becomes a key element. When studying the relationship of adherence to medical nutrition therapy with other

adherences, we should also remember that all these processes are influenced by how well a particular patient is able to solve problematic situations, i.e. how resourceful they are, and how advanced their diabetes is.

In our research, the adherent behavior related to blood glucose control showed a significant, moderate, positive correlation with adherence types related to medication and medical nutrition therapy. When comparing the results with the ones obtained by Hankó et al. (2007) as well as with the findings of the National Association of Diabetes Patients (CEOSZ) in Hungary and Szinapszis Market Research and Consulting (2018) conducted on a sample of Hungarian diabetes patients, it can be stated that our results are only partially similar to the findings of the aforementioned studies. The results of the first study show that DM patients follow blood glucose monitoring and medical nutrition therapy at a higher percentage on average; however, this is less true for regular medication. In the second study, 80% of DM patients reported that they follow instructions on medication and insulin dosage – thus presumably, they also measure their blood glucose levels more often – but adhere less to lifestyle therapies. There are several concerns regarding their results: adherence was mostly measured on a self-report basis, and the study by the National Association of Diabetes Patients (CEOSZ) and Szinapszis Market Research and Consulting (2018) included people with type 1 diabetes mellitus (T1DM) as well. Since following medical nutrition therapy adequately and monitoring blood glucose levels regularly can help to avoid the prevalence of hyper- and hypoglycaemic states and the occurrence of complications (Janapala et al., 2019.; Rubin, 2005; Sun & Lian, 2016), it is conceivable that these adherence types are inherently linked more closely. If we can truly consider adherence to blood glucose control as a key element of diabetes management, which may play an essential part in the detection and avoidance of hyper- or hypoglycaemia and the prevention of metabolic derailment, in the future it may also be beneficial to identify the possible underlying causes of inadequate blood glucose control. It is well known that before determining how adherent a person is to blood glucose control, it is necessary to investigate the sources of inadequate blood glucose measurements: patients not following dietary instructions, medication/insulin dosing not being well adjusted or failures in the treatment system (e.g. inadequate patient education) can be the reasons behind the problem. Another important aspect should not be overlooked, which will be mentioned only marginally due to the different focus and scope of this thesis: the role of the funding protocol itself in blood glucose monitoring. While all DM patients on insulin treatment have access to a blood glucose meter subsidised by social insurance, the prescription of test strips is no longer equally available

to all individuals (National Health Insurance Fund, 2016), and this may also influence how regularly someone measures their blood glucose levels. It would be important to document this information in the future when collecting data for further research. The underlying reasons for the obtained results are most likely caused by inadequate adherence to dietary instructions since the process of data collection was carried out under the supervision and with the cooperation of a medical professional. This is also confirmed by the fact that, since the participating patients were undergoing a transition to insulin, a change in their therapy was initially justified for them because the diabetes treatment they had been receiving up to that point did not provide them with the appropriate metabolic status. Overall, it can be concluded that the maintenance of blood glucose levels within the optimal range is not only connected to medication but it is also significantly related to the patient's carbohydrate intake and dietary habits.

Based on the results of this study, the lowest completion rate for lifestyle adherences was recorded in the adherence to physical exercise. Our results are also consistent with the findings of other studies, which show that the adherence of DM patients is lowest in the area of physical exercise therapy (CEOSZ and Szinapszis Market Research and Consulting, 2018; Hankó et al, 2007; Mogre et al., 2019; Sal et al., 2018; Schlesinger et al., 2020). One of the possible reasons behind this phenomenon could be that the definition of physical exercise therapy is often not well-defined and not properly described by health professionals. In fact, physical activity not only includes hours of sports or gym, but other forms as well, for eg., when a person is doing aerobic exercise or muscle stretching for 20 minutes. Taking a walk, gardening, doing housework, etc. is also considered as physical exercise (Hamasaki, 2016; Mertig, 2012). When interpreting the results, it is worth noting that, since we are mostly looking at the results of older diabetes patients, the low adherence to physical exercise may be due to the fact that medication therapy has been sufficient for the patients in the sample to control blood glucose levels for a long time when managing their diabetes, i.e. a lifestyle habit has been established over decades, and it can only be changed with proper motivation, effort and serious determination (Ferrari et al., 2021; McSharry et al., 2020; Wood & Rünger, 2016). This means that for the majority of patients, it is easier to take medication at scheduled times than to radically change their eating habits and lifestyle. In the case of elderly patients, this potential explanation may be extended by the emergence of a more rigid and conservative mindset that often accompanies ageing, as well as an increase in the prevalence of age-related diseases and complaints (Kobayashi et al., 2016; Pelimanni & Jehkonen, 2019).

Before drawing any major conclusions, it is important to consider that, although mapping and interpreting the adherent behaviors associated with the different elements of DM therapy is a key task, the ability of a person to follow medical recommendations associated with complex therapy and to successfully solve and implement these self-management tasks into their lifestyle also depends on their FHL and diabetes-specific numeracy skills. Based on our results, we have found that reading comprehension and diabetes-specific numeracy skills and knowledge as non-clinical factors, are critical in diabetes treatment and disease management. For this reason, our first step was to monitor HL test scores of individuals in the sample. Next we examined how well the competencies measured by the instruments interacted with each other. In the third step, we used variance-based path analysis to check the impact of the variables included in the model on one another.

Our cross-sectional study revealed that 34.6% of T2DM patients had inadequate or marginal reading and comprehension levels. These findings concur with the results of Papp-Zipernovszky et al. (2016), who compared the scores of several individuals suffering from chronic illness with those of the healthy population, and found that chronic patients such as DM patients had significantly lower FHL levels. International studies by Agad Hashim et al. (2020), Abdullah et al. (2019), Vandenbosch et al., (2018), Van der Heide et al. (2014), Bailey et al., (2014), Al Sayah et al., (2013), Yamashita & Kart, (2011), White et al., (2010), K. Cavanaugh et al., (2009), Ishikawa et al., (2008) also support the aforementioned result, i.e. the presence of T2DM is in association with the individuals' FHL levels. In addition, our results are consistent with the data reported by Cavanaugh et al. (2011), who found that lower levels of FHL among DM patients are between 15 and 40%. According to the results of the European Health Literacy Project (HLS-EU) designed to map the HL of the entire population, low FHL levels range from 1.8 to 26.9% globally depending on the country (Sørensen et al., 2015). In 2016, Hungary joined the HLS-EU and findings from this study indicated that more than 50% of the surveyed Hungarian population had a limited level of HL. However, the aforementioned study did not focus on disease-specific FHL (Koltai & Kun, 2016).

Results from the DNT-15 test show that problem areas for respondents mostly include food label interpretation and items that require multistep calculations, such as calculating insulin dosage based on current blood glucose level and carbohydrate intake. These results suggest that the majority of T2DM patients have insufficient knowledge and experience difficulties during nutrition therapy, and when measuring the correct insulin dosage as part of diabetes management. This may be due to a number of factors influencing these areas. Currently, there

are no diabetes-specific FHL and numeracy guidelines, and the DNT-15 measurement has not been validated on a Hungarian sample yet, so our results should be interpreted with caution. The PIACC (Programme for the International Assessment of Adult Competencies), a comprehensive international study, which tested a variety of key competencies used in everyday life and work of the adult population in participating countries, found that numeracy skills of the Hungarian adult population exceed the average of OECD countries. However, Hungary performs below the average result of OECD member countries in terms of reading comprehension and problem-solving skills (OECD, 2019). Based on these global results, it is possible that T2DM patients score lower on the DNT-15 test in the above-mentioned task types because they already have a lower level of numeracy skills, which is known to affect individuals' problem-solving skills (K. Cavanaugh et al., 2008). Another possible explanation could be that the course of DM varies from individual to individual and that social and environmental factors can also play an important part in chronic disease management. Furthermore, our previous study found that the majority of T2DM patients already have a lower adherence level in lifestyle therapy, so these individuals feel less motivated to understand the nutritional value of foods and they do not use these competencies during insulin administration. A third possible reason could be that diabetes education in Hungary does not place much emphasis on the acquisition of the above-mentioned competencies. Another study by our resarch team validating Diabetes Knowledge Test to Hungarian also drew attention to the necessity of enhancing the level of dietetic knowledge of T2DM patients (Papp-Zipernovszky et al., 2021). According to Rothman et al. (2008), there are patients with adequate literacy levels who still have difficulty comprehending numerical tasks. Due to the nature of the tasks, the test situation itself may have caused anxiety in respondents, which negatively affected their working memory and increased the number of errors when doing the tasks (Rothman et al., 2008). Furthermore, direct measures, such as the DNT-15 test, require good visual acuity and writing skills, so it is possible that elderly participants did not perform well on this test due to their lower cognitive and fuctional abilities (Al Sayah et al., 2013; Huizinga et al., 2008).

According to the Partial Least Squares Structural Equation Modeling (PLS-SEM), FHL, particularly the scores on reading comprehension, are influenced by age, marital status and educational background. The obtained results reflect the findings of Poureslami et al. (2017), Vogt et al. (2017), Lavin-Tompkins (2020), Papp-Zipernovszky et al. (2016), Liu et al. (2020) and Connor et al. (2013), which show that performance on tests deteriorates with age, educational attainment significantly affects the level of HL and family status may also play an

influential role. In this case, being married or in a relationship as family status and having a higher level of education increases the chances of performing better on FHL tests, presumably due to social support in the former and more developed critical thinking in the latter situation. It can be argued that with ageing, T2DM patients require increased attention to HL competencies, because this may generate difficulties in interpreting and following relevant healthcare information due to the general functional decline (e.g. in visual and auditory abilities, etc.) and cognitive decline (e.g. in processing information, working memory capacity, etc.) associated with ageing. FHL skills are closely related, i.e. reading comprehension influences numeracy test scores and affects the ability to solve problems. This is also consistent with the findings reported in scientific literature (Al Sayah et al., 2013; Huizinga et al., 2008). Based on the model, self-rated health status of T2DM patients impacts their scores on diabetes-numeracy skills tests. Although a weaker, negative effect is observed between the two variables, the willingness of a diabetes patient to perform numeracy and problem-solving tasks in disease-management is also essentially dependent on how they rate their own health. It is well known that an individual's self-rated health, as an indicator of the quality of life, is a very good indicator of the actual state of health, and its rating is influenced not only by perceived health but also by the economic, social and cultural situation of the individual (e.g. education, occupation, income, place of residence, etc.) (Au & Johnston, 2014; Verropoulou, 2012). The connection between socioeconomic status and the state of health is not one-directional, but they rather interact with each other. This means that not only those living in less favorable circumstances may have a more negative rating of their health status, but also that having a worse health status may result in varying levels of cost claims. Furthermore, education level and financial circumstances are also closely related to how individuals rate their state of health (Hungarian Central Statistical Office, 2018). The reason why only 21.6% of the participants in the sample rated their health as good, 75.5% as satisfactory and 2.9% as poor can also be explained by the fact that the majority of the participants in the sample were from an elder age group and 82% of them had already developed diabetes complications. This may be further supported by the fact that diabetes patients treated with insulin initially report poorer self-rated health (Pan & Ward, 2015). The negative directional effect of self-rated health on numeracy skills may be explained by the fact that those who rate their health status as worse are likely to actually have worse objective health parameters, an advanced status of diabetes and they are more likely to be on intensive insulin treatment. Consequently, they need to follow a much more complex therapy, possibly having to meet all these requirements while taking other health problems into account, which increases their distress about the disease and its management.

More specifically, they often have to deal with problematic situations related to their disease. Intensive insulin therapy requires them to measure blood glucose more often and perform diabetes-specific numeracy tasks, i.e. these specific competencies are used more frequently. The latter may explain why these patients have a higher total score on the DNT-15 test.

A positive directional effect of self-rated health can also be detected in the outcome variable i. e. HbA1c levels, and it has a negative effect on the frequency of daily insulin administration, which is one of the self-management behaviors and it may also have an impact on HbA1c levels influenced by the duration of insulin treatment. The obtained result can be explained by the fact that the longer a person has been required to use insulin, presumably, the greater the destruction of pancreatic beta cells becomes, the person is older and suffers from complications or co-morbidities, and has a shorter life expectancy. As a consequence, the expected target range of treatment may be more lenient (sometimes HbA1c targets above 8.0% are acceptable) than for their peers with better health. The positive effect between self-rated health and the health outcome variable (HbA1c level) supports what the literature and previous studies have found: people are able to reliably make complex ratings of their own health (Boros & Kovács, 2018), but they sometimes attempt to hide their own lack of competence with compensatory behavior (Lavin-Tompkins, 2020). Self-rated health has a weaker but negative directional effect on the number of daily insulin administrations, and it is related to the fact that those who feel more ill also need a more complex therapy, for which it is essential to perform multiple insulin administrations and to monitor their blood glucose levels several times a day, i.e. to put more effort into engaging in self-management tasks. Regarding indirect effects, the positive correlation between the level of education and DNT-15 scores is also consistent with previous findings which highlight that having a higher level of education contributes to being more skilled at numeracy and reasoning tasks and to having significantly better problem-solving skills (K. Cavanaugh et al., 2009; Kobayashi et al., 2016; Rothman et al., 2008). The positive mediational effect of improved FHL on the willingness of DM patients to control their blood glucose levels on a daily basis also suggests that this competence contributes to a more adherent behavior to therapies by helping patients to understand the medical instructions to be applied during self-management more easily, i.e., it has a positive effect on self-management. This statement is similar to the ones made by Al Sayah et al., (2013); K. Cavanaugh et al., (2008); K. L. Cavanaugh, (2011); White et al., (2010); Yamashita & Kart, (2011).

A further important step was to examine the impact of psychological and behavioral factors that play a substantial role in the treatment and care of T2DM in terms of adherence, quality of

life and treatment satisfaction. Insulin-treated T2DM patients must learn to live with the changes that come with chronic illness, to tolerate treatment modifications, and the remissions and relapses that occur during the course of the disease, which are often unpredictable and can be associated with unwanted changes even with adequate medical control. By definition, this may involve an increased occurence of anxiety. This suggests that only patients with more effective coping strategies will be able to handle and manage their illness adequately.

The therapeutic effectiveness of DM patients can be approached from a variety of perspectives (e.g. via the integrability of health behavior models or the complex exploration of patients' personality dimensions). It is important to emphasise that the focus of this study was not the examination of the aforementioned phenomena, but rather we aimed to address and understand the therapeutic effectiveness of insulin-treated T2DM patients along with psychological and disease-specific variables. In this study conducted with qualitative methodology, we sought to obtain a more complex picture of the everyday experiences of T2DM patients that may influence their adaptation to illness and its treatment. We also tried to explore how satisfied DM patients are with their current therapy and what determines their expectations and attitudes to new insulin delivery technologies.

According to the results of our qualitative analysis, the emotional correlates dominated in a significant proportion of responses of T2DM patients treated with insulin. Negative emotions (e.g. despair, fear, sadness, disappointment, anger, etc.) were dominant in the texts of the interviews. Most often, they centred around the dissatisfaction with the therapy and the progressive nature and management of the disease. These results are consistent with the study by Stuckey and Peyrot (2020). According to their literature review and secondary analysis of qualitative data, DM patients often experience negative emotions, which can mainly be organised around the characteristics of hypoglycemia, diabetes complications and DM treatment (Stuckey & Peyrot, 2020). This finding may also be explained by the fact that for a T2DM patient, the diagnosis and loss accompanying the treatment may appear similar to a traumatic experience. The sense of security and schemes used in the past are questioned, the ego of the individual is also wounded, which may take the form of post-traumatic stress reactions due to long-term untreated distress (O'Brien, 2010; Pintér, 2018).

A particular type of emotional response to DM was trivialization. This reaction, coded as an emotional response, could legitimately also be classified as a psychological defense mechanism; however, we interpreted long-term coping mechanisms in line with behavior and problem-solving; in this case, the feeling of trivialization as a coding unit could be interpreted

rather as emotional burnout resulting from the exhaustion associated with the acceptance and management of DM. The latter statement shows similarity with previous qualitative research findings, where trivialization was also observed as an emotional response to diabetes (Stuckey & Peyrot, 2020). Another study on stories of crisis situations points out that in narratives about negative life situations trivialization occurs significantly more often, probably due to adjustment disorders triggered by crisis situations (Puskás, 2019). In addition to this, the findings indicating that insulin-treated T2DM patients mostly experience negative emotions related to their illness and treatment may be explained by the fact that it is elderly adults who are affected by T2DM. The process of living with the disease and everyday treatment procedures may be complicated for them because of additional factors such as the reorganisation of their current lifestyle, the emergence of normative crises associated with life stages (e.g. relational, physiological, mental changes, restructuring of social functions and roles), crises caused by a variety of other life stressors and losses (e.g. changes in physical abilities, the emergence of other chronic illnesses and issues of care-taking, loss of a spouse, etc.). Our findings are also consistent with those of another study which attempted to identify DM patients with more problematic self-management and found that 'bitter' and 'overwhelmed' patients are more frequently treated with insulin while 'overwhelmed' patients appear to have feelings of depression more frequently and are overall less satisfied with their treatment (Mosnier-Pudar et al., 2010). Furthermore, negative emotions were dominant in the emotional responses of T2DM patients treated with insulin participating in this study because they inherently might have had lower self-efficacy (van Smoorenburg et al., 2019). The latter statement should also be verified by objective tests in the future.

Based on the results of our content-based thematic analysis, the second main topic with significant differences in responses was long-term coping strategies. Personalization as a long-term coping strategy was present in the majority of DM patients (76%). Since the diagnosis of this chronic disease and the introduction of treatments may trigger a temporary loss of psychological balance among diabetes patients (Pintér, 2018), i.e. they may experience the process as a kind of crisis, the only remaining option for them to exercise control may be to overcome the situation, adapt treatment guidelines to their individual lifestyle and experiment with dietary prescriptions and insulin dosing as well as monitoring blood glucose levels at the same time. This statement is in alignment with the findings of the research by Reinhardt (2007), which show that T2DM patients have fundamentally lower control over their health. However, according to our study, personalization may predict not only control but also the capacity for

long-term coping. For eg., those who were able to learn from the trials and experiments with optimal blood glucose levels and medical recommendations received during personalized therapy, were able to manage their DM better and could develop new attitudes towards the disease and treatments later on. These results are in line with previous research that found that some patients with T2DM are able to accept and integrate their illness into their life story (Stuckey & Peyrot, 2020). Furthermore, when examining long-term coping, it is necessary to consider which areas are most affected by adaptation: the development of adherent behavior to complex therapies, the incorporation of new behaviors and habits into the previous lifestyle, or the absorption of negative emotions associated with this chronic disease (van Smoorenburg et al., 2019).

The change accompanying the disease usually involves re-evaluation processes both in behavior and thinking. Experiencing negative emotions, some patients used defense mechanisms in the process of emotion regulation and coping with negative feelings. Especially those, who find it difficult to cope with DM and its management and instead of active coping they rather distance themselves from the issue or subconsciously gain strength to face the problem. As already mentioned in the results, this can essentially be considered as a maladaptive coping style if it persists for a long time and becomes a dominant one instead of restoring the altered self-image and life situation. It is important to note that more than half of the patients in the sample used defense mechanisms, which reinforces the fact that it would be important to explore coping styles in the future when providing psychological support to DM patients. This step would not only reveal the psychological resources of the particular patient but also their fixed problem-solving patterns. It is well-known that when individuals are emotionally overwhelmed, they mostly respond to diabetes as a disease and its management involves avoidance behaviors and emotion-focused coping styles (McCoy & Theeke, 2019; Zhang et al., 2009). In addition, elderly patients with DM are more prone to prioritise emotion-focused coping styles (Karlsen & Bru, 2002), and our results may also be explained by this phenomenon.

Based on our results, two different attitudes towards insulin were identifiable: ‘fears about taking insulin’ and ‘insulin as rescuer’. 84% ($N = 42$) of the individuals in the sample perceived insulin and the associated mode of administration (pen and needle) as fear-provoking, while 70% ($N = 35$) of them gave the medication a ‘rescuer’ connotation. The obtained results can be explained in several ways. Primarily from the patients’ point of view, the introduction of insulin therapy, and potentially its intensification, requires further learning processes which are also

affected by a number of personal, situational and social/cultural factors. This uncertainty causes tension that may generate fear and doubt in patients. Situational control, the side effects associated with insulin use, memories of previous inconvenient medical procedures, the pain experienced during insulin delivery play a critical part in forming attitudes towards treatment. This finding is consistent with the results of earlier studies that underline the high prevalence of negative attitudes towards insulin among patients with DM (Ellis et al., 2018; Gonder-Frederick et al., 2016; Stuckey & Peyrot, 2020). It is also important to stress that some patients have complained that professionals tend to attribute higher blood glucose levels to metabolic and dietary deficiencies. Still we should keep in mind that DM is a complex disease in which not only the aforementioned beta cells are damaged, but also cells that may help in the protection against hypoglycaemia. For example, damage to alpha cells can reduce the ability to recognise the sensations that occur during a hypoglycaemic state, which can create further problems for the patient. In such cases, it is essential to educate patients about the problem and not attribute everything to the inadequate effect of insulin (Tulassay, 2011). In the interviews, DM patients on intensive insulin therapy were more likely to have a fear of hypoglycaemia, more afraid of diabetes complications and reported greater distress, which findings have also been reflected in previous studies (Gonder-Frederick et al., 2016; Hendrieckx et al., 2020; Holmes-Truscott et al., 2018; Stuckey & Peyrot, 2020). It has also been shown that individuals' attitudes to insulin are most influenced by their previously formulated beliefs about insulin therapy (e.g. insulin is fattening, can cause infertility, needles are painful, etc.). These beliefs may have a significant impact on patients' attitudes and openness to new insulin delivery technologies, which may also be influenced by previous experience and the successful integration of self-management habits into their lifestyle.

Many T2DM patients consider insulin to be the preferred treatment in terms of improved well-being and slowing down the progression of complications. On the other hand, the introduction of insulin also provides them with relief from the rigid constraints of medical nutrition therapy accompanying lifestyle therapy, and a freer attitude towards the quantity of food consumed.

The attitude of 'insulin as a rescuer' was observed in 70% of the responses from the interviewees. To some extent, this attitude also reflects the way of 'Personalization' detected in long-term coping, and the need to regain a sense of control. It is important to underline that although the results suggest that this category, in contrast with the above mentioned, shows a positive attitude, it does not always indicate benefits in terms of blood glucose levels and

improved well-being, but it rather refers to the way in which patients can manipulate the often strict and rigid diabetes therapy with different insulin doses. This phenomenon is well supported by previous findings, namely, that professionals are trying to emphasise acceptable blood glucose levels while the primary goals of the patients are finding ways to accept and live with the disease (Bruno et al., 2019; Funnell & Anderson, 2000). The latter can be traced back to the paternalistic approach mentioned in the previous sections and to the fact that it is either knowledge, psychological resources or perhaps the right level of emotional engagement that patients lack. Adherence to medical nutrition therapy and factors linked to changes in dietary habits also imply a deterioration in the quality of life among patients with diabetes (Krzemińska, Bąk, et al., 2020), so they look at insulin use as a way to contradict these external expectations in order to assess their quality of life as better, which may explain the association of insulin with 'rescue'.

According to our results, 42% (N = 21) of the DM patients participating in the interviews were satisfied with their current insulin delivery device, while 46% (N = 23) expressed their aversions to using needles. At the same time, openness to new insulin administration technologies can be detected in 20 % (N = 10) of the patient sample. These findings show similarity with the results of an observational study in which researchers have stated that insulin-treated T2DM patients in eight European countries were less satisfied with their diabetes treatment than people who were treated with lifestyle therapy only or with oral blood glucose-lowering agents (Boels et al., 2017). Nevertheless, this is a contradictory finding since, while most patients with DM report that they are currently less satisfied with their diabetes therapy and insulin delivery pens, only 20 % of them are open to new insulin delivery devices. This may be explained by the fact that the average age of the individuals in the sample was 65 years, who belonged to an older age group and had lived with their DM for a significantly longer period of time; therefore, they may be essentially less open to new technologies due to lower levels of self-confidence, overload from diabetes therapy care and other health issues, which can take up a significant part of their psychological resources, thus reduce their willingness to learn to use new insulin delivery technologies. In addition, the accessibility of these technologies (both physical and financial), their easiest possible use, their perceived usefulness and the minimal occurrence of side effects may also be important factors. For instance, individuals in the sample would expect new developments in devices to be easier to use (e.g. most patients perceive the procedure of insulin administration as more time-consuming than taking antidiabetic drugs, they also complain about the high frequency of administration and

loss of spontaneity). Patients expect new technology to allow for discreet insulin application in social spaces, as well as to have a low number of side effects. These findings are similar to the results of previous studies, which outlined that one of the conditions for openness to new technologies is ease of use and unobtrusive application in social spaces (Abu Hassan et al., 2013; Ellis et al., 2018; Yan & Or, 2019). In the present study, some also complained that the current technological devices for blood glucose monitoring and the needle and pen used for insulin delivery are not environmentally friendly. This aspect should also be taken into account when developing new insulin delivery devices.

6. Conclusion

In terms of insulin-treated T2DM patients' adherence behavior in diabetes therapy, it can be concluded that patients can be both adherent and non-adherent in several areas of diabetes management. Since therapeutic elements are closely related to each other and together they contribute to successful diabetes management, adherence to therapy is essential. It can also be argued that a higher level of cooperation and appropriate disease-management can only be achieved if the cognitive component of adherence, i.e. the level of HL of patients, is also adequate. An adequate level of FHL skills not only refers to the skills to access, interpret and understand fundamental health-related information and services but also to the extent to which an individual is able to make decisions and solve problems in managing diabetes during the complex diabetes therapy.

The results of the research showed that the main differences in the behavioral characteristics of insulin-treated T2DM patients were in their emotional attitudes towards DM and the treatment regimen. A psychological crisis could be observed in the majority of DM patients, mainly at the beginning of their disease history or after the development of diabetes complications affecting their everyday life, or after changing the previous forms of therapeutic titrations. Of course, responses related to learning about having diabetes are varied, but overall it can be argued that all individuals experienced at least some temporary state of destabilization and disorganization during the course of their diabetes. Another important observation is that achieving an appropriate level of adherence can often be hindered by defense mechanisms, which are mostly response patterns to anxiety due to a reduced sense of control and lack of knowledge. Another key factor is how their expectations about insulin therapy, their confidence in the effectiveness of the treatment, and the feelings and symptoms associated with it influence their daily well-being, their coping with the disease and their quality of life. These experiences

may not only explain adherence to therapy but can also predict openness to new insulin delivery technologies. For instance, the measurement of attitudes to insulin treatment and current insulin delivery technologies showed that the fears and anxiety associated with insulin negatively influence the success of insulin treatment for those who perceive the introduction of insulin as a setback and the intensification of insulin dosage as a personal failure.

Altogether, it can be concluded that there are basically two ways to engage diabetes patients in therapy and to increase their engagement and adaptability. One can be achieved through the development of HL competencies, which we have conceptualized from the results of our research. The other aspect focuses on psychological support, reduction of anxiety, the importance of emotional engagement, the patient's psychological resources and experience of disease management, which can be leveraged to enhance therapeutic effectiveness by overriding cognitive biases and misconceptions.

In addition to the statements made above, it is important to stress that the analysis of the subject of this thesis left a number of questions open (e.g. no personality tests were included, no projective measurement tools were used, no medical records were included, which could have provided a more objective picture, etc.); and certain aspects require a more detailed study than the one described here (e.g. exploring coping strategies using objective measurement tools, using a diabetes distress scale, screening for depression, etc.). We consider it an advantage that the research could be carried out on a specific patient sample, which is less explored not only at a national level but also, without any exaggeration, at an international level too (e.g. qualitative studies on the treatment experiences, disease perceptions, openness to new technology etc. in T2DM patients treated with insulin).

A novelty of this dissertation is that the DNT-15 test measuring diabetes-specific numeracy skills has not been applied on a Hungarian T2DM patient sample before our study. Since the test has an excellent internal reliability value, it would certainly be reasonable to validate the instrument on a Hungarian patient sample in the future. Due to the complexity and diverse nature of the phenomenon, it would be important to verify the level of HL in this population with the help of additional measurement tools.

We took a step forward, and based on our findings, we have aimed to provide a comprehensive summary of the types of T2DM patients that are most recognisable in patient care. In alignment with these insights, we have formulated some concrete recommendations for the preparation of future research opportunities and prevention programmes. These guidelines

offer an opportunity for medical professionals and health care personnel to provide effective support to the affected people through the bio-psycho-social and spiritual perspectives of diabetes patients. Although these results are still rudimentary and not yet fully elaborated, we believe that they could be forerunners of future complex surveys and scales. They could be used to map the dilemmas and psychological state of T2DM patients regarding their treatment, thus making the individualised therapy, which is already a focus of professional guidelines for diabetes care, more integrated and more approachable from a behavioral and psychological point of view.

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9. Appendices

Annex 1

Measuring different types of adherence

How much do you agree with the following statements? I follow the prescribed treatment regimens for my illness with regard to:

(1 – strongly disagree, 5 – strongly agree)

1. Getting all the prescribed medicine.	1 – 2 – 3 – 4 – 5
2. Take medication according to the prescription.	1 – 2 – 3 – 4 – 5
3. Measuring blood glucose level.	1 – 2 – 3 – 4 – 5
4. Medical nutrition therapy.	1 – 2 – 3 – 4 – 5
5. Daily physical exercise.	1 – 2 – 3 – 4 – 5

Annex 2

A Shortened Version of the Diabetes Numeracy Test (DNT – 15)

Huizinga, M. M., Elasy, T. A., Wallston, K. A., Cavanaugh, K., Davis, D., Gregory, R. P., Fuchs, L. S., Malone, R., Cherrington, A., Dewalt, D. A., Buse, J., Pignone, M., & Rothman, R. L. (2008). Development and validation of the Diabetes Numeracy Test (DNT). BMC Health Services Research, 8(1), 96–104.

1. If you ate the entire bag of chips, how many total grams of carbohydrate would you eat?

Nutrition Facts Serving Size 1oz. (28g/About 10 chips) Servings Per Container 3.5	
Amount Per Serving	
Calories 140	Calories from Fat 60
	% Daily Value*
Total Fat 6g	**10%**
Saturated Fat 0.5g	**4%**
Cholesterol 0mg	**0%**
Sodium 150 mg	**7%**
Total Carbohydrate 18g	**6%**

1. ANSWER _____ total grams

2. 1/2 cup of potatoes counts as 1 carbohydrate choice. How many choices does 2 cups of potatoes count as?

2. ANSWER _____ choices

3. You ate 1 and 1/2 cups from the food labeled below.
How many grams of carbohydrate did you eat?

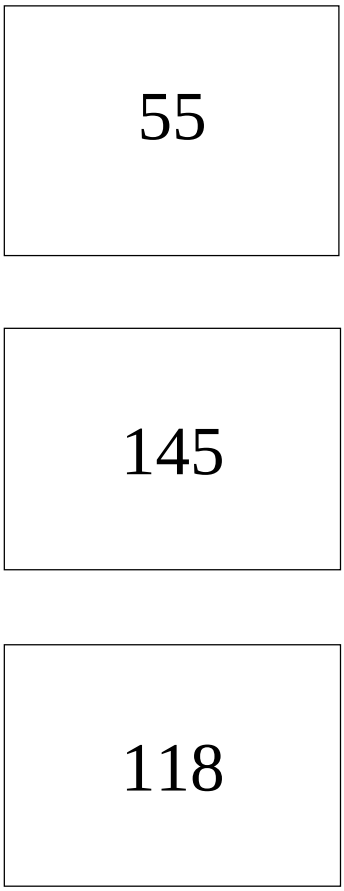
Nutrition Facts
Serving size: ¾ cup Servings per container 10
Amount per Serving **Calories** 150 Calories
Total Fat 7g **Total Carbohydrates** 18 grams Dietary Fiber 3g Sugars 3g **Protein** 3g

3. ANSWER _____ grams

4. You have to eat 6 grams of carbohydrate for each 30 minutes you plan to walk. You are planning to walk for one hour. You have a bag with 12 crackers. Each cracker contains 10 grams of carbohydrate. How many crackers do you need to eat before your walk?

4. ANSWER _____ crackers

5. Your target blood sugar is between 60 and 120. Please circle the values below that are in the target range (circle all that apply):



6. You test your blood sugar 4 times a day. How many strips do you need to take with you on a 2-week vacation?

6. ANSWER_____strips

7. You test your blood sugar 3 times a day. You purchase a prescription of 50 strips on March 5th. Of the dates below, by when will you need to buy new strips?

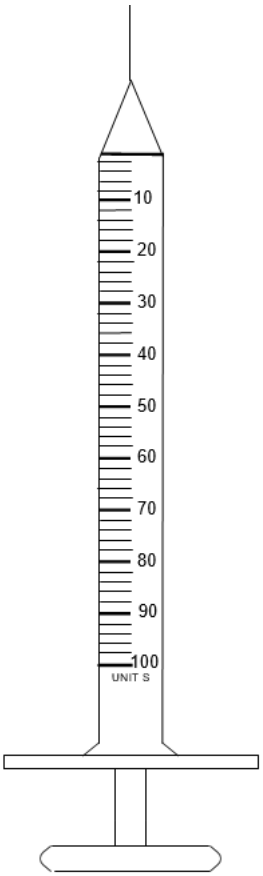
March 21st
April 21st
May 21st
June 21st

8. You have a prescription for metformin extended release 500 mg tablets. The label says, *"Take 1 tablet with supper each night for the first week. Then, increase by 1 tablet each week for a total of 4 tablets daily with supper."*

How many tablets should you take with supper each night the **second** week?

8. ANSWER_____tablets

9. Your insulin dose is increased to 54 units and you begin using a larger syringe that holds 100 units. On the syringe below, circle the line/marking that shows you have drawn 54 units.



10. Please round down to the nearest whole number.

You are given the following instructions: "Take 1 unit of insulin for every 7 grams of carbohydrate you eat." How much insulin do you take:

When you eat 98 grams at supper?

98g

10.ANSWER _____units

11. You are told to follow the sliding scale shown here. The sliding scale indicates the amount of insulin you take based upon your blood sugar levels.

If Blood sugar is:	**Units of Insulin**
130-180	0
181-230	1
231-280	2
281-330	3
331-380	4

How much insulin would you take for a blood sugar of 295?

11. ANSWER_____units

Use the following information for questions 12, 13

You check your blood sugar just before eating. You take 1 unit of insulin for every 10 grams of carbohydrates you eat. You are also given the sliding scale shown below. The sliding scale indicates the amount of insulin you should add to your usual dose based upon your blood sugar levels:

If your blood sugar is greater than 120 points at breakfast, lunch or supper, add 2 units of insulin. If your blood sugar is greater than 150 points at breakfast, lunch or supper, add 4 units of insulin. If your blood sugar is greater than 180 points at breakfast, lunch or supper, add 6 units of insulin.

If Blood sugar is:	Breakfast	Lunch	Supper
> 120	+ 2	+ 2	+ 2
> 150	+ 4	+ 4	+ 4
> 180	+ 6	+ 6	+ 6

12. Your blood sugar is 284 and you ate 40 grams of carbohydrate at breakfast. How much total insulin do you need to take?

284 mg/dl		40 grams

12. ANSWER_____units

13. Your blood sugar is 380 and you will eat 60 grams of carbohydrate at supper.

How much total insulin do you need to take?

380 mg/dl		60 grams

13. ANSWER_____units

Questions 14-15

You have been asked to start taking 32 units of NPH insulin tonight at bedtime.

This insulin will work during the night and will lower your blood sugar first thing in the morning. You were given the following instructions:

- Your goal is to have the morning (fasting) blood sugar below 120.
- Check your blood sugar every morning before breakfast.
- Start with 32 units of NPH tonight. Increase the dose by 2 units **every other** day until your blood sugar is at or below 120.
- Your fasting blood sugar **must** be above 120 for 2 mornings in a row in order for you to increase the insulin dose by 2 units.
- Once your blood sugar is staying below 120, stop increasing the nighttime insulin.

You begin with 32 units of NPH insulin last night. How much NPH insulin will you take on each of the following nights?

14. Morning of day 1, your blood sugar is 164. How much insulin will you take that night?

14. ANSWER _____ units

15. Morning of day 2, your blood sugar is 136. How much insulin will you take that night?

15. ANSWER _____ units

Annex 3

Brief Health Literacy Screen (BHLS)

Chew, L. D., Griffin, J. M., Partin, M. R., Noorbaloochi, S., Grill, J. P., Snyder, A., Bradley, K. A., Nugent, S. M., Baines, A. D., & Vanryn, M. (2008). Validation of screening questions for limited health literacy in a large VA outpatient population. Journal of General Internal Medicine, 23(5), 561–566.

The 3 health literacy screening questions:

0 = never, 1 = occasionally, 2 = sometimes, 3 = often, 4 = always

1. How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?	0	1	2	3	4
2. How often do you have problems learning about your medical condition because of difficulty understanding written information?	0	1	2	3	4
3. How confident are you filling out forms by yourself?	0	1	2	3	4

Annex 4

Short Test of Functional Literacy in Adults

S-TOFHLA

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. (1999). Development of a brief test to measure functional health literacy. Patient Education and Counseling, 38(1), 33–42.

Reading comprehension

Hand patient the reading comprehension passages to be completed. Fold back the page opposite the text so that the patient sees only the text.

Preface the reading comprehension exercise with:

Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, circle the letter in front of that word, and go on to the next one. When you finish the page, turn the page and keep going until you finish all the pages.

STOP AT THE END OF 7 MINUTES

PASSAGE A: X – RAY PREPARATION

PASSAGE B: MEDICAID RIGHTS AND RESPONSIBILITIES

PASSAGE A

A1	(1)	0
a.		
b.		
c.		
d.		

A2	(1)	0
a.		
b.		
c.		
d.		

A3	(1)	0
a.		
b.		
c.		
d.		

A4	(1)	0
a.		
b.		
c.		
d.		

A5	(1)	0
a.		
b.		
c.		
d.		

Sub-Total

PASSAGE A

Your doctor has sent you to have a _____ X-ray.

a. stomach
b. diabetes
c. stitches
d. germs

You must have an _____ stomach when you come for _____.

a. asthma
b. empty
c. incest
d. anemia

a. is.
b. am.
c. if.
d. it.

The X-ray will _____ from 1 to 3 _____ to do.

a. take
b. view
c. talk
d. look

a. beds
b. brains
c. hours
d. diets

A6	(1)	0	A7	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A8	(1)	0	A9	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A10	(1)	0	A11	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

THE DAY BEFORE THE X-RAY.

For supper have only a _____ snack of fruit, _____ and jelly,

a. little	a. toes
b. broth	b. throat
c. attack	c. toast
d. nausea	d. thigh

with coffee or tea.

After _____ , you must not _____ or drink

a. minute,	a. easy
b. midnight,	b. ate
c. during,	c. drank
d. before,	d. eat

anything at _____ until after you have _____ the X-ray.

a. ill	a. are
b. all	b. has
c. each	c. had
d. any	d. was

A12	(1)	0
a.		
b.		
c.		
d.		

A13	(1)	0	A14	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A15	(1)	0	A16	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

THE DAY OF THE X-RAY.

Do not eat _____.

a. appointment.
b. walk-in.
c. breakfast.
d. clinic.

Do not _____ , even _____.

a. drive,	a. heart.
b. drink,	b. breath.
c. dress,	c. water.
d. dose,	d. cancer.

If you have any _____ , call the X-ray _____ at 616-4500.

a. answers,	a. Department
b. exercises,	b. Sprain
c. tracts,	c. Pharmacy
d. questions,	d. Toothache

B17	(1)	0
a.		
b.		
c.		
d.		

B18	(1)	0	B19	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

B20	(1)	0
a.		
b.		
c.		
d.		

B21	(1)	0	B22	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

B23	(1)	0
a.		
b.		
c.		
d.		

Sub-Total

PASSAGE B

I agree to give correct information to _____ if I can receive Medicaid.

a. hair
b. salt
c. see
d. ache

I _____ to provide the county information to _____ any

a. agree
b. probe
c. send
d. gain

a. hide
b. risk
c. discharge
d. prove

statements given in this _____ and hereby give permission to

a. emphysema
b. application
c. gallbladder
d. relationship

the _____ to get such proof. I _____ that for

a. inflammation
b. religion
c. iron
d. county

a. investigate
b. entertain
c. understand
d. establish

Medicaid I must report any _____ in my circumstances

a. changes
b. hormones
c. antacids
d. charges

B24	(1)	0
a.		
b.		
c.		
d.		

B25	(1)	0
a.		
b.		
c.		
d.		

B26	(1)	0
a.		
b.		
c.		
d.		

B27	(1)	0
a.		
b.		
c.		
d.		

B28	(1)	0
a.		
b.		
c.		
d.		

B29	(1)	0
a.		
b.		
c.		
d.		

B30	(1)	0
a.		
b.		
c.		
d.		

B31	(1)	0
a.		
b.		
c.		
d.		

B32	(1)	0
a.		
b.		
c.		
d.		

Sub-Total

within _____ (10) days of becoming _____ of the change.

a. three
b. one
c. five
d. ten

a. award
b. aware
c. away
d. await

I understand _____ if I DO NOT like the _____ made on my

a. thus
b. this
c. that
d. than

a. marital
b. occupation
c. adult
d. decision

case, I have the _____ to a fair hearing. I can _____ a

a. bright
b. left
c. wrong
d. right

a. request
b. refuse
c. fail
d. mend

hearing by writing or _____ the county where I applied.

a. counting
b. reading
c. calling
d. smelling

If you _____ TANF for any family _____ , you will have to

a. wash
b. want
c. cover
d. tape

a. member,
b. history,
c. weight,
d. seatbelt,

_____ a different application form. _____ , we will use

a. relax
b. break
c. inhale
d. sign

a. Since,
b. Whether,
c. However,
d. Because,

the _____ on this form to determine your _____ .

a. lung
b. date
c. meal
d. pelvic

a. hypoglycemia.
b. eligibility.
c. osteoporosis.
d. schizophrenia.

B33	(1)	0	B34	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

B35	(1)	0	B36	(1)	0
a.			a.		
b.			b.		
c.			c.		
d.			d.		

READING COMPREHENSION RAW SCORE	Sub-Total

Short Test of Functional Health Literacy in Adults (STOFHLA)
Joanne R. Nurss, Ph.D., Ruth M. Parker, M.D., Mark V. Williams, M.D., & David W. Baker, M.D., M.P.H.

TOFHLA is a measure of the patient's ability to read and understand health care information, their functional health literacy. TOFHLA Numeracy assesses their understanding of prescription labels, appointment slips, and glucose monitoring. TOFHLA Reading Comprehension assesses their understanding of health care texts such as preparation for a diagnostic procedure and Medicare Rights & Responsibilities.

Date ____/____/____

Name _____ ____M ____F

Birthdate ____/____/____ Age ____ SSN or ID# _____

Hospital or Health-care Setting _____

City, State _____

Short Form Administered: __English ___Spanish

STOFHLA - Score

TOFHLA Total Score:
Reading Comprehension Raw Score (0-36)

Functional Health Literacy Level:

0 - 16 -- Inadequate Functional Health Literacy

17 - 22 -- Marginal Functional Health Literacy

23 - 36 -- Adequate Functional Health Literacy

STOFHLA: Reading Comprehension Scoring Key

14 Point Font

Passage A	Passage A	Passage A	Passage B	Passage B	Passage B
A1 a	A6 a	A12 c	B17 c	B24 d	B33 d
A2 b	A7 c	A13 b	B18 a	B25 b	B34 c
A3 d	A8 b	A14 c	B19 d	B26 c	B35 b
A4 a	A9 d	A15 d	B20 b	B27 d	B36 b
A5 c	A10 b	A16 a	B21 d	B28 d	
	A11 c		B22 c	B29 a	
			B23 a	B30 c	
				B31 b	
				B32 a	

Annex 5

Data and questions in the diabetes mellitus questionnaire

Research question: *How does patients' attitude to treatment impact their adherence and quality of life?*

Data:

Age:

Gender:

Level of education:

Marital status:

Duration of disease:

Concomitant diseases:

Who do you live with (name them: daughter/son, husband/wife, sibling, etc.)

Subjective financial status:

Rate your satisfaction on a scale of 1-10 with your current financial status:

1 2 3 4 5 6 7 8 9 10

1. History of disease

Recollect the situation when you were diagnosed with diabetes.

How did you feel about the diagnosis?

What does living with diabetes mean to you?

Have you ever thought about what factors have impacted the development of your diabetes?

What treatment have you been prescribed?

How has that changed your daily routine? (family life, social relationships, work, leisure, your body perception)

Are there any situations in your life when you feel burdened by your diabetes?

How has your treatment application changed? What experiences have influenced it?

Based on your experience, how can you keep control of your condition?

How have prescribed treatments added to your daily well-being? (positive experiences)

Where have these treatments damaged or threatened your daily well-being? (negative experiences)

2. Current treatment regimen

How long have you been applying your current treatment regimen? In what way is it more beneficial / more detrimental compared with previous ones?

How do you feel about the way the current treatment regimen has been chosen for you? How satisfied are you with having a voice in making this decision?

How would you describe your relationship with the physician who has prescribed this treatment? How do you feel during consultations?

How does this treatment method help you in your daily routine? How does it make your daily routine burdensome?

Which medical advice related to diabetes treatment do you find difficult to keep to or include in your routine?

In which periods is it the easiest to follow medical advice? When is it the hardest? Please, recollect some situations. (What happens then?)

When did you apply the treatment most frequently?

How do you feel about keeping to treatment directions?

What helps you not to forget to take / apply it?

What helps you persist in going on with your treatment?

What would you do if you had to apply it more freqently?

How do you think the treatment impacts the development of your disease? (complications)

How satisfied are you with your current treatment? If you need to inject (pen): how does this influence your contentment?

How much are you able to control your disease?

How have you changed the application of your treatment (if you have done so)?

What would you like to change about your treatment method?

Have you heard or read about other treatment (insulin application) methods? Any you have not tried before or ones that are not available to you?

Would you try them? What does this depend on?

3. The environmental context of the treatment

How do your family members / closer / wider environment relate to your disease and its treatment?

How does it feel to use/inject insulin in front of others?

In what environment is it the best for you to apply the treatment (at home, at work, when travelling...)? Describe some situations.

In what environment is it the hardest for you to apply the treatment? Describe some situations.

Besides your physician's, who else's advice do you take related to your treatment?

Apart from the treatment prescribed by your physician, what else do you do about your condition? (are there alternative treatments)

Do you have any fears about the development of your disease?

Have there been any diabetics in your family, circle of friends or acquaintances whose condition development you were able to witness?

How can you keep to your regular routine while applying the treatment? (dependence topic)

4. Closing the interview

Is there anything else not mentioned so far you think should have been said about your treatment?

How did you feel during the interview? What kind of an experience was it?

I.

Patient Preference and Adherence

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ORIGINAL RESEARCH

Associations of different adherences in patients with type 2 diabetes mellitus

This article was published in the following Dove Medical Press journal:
Patient Preference and Adherence

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Purpose: The objective of our cross-sectional study is to explore the adherence behavior of patients with type 2 diabetes mellitus (T2DM) by examining the association between the various types of adherence. The success of diabetic therapy partly relies on patient motivation, psychodemographic variables (self-efficacy, health literacy, and health locus of control [HLOC]), and adherence. The aim of our research was to explore the attitudes of T2DM patients toward medication and lifestyle therapy, thus gaining a deeper insight into the role of adherence-determining parameters in disease management.

Patients and methods: The sample for the present study consisted of 113 T2DM inpatients (75 women and 38 men) with a mean age of 60.56 years (SD=12.94, range: 20–85 years) diagnosed with T2DM for an average of 13 years (SD=8.23). Participants completed the Diabetes Adherence Questionnaire conceptualized by the research team in accordance with the mapping of psychological and psychosocial parameters. We examined the associations between variables using Spearman's rank correlation. Multivariate regression analysis was used to examine predictive variables for adherent behavior. In addition, we attempted to examine factors with a negative effect on adherence using factor analysis.

Results: Based on our results, a high level of medication adherence negatively correlated with lifestyle adherence. Multivariate regression analysis showed that blood glucose monitoring adherence is mostly predicted by social–external HLOC, diabetes self-efficacy, and internal HLOC, while dietary adherence is predicted by the patient's self-efficacy and duration of the illness. Additionally, understanding and following the diabetes treatment were significantly associated with dietary adherence and high levels of patient self-efficacy, while health literacy was mostly predicted by internal HLOC.

Conclusion: Adherence to medication, diet, glucose monitoring, and physical exercise showed different levels in T2DM patients and were in association with psychodemographic factors.

Keywords: type 2 diabetes mellitus, T2DM, medication adherence, lifestyle adherence, self-efficacy, health literacy, health locus of control

Introduction

According to the WHO, type 2 diabetes mellitus (T2DM) is a chronic disease caused by the body's ineffective use of insulin.[1] Treatment of T2DM requires complex lifestyle therapy in addition to medication.[2] This means that people with T2DM must control their blood glucose levels and concurrently keep their body weight and blood pressure at an optimum level, requiring dietary therapy as well as regular physical exercise.[3] It is important to highlight that uncontrolled blood glucose levels can increase the risk of microvascular and macrovascular complications. Microvascular complications include retinopathy, nephropathy, and neuropathy, while macrovascular complications affect the large blood vessels and include cardiovascular diseases and

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strokes.[1,4] If the patient is required to take medication to lower blood glucose levels, this can only be effective if the patient also undergoes lifestyle therapy. It is important to note that personalized diabetes therapy is based on patients' health condition.[3]

The importance of adherence

The therapy administered to people diagnosed with T2DM is usually designed to meet requirements and needs, with adherence (therapy loyalty) being of key importance.[5] Adherence behavior among people with diabetes generally lowers blood glucose levels and shows a higher correlation with self-efficacy, health literacy, and health locus of control (HLOC) of patients than with demographic variables.[6,7] The underlying reasons for nonadherence among patients with diabetes should be examined in association with psychosocial factors, and it is also worth considering what led to lower adherence and what form it took.[8]

In the literature on the subject, the most often cited psychosocial factor for patient adherence is diabetes self-efficacy,[9,10] which determines coping behavior of individuals, the amount of effort they are capable of expending, and the amount of time they will face obstacles and adverse experiences.[11] More precisely, self-efficacy means that people believe in their own abilities and feel that they have control over events around them.[11] According to the research conducted by Indelicato et al in 2017, there is a significant correlation between the glycemic level of patients with diabetes and the level of confidence patients have in their own ability to exercise a positive effect on their own health status.[9] Apart from this confidence, another often cited psychosocial factor for adherence is patients' HLOC belief.[12] In internal HLOC, individuals attribute their health to their own actions and they believe that health outcomes are under their control. In contrast, external HLOC beliefs include chance expectations or environmental circumstances and control by powerful others such as physician or family members.[13] Further research findings indicate that there is a significant, positive correlation between the self-efficacy of individuals and their internal HLOC on the one hand and medication adherence on the other.[10] Additionally, there are studies highlighting the importance of health literacy during diabetes adherence: "Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[14] Recent studies show a correlation between adherence and health literacy[8,15–17] and between patients' HLOC[17,18] and their health belief,[19] as adherence is determined by the amount of information they understand and internalize about the illness and the treatment.

There are various reasons for nonadherence behavior in patients with diabetes. Patients' attitude can be affected by an inappropriate level of health literacy, fear of side effects of medication, or even the complexity of managing medication. Patient–physician communication is an important factor in adherence; there is a significant, positive correlation between physician communication and patient adherence.[20–22] Of course, patients must possess appropriate cognitive functions, memory, and ability to understand to follow doctor's instructions, as well as personality and psychological resources that may contribute to coping with diabetes successfully.[19] The importance of these variables and their relation to diabetic therapy and adherence are discussed below in great detail following a review of the types of adherence.

Various types of adherence in diabetic therapy

In the present study, we determine medication adherence (adherence-M), glucose monitoring adherence (adherence-GM), dietary adherence (adherence-D), and physical exercise adherence (adherence-PE). It is currently becoming part of efficient and effective treatment to explore and understand the correlations between various types of adherence; it can be considered key to therapy success. Few studies examine the diverse types of adherence among T2DM patients, and most of these studies focus on the adherence-M.[2,5,18,23] This is probably due to the fact that this type of adherence is the easiest to examine and quantify, as, in addition to self-reporting, there are various objective measurements at our disposal to follow the drug regimen; furthermore, the majority of doctors place an emphasis on a pharmaceutical solution.[4,18,23] However, diabetes requires lifelong professional care, and the key to preparing tertiary prevention regimens is to explore the correlation between additional adherences in depth and to understand them.[24]

According to Debussche, one of the key factors required for adherence is that patients must be able to make informed decisions on their own, possess good problem-solving skills, be able to manage their disease, and be open to cooperation with health care professionals, as this will enable them to achieve a higher quality of life.[25] Adherent attitude toward diet can only be successful if the disease does not directly affect the person's well-being; that is, the criteria for dietary therapy can be adapted to the lifestyle of the person. Eckert

underlined the point that for lifestyle therapies social context and social support play a central role in the strategies the patient develops for coping with the disease, while the success of self-management depends more on the person's self-efficacy. However, it should be pointed out that self-efficacy develops parallel to successful adaptation and the development of coping strategies; it is not a result of the process. Eckert also stressed that based on studies conducted on adherence-PE, people with T2DM over 63 years of age who exhibit adherence behavior regarding physical exercise incurred lower health care expenditures on antidiabetics and other medication and required medical services less frequently.[3] It is important to note that a high level of patient adherence to physical exercise therapy significantly improves blood glucose levels, as the blood supply to muscles improves, thus increasing the body's glucose utilization.[26] Moreover, regular physical exercise helps maintain optimal body weight, boosts life satisfaction, improves lipid profile, and benefits mental health.[27] In general, we can say that nonadherence behavior in relation to lifestyle therapy shows a significant inverse correlation with more severe complications in patients and their frequency.[24]

Adherence to self-monitoring of blood glucose poses a considerable challenge among diabetes patients, firstly, because it imposes restrictions on patient lifestyle, telling them when to eat, and it shows a strong correlation with adherence-D and adherence-PE. Secondly, if it is not appropriately regulated, it can cause frequent low blood glucose levels as well as increase the incidence of complications.[28,29] More precisely, since the therapy of patients with T2DM is determined by changes in HbA1c levels, adherence rate for glycemic monitoring is affected significantly by patients' problem-solving skills as well as by the proper setting of treatment targets.[30] In addition to these considerations, adherence to self-monitoring of blood glucose levels is closely associated with lifestyle therapies and can indeed be considered the key lifestyle therapy. This type of adherence is usually associated with a higher level of health literacy, including a sufficient amount of information about the illness. Indeed, how much patients can manage their own diabetes depends first and foremost on their knowledge of the self-monitoring of blood glucose levels.[31]

Findings from previous studies indicate that it would be important to explore types of adherence one by one as well as to review factors affecting adherence in diabetes patients from perspectives that would shed light on the dynamics and modes of action of correlations. In the following sections, we explore the literature on the relationship of the psychosocial factors to adherence that presumably have a significant effect on the management of diabetes.

The importance of health literacy and its effect on adherence

Fransen et al collected and analyzed empirical studies on health literacy and patient self-management behaviors. They concluded that for diabetic therapy to be successful, it was necessary for patients not only to be motivated, but also to have great self-efficacy as well as high health literacy.[32] This is because low health literacy in patients with diabetes may hinder their adherence behavior as they cannot comprehend and organize information effectively, thus potentially causing further difficulties with regard to following doctor's orders.[33] These findings are confirmed by further studies, which have found that patients' disease knowledge correlates with their perceived self-efficacy.[15,34] A low level of health literacy has a negative effect on the health of the patients concerned;[16,35] moreover, patients' disease knowledge has an influence on their therapy adherence rate.[31,36,37] Based on a comprehensive meta-analysis and a review, the relationship between health literacy, adherence, and self-efficacy is inconsistent.[34,38]

The role of the locus-of-control belief in diabetic therapy

With chronic patients, in addition to adherence, the locus-of-control belief can also be crucial for further improvement of health status.[39] Internal control has a positive effect on the health behavior of the patient;[40] it may influence which health-related behaviors a person will prefer or perform during diabetes therapy.[41] However, a lack of internal control may lead to unhealthy dietary choices among people with diabetes.[42] These points are also supported by the research conducted by Wallston and Wallston among patients diagnosed with chronic illnesses; they found that with regard to the dimensions of HLOC patients with a high level of both internal and external–social control exhibited a higher level of adherence among the medical staff.[57] If we look at it from the diabetes patients' perspective, it is probable that the high level of internal HLOC in conjunction with other psychosocial resources may improve the adherence behavior of patients toward the therapy.

Self-efficacy and its relationship to lifestyle therapy

As belief in one's self-efficacy can bring about behavioral changes, it plays an important role among diabetes patients, particularly in managing the therapy.[15] Patients with T2DM

who have more severe symptoms of depression and anxiety and experience greater stress tend to feel less efficient and committed to diabetic therapy.[15,43] It has also previously been observed that lower self-efficacy in diabetes has a negative effect on the control of HbA1c level in patients[15,44] and shows a relationship with lower health literacy.[43] As noted earlier, therapy for patients with diabetes requires lifestyle changes as well, so how much patients are able to face initial difficulties greatly depends on their level of self-efficacy: patients with low self-efficacy tend to be stopped by the first obstacle and focus on the unfavorable outcome of their illness.[45]

Objectives

The objective of this study is to explore the adherence behavior of patients with T2DM by examining the associations between the various types of adherence: adherence-M, adherence-GM, adherence-D, and adherence-PE. Moreover, we would also like to test whether health literacy, self-efficacy, and HLOC belief affect therapy adherence. Additionally, we made first steps to explore patient-related barrier factors which hypothetically affect adherence during diabetes therapy.

Patients and methods

Settings and sample

Study participants were patients diagnosed with T2DM receiving treatment at the Diabetes Unit, 1st Department of Internal Medicine, Szent-Györgyi Albert Health Centre, University of Szeged. The patients were in the process of switching from antidiabetics to insulin, or from one type of insulin to another. A diabetologist participated in the development of instruments. Data were collected between February and November 2016 by convenience sampling conducted by an interviewer who asked the participants to evaluate their adherence to diabetic therapy by filling out a questionnaire. The final sample consisted of responses from 113 patients, including 38 men and 75 women. The average age of the participants was 60.56 years (SD=12.9, minimum: 20 years, maximum: 85 years), and the participants were diagnosed with diabetes mellitus for an average of 13 years (SD=8.2). When the data were processed, one patient's data had to be excluded as the person had been diagnosed with diabetes for 60 years, which was an outlier in our sample.

Study measurements

The psychosocial parameters for adherence were measured using our own questions based on validated questionnaires, which contained certain items on HLOC belief, health belief, and perceived self-efficacy as well as some items on treatment methods and health literacy. In addition, we used an adherence questionnaire conceptualized by the research group to explore the different adherence types and collected participants' demographic data (Table 1). Our questionnaire measures diverse types of adherence: adherence-M, adherence-GM, adherence-D, and adherence-PE. The section about adherence-M contains statements related to medication prescription and taking medication according to prescription. Adherence-GM, which means a consistent and regular blood glucose level monitoring, was measured with a statement related to prescribed treatment regimens. Lifestyle therapy adherences (adherence-D and adherence-PE) were measured with statements related to medical nutrition therapy and daily physical exercise (Figure S1).

Table 1 Sociodemographic characteristics of the sample and descriptive statistics for the study variables

Sociodemographic factors	N=113
Sex	
Male, n (%)	38 (33.6)
Female, n (%)	75 (66.4)
Age (years), mean (SD), range	60.56 (12.9), 20–85
20–63 years old, n (%)	62 (54.9)
≥63 years old, n (%)	51 (45.1)
Duration of diabetes (years), mean (SD)	13 (8.2)
Labor market status	
Employed, n (%)	33 (29.2)
Retired, n (%)	80 (70.8)
Education level	
Low level, n (%)	60 (53.1)
High level, n (%)	53 (46.9)

Note: Sociodemographic characteristics of the sample show normal distributions.

The statements regarding adherence inhibitors were formulated specifically for the target group and were consistent with study objectives. The adherence inhibitors included financial difficulties, forgetfulness, lack of time, family problems, disagreement with doctor's instructions, the ineffectiveness/harmfulness of prescribed medical therapy according to other sources, fear of side effects and long-term effects, lack of clear instructions given by the doctor, lack of clear instructions in the product description of the medication, overly complicated/complex therapy, self-restraint to therapy, and lack of motivation to follow a regimen.

Multidimensional HLOC scale

The scale used for evaluating HLOC in this study was based on the validated questionnaire created by Wallston; however,

unlike the original, it contained diabetes-specific statements to assess patients, and also had fewer questions. One statement about internal HLOC belief was "Diabetes basically depends on your own self-strength", while a statement "In the treatment of diabetes, the social environment (physician, family, friends) is extremely important" was an item present on the strong social–external HLOC subscale. Furthermore, external HLOC belief was measured with statements like "The improvement or decline of health condition related to diabetes is mostly random". The internal consistency value on the internal HLOC scale proved to be acceptable, while with the social–external and chance external HLOC the small number of items meant that no relevant reliability could be measured.

Health belief scale

According to the literature, one of the most widespread models of health behavior is the health belief model. A primary objective of the model is to predict the factors that determine health behavior, mainly through participation in screening examinations. Health behavior is primarily influenced by perceived danger, which is a combination of the severity of a perceived illness or the consequence of failing to take preventive measures to prevent illness and an estimate of the degree to which a person feels affected by it. Other components of the model are the benefits the behavior can bring as well as the obstacles, costs, and disadvantages of the behavior. In addition to the health-related beliefs factor, the model contains a perceived efficacy variable, as in "You are able to effectively treat your illness and its symptoms, to cope with the illness and to comply with the treatment requirements". The internal reliability index for the health belief factor on the questionnaire was 0.651, while the internal consistency for self-efficacy amounted to a somewhat lower value due to the small number of items.

Data analysis

Statistical analysis of the data was performed using IBM SPSS for Windows 22 (IBM Corporation, Armonk, NY, USA). The first step was to prepare statistical data, so we detected missing values and screened the outliers. Before selecting the trial, it is important to know whether we can perform a parametric test or not. While processing the data, we checked the distributions of participants' sociodemographic data and statistics by analyzing their scores (mean ± SD) (Table 1). We checked normality by item, questionnaire, and group to select the relevant statistical hypothesis tests. Since the Kolmogorov–Smirnov hypothesis testing procedure showed that the conditions for normality deviation were not always met, we decided to use nonparametric tests. As we wanted to measure the effect of several independent variables, a multivariate regression analysis was performed. In addition, we decided to use the stepwise method, which is one of the most stringent methods. We paid careful attention to the fact that multivariate regression analysis is extremely sensitive to outliers. In order to get more reliable results, we standardized the variables. With this in mind, we decided to use nonparametric tests. We also agreed that the statistically significant *P*-value should be <0.05. We examined the associations between variables using Spearman's rank correlation and used multivariate regression analysis to identify predictive variables for adherent behavior. As mentioned before, the variables were standardized and we used these in all our measurements (Spearman's rank correlation, multivariate regression analysis). In addition, we attempted to examine factors with a negative effect on adherence using factor analysis.

We performed an exploratory factor analysis for adherence inhibitors to identify items that measure similar phenomena and content. The exploratory factor analysis was performed using the principal component analysis method with oblimin rotation. The applicability of data for factor analysis was tested using Bartlett's test of sphericity as well as the Kaiser–Meyer–Olkin index. In addition, variables with a factor loading <0.3 were not considered.

Results

The final sample consisted of 113 T2DM inpatients with a mean age of 60.56 years (SD=12.94, range: 20–85 years) and an average diabetes duration of 13 years. On the Diabetes Adherence Questionnaire, 87.6% of the respondents stated that they get all the prescribed medicines, and 80.5% of respondents reported taking medications according to prescriptions. Furthermore, 78.8% of the patients stated being adherent to measuring blood glucose level, while adherence to diet was stated by only 13.3% of respondents. Moreover, only 12.4% of respondents reported adherence to physical exercise. Table 2 shows the different frequencies of responses as not all participants were willing to provide response to each item. In the case of items about psychosocial variables, the majority of responses indicated a high level of adherence (Table 3).

Examining the association between the various types of adherence

Adherence-M showed a positive, significant correlation with adherence-GM among patients ($r=0.322$, $P<0.001$); that is, the patients are more adherent to drug treatment,

Table 2 Response rate for the diverse types of adherence

Type of evaluated adherence	Questions	Percentage of adherent responses
Medication adherence	Getting all the prescribed medicine	87.6%
	Take medication according to the prescription	80.5%
Glucose monitoring adherence	Measuring blood glucose level	78.8%
Dietary adherence	Medical nutrition therapy	13.3%
Physical exercise adherence	Daily physical exercise	12.4%

Notes: The table shows the items of different types of adherence based on the Diabetes Adherence Questionnaire. It is important to note that only values 4 and 5 on the 5-degree Likert-scale were interpreted as adherent responses.

the more likely they are to follow doctor's orders on the self-monitoring of glucose levels. However, adherence-M showed a moderate-to-negative correlation with patients' adherence-D (r=–0.575, P<0.001). This finding suggests that the more patients adhere to taking antidiabetics regularly and properly, the less motivated they feel to adhere to carbohydrate intake and to meet the criteria for a proper diet. Furthermore, we found a moderate, significant, and inverse correlation between adherence-M and adherence-PE (r=–0.496, P<0.001), suggesting that the more patients follow medication orders, the less they will adhere to physical exercise therapy. Adherence-D showed a correlation with adherence-GM (r=0.414, P<0.001) as well as with adherence-PE (r=0.279, P=0.003). Based on these findings, we can say that the evaluated subjects attempted to integrate the diet prescribed for people with diabetes, were more likely to control their blood glucose levels, and found time to follow the prescribed physical exercise regimen (Table 4).

Association of lifestyle, glucose monitoring, and medication adherence with psychosocial variables

As emphasized in the "Introduction" section, T2DM requires a complex therapy, in which lifestyle plays a key role, so we thought it is imperative to examine in greater detail the factors that influence adherence-D and adherence-PE. When developing the linear regression model for adherence-D, we found that the model is significant (F (2.81)=8.466, MSE =0.887, P<0.001); its explanatory power for the whole range was 17.3%. The independent variables were the following: duration of diagnosed diabetes, age, education level, self-efficacy, health literacy, internal HLOC belief, social–external HLOC belief, and external HLOC belief. Adherence-D was predicted by patient self-efficacy (β=0.366, t_{81}=3.622, P=0.001) and the duration of diagnosed diabetes (β=0.208, t_{81}=2.062, P=0.042). The data on adherence-PE proved insufficient to set up the linear model due to the disproportionate number of responses given to a particular statement.

Adherence-GM showed a significant, positive correlation with patients' internal HLOC belief (r=0.380, P<0.001) as well as the number of antidiabetics taken daily (r=0.211, P=0.049). The linear regression model used proved significant (F (3.78)=10.077, MSE =0.744, P<0.001); its explanatory power for the entire range was 27.9%. The independent variables were the following: duration of diagnosed diabetes, age, education level, self-efficacy, health literacy, internal HLOC belief, social–external HLOC belief, and external HLOC belief. Of the variables measured, social–external HLOC

Table 3 Response rate for perceived self-efficacy, health literacy, and HLOC belief

Type of evaluated phenomenon	Questions	Percentage of "agree" responses
Health literacy	You are perfectly informed about your illness and its healing and treatment.	76.9%
	You are perfectly able to apply the prescribed treatment for your illness.	75.2%
Self-efficacy	Following the prescribed treatment regimens for my illness is efficient in treating its symptoms and effectively improve my health status.	83.2%
	You are able to effectively treat your illness and its symptoms, to cope with the illness, and to comply with the treatment requirements.	76.1%
Health locus of control	Diabetes basically depends on your own self-strength.	84.1%
	In the treatment of diabetes, the social environment (physician, family, and friends) is extremely important.	80.5%
	The improvement or decline of health condition related to diabetes is mostly random.	26.6%

Notes: The table shows the items of self-efficacy, health literacy, and HLOC belief based on the Diabetes Adherence Questionnaire. It is important to note that only values 4 and 5 on the 5-degree Likert-scale were interpreted as adherent responses.
Abbreviation: HLOC, health locus of control.

Table 4 The relationship between various adherence types and Spearman's rank correlation values

Group	Adherence-M	Adherence-GM	Adherence-D	Adherence-PE
Adherence-M		0.322*	–0.575**	–0.496**
Adherence-GM	0.322*		0.414**	
Adherence-D	–0.575**	0.414**		0.279*
Adherence-PE	–0.496**		0.279*	

Notes: *$P<0.05$; **$P<0.01$.
Abbreviations: Adherence-M, medication adherence; Adherence-GM, glucose monitoring adherence; Adherence-D, dietary adherence; Adherence-PE, physical exercise adherence.

(β=0.312, t_{78}=2.941, P=0.004), perceived self-efficacy (β=0.241, t_{78}=2.484, P=0.015), and internal HLOC were found to be the strongest predictors of adherence-GM (Figure 1).

Results from the factor analysis of adherence inhibitors

Based on our results, we identified five factors. In accordance with statistical standards, we discuss the "doubts about therapy" and "cognitive skills" factors at length below.

The "doubts about therapy" factor contained items that may have caused adherence inhibition, such as sacrifices, the complexity of therapy, and fear of side effects. The internal consistency of the "doubts about therapy" factor was 0.672, which indicates an acceptable reliability.

The "cognitive skills" factor contained all those variables inhibiting adherence linked to medication instructions provided with the product and agreement with doctor's orders. The internal consistency of "cognitive skills" turned out to be 0.731, which indicates high reliability (Figure 2).

Having obtained all these results, we also checked whether the factors with high internal reliability showed any correlation with the various types of adherence. After performing the statistical analyses, we found that there was a significant negative correlation between the "doubts about therapy" factor and adherence-D (r=–0.368, P=0.001).

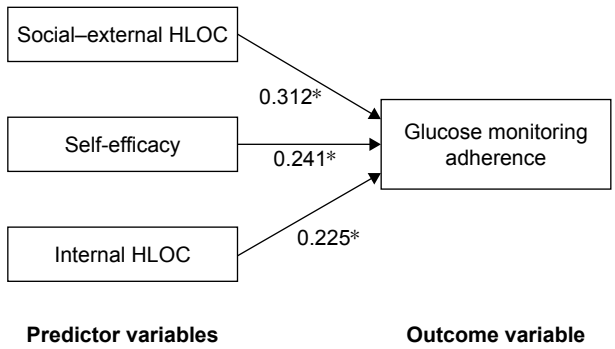

Figure 1 Psychosocial variables predicting glucose monitoring adherence indicated with beta values.
Notes: The multivariate regression analysis showed that adherence-GM was mostly predicted by self-efficacy, internal HLOC belief, and social–external HLOC belief. The numbers show beta values or coefficients which show the degree of change in the outcome variable for every one unit of change in the predictor variable. *$P<0.05$.
Abbreviations: Adherence-GM, glucose monitoring adherence; HLOC, health locus of control.

Discussion

The objective of our study was to explore the adherence behavior of patients with T2DM, mainly by ascertaining the association between the diverse types of adherence and their determining psychosocial factors. Since previous studies have focused primarily on adherence-M,[2,5,21,28] we believe the advantage of our study is that we considered the complexity of variables (the diverse types of adherence and health literacy, self-efficacy, and HLOC belief affecting them) and that we focused mainly on determining the associations between them.

Under examination, we found that there was a moderate, significant, and inverse correlation between adherence-M and lifestyle factors. More specifically, the more patients adhere to taking medication as prescribed, the less likely they were to adhere to dietary therapy and physical exercise. The unexpected finding that higher adherence-M correlates to significantly lower adherence-D and adherence-PE is explained in a number of studies by the fact that in an early phase of the disease patients can avoid hyperglycemia by taking medication that reduces blood glucose.[3,16,18] However, this is only a temporary solution, and patients with diabetes must follow a special diet and start doing physical exercise, as the dose–response curve of the medication used cannot offset the blood glucose increase caused by absorption of carbohydrates from food.

In our study, adherence-GM showed a significant, positive correlation with adherence-M and adherence-D. These findings are consistent with observations found in the literature.[29,46,47] If adherence-GM is to be considered as one of the main means of diabetic therapy, which can help recognize and prevent hypoglycemia and avert metabolic crises, then it would also be imperative to examine what may cause inappropriate glucose tests in future. The underlying reasons for the study findings can probably be traced back to patients not following dietary instructions closely, as the data collection

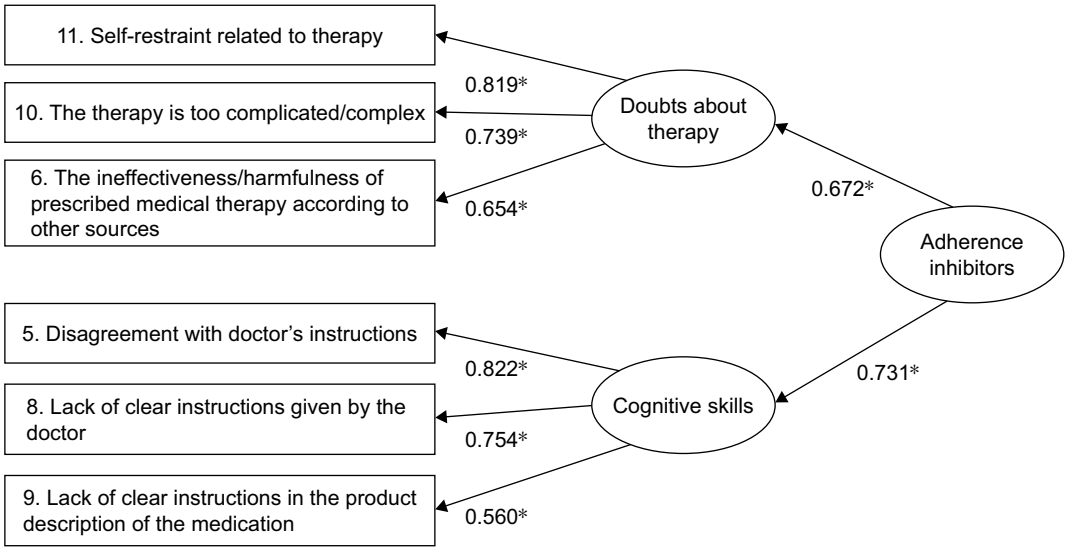

Figure 2 The factor structure of adherence inhibitors.
Notes: The path diagram of exploratory factor analysis displays the final model. The numbers show standardized factor loadings, and the items related to the factors "doubts about therapy" and "cognitive skills". The numbers attached to each item within each rectangular box indicate the item numbers in the adherence inhibitors scale. *$P<0.05$.

was supervised by a medical professional. This is confirmed by the fact that since the participating patients were in the process of switching to insulin, it was reasonable to change therapies because the various types of diabetic therapy did not provide them with the metabolic status they wanted to achieve. Overall, if we only attempt to draw conclusions from the perspective of various adherences, we can say that keeping glucose levels within an optimal range takes more than just medication; patients' carbohydrate intake and dietary habits are also crucial.

Based on our findings, we can say that the degree of adherence-D does not only correlate with adherence-GM, but shows a significant correlation with adherence-PE as well. Thus, if patients can tell the difference between their blood glucose conditions and can regulate their blood glucose levels accordingly, they are more likely to pay attention to what they eat and make sure they lead a healthy lifestyle. We believe the underlying reason for this is that appropriately educated patients are aware of the fact that their body will initiate insulin secretion with some delay after the ingestion of food and that blood glucose levels may shoot up as a result, so adherence to dietary therapy may become crucial. When we look at the association of adherence-D to other types of adherence, we must keep in mind that these processes are also affected by how much patients are able to resolve problematic situations, that is, how resourceful they are, as well as how advanced their diabetes is.

The findings of the study demonstrated the lowest response rate among lifestyle adherences for adherence-PE. A potential reason for this is that it is often unclear even to health care professionals what is meant by physical exercise therapy, as it is not clearly defined.[48] Our findings suggest that adherence-PE was in inverse correlation with the degree of adherence-M. In interpreting the findings, it should be noted that we examined results for elderly diabetes patients for the most part. The reason for low adherence-PE may be that long-running medication therapy for the patients in the sample was sufficient to control blood glucose levels, suggesting that they had had decades-long lifestyle habits that could only be changed with sufficient motivation, effort, and determination.[7] Having discussed the correlations between the various adherences, let us now focus on an understanding of the effects the presumed psychosocial factors exercise on adherences. In a number of studies, adherence-D shows a positive correlation with patient self-efficacy, internal and external professional HLOC belief, and health literacy.[8,15,33,34,39,41,44] Our results are consistent with these findings in confirming that internal HLOC plays an important role in dietary therapy adherence. Where our findings differ from the literature is the effect of external HLOC on the degree of dietary adherence. We attempt to explain the unexpected findings by drawing on an assertion in the literature: in the period of switching from one therapy to another, patients may have felt lower motivation and internal control due to previous failures, an experience which is even greater among the elderly as they may have other comorbidities beyond diabetes that render their everyday life difficult.[44,46] Closely related to this is the finding that patients who are exposed

to excessive stress and exhaustion generally score lower on health literacy scales.[49] However, it seems productive to explore the link between health literacy and beliefs about the harmfulness of treatment.[38]

In addition to these tests, we also wished to ascertain which psychosocial factors measured would be the best predictors of adherence-D. Our findings showed that there was a 17.3% correlation between adherence-D and the patient's perceived self-efficacy and the years of diagnosed diabetes. Furthermore, these are the variables that best predict a patient's adherence. The results can be explained by a fact familiar to us through the literature that self-efficacy is a self-regulation skill which suggests a belief in oneself being able to overcome difficulties and as such can only be achieved through a learning process. This means that patients with diabetes generally do not begin dietary therapy overnight, but face difficulties at the beginning, set their minds to it, and exercise strict self-control.

Adherence-GM shows the most significant, positive correlation with patient health literacy and internal HLOC. Our findings confirmed that adherence-GM among patients with diabetes shows a correlation with internal HLOC as well as the number of antidiabetic pills taken every day. In other words, the better patients are at keeping their HbA1c levels within the normal range, the more likely they are to have HLOC and the more antidiabetics they will take every day.[5,8,50] If we explain the findings by saying that the number of pills in this case simply reflects the degree of adherence-M, then it means that HLOC belief is a key to effective medication therapy. However, it is important to note that we also ascribed a key role to health literacy in connection with this type of adherence in our study; however, no significant correlation could be shown between the two variables. Any result that differs from what we expect should be considered carefully, as it may be assumed that the items on health literacy did not test for all the health literacy skills. The latter confirms that the knowledge patients possess about their health is formulated through very complex processes, and this underlines the complexity of the phenomenon.[30]

In addition to the psychosocial factors affecting adherence-GM, we also set up a linear model to measure which psychological and psychosocial factors most predict a higher degree of patient adherence. Our findings suggest that adherence-GM was 27.9% depending on the personality traits of the patients. More specifically, of the personality factors measured, it was social–external HLOC that predicted adherence-GM, while diabetes self-efficacy was most accurately predicted by internal HLOC. According to Krapek et al,[7] adherence increases when blood glucose level is adequately regulated. Furthermore, if we make a comparison based on this finding, we can say that patients with high self-efficacy can affect their health status better, an assertion which is consistent with the theoretical concept that perceived control and a feeling of self-efficacy reduce stress and help cope with the disease.

In addition, the relationship between adherence and self-efficacy plays an important role not only in adherence-M, but also in adherence-GM.[9,10,15] Indeed, in order to regulate blood glucose levels, it is necessary for patients to experience a sense of effectiveness and be able to make independent decisions that comply with the doctor's orders with regard to the self-management of diabetes.

Our statements on health literacy, which consist of information on methods of treatment for the disease, showed a correlation with the types of adherence measured. We found that a significant, positive correlation can be seen between adherence-D and items on knowing appropriate methods of the treatment. Furthermore, we found that the diverse types of adherence can be affected by perceived self-efficacy. We can thus assume that those who can maintain their metabolic state and regulate their blood glucose levels tend to follow recommendations on diet and believe that they can manage their illness. In our research project, we also grouped factors that inhibit adherence, and we concluded that the factors that trigger nonadherence include doubts about therapy and the person's cognitive skills. Since it is difficult to explore factors inhibiting adherence due to the complexity of the phenomenon and it therefore requires additional investigation, the findings should be handled with caution.

The "doubts about therapy" factor refers to adherence inhibitors from the perspective of socioeconomic factors and factors that depend on therapeutic treatment, such as self-restraint in connection with therapy, complexity of therapy, and fear of side effects. Variables inhibiting adherence that fall within this factor are not often discussed in the literature, since it tends to vary from one person to another among those with diabetes as to what they see as sacrifice and what personal fears they have as regards diabetic therapy. However, the complexity of therapy is considered an inhibiting factor that determines the adherence behavior of patients. This finding is consistent with that of Donnan et al[18] and Rubin[28] that the complexity of diabetic therapy may decrease patient adherence by as much as 10%–20%. This result is in line with those of our investigation into adherence-M and lifestyle therapy.

The "cognitive skills" factor differs from the factors above in that the patient's health status and attitudes play a more marked role. Disagreeing with doctor's orders is often accompanied by lower health literacy, a tendency which is linked to patients not clearly grasping what the doctor has told them or not being able to adequately understand medication instructions provided with the product. Furthermore, it should be noted that doctors and health professionals tend to overrate patients' cognitive skills, adherence, and knowledge about the therapy,[17,51,52] thus rendering it more difficult to recognize adherence inhibitors in a timely manner.

A key point in our exploratory research project was that once we had collected adherence inhibitors and analyzed their nature and characteristics, we also examined which of the diverse types of adherence showed a statistically significant correlation. We found that among the adherence inhibitors, "doubts about therapy" demonstrated a significant, inverse correlation with adherence-D, suggesting that of the types of adherence, following dietary recommendations depended greatly on how complex and complicated the diet seems to the patient and how much the dietary therapy fits into the lifestyle the person has led thus far.

To our knowledge, our investigation of adherence inhibitors is among the few that have used quantitative methods. Most studies examining this topic are qualitative.[53–55] The literature to date has attempted to explore phenomena affecting adherence behavior mainly along the lines of the doctor–patient relationship and the characteristics of the health care system, even though factors affecting patient adherence also include information on the patient's health status, patient-dependent factors, and financial considerations.[25] As noted above, this study mainly reviews results from elderly patients with diabetes. With this in mind, it is worth considering that a study conducted in 11 European countries with a sample of people aged above 70 years with diabetes found that good communication with the doctor and health care staff was key to adherence behavior. In such situations, it is not only possible for patients to ask their doctors, questions, but also to obtain answers and solutions for the dilemmas they face, thus possibly allaying the fears they may have about the side effects.[56]

Limitations and future directions

Since this work was an exploratory research where we used the questionnaire compiled by ourselves, it would be advisable to increase the size of the sample and check the validity of our conclusions on a larger patient population. Another limitation is that the sample consisted of inpatients who were undergoing insulin replacement. Hence, it would be worthy to perform this study on T2DM outpatients who are not involved in a therapeutic regime change. A third limitation is that this research is self-explanatory; thus, social compliance may have an effect on the results obtained.

Overall, the current study can be considered innovative among scientific surveys of adherence, as to the best of our knowledge relatively few studies have dealt with correlations between adherences with such heterogeneous syndromes as T2DM. This claim is confirmed by the fact that to date no internationally validated measurement tool has been designed to explore the various types of adherence. Although we relied on the scientific literature in our study to design the models to be used to examine the phenomena, it would be worthwhile to develop these concepts further and investigate them in greater depth in future. This is linked to our aspiration for this study to serve as a starting point for developing future Hungarian standards, to set down a precise description of the psychosocial factors in adherence behavior and to design complex therapy programs that rely both on adherence-M and on dietary therapy and physical exercise therapy.

Conclusion

Thus, the study recommends to measure and understand diverse types of adherence of T2DM patients. The results of the current study also show that there are associations between diverse types of adherence and patients' psychosocial attributes.

Ethical approval

Ethical approval for the study was obtained from the Human Investigation Review Board at the University of Szeged, Hungary (registration number 5/2016 – SZTE). All the required ethical statements were collected during the research.

Informed consent

Written informed consent in accordance with the Declaration of Helsinki was provided by all the participants of the study.

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Author contributions

Andrea Klinovszky performed statistical analysis and interpretation of data, and drafted and wrote the manuscript. István Márton Kiss contributed to study design, data collection, and construction of study measurements. Orsolya

Papp-Zipernovszky supervised the work, performed critical revision, and provided scientific advice. Csaba Lengyel served as the diabetologist, contributed to sample composition and discussion, and provided scientific advice. Norbert Buzás planned and supervised the work, participated in construction of study measurements, drafted and wrote the manuscript, and performed critical revision. All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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Supplementary materials

Measuring different types of adherence:

How much do you agree with the following statements? I follow the prescribed treatment regimens for my illness with regard to:

(1 – strongly disagree, 5 – strongly agree)

1. Getting all the prescribed medicine.	1 - 2 - 3 - 4 - 5
2. Take medication according to the prescription.	1 - 2 - 3 - 4 - 5
3. Measuring blood glucose level.	1 - 2 - 3 - 4 - 5
4. Medical nutrition therapy.	1 - 2 - 3 - 4 - 5
5. Daily physical exercise.	1 - 2 - 3 - 4 - 5

Self-efficacy, health literacy, health locus of control:

How much do you agree with the following statements? Please evaluate the following questions from 1 to 5.

(1 – strongly disagree, 5 – strongly agree)

1. You are perfectly informed about your illness and its healing and treatment.	1 - 2 - 3 - 4 - 5
2. You are perfectly able to apply the prescribed treatment for your illness.	1 - 2 - 3 - 4 - 5
3. Following the prescribed treatment regimens for my illness is efficient in treating its symptoms and effectively improve my health status.	1 - 2 - 3 - 4 - 5
4. You are able to effectively treat your illness and its symptoms, to cope with the illness, and to comply with the treatment requirements.	1 - 2 - 3 - 4 - 5
5. Diabetes basically depends on your own self-strength.	1 - 2 - 3 - 4 - 5
6. In the treatment of diabetes, the social environment (physician, family, and friends) is extremely important.	1 - 2 - 3 - 4 - 5
7. The improvement or decline of health condition related to diabetes is mostly random.	1 - 2 - 3 - 4 - 5

Adherence inhibitors:

If you do not follow a particular prescribed treatment, which of the below-listed reasons do you attribute it to?

(1 – strongly disagree, 5 – strongly agree)

1. Financial difficulties	1 - 2 - 3 - 4 - 5
2. Forgetfulness	1 - 2 - 3 - 4 - 5
3. Lack of time	1 - 2 - 3 - 4 - 5
4. Family problems	1 - 2 - 3 - 4 - 5
5. Disagreement with doctor's instructions	1 - 2 - 3 - 4 - 5
6. The ineffectiveness/harmfulness of prescribed medical therapy according to other sources	1 - 2 - 3 - 4 - 5
7. Fear of side effects	1 - 2 - 3 - 4 - 5
8. Lack of clear instructions given by the doctor	1 - 2 - 3 - 4 - 5
9. Lack of clear instructions in the product description of the medication	1 - 2 - 3 - 4 - 5
10. Overly complicated/complex therapy	1 - 2 - 3 - 4 - 5
11. Self-restraint related to therapy	1 - 2 - 3 - 4 - 5
12. Lack of motivation to follow a regimen	1 - 2 - 3 - 4 - 5

Figure S1 Diabetes Adherence Questionnaire.

II.

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Article

Building a House of Skills—A Study of Functional Health Literacy and Numeracy among Patients with Type 2 Diabetes in Hungary

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Abstract: The purpose of this study is to explore functional health literacy (FHL) and numeracy skills in an insulin-treated, type 2 diabetes mellitus (T2DM) patient population, and their impact on diabetes self-care activities. A non-experimental, cross-sectional quantitative design was used for this study. The sample consisted of 102 T2DM patients on insulin therapy, including 42 males and 60 females, with a mean age of 64.75 years (SD = 9.180) and an average diabetes duration of 10.76 years (SD = 6.702). Independent variables were sociodemographic variables (e.g., age, educational level, etc.) and diabetes and health-related factors (e.g., duration of diabetes (years), the frequency of blood glucose testing/day, etc.). For this study, the participants completed the reading comprehension exercise from the Short Test of Functional Health Literacy (S-TOFHLA) and the Shortened Version of the Diabetes Numeracy Test (DNT-15), which specifically evaluates the numeracy skills of patients living with diabetes. The associations between the variables were examined with Spearman's rank correlation. Multivariate regression analysis was performed to examine whether measured FHL skills impact diabetes self-care activities. We found that DNT-15 test (β = 0.174, $t(96)$ = 2.412, $p < 0.018$) had significant effect on the frequency of blood glucose testing/day. Moreover, the problem areas for patients with T2DM mostly included multi-step calculations according to food label interpretations, and adequate insulin dosage based on current blood glucose levels and carbohydrate intake. The results of regression analyses and Spearman's rank correlation indicated that limited FHL and diabetes numeracy skills not only influenced the participants' behaviors related to self-management, but they also affected their health outcomes. Thus, besides the personalization of insulin treatment, it is indispensable to provide more precise information on different types of insulin administration and more refined educational materials based on medical nutrition therapy.

Keywords: patients with T2DM; insulin therapy; functional health literacy; diabetes-specific numeracy skills

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1. Introduction

According to the International Diabetes Federation (IDF), the number of people diagnosed with diabetes mellitus (DM) has more than tripled over the past 20 years. This report also indicated that there are currently 463 million people living with diabetes, and this number will increase to 700 million by 2045 [1]. In Europe, it is estimated that among adults aged 20 to 79, there are 59.3 million people who are diagnosed with DM, with the majority affected by type 2 diabetes mellitus (T2DM) [2]. Previous studies have shown that T2DM negatively affects patients' quality of life and life expectancy [3], and it often places serious economic burdens on society and its healthcare systems [4].

It is well-known that patients with T2DM are required to perform daily self-care tasks such as monitoring glucose levels, following a diet plan, remembering to take antidiabetic medications and insulin at the right time, preparing the correct dosage, and performing

regular physical activities, all of which can be emotionally stressful [5]. In other words, a significant number of responsibilities rests on the shoulders of patients, since appropriate disease management of T2DM is essential [6]. Thus, it has become indispensable to explore what types of specific basic skills are necessary during diabetes self-management, and how effectively patients can function in the healthcare environment [7].

In general, individuals living with diabetes are required to use multiple strategies and possess adequate skills in order to cope with their condition and reduce diabetes-related complications [8]. One of these fundamental skills is the patients' health literacy level, which is not only a highly relevant skill for diabetes management [9,10], but it has become a critical component in improving the health outcomes of chronic illnesses (e.g., T2DM) [7]. It also plays a fundamental role in improving patients' diabetes knowledge and competencies [11]. According to the U.S. Department of Health and Human Services (HHS), health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [12]." The World Health Organization (WHO) adds to this definition by including cognitive and social skills as essential parts of health literacy [13].

In the literature, there are two types of health literacy: one is related to individuals' performance and it is called performance-based health literacy, while the other one is self-assessed health literacy [14]. Martensson and Hensing point out that health literacy shows a fluctuation from situation to situation and many times depends on the environmental context of the patient [15]. Because of this, professionals often divide health literacy into three different dimensions: functional, communicative and critical health literacy [16–18]. One of the most widely studied dimensions is functional health literacy (FHL), which focuses on basic functional skills such as reading, writing, and numeracy [17,19]. More precisely, these skills include the ability to read and comprehend written text, complete health care forms or be able to use numeric information related to health care instructions during disease-management [10,20].

Previous empirical studies found that limited HL affects a great number of European regions, such as Italy, which is reported to have the highest number of people living with inadequate HL, and it is followed by Bulgaria, Spain and Austria [21]. It is important to mention that in 2016, Hungary joined to the European Health Literacy Project (HLS-EU) and findings from this study indicated that more than 50% of the surveyed Hungarian population had limited level of health literacy [22]. However, the aforementioned study did not focus on disease-specific FHL.

Although the number of national and international studies examining this complex phenomenon has been increasing, there are still relatively few studies on disease-specific FHL [23]. Furthermore, little is known about FHL levels and their impact on diabetes outcomes (e.g., knowledge, self-care, glycemic control) [24,25], maybe due to the complexity of the phenomenon, which is highlighted by the quantitative studies in the past 5 years. According to a meta-analysis published in 2019, HL prevalence studies among patients with T2DM were done mostly in the USA and these results mainly date back to the early 2000's [11]. However, according to Poureslami et al. (2017), health literacy is fundamental to a successful management and prevention of chronic disease [26]. Therefore, it would be especially important to explore health literacy level in high-risk groups and its relationship with health outcomes.

1.1. Association between FHL and Diabetes Self-Management

Related studies have also shown that FHL levels are lower among patients with chronic diseases, compared to healthy populations [25,27–29]. Individuals with low FHL levels have also been shown to have less knowledge about their chronic diseases and limited self-management skills [30–34]. Moreover, previous research has indicated that lower FHL levels are associated with higher mortality rates, less adequate health status, more hospitalization, and lower levels of medication taken during self-management [19,24,32,33], i.e., difficulties in naming their medications and describing their indications [25].

FHL is a critical component of diabetes self-management as well. However, it is not the only variable that influences patients' self-care skills. Both theoretical and empirical studies confirm that an individual's self-efficacy, attitude, motivation, degree of illness severity, and social factors also impact his/her self-management behavior [35]. In addition, the connection between FHL and diabetes self-management is not straightforward, and it depends on the type of self-management behavior followed by patients [36,37]. This is especially true for individuals with diabetes and inadequate FHL, since they are recommended to follow complex treatment plans, manage visits to multiple clinicians, monitor changes in their health status, and initiate positive health behaviors [38].

Based on previous research, lower FHL levels are not necessarily associated with worse A1C levels among DM patients [10,39], but lower FHL and A1C levels are correlated with more diabetes complications [40,41]. It is also important to mention that there is a limited number of studies on understanding the pathways or potential mechanisms through which FHL influences patients' A1C levels [42].

Although FHL affects patients' ability to function in a healthcare system [43], this skillset could help them cope with the consequences of a chronic illness and increase their confidence during medical consultations [19]. In sum, adequate FHL can enhance patients' understanding and awareness about a chronic disease and help facilitate their engagement in diabetes self-management [26].

1.2. Diabetes-Specific Numeracy Skills and Their Impact on Health Outcomes

Low diabetes-related numeracy is common among individuals with diabetes [44]. The number of clinical studies on general HL and numeracy is growing; there are much fewer still (especially in Europe) focusing on patients with specific chronic diseases such as those diagnosed with T2DM and prescribed different insulin regimes. The research by Alghodaier et al. (2017) clearly states that the influence of numeracy on the health of patients with diabetes has been investigated in a small number of studies [45]. Based on one meta-analysis it is recommended to invest the assessment of diabetes numeracy to produce more evidence on the relationship with different diabetes outcomes, including self-care activities [11]. According to previous research, numeracy refers to the ability to understand and use numbers in daily life [46] (p. 392). More precisely, in the healthcare context, numeracy not only includes the ability to interpret risk, but also the ability to estimate time and measure, think logically, and perform the mathematical skills required to solve problems and make appropriate health-related decisions [47]. In addition, Huizinga et al. (2008) emphasized that higher numeracy levels can help DM patients understand medical graphic representations [48].

Besides reading skills, numeracy skills are required in many health-related tasks such as understanding food labels, measuring medications, interpreting blood parameters, and understanding health risks and symptoms [10,31,49]. However, according to previous research, only 50% of patients with inadequate FHL and numeracy skills recognize common symptoms of hypoglycemia, while only 38% correctly respond to the need to eat when experiencing such symptoms [49]. Meanwhile, self-management of T2DM requires advanced FHL and numeracy skills [7,50,51]. They are also indispensable because patients with limited skills in reading comprehension, oral communication, and diabetes-specific numeracy will be unable to adequately participate in traditional health education and act on any instructions from healthcare providers [16]. In sum, lower levels of diabetes-specific numeracy skills not only impact patients' health behaviors [47] but are also associated with higher A1C levels in patients with T2DM [52], which can negatively affect their adherence to recommendations and cause more complications [24,53]. Meanwhile, individuals with better mathematical skills are able to apply such knowledge, thus increasing their confidence in performing self-care tasks [49].

The purpose of this study is to explore FHL levels and numeracy skills in an insulin-treated T2DM patient population are related to diabetes, and they impact on diabetes

therapy. In addition, diabetes and health-related variables and diabetes self-care activities associated with FHL and numeracy are examined.

2. Materials and Methods

2.1. Research Design

A non-experimental, cross-sectional quantitative research design was used in this study, with stratified convenience sampling method.

2.2. Data Collection

This research was conducted between January and March 2020. The participants were recruited with the help of three diabetes associations in Csongrád County, Hungary. The members of the diabetes associations were selected with stratified convenience sampling. They were notified about the research in advance by the president of the association. Research subjects who satisfied the requirements and expressed their willingness to participate in the study came to the study location at a time which was agreed upon in advance. Before the interview, research subjects were notified in detail about the purpose of the study and that their information would be kept strictly confidential and anonymous. The patients were also informed about their right to discontinue the interview and that there would be no consequences whatsoever to their participation. The response rate was 78.46% (out of 130 patients contacted, 102 were interviewed). All of the participants were involved on a voluntary basis and their written informed consent was obtained in accordance with the Declaration of Helsinki. This study was approved by the University of Szeged Human Investigation Review Board (Approval No. 4639).

2.3. Study Sample and Inclusion/Exclusion Criteria

The inclusion criteria for the participants were as follows: 18 to 89 years of age; diagnosed with T2DM; use of insulin therapy; voluntary participation in the study. Regarding the exclusion criteria, cerebral stroke affecting cognitive processes or previous head injuries were listed.

2.4. Study Measurements

2.4.1. Short Test of Functional Health Literacy (S-TOFHLA)

The Short Test of Functional Health Literacy (S-TOFHLA) normally includes reading comprehension and numeracy tasks. However, since the goal of this study was to examine diabetes-related health literacy, a diabetes-specific numeracy test was included, instead of the original calculation exercises. The other reason why the S-TOFHLA's computational tasks were not used was because the numeracy portion of the Hungarian version showed low internal reliability. During the S-TOFHLA's reading comprehension exercise, the participants were asked to read medical information on abdominal x-rays (3rd grade comprehension level; 16 questions) and a text related to health insurance contracts (9th grade comprehension level; 20 questions), after which they were asked to complete certain sentences by choosing one out of four options. Although the total time to complete the exercise was seven minutes, the participants were not informed about this time constraint. Thus, the interviewer stopped the exercise when the time limit was reached. Overall, each correct answer was worth 1 point, while any questions that were incorrect, left blank, or answered after the time limit were worth 0 points. The maximum score for the reading comprehension exercise was 36 points. Based on the scores from the exercise, 0–16 points indicated inadequate health literacy, 17–22 points indicated marginal health literacy, and 23–36 points indicated adequate health literacy [27,34].

2.4.2. Shortened Version of the Diabetes Numeracy Test (DNT-15)

In order to better understand numeracy in T2DM, a shortened version of the Diabetes Numeracy Test (DNT-15) was used. In general, the DNT-15 evaluates the numeracy skills of diabetes patients, and it consists of 15 questions in five domains: nutrition (three items);

exercise (one item); blood glucose monitoring (three item); oral medications (one item); insulin administration (seven items). The estimated administration time of the DNT-15 is 15 to 20 min. This scale also covers different types of mathematical problems such as addition, multiplication/division, fractions, multi-step mathematics, and numeration/number hierarchy [49].

2.4.3. Principles of the DNT-15, Including Interpretation and Measurement Characteristics

To the best of the authors' knowledge, diabetes-specific numeracy skills have not been studied in Hungary among T2DM patients on insulin therapy. Since the S-TOFHLA's numeracy tasks in the Hungarian version showed low reliability, and in an effort to use a test that effectively measures diabetes-specific numeracy skills, the decision was made to translate one of the most common instruments for measuring diabetes-specific numeracy skills, i.e., the DNT-15. The test was translated from English into Hungarian by applying standardized translation methods, such as back-translation and cultural adaptations, which are essential steps before implementing an instrument in research [54–57]. Before using the translated version of the DNT-15 instrument on a larger sample, a pretest was conducted with 10 independent respondents, who completed the test in order to determine if the tasks were comprehensible and if there were any legitimate comments about the test questions. It is important to note that although the Hungarian version of the DNT-15 test had adequate reliability, the results of this study should be interpreted with caution, mainly due to the fact that the Hungarian version of the DNT-15 has yet to be validated.

2.5. Additional Independent Variables

Overall, the analysis included two groups of independent variables. The first group included sociodemographic variables such as age, gender, labor market status, education level, and whether the participant possessed healthcare education. The second group of independent variables included diabetes and health-related factors such as duration of diabetes (years), duration of insulin treatment (years), daily frequency of self-monitoring blood glucose levels, self-assessed three-month A1C level, frequency of insulin administration per day, existence of diabetes complications, and type of diabetes therapy (e.g., only insulin/insulin + antidiabetic drugs/insulin + lifestyle therapy/insulin + antidiabetic drugs + lifestyle therapy).

2.6. Statistical Analysis

The statistical analysis was performed by using IBM SPSS Statistics for Windows 22 (IBM Corporation, Armonk, NY, USA). After the preparation of the statistical data, any missing values were detected and the outliers in the sample were appropriately checked. In addition, the Kolmogorov-Smirnov Goodness-of-Fit Test was used to assess the data distribution. For the purpose of obtaining correct results from the statistical analysis, it was important to note the following: the analysis was conducted on a smaller sample; there was data with variables that also included ordinal scales; the conditions for normality deviation were not always met. Thus, non-parametric tests were performed. In order to describe the population's characteristics and provide basic information about the variables in the dataset, descriptive statistics were used. Internal consistency and reliability of the measurements were tested with Cronbach's alpha and Kuder–Richardson's reliability coefficient, while the associations between the variables were examined with Spearman's rank correlation. Any differences between the groups were then examined with the Mann–Whitney test. In order to suppress any type 1 errors, the significance value of the tests was examined using Bonferroni correction, while the dependent variables with ordinal values were examined using the Kruskal–Wallis test. Multivariate regression analysis was performed to examine whether measured FHL and diabetes numeracy skills impact diabetes self-care activities.

3. Results

3.1. Descriptive Statistics

The final sample consisted of 102 patients (41.2% male and 58.8% female) diagnosed with T2DM for an average of 10.76 years (*SD* = 6.702). The mean age of the sample was 64.75 years (*SD* = 9.180; range 37–85 years). The majority of the participants had high school (*N* = 58) education, while 29 participants completed primary school and 15 possessed a university degree. The average duration of insulin treatment was 6.59 years (*SD* = 5.098), while the majority (45.1%) of the participants reported administering insulin four times per day. It is important to note that most of the patients (67.6%) measured their blood glucose levels more than twice per day, while 73.5% had diabetes complications. In terms of the latter, the distribution was as follows: vision impairment (retinopathy): 52% (*N* = 53); cardiovascular disease: 44.1% (*N* = 45); kidney failure (nephropathy): 7.8% (*N* = 8); nerve damage (neuropathy): 45.1% (*N* = 46); lower limb amputation: 6.9% (*N* = 7) (Table 1).

Table 1. Sociodemographic characteristics of the sample and descriptive statistics of the study variables.

Sociodemographic Factors	*N* = 102
Gender	
Male, n (%)	42 (41.2%)
Female, n (%)	60 (58.8%)
Age (years), mean (SD), range	64.75 (9.180), 37−85
37−49	8 (7.8%)
50−59	14 (13.8%)
60−69	49 (48%)
70−79	27 (26.5%)
80−85	4 (3.9%)
Education level	
Primary school	29 (28.4%)
High school	58 (56.8%)
University	15 (14.7%)
Diabetes complications	
Vision impairment	53 (52%)
Cardiovascular disease	45 (44.1%)
Kidney failure	8 (7.8%)
Nerve damage	46 (45.1%)
Lower limb amputation	7 (6.9%)
Duration of diabetes (years) mean (*SD*)	11 (6.702)
Duration of insulin injection (years) mean (*SD*)	7 (5.098)
Number of insulin injections/day mean (*SD*)	3 (1.016)
Once	8 (7.8%)
Twice per day	23 (22.5%)
Three times per day	24 (23.5%)
Four times per day	46 (45.1%)
More than four times per day	1 (1%)
Frequency of blood glucose testing/daymean (*SD*)	3 (1.320)

Percentage based on the number of participants per item. Abbreviations: *SD* = standard deviation.

3.2. Average Score of the Correct Responses on the S-TOFHLA and DNT-15, and the Internal Consistency of the Measurements

In the S-TOFHLA's reading comprehension task, participants were asked to read medical information on abdominal x-rays (3rd grade comprehension level; 16 questions) and a text related to health insurance contracts (9th grade comprehension level; 20 questions). Average score of correct responses for task "A" (3rd grade comprehension level) was 78.5%, while average score of correct responses for task "B" (9th grade comprehension level) was 56.4%. Because of the 7-min timeframe, the rate of correct responses for item 6 in task "B" was lower. The average score on the S-TOFHLA was 23.78 points (*SD* = 10.084), while the 36-item scale included a Cronbach's alpha of 0.957, indicating high reliability. Based on the

results, 27.7% of the participants (28 patients) had inadequate FHL, 6.9% (7 patients) had marginal FHL, and 65.3% (66 patients) had adequate FHL (Table 2).

Table 2. The percentage distribution of the sample's FHL levels in the S-TOFHLA.

S-TOFHLA Scores	*N* (%)
Inadequate functional health literacy (0−16)	28 (27.7%)
Marginal functional health literacy (17−22)	7 (6.9%)
Adequate functional health literacy (23−36)	66 (65.3%)

As for the DNT-15, it showed good internal reliability (KR-20 = 0.85), with an average score of 7.51 (*SD* = 3.509). The results also indicated that the problem areas for the participants included food label interpretation and items that required multi-step calculations such as calculating insulin dosage based on current blood glucose levels and carbohydrate intake.

3.3. Associations between the S-TOFHLA Scores and the Diabetes and Health-Related Factors

The associations between the S-TOFHLA scores and the diabetes and health-related variables were analyzed with Spearman's rank correlation. The results showed a significant negative, weak relationship between the S-TOFHLA scores and the years of diabetes duration (r_s (99) = −0.198, p = 0.048), with a significance level of 0.05.

As for the relationship between the S-TOFHLA scores and the frequency of self-monitoring blood glucose levels per day, the results showed a significant positive, weak correlation (r_s (99) = 0.370, $p < 0.001$), with a significance level of 0.01. However, there was no significant relationship between the S-TOFHLA test scores, the self-assessed three-month A1C level (r_s (99) = −0.189, p = 0.058), and the patients' daily insulin administration (r_s (99) = −0.175, p = 0.081) (Table 3).

Table 3. The relationship between the S-TOFHLA and the DNT-15 scores, diabetes and health-related variables and Spearman's rank correlation values.

	S-TOFHLA	DNT-15
Duration of diabetes	−0.198 *	−0.108
Frequency of blood glucose testing/day	0.370 **	0.473 **
Self-assessed three-month A1C level	−0.189	−0.086
Daily insulin administration	−0.175	0.272 *

Notes: * $p < 0.05$; ** $p < 0.01$.

3.4. Associations between the DNT-15 Scores and the Patients' Diabetes and Health-Related Factors

The associations between the DNT-15 scores and the patients' diabetes and health-related variables were also analyzed with Spearman's rank correlation. The results showed a significant positive, weak correlation between the DNT-15 scores and the patients' daily insulin administration (r_s (100) = 0.272, p = 0.006), while the relationship between the DNT-15 scores and the frequency of self-monitoring blood glucose levels per day indicated a significant positive, moderate correlation (r_s (100) = 0.473, $p < 0.001$). Based on the findings, the higher scores on the DNT-15 test showed no statistically significant association with the duration of diabetes (r_s (100) = −0.108, p = 0.282), and the self-assessed three-month A1C level (r_s (100) = −0.086, p = 0.392) (Table 3).

3.5. Associations between the Number of Diabetes Complications and the DNT-15 Scores

In order to determine the differences between the various groups of patients with diabetes complications and their DNT-15 scores, the Kruskal–Wallis test was used. Based on the statistical analysis, the Kruskal–Wallis test was significant (H (4) = 12.690, p = 0.013). To determine which groups significantly differed, the Mann–Whitney test was used. In addition, the Bonferroni corrected significance level was 0.0125. Based on the findings,

the participants who performed significantly better on the DNT-15 had significantly fewer diabetes complications.

3.6. The Effect of Sociodemographic Variables on the Results of the S-TOFHLA Test Measuring Functional Health Literacy

In order to reveal which sociodemographic variables have the most powerful effect on the results of the S-TOFHLA test, we performed a Multivariate Regression Analysis. The dependent variable was the total score on the S-TOFHLA, and the independent variables were age, education level and the possession of healthcare education. The model proved to be significant during the multivariate regression analysis ($F(2,98) = 47.438$, $MSE = 0.518$, $p < 0.001$). Its explanatory power was $R^2 = 49.2\%$ in the sample, $R^2_{Adj} = 48.2\%$ in the population. From the sociodemographic variables, age had a greater effect on the S-TOFHLA results ($\beta = -0.415$, $t(98) = -5.712$, $p < 0.001$), but the effect of the education level was also significant ($\beta = 0.513$, $t(98) = 7.059$, $p < 0.001$).

3.7. The Effect of Sociodemographic Variables on the Results of the DNT-15 Test Measuring Numeracy Skills

We used a Multivariate Regression Analysis in order to reveal which sociodemographic variables have the greatest effect on the results of the DNT-15 test. During the analysis, we used standardized values. The dependent variable was the total score on the DNT-15, and the independent variables were age, education level and the possession of healthcare education. The model proved to be significant during the multivariate regression analysis ($F(2,99) = 26.765$, $MSE = 0.662$, $p < 0.001$). Its explanatory power was $R^2 = 35.1\%$ in the sample and $R^2_{Adj} = 33.8\%$ in the population. From the sociodemographic variables, age had a greater effect on the DNT-15 results ($\beta = -0.380$, $t(99) = -4.657$, $p < 0.001$), but the effect of the education level was also significant ($\beta = 0.408$, $t(99) = 4.997$, $p < 0.001$).

3.8. The Broadest Multivariate Regression Model Including Control Variables

In order to investigate the effects of FHL on managing diabetes we examined the daily frequency of self-monitoring blood glucose levels as a dependent variable. The model proved to be significant ($F(1,99) = 17.430$, $MSE = 0.867$, $p < 0.001$). Its explanatory power was $R^2 = 15\%$ in the sample and $R^2_{Adj} = 14.1\%$ in the population. The effect of the total scores on S-TOFHLA was significant ($\beta = 0.387$, $t(99) = 4.175$, $p < 0.001$). After that we added the DNT-15 test results to the model as a control variable. The model proved to be significant ($F(1,99) = 27.486$, $MSE = 0.799$, $p < 0.001$). Its explanatory power was $R^2 = 21.7\%$ in the sample and $R^2_{Adj} = 20.9\%$ in the population. The effect of the total scores on S-TOFHLA was not significant to the dependent variable in the presence of the control variable; since according to the regression analysis, the total score on the DNT-15 had a greater effect on the frequency of blood glucose testing/day variable ($\beta = 0.466$, $t(98) = 5.243$, $p < 0.001$).

We examined which sociodemographic, diabetes and health-related variables can predict most effectively the frequency of blood glucose testing/day besides the total scores on the two FHL tests (S-TOFHLA and DNT-15). The independent variables were the following: age, education level, possession of the healthcare education, diabetes duration (years), duration of insulin treatment (years), self-assessed three-month A1C level (mmol/L) and frequency of insulin administration per day. The regression model proved to be significant ($F(4,96) = 41.920$, $MSE = 0.383$, $p < 0.001$). Its explanatory power was $R^2 = 63.6\%$ in the sample and $R^2_{Adj} = 62.1\%$ in the population. According to the results, the frequency of insulin administration per day ($\beta = 0.609$, $t(96) = 9.475$, $p < 0.001$), the education level ($\beta = 0.324$, $t(96) = 4.365$, $p < 0.001$), the possession of healthcare education ($\beta = 0.171$, $t(96) = 2.561$, $p < 0.012$) and the total scores on the DNT-15 test ($\beta = 0.174$, $t(96) = 2.412$, $p < 0.018$) had an effect on the frequency of blood glucose testing/day.

4. Discussion

This cross-sectional study revealed that 34.6% of the patients with T2DM had inadequate/marginal reading and comprehension levels. This finding is in line with the

study by Papp-Zipernovszky et al. (2016), which was the first research in Hungary that compared the scores of individuals with chronic illness to those of a healthy population and found that chronic patients had significantly lower FHL levels. Related studies by Agad Hashim et al. (2020), Abdullah et al. (2019) and Van der Heide et al. (2014) also support the aforementioned result in which the presence of type 2 diabetes is in association with the individuals' FHL levels [35,58,59]. In addition, the results of the present study are consistent with the data of Cavanaugh et al. (2011), in which lower FHL levels among diabetes patients were between 15 and 40%, depending on the sample. It seems the Hungarian insulin-user T2DM population belongs to the worse performing range.

The results of the DNT-15 showed that the problem areas for the participants included food label interpretation and items that required multi-step calculations such as calculating insulin dosage based on current blood glucose levels and carbohydrate intake. These findings suggest that the majority of patients with T2DM provides lower average score of correct answers on these tasks within the DNT-15 test. In addition, most of these patients may also experience difficulties during nutrition therapy and when measuring the correct insulin dosage, as part of their diabetes management. This may be due to a number of factors. First, there are currently no diabetes-specific FHL and numeracy guidelines. It is also important to note that since the DNT-15 has yet to be validated on a Hungarian sample, the results should be interpreted with caution. Second, the course of diabetes varies from individual to individual, and that social and environmental factors play an important role during chronic disease management. Third, the authors' previous study found that the majority of patients with T2DM already had a lower engagement level in lifestyle therapy. Thus, they felt less motivated to understand the nutritional value of foods, and they did not apply these competencies during insulin administration [60]. Fourth, diabetes education in Hungary does not emphasize the acquisition of the aforementioned competencies. Finally, due to the nature of the tasks, it may have caused anxiety among the participants, which, in turn, may have negatively affected their working memory and increased the number of errors performed during the tasks [31].

The associations between the S-TOFHLA scores and the years of diabetes duration showed a significant negative, weak relationship. This result suggests that patients diagnosed with T2DM for a longer period of time performed worse on the S-TOFHLA. These findings are consistent with the observations of previous research [35,51]. A potential explanation may be that diabetes negatively affects the cognitive performance of patients with DM [32]. In addition, some studies indicated that individuals who have had diabetes for more than 10 years have significantly lower FHL levels [35]. This finding is in line with the study by Yamashita and Kart, which found that some health-literate patients are overwhelmed by long-term diabetes self-management, and as a result, they feel less motivated to concentrate on the required tasks [51].

According to the findings of the present study, the relationship between the S-TOFHLA scores and the frequency of self-monitoring blood glucose levels per day showed a significant positive weak correlation. This indicates that the individuals who performed better on the S-TOFHLA reading and comprehension tasks measured their blood glucose levels more frequently. This finding is in line with previous conclusions about the associations between different FHL measurements and diabetes self-care behaviors [23,27–29,31]. More precisely, patients with adequate FHL skills have more knowledge about their disease. Hence, they are more conscious about their diabetes self-care activities.

A significant positive weak correlation between the DNT-15 scores and the patients' daily insulin administration was also found. This suggests that patients with T2DM who performed better on the DNT-15 injected insulin more frequently. This finding can be explained by the fact that patients in intensive insulin therapy generally require advanced diabetes-specific numeracy skills, i.e., interpreting blood glucose meter data, administering medication dosages, and following nutritional recommendations [31,48,61]. Moreover, a significant positive, moderate correlation was found between the DNT-15 results and the

frequency of self-monitoring of blood glucose levels per day. This supports the fact that numeracy, as a component of FHL, plays an important role in diabetes self-management [47].

Based on the results, the higher scores on the DNT-15 test showed no statistically significant association with the duration of diabetes. This finding is consistent with the observations of previous studies [45,47]. However, it is possible that the diabetes-specific numeracy skills do not show an explicit connection with the time of diabetes diagnosis, since such skills may be more related to an individual's self-efficacy and self-management behavior [62]. In other words, it may be interpreted as part of the overall learning process [60]. Yet, it is feasible that patients in Hungary require more education of these skills, due to previous paternalistic viewpoints [63]. More precisely, these paternalistic viewpoints imply the fact that the physicians make decisions based on what they discern to be in the patient's best interests and neglecting the involvement of patients in therapy [64].

In this study, the DNT-15 scores showed no statistically significant association with the patients' self-assessed three-month A1C level. This finding supports the outcomes of previous research [52,61,65,66], which is not surprising since glycemic control is most likely influenced by a large number of heterogeneous social and biological determinants [61]. This also indicates that the impact of other variables is equally important when explaining the background of A1C level changes.

In the present study, the participants who performed better on the DNT-15 had significantly fewer diabetes complications. This result is similar to the findings of Chakkalakal et al. (2017) and Rothman et al. (2008) [29,31]. It is widely shown that adequate FHL and numeracy skills influence the health outcomes of patients, and they also improve an individual's self-efficacy and self-care behavior. In light of the results of the DNT-15, it could be stated that diabetes patients with good numeracy skills are more likely to have greater confidence in performing self-care tasks [61]. Consequently, the number of hypoglycemic episodes and diabetes complications should also decrease [48]. We found that two the sociodemographic variables, age and education level had a greater impact on the results of the S-TOFHLA and the DNT-15 tests. These findings are similar to the findings of Gomes et al. (2020), Abdullah et al. (2019) and Yeh et al. (2019) who emphasize that age and education level are important predictors of the individuals' FHL performance [25,59,67]. It could also be stated that patients with T2DM who are older and have a lower education level may require more attention from health care providers and diabetes educators.

Our research also tried to find answers to the questions whether FHL and diabetes-numeracy levels with sociodemographic, diabetes-specific and health-related variables impact patients' diabetes self-care activities. During our analyses, the effect of the total scores of S-TOFHLA was significant, still we added the DNT-15 test results to the model as a control variable. When S-TOFHLA and DNT-15 were both part of the regression analysis, the total score of the DNT-15 had a greater effect on the frequency of blood glucose testing per day, which is one of the most important diabetes self-care activities during diabetes self-management [42]. Previous studies by Yarmohammadi et al. (2019), Lee et al. (2016), van der Heide et al. (2014), [35,39,42] showed similarities with the current findings and they also emphasized that self-management of T2DM requires advanced FHL and numeracy skills. These results can be interpreted by the fact that patients with a higher health literacy level check their blood-glucose levels more frequently, which is vital for patients under insulin therapy. Scores on the DNT-15 test seem to have a greater impact on diabetes self-management because diabetes numeracy does not only include the ability to interpret risk, but also to interpret blood parameters, understand food labels and measure medications. Diabetes numeracy also helps patients solve problems and make appropriate health-related decisions. This is, in practice, much more closely related to daily diabetes self-management tasks than reading and comprehension. All in all, it is conceivable that diabetes numeracy as a component of FHL skills has an important effect on patients' diabetes self-care.

In addition to these analyses, it was also examined which sociodemographic, diabetes and health-related variables besides the total scores on the two FHL tests (S-TOFHLA and DNT-15) could have a greater impact on the frequency of blood glucose testing per day

among patients with T2DM. The findings showed that the frequency of blood glucose testing per day is mostly predicted by the frequency of insulin administration per day, education level, possession of healthcare education and the total score on the DNT-15 test. The results can be explained by a fact that self-care activities, such as the frequency of blood glucose testing and the frequency of insulin administration, many times go hand in hand and both are important parts of T2DM therapy. The findings of the study are in line with the previous researches according to which diabetes therapy and self-management can be successful only if patients follow complex treatment plans of diabetes therapy [25,32,68]. In sum, it seems that one of the important key factors for successful diabetes self-care are diabetes numeracy skills which could help patients to cope with the consequences of a chronic illness, increase patients' understanding and awareness of their chronic disease and help facilitate their engagement in diabetes self-management [19,26].

Limitations and Future Directions

There are several limitations in this study worth noting. First, this research was based on a cross-sectional design, and it may require a larger sample size to provide higher accuracy. Second, the participants were involved on a voluntary basis. Thus, it is possible that those who were less motivated and had more problematic FHL and numeracy skills were not included. Third, all of the participants were members of various diabetes associations. Hence, they were possibly more informed and had higher FHL and numeracy skills, compared to other patients. The fourth limitation is that the DNT-15 test has not yet been validated on a Hungarian sample, so it would be recommended to do the validation procedure and only then formulate conclusions. According to the information given by patients, it is important to state that the majority of respondents self-reported a three-month A1C level. It is conceivable that some individuals did not reveal their real three-month A1C values. Our study can be considered innovative among scientific surveys because FHL and numeracy are less explored in patients diagnosed with T2DM. Furthermore, these T2DM-specific results are among first ones measured in Central-Eastern European regions, such as Hungary. It would be advisable to carry out group comparisons in the future and test these factors with patients who are not motivated to join associations. All in all, one of the most important future steps could be to carry out a longitudinal investigation which could help to explore patterns of change in and the dynamics of patients' behavior, and also gain more insights into the cause and effect processes. Overall, it could be stated that the results obtained may also be useful in the preparation of future diabetes education materials and programs. Overall, the findings of this study could serve as a helpful reference in the preparation of future diabetes education materials and programs.

5. Conclusions

The study explored FHL levels and numeracy skills in an insulin-treated T2DM patient population, and their impact on diabetes self-care activities. Based on the findings, FHL and diabetes-specific quantitative skills influenced the patients' health outcomes (e.g., the existence of diabetes-related complications) and impacted their diabetes self-care activities such as the daily blood glucose testing or daily insulin administration. This implies that diabetes numeracy skills also influence patients' behavior towards diabetes treatment. The results also showed that the problem areas for patients with T2DM included multi-step calculations such as food label interpretation and adequate insulin dosage based on current blood glucose levels and carbohydrate intake. Therefore, besides the personalization of insulin treatment, it is indispensable to provide more precise information on different types of insulin administration and more refined educational materials based on medical nutrition therapy.

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Data Availability Statement: The data presented in this study are available upon request from the corresponding author. The data are not publicly available due to participants of this study not agreeing for their data to be shared publicly and because health data belong to the category of 'sensitive data'.

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III.

Betegségismeret 2-es típusú diabetesszel élők körében: a Diabetes Knowledge Test magyar nyelvű validálása

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Bevezetés: Magyarországon a KSH szerint több mint 1 millió ismert cukorbeteg él. A diabetes karbantartásához elengedhetetlen a betegek tudásának, készségeinek és önhatékonyságának növelése és fenntartása. A legelterjedtebb diabetes-betegségismeretteszt a 23 kérdéses Michigan Diabetes Knowledge Test. Első 14 tétele általános tudást mér, például az ételek tápanyagtartalmával és a vércukorszint-változás okaival kapcsolatban. További 9 kérdése az inzulinhasználatról szól.
Célkitűzés: Célunk ennek a tesztnek a magyar nyelvű validálása, valamint összefüggéseinek vizsgálata szociodemográfiai és betegségváltozókkal.
Módszer: Keresztmetszeti kérdőíves kutatásunkban a tesztcsomagot 129, inzulint használó, 2-es típusú diabeteses beteg töltötte ki (84 nő, átlagéletkor: 59,67; szórás: 12,6) elsősorban online, betegszervezeteken keresztül.
Eredmények: A betegségismeret-teszt belső konzisztenciája 0,603, ami elfogadható érték. A 23 kérdés helyes kitöltési arányának átlaga 81,66%, ami az amerikai arányokhoz hasonló, más kutatások speciális csoportjaihoz képest azonban kifejezetten magas érték. A válaszadók a ketoacidosis fogalmát, az egyes ételek tápanyag-összetevőit és az elfogyasztott ételek vércukorszintre gyakorolt hatását illető kérdésekre tudták a választ a legkevésbé. A magyar teszt a szakirodalomnak megfelelő gyenge, negatív irányú összefüggésben áll az életkorral, és pozitív a kapcsolata az inzulinhasználat hosszával, valamint a napi vércukorszintmérés és inzulinbeadás számával. A betegségismeretet függetlenül egyedül a napi vércukorszintmérés mennyisége jósolta meg. A teszt konvergens validitását mutatja gyenge, de szignifikáns összefüggése az egészségértést mérő Brief Health Literacy Screening kérdésekkel.
Következtetés: A magyar nyelvű Diabetes Betegségismeret Teszt alkalmas a diabetesszel élők tudásszintjének felmérésére. Mintánkban a betegségismeret magas szintje az inzulint használók megfelelő edukációjával függhet össze. Ugyanakkor eredményeink felhívják a figyelmet a betegek diétával kapcsolatos magasabb szintű tudásának szükségességére.
Orv Hetil. 2021; 162(22): 870–877.

Kulcsszavak: egészségértés, betegségismeret, validálás, Diabetes Betegségismeret Teszt

Illness knowledge of type 2 diabetes patients: the Hungarian validation of Diabetes Knowledge Test

Introduction: According to the Hungarian Central Statistical Office, more than 1 million diabetic patients live in Hungary. It is essential to enhance and sustain the knowledge, skills and self-efficacy of patients. The most widely used measurement of illness knowledge is the 23-item Michigan Diabetes Knowledge Test (DKT). Its first 14 items measure general knowledge: the nutritional value of food, and causes of change in blood glucose level. Its further 9 items are about insulin usage.
Objective: To examine the reliability and the validity of the Hungarian version of DKT2 as well as its association with sociodemographic and illness-related variables.
Methods: In our cross-sectional quantitative study, 129 patients (84 women, mean age: 59.67; SD = 12.6) diagnosed with type 2 diabetes mellitus using insulin therapy filled in a questionnaire online.
Results: The α coefficient for the test is 0.603, which is acceptable. The mean of the correct answer rate is 81.66%, which resembles the American results, but it is higher than that of other specific groups. Problem areas for our patients included interpreting ketoacidosis, the nutritional value of foods and the effect of foods on blood glucose

level. The score of the Hungarian test – in accordance with the literature – correlates negatively with age, positively with the year of insulin-usage and with the number of daily insulin intake and of blood glucose measurement. Illness knowledge was independently predicted only by the number of daily blood glucose measurement. The convergent validity of the Hungarian test is supported by its weak but significant association with Brief Health Literacy Screen questions.
Conclusion: The Hungarian DKT2 properly measures the illness knowledge of diabetic patients. Their high level of knowledge can be traced back to the speciality of the subjects as well as to the overall education of insulin users. Nevertheless, our results draw attention to the necessity of enhancing the level of dietetic knowledge of patients.

Keywords: health literacy, illness knowledge, validity, Diabetes Knowledge Test

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Rövidítések

BHLS = (Brief Health Literacy Screen) az egészségértés gyors előszűrése; DKN scales = (Diabetes Knowledge scales) a diabetesszel kapcsolatos ismereteket értékelő skálák; DKQ = (Diabetes Knowledge Questionnaire) a diabetesszel kapcsolatos ismereteket mérő kérdőív; DKT2 = (Diabetes Knowledge Test 2) Diabetes Betegségismeret Teszt; DPKT = (Diabetes Patient Knowledge Test) betegségismeretet felmérő teszt diabetesesek számára; EFOP = Emberi Erőforrás Fejlesztési Operatív Program; HbA1c = hemoglobin-A-1c; KSH = Központi Statisztikai Hivatal; SD = standard deviáció; SZTE ÁOK = Szegedi Tudományegyetem, Általános Orvostudományi Kar

Az International Diabetes Federation 2019. évi adatai 463 millió, diabetesszel élő felnőttről számolnak be világszerte; becslésük szerint ez a szám 25 éven belül 700 millióra emelkedhet [1]. Magyarországon a KSH 2017. évi összesítése szerint több mint 1 millió ismert cukorbeteg él.

A 2-es típusú diabetes ellátása az esetek többségében a gyógyszeres terápián túl komplex életmód-terápiát is igényel, amely magában foglalja speciális diéta követését és a rendszeres testmozgást. Ennek megfelelően a beteg önmaga is aktív részese a kezelésnek, így tudásának, készségeinek és önhatékonyságának szintje alapvetően határozza meg betegsége karbantartását [2]. *Al-Qazaz és mtsai* [3] a diabeteskezelés és az egészségügyi kimenetelek javítása szempontjából is az öngondoskodás edukációját tartják a legfontosabbnak.

Vizsgálatunkban a betegek tudását mérő, klinikai gyakorlatban is széles körben alkalmazott Diabetes Betegségismeret Teszt magyar validálását végeztük el.

Az egészségértés és a betegségismeret szerepe a diabetes ellátásában

Az egészségértés „… az egészséggel kapcsolatos alapvető információk és szolgáltatások elérésének, értelmezésének és megértésének képessége, valamint ezen információk és szolgáltatások felhasználásának kompetenciája az egészség fejlesztése érdekében” [4]. Komplex kognitív, motivációs és szociális készségeket magában foglaló fogalomról van szó, amely erős, pozitív kapcsolatban áll a mortalitással [5], és jobban képes megjósolni az egészségi állapotot, mint az életkor, a jövedelem, a foglalkoztatási státusz, az iskolázottság vagy a faji, etnikai csoporthoz való tartozás [6]. *Schillinger* [7] krónikus betegséggel élők (diabetes, asztma, magas vérnyomás) esetében foglalta össze gyakorlati példákon keresztül az alacsony egészségértés jeleit és következményeit: kevésbé értik az állapotukat és annak kezelését, kevésbé tudják megnevezni gyógyszereiket és leírni, hogy mire kapják azokat, gyakrabban vannak olyan hiedelmeik, amelyek az adherenciát akadályozzák. Gyakran olvassák félre még az egyszerűbb betegtájékoztatókat is. Emellett nehézségeik lehetnek a szóbeli kommunikáció során és az egészségügyi kockázatok felmérésekor is.

Szociodemográfiai szempontból az alacsonyabb egészségértésű cukorbetegek idősebbek, nők, alacsonyabb iskolai végzettségűek, és régebb óta élnek együtt a betegséggel [7]. *Fransen és kutatócsoportja* [8] több empirikus tanulmányt elemzett diabetesesek egészségértésével és önmenedzselési szokásaival kapcsolatban. Következtetésük szerint a sikeres terápiához a betegnek nemcsak kellő motiváltsággal kell rendelkeznie, hanem fejlett önhatékonysággal és magas egészségértési szinttel is. Az eddigi legátfogóbb metaelemzést diabetesesek egészségértése és együttjárásai, következményei között *Al Sayah és mtsai* [9] végezték. Ebben konzisztens kapcsolatot az egészségértés és a szövődmények kialakulása között mutattak ki.

A betegcsoportok egészségértés-vizsgálata gyakran tartalmaz a betegségről (tünetei, progressziója) és kezeléséről való tudást felmérő kérdéseket. Az egészségértés és a betegségről való tudás (betegségismeret) összefüggése *Al Sayah és mtsai* [9] metaelemzésében pozitív irányú és konzisztens volt. A páciensek betegségismerete további tudományos vizsgálatokban összefüggött a felnőtt betegek korával (negatív irányban [10]), önhaté-

konyság-érzetével [11], alacsony szintje negatív befolyással bírt az egészségi állapotra (például a metabolikus kontrollra [9]) és a terápiás adherencia mértékére [12].

Diabetes-tudástesztek

Az 1980-as évek óta készülnek betegségismeretet felmérő tesztek diabetesesek számára (Diabetes Patient Knowledge Test [DPKT] [13]; Diabetes Knowledge [DKN] scales [10]; Diabetes Knowledge Questionnaire [DKQ] [11]). Az „alapismeretek" között megtalálhatók a glikémiás állapot felborulásának okai, tünetei és kezelése, a magas szénhidráttartalmú ételek azonosítása, a cukorbetegség lefolyása, kezelésének célkitűzései, a vércukor mérése és a betegség komplikációinak felismerése. A DPKT külön kérdéscsoportot szentel az inzulinmenedzsmentnek, a DKQ-ban pedig megjelenik a cukorbetegség típusainak ismerete és az önmenedzselési készségek felmérése is (ez utóbbit méri serdülőknél magyar nyelven a Diabetes Adherencia Kérdőív [14]).

A legelterjedtebb betegségismeret-teszt a Michigan Diabetes Knowledge Test [15], melynek átdolgozott változatát 2016-ban publikálták [16]. Széles körű használata (több mint tíz nyelvre fordították le, Európában például portugál, norvég és szlovén, illetve több arab és afrikai nyelvre, valamint malájra is) és a kutatási eredmények elérhetősége miatt mi is ennek a magyar nyelvű validálása mellett döntöttünk.

A DKT2 és összefüggései

A teszt első változatát 1998-ban publikálta a Michigan Diabetes Research and Training Center, diabetes-szakértők bevonásával [15]. A 23 kérdés első 14 kérdése mindkét típusú diabetesszel élő számára releváns, általános tudás felmérésére vonatkozik. Tartalmaz állításokat az ételek tápanyagtartalmával, a HbA1c-érték jelentésével, a vércukorszint mérésével, a vércukorszint-változás okaival és kezelésével, valamint a szövődmények felismerésével kapcsolatban. A további 9 kérdés az inzulinhasználatról szól. A teljes teszt kitöltése kb. 15 percet vesz igénybe, és 6. osztályos szövegértési szintre tervezték, elsősorban klinikai kutatások számára, nem specifikus gondozási kérdések megválaszolására [15].

2016-ban az eredeti tesztet átdolgozták (13 tételt módosítottak) az újabb diabetesgondozási és -oktatási iránymutatók figyelembevételével [16] – mi ezt a változatot validáltuk Joseph T. Fitzgerald írásos engedélyével. Az általános teszt megbízhatósága 0,77, az inzulinalskáláé pedig 0,84 – mindkét érték a kiváló megbízhatóság mutatója. A 23 tételre a teszt megalkotói nem közöltek reliabilitásértékeket. A betegségismeret az iskolai végzettséggel mutatott összefüggést (a gimnáziumi érettségi vagy az alatti végzettségűek pontszáma szignifikánsan alacsonyabb volt), emellett a diabetes típusával (az 1-es típusú betegek pontszáma magasabb volt), a kezelés típusával (magasabb pontszáma volt a csak inzulint használóknak, mint az inzulin és gyógyszer kombinációjának) és a diabetesoktatással [16]. A teszt más nyelveken való validálása során alacsonyabb pontszámot értek el azok, akik idősebbek, és alacsonyabb a családi összjövedelmük [17]. A betegségváltozóknál az alacsonyabb szintű tudás a rövidebb diabetes- és inzulinhasználati időtartammal, a kevésbé gyakori inzulininjekciózással és otthoni vércukorszintméréssel függött össze [17].

2018-ban szaúd-arábiai mintán *Zowgar és mtsai* [18] – a funkcionális egészségértés mérésében gyakori – inadekvát, marginális és adekvát övezeteket állítottak fel a cukorbetegség-ismeret mértékének jelzésére. A DKT2-pontszám 1 és 11 között alacsony, 12 és 18 között átlagos, 19 és 23 között pedig magas cukorbetegség-ismeretet jelez. A sávos felosztás segíti a teszt klinikai alkalmazását, a betegedukáció szintjének illesztését.

Módszer

Résztvevők

Az adatgyűjtés 2019. november és 2020. augusztus között történt elsősorban online, a teszt linkjének diabetesszervezetekhez és a közösségi médiában zárt diabetescsoportokhoz történő eljuttatásával. (A kérdőív 2016. évi átdolgozásakor szintén részben online mintán történt az adatfelvétel [16].) Ezt egészítettük ki kiképzett tesztfelvevők ismeretségi körében, háziorvosoknál és a Szegedi Klinikán személyes adatfelvétellel. A végleges mintába 129, 2-es típusú diabeteses személy adatai kerültek be (84 nő, átlagéletkor: 59,67; szórás: 12,6), akik legalább fél éve használnak inzulint, 18 év felettiek, és magyar az anyanyelvük. A kutatást a Tudományos Kutatásetikai Bizottság engedélyezte (25866-2/2019/EKU).

Vizsgálati eszközök

A kutatás elsődleges célja az EFOP-3.6.1-16-2016-00008. számú alprojekt keretében a közös értékteremtés-modell adaptálása volt a hazai gyógyszerfejlesztési folyamatra – inzulint használó diabetesesek esetében. Ennek egyik szakaszában kérdőíven felmértük a betegek inzulinhasználattal kapcsolatos élményeit, egészségértését és elvárásait, valamint az új technológiákkal szembeni hajlandóságukat. Az összeállított tesztbattéria az informált beleegyezésen, a demográfiai, valamint betegségjellemzőkön kívül 7, magyar nyelvre fordított vagy validált kérdőívet, az inzulinhasználattal kapcsolatos, általunk szerkesztett érzéslistát és szemantikus differenciálskálát tartalmazott. A jelen tanulmányban nemzetközileg is a leggyakrabban használt, klinikai környezetben elterjedt DKT2-kérdőív [16] magyar adaptációját mutatjuk be (a teszt magyar változatát az *1. melléklet* tartalmazza) a demográfiai és betegségváltozókkal, valamint konvergens validitásként az önjellemző, előszűrésre kifejlesztett egészségértés-kérdésekkel, a Brief Health Literacy

1. melléklet | A magyar nyelvű Diabetes Betegségismeret Teszt (DKT2) kérdései. A helyes választ * jelöli

Általános kérdések	Inzulinhasználati kérdések
1. A cukorbetegek étrendje:	*15. A ketoacidosis tünetei közé tartozik:*
a. ahogyan a legtöbb magyar ember étkezik*	a. reszketés
b. egy egészséges étrend a legtöbb ember számára	b. izzadás
c. a legtöbb ember számára túl sok szénhidrátot tartalmaz	c. hányás*
d. a legtöbb ember számára túl sok fehérjét tartalmaz	d. alacsony vércukorszint
2. Az alábbiak közül melyiknek van a legmagasabb szénhidráttartalma?	*16. Amennyiben egy cukorbeteg influenzás:*
a. Sült csirke	a. kevesebb inzulint kell bevinnie
b. Ementáli sajt	b. kevesebb folyadékot kell innia
c. Sült krumpli	c. több fehérjét kell ennie
d. Mogyorókrém*	d. gyakrabban kell mérnie a vércukorszintjét*
3. Az alábbiak közül melyiknek a legmagasabb a zsírtartalma?	*17. Amennyiben gyors hatású inzulint vitt be, vércukorszintje nagy valószínűséggel csökkeni fog:*
a. Alacsony zsírtartalmú (1,5%) tej*	a. kevesebb mint 2 órán belül*
b. Narancslé	b. 3–5 órán belül
c. Tarkabab	c. 6–12 órán belül
d. Méz	d. több mint 13 órán belül
4. Az alábbiak közül melyik ételt „szabad bármikor enni”?	*18. Ebéd előtt veszi észre, hogy elfelejtette a reggeli előtt bevinni az inzulinadagját. Mit kell tennie most?*
a. Bármilyen, nem édesített étel	a. Kihagyni az ebédet, hogy lejjebb vigye a vércukorszintjét
b. Bármilyen olyan étel, amely címkéjén az szerepel, hogy „zsírmentes”	b. Azt a mennyiségű inuzlint bevinni, amelyet általában reggeli előtt szokott
c. Bármilyen cukormentes étel	c. A reggeli mennyiség kétszeresét kellene bevinnie
d. Bármilyen olyan étel, amelyben kevesebb mint 20 kalória van adagonként*	d. Ellenőrizni kell a vércukorszintjét, hogy eldöntse, mennyi inzulint vigyen be*
5. A HbA1c az átlagos vércukorszint értéke az elmúlt:	*19. Ha kezdeti alacsonyvércukorszint-reakciót észlel magán:*
a. 1 napra vonatkozóan	a. testmozgást kell végeznie
b. 1 hétre vonatkozóan	b. le kell feküdnie és pihennie kell
c. 6–12 hétre vonatkozóan*	c. gyümölcslevet kell innia*
d. 6 hónapra vonatkozóan	d. gyorsan ható inzulint kell bevinnie
6. Mi a legjobb módja az otthoni vércukorszintmérésnek?	*20. Alacsonyvércukorszint-reakciót okozhat:*
a. Vizeletvizsgálat	a. túl sok inzulin*
b. Vérvizsgálat*	b. túl kevés inzulin
c. Mindkettő egyformán jó	c. túl sok étel
	d. túl kevés testmozgás
7. Milyen hatása van az édesítés nélküli gyümölcslének a vércukorszintre?	*21. Ha beviszi a reggeli inzulinadagját, de kihagyja a reggelit, a vércukorszintje általában:*
a. Csökkenti	a. emelkedni fog
b. Növeli*	b. csökkenni fog*
c. Nincs hatása	c. ugyanannyi marad
8. Melyik nem alkalmazható alacsony vércukorszint kezelésére?	*22. Mindenképpen magas vércukorszintet okoz:*
a. 3 szem kemény cukorka	a. a nem elegendő inzulin*
b. ½ pohár narancslé	b. az étkezések kihagyása
c. 1 pohár diétás üdítőital*	c. az uzsonna késleltetése
d. 1 pohár sovány tej	d. a testmozgás kihagyása
9. Milyen hatása van a testmozgásnak a vércukorszintre egy jó egészségi állapotban levő személynél?	*23. Alacsonyvércukorszint-reakciót okozhat:*
a. Csökkenti*	a. fokozott testmozgás*
b. Növeli	b. fertőzés
c. Nincs hatása	c. túlevés
	d. ha nem veszi be az inzulinadagját
10. A legtöbb fertőző betegség okozhat:	
a. vércukorszint-emelkedést*	
b. vércukorszint-csökkenést	
c. változatlan vércukorszintet	
11. A lábápolás legjobb módja:	
a. naponta átnézni és megmosni őket*	
b. naponta átmasszírozni alkohollal	
c. napi egyórás áztatás	
d. a szokásosnál eggyel nagyobb méretű cipő vásárlása	
12. A csökkentett zsírtartalmú ételek fogyasztása csökkenti az esélyét:	
a. az idegrendszeri betegségek kialakulásának	
b. a vesebetegségek kialakulásának	
c. a szívbetegségek kialakulásának*	
d. a szembetegségek kialakulásának	
13. Minek a tünete lehet a zsibbadás és bizsergés?	
a. Vesebetegségnek	
b. Idegrendszeri betegségnek*	
c. Szembetegségeknek	
d. Májbetegségnek	
14. Az alábbiak közül melyik nem kapcsolódik a cukorbetegséghez?	
a. Látási problémák	
b. Veseproblémák	
c. Idegrendszeri problémák	
d. Tüdőproblémák*	

HbA1c = hemoglobin-A-1c

1. táblázat | A magyar nyelvű Diabetes Betegségismeret Teszt (DKT2) egyes kérdéseire adott helyes válaszok aránya

A DKT2-kérdések sorszáma	A helyesen válaszolók száma (%)
Általános kérdések	
DKT2_1.	104 (80,6)
DKT2_2.	82 (63,6)
DKT2_3.	95 (73,6)
DKT2_4.	70 (54,3)
DKT2_5.	102 (79,1)
DKT2_6.	125 (96,9)
DKT2_7.	107 (82,9)
DKT2_8.	93 (72,1)
DKT2_9.	113 (87,6)
DKT2_10.	108 (83,7)
DKT2_11.	118 (91,5)
DKT2_12.	117 (90,7)
DKT2_13.	123 (95,3)
DKT2_14.	127 (98,4)
Inzulinhasználati kérdések	
DKT2_15.	34 (26,4)
DKT2_16.	122 (94,6)
DKT2_17.	115 (89,1)
DKT2_18.	121 (93,8)
DKT2_19.	113 (87,6)
DKT2_20.	110 (85,3)
DKT2_21.	113 (87,6)
DKT2_22.	106 (82,2)
DKT2_23.	105 (81,4)

A teljes teszt helyes kitöltési arányának átlaga: 81,66%
Az általános tudástételek helyes kitöltési arányának átlaga: 82,16%
Az inzulinspecifikus tudástételek helyes kitöltési arányának átlaga: 80,89%

Screen-nel (BHLS [19], magyarul [20]) összefüggéseiben.

A DKT2-kérdőív – ahogy fentebb részletesen bemutattuk – egy 23 kérdésből álló tudásteszt diabetesesek betegség- és betegséggondozásának mérésére. A kérdésekre előre megadott tételek közül kell válaszolni, minden esetben 1 helyes válasz van. Ezek összege adja a teszt pontértékét: a magasabb pontszám nagyobb tudást jelent a betegségről [16]. Az angol nyelvű teszt magyarra fordításakor *Gudmundsson* [21] ajánlásait követtük: két független, mindkét nyelvet magas szinten beszélő, hozzáértő személy lefordította a teszteket angolról magyar nyelvre. Közös egyeztetés után létrehoztak egy egységes magyar verziót. A felmerülő kérdésekről jegyzőkönyv készült. A két változat, a jegyzőkönyv és *Fitzgerald és mtsai* [16] ajánlásai alapján a jelen tanulmány szerzőit tartalmazó szakértői csoport alakított ki egy előzetes változatot. Ezzel 2018. január és július között 89 fő részvételével pilotvizsgálatot végeztünk, melyben teszteltük a kérdések értelmezhetőségét is. Összességében a kérdőív 4 tételén módosítottunk: *Fitzgerald és mtsai* [16] ajánlása szerint (nem amerikai mintán javasolt az 1., 2., 3., 4. és 8. tétel felülvizsgálata kulturális szempontból) az ételek ismertségének figyelembevételével a 2. tételben svájci sajt helyett ementáli sajt, mogyoróvaj helyett pedig mogyorókrém szerepel, a 3. tételben 2%-os helyett 1,5%-os tejzsírtartalom, míg kukorica helyett tarkabab. A tételek módosításakor ellenőriztük a válaszok helyességét is az új választási lehetőségekkel, ami a 2. tételnél megváltoztatta a helyes választ. A betegek visszajelzései alapján a 10. és a 22. tételre több jó válasz is adható volt – ezek esetében diabetológus szakorvossal konzultáltunk az egyértelműsítés előtt. Így a 10. tételbe „A fertőzés okozhat" helyett „A legtöbb fertőző betegség okozhat" kezdő mondat került, a 22.-be pedig a „Magas vércukorszintet okozhat" helyett a „Mindenképpen magas vércukorszintet okoz".

A BHLS-kérdéseket [19] az egészségértés önbevallás alapuló, a klinikumban alkalmazható gyors előszűrésére fejlesztették ki, ezért minél magasabb pontszámot ér el valaki az egyes válaszok pontértékeinek összeadása után, annál problémásabb egészségműveltségről beszélhetünk. A 3 tétel pontozása 5 fokozatú Likert-skálán történik, amelyen 0 = *Soha*, 1 = *Kevésszer*, 2 = *Néha*, 3 = *A legtöbbször* és 4 = *Mindig*. Az eredeti pontozás szerint az első tételre adott pontérték számítása fordított.

Eljárás

A kérdőívcsomag kitöltése nagyrészt online zajlott 2019. november és 2020. augusztus között. A tesztek kitöltése egy személy esetében körülbelül 30 percet vett igénybe. A betegtájékoztató megismerése után egyetértés esetén a páciensek aláírták a beteg-beleegyező nyilatkozatot (az online kérdőívkitöltéskor az elfogadást egy pipa bekattintásával jelezték). Az adatgyűjtést az SZTE ÁOK Egészséggazdaságtani Intézetének számítógépén, a Survio nevű szoftverrel (Brno, Csehország) végeztük.

Eredmények

A célteszt megbízhatóságának, szociodemográfiai változókkal való összefüggéseinek és konvergens validitásának megállapítására az SPSS statisztikai programcsomag 22-es verzióját (IBM Corporation, Armonk, NY, Amerikai Egyesült Államok) használtuk. Statisztikailag szignifikáns eltérésnek a <0,05 p-értéket fogadtuk el.

Leíró statisztika: a tesztek megbízhatósága, az egyes tételek helyes kitöltési arányai

A DKT2 23 kérdésének konzisztenciája (Cronbach-α-értéke) 0,603, amely elfogadható érték. Mivel inzulint használó cukorbetegekkel validáltuk a tesztet, nem vizsgáltuk külön az első 14 általános és a 9 inzulinhasználati

kérdés megbízhatóságát, az átlag- és szórásértékeket azonban mindhárom esetben megadjuk: M_{23} = 18,78 (SD = 0,23); M_{14} =11,5 (SD = 0,14) és M_9 = 7,28 (SD = 0,12).

A mintában a teszteredmények nem követik a normáleloszlást (Kolmogorov–Szmirnov-érték a 23 tételre: 0,208), így a továbbiakban nemparaméteres statisztikai próbákat használtunk a számításokhoz. Az általános és az inzulinhasználatra vonatkozó tesztrészek közötti korreláció 0,392 volt (ρ_{127} = 0,392; p<0,000), ami szignifikáns, gyenge, pozitív együttjárásnak számít. Az egyes tesztrészek szignifikáns, erős, pozitív korrelációt mutattak az összpontszámmal ($DKT_{14 \text{ és } 23 \text{ között}}$ ρ_{127} = 0,873; p<0,000; $DKT_{9 \text{ és } 23 \text{ között}}$ ρ_{127} = 0,766; p<0,000).

Az *1. táblázat* foglalja össze, hogy a minta hány százaléka válaszolt helyesen az egyes kérdésekre. A teljes teszt helyes kitöltési arányának átlaga 81,66%, ehhez közeli átlagot mértünk az általános tudástételek (82,16%) és az inzulinspecifikus tudástételek (80,89%) esetében is. Az arányok alapján az látszik, hogy a betegek az általános kérdések közül a legnehezebbnek az egyes ételek tápanyag-összetevőinek, valamint az elfogyasztott ételek vércukorszintre gyakorolt hatásának a megítélését tartották, a legkönnyebbnek pedig a szövődmények tüneteinek felismerését. Az inzulinspecifikus kérdéseknél a mindennapi tevékenységek következményeként fellépő inzulinváltozás irányát minden esetben 80% felett válaszolták meg helyesen a betegek, kiugró érték a ketoacidosis-fogalom ismeretének hiánya miatt jelentkezett.

Zowgar és mtsai [18] felosztása alapján meghatároztuk mintánkban az alacsony (2,3%), átlagos (30,2%) és magas (67,4%) betegségismerettel rendelkezők arányát. Mintánkban a leggyakoribb a magas betegségismeret volt.

A konvergens validálás ellenőrzéséhez önbevalláson alapuló, magyar sztenderd értékekkel rendelkező egészségértéstesztet alkalmaztunk, a BHLS-t. A teszt belső konzisztenciája a mintánkon 0,719 volt, ami kiváló megbízhatóságra utal. A DKT2-összpontszámmal szignifikáns, gyenge, negatív együttjárást mutat (ρ_{127} = –0,246; p<0,005). A negatív korreláció oka, hogy a BHLS-en minél magasabb értéket kap egy személy, annál problémásabb az egészségműveltsége.

A DKT2-teszt összefüggése a demográfiai és betegségváltozókkal

A szakirodalomnak megfelelően a szociodemográfiai változók közül a nemmel, az iskolai végzettséggel, az életkorral és a betegségre fordított jövedelem mértékével vetettük össze a betegségismeretet. A betegségváltozók közül a diagnózis óta eltelt évek számának, az inzulinhasználat idejének (év), a kezelés típusának (inzulin vagy inzulin és tabletta), a szövődmények számának, a napi inzulinbeadás és a vércukorszintmérés számának összefüggéseiben vizsgáltuk a DKT2-kérdőívet. A gyakorlat szempontjából az egészségügyi kimenetelek közül a szubjektív egészségi állapotra gyakorolt jóslóértékét teszteltük.

A szociodemográfiai változók közül a DKT2 összpontszáma az életkorral szignifikáns, gyenge, negatív összefüggésben áll (ρ_{127} = –0,194, p = 0,028), a nemmel, az iskolai végzettséggel és a betegségre költött jövedelemmel azonban nincs kapcsolatban. A betegségváltozók közül a DKT2 az inzulinhasználat idejével, valamint a napi vércukorszintmérés és inzulinbeadás számával mutatott szignifikáns pozitív korrelációt (ρ_{127} = 0,174, p = 0,048; ρ_{127} = 0,444, p<0,000; ρ_{127} = 0,217, p = 0,014). A DKT2-összpontszámmal együtt járó változók hatását lineáris regressziós elemzéssel is teszteltük ('Enter' módszer), melyben a modell szignifikáns lett (F_4 = 8,92; p<0,000), a variancia 22,3%-át magyarázta, a többi változótól függetlenül azonban csak a napi vércukorszintmérés száma jósolta be a betegségismeret mértékét (β = 0,37, t = 3,58, p<0,000). A mért szövődmények közül a betegségismeret egyedül a szív- és érrendszeri problémák jelenlétével függött össze szignifikánsan: alacsonyabb összpontszám (M = 18 SD = 3,12 vs. M = 19,1 SD = 2,31, t_{127} = 2,2, p = 0,03) jellemezte azokat a cukorbetegeket, akiknél megjelent ez a szövődménytípus.

A DKT2 nem függött össze a szubjektív egészségi állapottal, a BHLS azonban igen (ρ_{127} = –0,277, p = 0,02): a problémásabb szubjektív egészségértés rosszabb szubjektív egészségi állapottal járt együtt.

Megbeszélés

Tanulmányunk célja a DKT2-teszt magyar nyelvű validálása volt. A teszt belső konzisztenciája inzulint használó, 2-es típusú cukorbetegeknél 0,603 volt, ami elfogadható érték. *Fitzgerald* 1998-ban és 2016-ban [15, 16] 0,7 feletti értékekről számolt be, azonban a 23 kérdésre együtt nem adott meg Cronbach-α-értéket, a michigani egyetemi klinika diabetes-nyilvántartásában szereplő mintán pedig 0,5 alatti értékeket kapott. Ez arra is felhívja a figyelmet, hogy a DKT2 megbízhatóságát érdemes külön ellenőrizni 1-es és 2-es típusú diabeteses minta esetén.

A 23 kérdés helyes kitöltési arányának átlaga kutatásunkban 81,66%, ami az amerikai arányokhoz hasonló (általános teszt: 77%, inzulinalskála: 73% [16]), más kutatásokban vizsgált speciális csoportokhoz képest azonban kifejezetten magas értéknek számít (például amerikai veteránoknál 64,6% [22]). Mintánk magas tudásszintjét mutatja *Zowgar és mtsai* [18] tudásövezet szerinti felosztásának alkalmazása is. Míg kutatásunkban a betegek 2,3%-a tartozott az alacsony, 30,2%-a az átlagos és 67,4%-a a magas tudásövezetbe, arab mintán ez az arány sorrendben 29,2%, 66,1% és 4,7%, bengálin pedig 18%, 66% és 16% volt [23]. A különbségek adódhatnak a minták eltéréseiből, az adatgyűjtés módjából (mi elsősorban országos betegszervezeten keresztül online toboroztunk) és az adott ország diabetesoktatásának jellegzetességeiből is. Az a következtetés levonható, hogy a magyar tudásszint a DKT2-teszten átlagos vagy annál

magasabb, ami a több mint két évtizede bevezetett „diabetológiai szakápoló és edukátor” posztgraduális képzés eredményességét tükrözheti.

Az orvosi gyakorlatban fontos kérdés, hogy melyek voltak azok az itemek, amelyekre a legkevésbé tudták a választ a betegek. A ketoacidosis fogalma egyértelműen ilyen tétel, ezenkívül, ahogy fentebb kiemeltük, a betegek a legkevésbé az egyes ételek tápanyag-összetevőit (szénhidráttartalom, zsírtartalom), valamint az elfogyasztott ételek vércukorszintre gyakorolt hatását ismerték. Az előbbi hiányosság az arab mintában is megjelent a 2. és 3. tételnél, és felhívja a figyelmet a betegek diétára vonatkozó magasabb szintű tudásának szükségességére. A cukorbetegek diétájának önmenedzselését segítő applikációk áttekintésekor *Szálka és mtsai* [24] is arra mutatnak rá, hogy azok az alkalmazások hasznosak, amelyek a szénhidrátok mennyiségének összegzésén túl azok vércukorszint-emelő hatásáról is informálnak.

A szakirodalomban egyértelmű az önbevalláson alapuló, illetve a funkcionális egészségértés összefüggése a betegségismerettel ([9] metaelemzése). Kutatásunk eredménye is ezt mutatja a BHLS és a DKT2 között, vagyis akinek nagyobb tudása van betegségéről, az magabiztosabb az egészségügyi kérdésekben való eligazodásban. A két változó közötti kapcsolat erőssége ugyanakkor alátámasztja az eltérő egészségértési formák létezését is.

A szociodemográfiai változók közül a magyar DKT2 a szakirodalomnak megfelelő gyenge, negatív irányú összefüggésben áll az életkorral [10, 18], nincs kapcsolatban azonban a nemmel, az iskolai végzettséggel és a betegségre költött jövedelemmel. A nemzetközi szakirodalom ellentmondásos eredményeket közöl az általános egészségműveltség nemi különbségeinek tekintetében. Magyar mintán korábban nem találtunk különbséget a nemek között [20], így nem meglepő, hogy ez a mostani, diabeteses mintában sem jelent meg. Konzisztensebb a kapcsolat a magasabb jövedelem és a jobb egészségértés között mind általános mintán [20], mind diabetesesek körében [17]. Kutatásunkban az összefüggés hiánya eredhet abból, hogy nem az összjövedelem megbecsülését kértük, hanem a betegségre fordított részét. A magasabb kiadások súlyosabb állapotra és így rosszabb egészségértésre utalhatnak – ezt a BHLS-sel kapott tendenciaszintű, pozitív kapcsolat mutatja.

A szociodemográfiai változók közül visszatérő, robusztus összefüggést minden típusú egészségértéssel az iskolai végzettség mutat (általános, magyar mintán [20]; a cukorbetegség ismeretét felmérő teszten [16–18, 25]), így ennek hiánya a DKT2-vel kutatásunkban magyarázatot kíván. Felvethető, hogy az inzulinnal kezelt cukorbetegek Magyarországon megfelelő betegoktatásban részesülnek, ami kiegyenlíti az iskolázottságból adódó alapvető betegségismeretük szintjei közti különbséget.

A betegségváltozók közül a DKT2 az inzulinhasználat hosszával, valamint a napi vércukorszintmérés és inzulinbeadás számával mutatott pozitív kapcsolatot – melyek a szakirodalommal [17, 18] megegyező eredmények. Ezek közül a betegségismeretet függetlenül egyedül a napi vércukorszintmérés mennyisége jósolta be. A szakirodalomnak ellentmondóan nem volt összefüggés a kezelés típusával [16], a cukorbetegség időtartamával [17, 18] és a szövődmények számával sem [9, 26]. Egyetlen szövődménytípus képezett kivételt: azoknál a cukorbetegeknél, akiknél megjelentek szív- és érrendszeri szövődmények, szignifikánsan alacsonyabb betegségismeretet mértünk. Ezek magyarázatában ismét utalnánk mintánk speciális jellegére: az inzulint használó, 2-es típusú cukorbetegek jellemzően hosszabb ideje élnek együtt a betegséggel, tudás szempontjából az egyik legerősebb csoportot képezik. A szövődmények tüneteinek felismerése a legmagasabb helyes válaszarányú volt a kutatásban, ami oka lehet annak, hogy miért nincs különbség a szövődmények száma mentén a tudásszintben.

A szakirodalom szerint az egészségértés alacsony szintje negatívan befolyásolja az egészségi állapotot [27, 28], kutatásunkban azonban ezt az összefüggést csak a BHLS esetén kaptuk meg. Ennek okát az alkalmazott tesztek típusában is kereshetjük: az önbevalláson alapulók egyfajta attitűdöt, hatékonyságérzetet is mérhetnek, míg a DKT2 objektív eredményt ad. A teszttel folytatott jövőbeli kutatásoknak érdemes az egészségügyi állapot objektívabb változóit is felhasználniuk az egészségértés következményeinek felmérésében.

Következtetés

A magyar nyelvű Diabetes Betegségismeret Teszt alkalmas a diabetesszel élők tudásszintjének felmérésére. Mintánkban a betegségismeret szintje átlagos vagy annál magasabb, ami mintánk jellegével (inzulint használó, 2-es típusú cukorbetegek) és az inzulint használók megfelelő hazai edukációjával függhet össze. Ugyanakkor eredményeink felhívják a figyelmet a betegek diétára vonatkozó magasabb szintű tudásának szükségességére.

Anyagi támogatás: A kézirat elkészítéséhez kapcsolódó kutatómunka az EFOP-3.6.1-16-2016-00008. számú alprojekt keretében anyagi támogatásban részesült.

Szerzői munkamegosztás: P.-Z. O.: A tesztbattéria kérdőíveinek kiválasztásában való részvétel és annak koordinálása, a fordítási munka végzése, a tesztfelvétel betanítása és az adatfelvételben való részvétel, adatelemzés, valamint a kézirat megszövegezése. K. A.: A tesztanyag kérdőíveinek kiválasztásában és az adatfelvételben való részvétel és a kézirat szövegének javítása. B. N.: A tesztanyag kérdőíveinek kiválasztásában való részvétel, a fordítási munka végső jóváhagyása, a kutatás menetének felügyelése, valamint a kézirat szövegének javítása. A cikk végleges változatát valamennyi szerző elolvasta és jóváhagyta.

Érdekeltségek: A szerzőknek nincsenek érdekeltségeik.

Köszönetnyilvánítás

Köszönetet mondunk az adatfelvételt lehetővé tevő betegszervezeteknek, valamint az intézmények vezetőinek, a részt vevő betanított hallgatóknak, a tesztbattériát kitöltőknek, *dr. Martos Tamás*nak a statisztikai elemzésben nyújtott tanácsaiért, valamint *dr. Lengyel Csaba*nak a diabetológiai szakkérdések megvitatásáért.

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