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A WEB-BASED, INTERACTIVE HEALTH INFORMATION SYSTEM FOR PATIENTS WITH TYPE 2 DIABETES

DEVELOPMENT AND RANDOMIZED CONTROLLED TRIAL

University Medical Center Hamburg-Eppendorf

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EIN WEB-BASIERTES, INTERAKTIVES INFORMATIONSANGEBOT FÜR PATIENTEN MIT DIABETES MELLITUS TYP 2

ENTWICKLUNG UND RANDOMISIERTE KONTROLLIERTE EVALUATION

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PREFACE

The present cumulative dissertation has been prepared within a study at the Department for Medical Psychology at the University Medical Center Hamburg-Eppendorf. I would like to thank Prof. Dr. Dr. Martin Härter and Dr. Jörg Dirmaier for giving me this opportunity and for their valuable feedback. For their support in different stages of the study I would like to thank the irreplaceable student assistants Iniobong Essien and Franziska Dierks.

For his understanding and patience I would like to thank my husband Jörg Jabusch who always made me feel like I could do this but didn´t have to, and who was my rock in the surf in the ups and downs of trying to be a scientist-practitioner. I would like to thank my parents, who reliably accompanied and supported me, for showing me that curiosity, passion and scepticism are a good match not only in science but in life.

The challenge of living with a chronic condition, be it as a patient or as friend or family, has been a major topic in my life, and I am thankful for the people who shared with me their thoughts and feelings and their ways of coping. This includes friends and family, patients and health professionals, and people who share their experiences online. To their courage, tenacity, and sense of humour I dedicate this thesis.

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SUMMARY

Type 2 diabetes (T2D) is an increasingly common chronic condition. Patient empowerment is a cornerstone in its treatment that can be fostered by web-based Interactive Health Communication Applications (IHCAs) combining health information with decision support, social support and/or behavior change support. They offer the opportunity to reach great numbers of patients at low cost and provide them with high-quality information and support at the time, place and learning speed they prefer.

This cumulative dissertation describes two preliminary studies, the development, and evaluation of an IHCA presenting diabetes information, behavior change and decision support in a dialogue-based, tailored format. In a randomized controlled trial the IHCA was tested against a standard website (SW) presenting the same information in a content tree without dialogue or tailoring. The primary hypothesis was that the IHCA has larger effects on diabetes knowledge and patient empowerment than the SW. The secondary hypothesis was that users facing a health decision experience less decisional conflict and feel better prepared for the consultation after using the IHCA rather than the SW. All measurements were conducted by online self-report questionnaires. Intention-to-treat (ITT) and available cases (AC) analyses were performed for all outcomes.

N = 179 users with T2D agreed to participate in the study. Usage was significantly higher in the IHCA (M = 51.2 minutes) than in the SW (M = 37.6 minutes; $p < 0.001$). Three months after system use, 52.4% of the sample was retained. There was no significant intervention effect in the ITT analysis. In the AC analysis, participants using the tailored system displayed significantly more knowledge at t_1 ($p = 0.02$) and more emotional wellbeing (subscale of empowerment) at t_2 ($p = 0.009$). The estimated mean difference between the groups was 3.9 [95%CI: 0.5-7.3] points for knowledge and 25.4 [95%CI: 6.3-44.5] points for emotional wellbeing on a 0 to 100 points scale.

The primary analysis did not support the study hypothesis. However, content tailoring and interactivity may increase knowledge and reduce health-related negative effects in persons who use IHCAs. There were no main effects of the intervention on other dimensions of patient empowerment or decision-related outcomes. This might be due to our tailored IHCA being, at its core, an educational intervention offering health information. The focus on decision-making might not be sufficient to affect decision-related outcomes.

ZUSAMMENFASSUNG

Diabetes mellitus Typ 2 (T2D) ist eine chronische Erkrankung mit steigender Prävalenz. Empowerment ist zentraler Bestandteil der Diabetesbehandlung und kann durch web-basierte interaktive Angebote (Interactive Health Communication Applications, IHCAs) gefördert werden. IHCAs kombinieren Gesundheitsinformationen mit Entscheidungsunterstützung, sozialer Unterstützung und / oder Unterstützung bei Verhaltensänderungen. Sie ermöglichen es, viele Patienten zu erreichen und ihnen zu geringen Kosten hochwertige Information und Unterstützung zu bieten – an dem Ort, zu der Zeit und in dem Tempo, die sie bevorzugen.

Die vorliegende kumulative Dissertation beschreibt zwei Vorstudien, die Entwicklung und Evaluation eines IHCA, das Diabetesinformation mit Unterstützung zur Verhaltensänderung und zum Treffen medizinischer Entscheidungen kombiniert und in einem dialogähnlichen, auf den individuellen Nutzer zugeschnittenen Format präsentiert. In einer randomisierten kontrollierten Studie wurde das IHCA mit einer Standardwebsite (SW) verglichen, die die gleichen Inhalte in einem Inhaltsbaum ohne Dialogform oder Individualisierung präsentiert. Die primäre Hypothese war, dass die IHCA größere Effekte in Bezug auf Diabeteswissen und Empowerment hat als die Standardwebsite. Die sekundäre Hypothese war, dass vor einer medizinischen Entscheidung stehende Nutzer, die das IHCA benutzt haben, weniger Entscheidungskonflikte erleben und sich besser auf die Entscheidung vorbereitet fühlen als jene, die die SW genutzt haben. Alle Erhebungsinstrumente waren Online-Selbstauskünfte. Intention-to-treat (ITT) und available cases (AC) Analysen wurden für alle Outcomes gerechnet.

N = 179 Nutzer mit T2D wurden in die Studie eingeschlossen. Das IHCA wurde signifikant mehr genutzt (M = 51,2 Minuten) als die SW (M = 37,6 Minuten; $p < 0.001$). Zum 3 Monats-Follow-up wurden noch 52,4% der Stichprobe erreicht. In der ITT Analyse gab es keinen signifikanten Haupteffekt der Intervention. In der AC Analyse zeigte die IHCA Gruppe signifikant mehr Wissen zu t_1 ($p = 0{,}02$) und größeres emotionales Wohlbefinden (Subskala von Empowerment) zu t_2 ($p = 0{,}009$). Der geschätzte Mittelwertsunterschied zwischen den Gruppen betrug 3,9 [95%CI: 0,5-7,3] Punkte für Wissen und 25,4 [95%CI: 6,3-44,5] Punkte für emotionales Wohlbefinden auf einer Skala von 0 bis 100 Punkten.

Die primäre Analyse bestätigte die Hypothesen nicht. Bei Menschen, die IHCAs nutzen, können Tailoring und Interaktivität aber Wissen verbessern und gesundheitsbezogene negative Affekte reduzieren. Es gab keine Haupteffekte der Intervention bezüglich weiterer Dimensionen von Empowerment oder bezüglich entscheidungsbezogener Maße. Dies mag darauf zurückzuführen sein, dass unser IHCA im Kern eine edukative Intervention war, die mit Entscheidungsunterstützung lediglich ergänzt wurde.

LIST OF PUBLICATIONS

The thesis is based on the following publications:

1. Weymann, N, Dirmaier, J, Härter, M (2013). Partizipative Entscheidungsfindung in der Diabetestherapie: Von der guten Absicht zur guten Tat. In: Petrak F, Herpertz S. Handbuch der Psychodiabetologie. Springer. 281-297.
2. Weymann, N, Härter, M, Dirmaier, J (2014) Information and decision support needs in patients with type 2 diabetes. Health Informatics Journal. doi:10.1177/1460458214534090.
3. Weymann N, Härter M, Dirmaier J (2014). Quality of online diabetes patient information: a cross-sectional study. Health Promotion International, doi: 10.1093/heapro/dau019.
4. Weymann N, Härter M, Petrak F, Dirmaier J (2013). Health information, behavior change, and decision support for patients with type 2 diabetes: development of a tailored, preference-sensitive health communication application. Patient Preference and Adherence. 7:1091-1099.
5. Weymann, N, Härter, M, Dirmaier, J (2013) A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial. BMC Medical Informatics and Decision Making, 13:24.
6. Weymann N, Dirmaier J, von Wolff A, Kriston L, Härter M (2015). Effectiveness of a web-based tailored, interactive health communication application for patients with type 2 diabetes or chronic low back pain: a randomized controlled trial. Journal of Medical Internet Research. 17(3):E53.

Full texts of the publications are included in the appendix.

1. BACKGROUND

The present cumulative dissertation describes two preliminary studies, the development, and the evaluation of an e-health tool fostering empowerment in patients with T2D. In section 1, the context this dissertation has been prepared in is presented, and the three elements constituting the background of this research – T2D, patient involvement, and e-health – are introduced. In section 2, the research questions and hypotheses are presented. Section 3 gives an overview of the publications addressing these questions. In section 4, the results are comprehensively discussed. Conclusions are drawn in section 5.

1.1. Context of the dissertation

The dissertation has been prepared in a research project called “Development and evaluation of an interactive information system for patients with chronic diseases (InfoChron)”. It was funded in a funding priority called “Translational research on patient-centered approaches to chronic disease care” that has been set up in 2006 by the Federal Ministries of Education and Research (BMBF), of Health (BMG) and of Labor and Social Affairs (BMAS), the German Pension Insurance, Associations of Statutory Health Insurers on the Federal level and the Association of Private Health Insurance Companies. The goal of the funding priority was to put the chronically ill patient in the center of medicine and rehabilitation, cutting across health care sectors.

Three fields of patient orientation are being funded: targeted patient information, training programs for the chronically ill, and shared decision-making (SDM). There are four modules covering (1) cross-sector care, (2) rehabilitation, (3) acute care, and (4) scientific foundations of care-based research. The project the present dissertation has been prepared in was funded in the first funding period (2007-2012) in Module 1 (“Research projects on cross-sector care”). The project aimed at developing and evaluating an IHCA for patients with T2D or chronic low back pain (CLBP). This dissertation focuses on T2D and adds preliminary studies to the original research project.

1.2. Type 2 diabetes

T2D is an increasingly common chronic condition that affects about 7 million people in Germany. Prevalence is rising in Germany (Kellerer & Häring, 2011) and globally (Danaei et al., 2011). It is estimated that there are as many people in Germany living with undiagnosed diabetes as people living with the diagnosis (Heidemann, Du, & Scheidt-Nave, 2011). T2D mostly occurs in the age range above 40. Among people aged 60 and older 18-28% live with T2D (Hauner, Koster, & von Ferber, 2003). There is not much literature on the epidemiology among children and adolescents but studies suggest that prevalence is rising in this age group as well (Wabitsch et al., 2004).

T2D is caused by an interaction of genetic and lifestyle factors. The most important lifestyle factors are a sedentary lifestyle and a diet high in fat and calories and low in fibers leading to visceral adiposity (defined as waist circumference ≥88cm in women or ≥102cm in men) (Tsigos et al., 2008; WHO (World Health Organization), 2000). Visceral obesity has been associated with glucose intolerance and with hyperinsulinaemia resulting from insulin resistance (Kissebah, Freedman, & Peiris, 1989; Pouliot et al., 1992). Insulin resistance is defined as “the inability of a known quantity of endogenous or exogenous insulin to increase glucose uptake and utilization in an individual as much as it does in a normal population” (Lebovitz, 2001) and is the core mechanism of T2D. Due to insulin resistance, the insulin secreted by the pancreas is not sufficient to keep blood glucose at a healthy level.

Beta cells are those cells in the pancreas that secrete insulin. In the course of T2D, insulin resistance usually remains quite stable while beta cells decrease in mass and function (Kellerer & Häring, 2011). In most people with T2D both insulin resistance and beta cell dysfunction can be found. Often insulin resistance and visceral obesity are accompanied by hyperlipidaemia and hypertension. These four factors together form the “metabolic syndrome”. Often a proinflammatory state and a prothrombotic state are also included in the definition of the metabolic syndrome (Grundy, Hansen, Smith, Cleeman, & Kahn, 2004). Depending on the definition used, between 26% and over 80% of people with T2D in Germany show all signs of a metabolic syndrome (Koehler, Ott, Benke, & Hanefeld, 2007).

The decline of beta cells is thought to be the cause for the need to substitute insulin in advanced T2D. After the diagnosis of T2D a reduction of insulin resistance – or improvement of insulin sensitivity – is the primary treatment strategy. Methods of choice are lifestyle interventions – diet and exercise – and oral antidiabetics. Later in the course of the disease an additional substitution of insulin might become necessary (Bundesärztekammer (BÄK), Kassenärztliche Bundesvereinigung (KBV), & Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2013).

T2D is a major risk factor for macrovascular complications (e.g., stroke, cardiac infarction, and peripheral arterial occlusive disease), microvascular complications (e.g., retinopathy, nephropathy, chronic cardiac insufficieny, and diabetic foot), and sensomotoric (e.g., diabetic foot) and autonomous neuropathy (e.g., cardiac arrhythmias or gastroparesis) (Heidemann et al., 2011). There is major evidence that these secondary diseases can be avoided, delayed or mitigated by a near-normal blood glucose (UK Prospective Diabetes Study (UKPDS), 1998a), blood pressure (UK Prospective Diabetes Study Group (UKPDS), 1998b), blood lipids (Kearney et al., 2008), and by reducing other risk factors such as smoking (Buse et al., 2007). Other large studies (The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Study Group, 2008; The ADVANCE Collaborative Group, 2008) cast doubt on the influence of improved glycaemic control on these complications.

For those affected by T2D the diagnosis means that they are confronted with a major health threat and the requirement to live with it, cope with it, and take responsibility on a daily basis: Patients are expected to choose their food carefully, estimate its impact on blood glucose, exercise regularly, take pills and measure their blood glucose on a regular basis and, if necessary, dose and administer insulin several times a day. Patients face these challenging tasks and make treatment decisions by themselves more than 99.9% of the time (Kaltheuner, 2013). This is why successful diabetes self-management is only possible if a patient (1) accepts and adopts it as an integral part of his[1] life and (2) objectively and subjectively has sufficient understanding of the disease and its treatment. In other words, there is no successful diabetes management without patient involvement.

1.3. Patient involvement in diabetes management

In research and practice there are various concepts related to the idea of patient involvement. As an overall trend, the role of the patient in health care has become more active in the last two decades. A growing number of patients expect to be thoroughly informed and educated on their condition and the treatment options at hand (Levinson, Kao, Kuby, & Thisted, 2005), and to be involved in decision-making (Chewning et al., 2012) and treatment (Coulter & Magee, 2003). On a health policy level, patient involvement is hoped to improve self-management (Forster & Kranich, 2007) and so disburden the health care system (Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (SVRKAiG), 2003). Our present health care system has been mainly designed for acute care and is not prepared to satisfactorily meet the needs of the growing number of chronically ill. Prominent answers to this challenge were the Chronic Care Model (CCM) proposed by Wagner and colleagues (Wagner, Austin, & Von Korff, 1996) in 1996 and the 2001 Institute of Medicine (IOM) report “Crossing the Quality Chasm. A New Health System for the 21st Century” (Institute of Medicine (Washington), 2001). Both advocate, along with political and structural changes, patient involvement and self-management. Research findings support this notion, reporting that interventions based on the CCM have substantial effects (Coleman, Austin, Brach, & Wagner, 2009; Elissen et al., 2013; Musacchio et al., 2011; O'Toole et al., 2010)

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[1] For the sake of readability, the masculine grammatical form has been chosen to refer to both men and women throughout this dissertation.

and stating that patient involvement improves knowledge on the condition, reduces decisional conflict, strengthens treatment adherence (Bieber, Loh, Ringel, Eich, & Härter, 2007), improves health behavior and self-management (Hibbard, Mahoney, Stock, & Tusler, 2007), and can ultimately contribute to an improved health status and reduced utilization of health care services (Coulter & Ellins, 2007).

Patient involvement can take place on different levels. The macro, meaning health policy, and the meso level, meaning structural and institutional involvement, will not be discussed in detail in the present dissertation. On the micro level, meaning the concrete clinical encounter, patient-centered care (PCC) can be seen as the basic concept. SDM deepens this concept with a focus on medical decisions. Empowerment is the most commonly used concept in the diabetology context.

Patient-Centered Care

The idea of PCC goes back to the early 1950s (Leino, 1952), but has gained impetus during the last two decades (Epstein & Street, 2011; Gerteis M, Edgman-Levitan, Daley, & Delbanco, 1993; Lewin, Skea, Entwistle, Zwarenstein, & Dick, 2001). The IOM listed PCC as one of the six aims for crossing the “quality chasm” between the existing and the envisioned “new health system for the 21st century” (Institute of Medicine (Washington), 2001). The concept appears to be as vague as it is appealing: In 2000, Mead and Bower (Mead & Bower, 2000) identified five dimensions of patient-centeredness: biopsychosocial perspective, 'patient-as-person', sharing power and responsibility, therapeutic alliance, and 'doctor-as-person'. In their recent review, Constand et al. (Constand, MacDermid, Dal Bello-Haas, & Law, 2014) identified three main components: communication (sharing information, compassionate and empowering care provision, sensitivity to patient needs), partnership (relationship building, inter-professional collaboration), and health promotion (effective case management, efficient use of resources). A systematic review and comprehensive model of patient-centeredness has been published in 2014. The authors identified 15 dimensions of patient-centeredness, differentiated them into principles, enablers and activities and mapped them onto the micro, meso, and macro level of care. On the micro level they identified the following dimensions (all of them being activities): patient information, patient involvement in care, involvement of family and friends, patient empowerment, physical support, and emotional support (Scholl, Zill, Harter, & Dirmaier, 2014).

Shared Decision-Making

SDM has entered the stage of patient involvement in 1982 (President´s Commission, 1982) and “draws on and deepens the principles of patient centered care” (Elwyn et al., 2012). SDM has been defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options to achieve informed preferences” (Elwyn et al., 2010). When deliberating on a medical decision, information flows both ways: the professional informs the patient about treatment options and their advantages and disadvantages. The patient informs the professional about his personal needs, values and feelings in view of these options (Bieber et al., 2007). SDM falls between the paternalistic model of medical decision-making where the medical professional takes the bigger part of the responsibility while the patient takes the role of the passive recipient (Coulter, 1999), and the information model, where the professional tries to provide the patient with the necessary information without taking sides or giving advice (Montori, Gafni, & Charles, 2006).

At the core of SDM is the medical decision, but it is recognized that a safe and stable relationship between the patient and the professional is a necessary prerequisite, and that sometimes decisions do not take place in one point in time but take the form of a longer process - especially in the management of chronic conditions like diabetes (Montori et al., 2006). Consequently, definitions of SDM vary in breadth and focus (Legare et al., 2010; Stacey, Legare, Pouliot, Kryworuchko, & Dunn, 2010). When talking about chronic conditions, the importance of understanding the patient´s everyday reality and broadening the perspective from the single decision to the continued communication and team work of the professional (team) and the patient (and his loved ones) is stressed (Entwistle, Prior, Skea, & Francis, 2008; Zoffmann, Harder, & Kirkevold, 2008), building a smooth transition between SDM and patient empowerment.

Empowerment

Patient empowerment has been established as a cornerstone of diabetes management since the 1989 St Vincent Declaration, an initiative resulting from collaboration between the WHO and the International Diabetes Federation (Krans, Porta, & Keen, 1992). Its two general goals were 1) improvement in health and a life expectancy and quality approaching that of people without diabetes and 2) finding better ways for the prevention and ultimately the cure of diabetes. The declaration explicitly acknowledged that these goals can only be reached if people with diabetes are actively involved in the process.

As much as for PCC and SDM there are different conceptions and definitions for empowerment (Anderson & Funnell, 2010; Asimakopoulou, Newton, Sinclair, & Scambler, 2012). The most popular is probably the one by Funnell et al. (1991) who defined patient empowerment as „the discovery and development of one's inherent capacity to be responsible for one's own life. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of their decisions." In this view patients and professionals work together as equals, the patient being the well-informed active partner while the professional offers education, recommendations, and support. Basically, the empowerment model is about the patient´s goals and the patient´s decisions. The professional creates the climate and offers the tools the patient needs for this task, including his professional opinion or advice, but recognizes that the patient is in the center of the process.

In summary, the notion of involving patients in health care has taken off in the last two decades and is, on the micro level, expressed in distinct but overlapping concepts. A core question on the conceptual as well as on the clinical level appears to be finding the appropriate amount of information and responsibility for the individual patient (and professional) in the individual situation.

During these last two decades another development has taken place: the Internet has become a common and for many even indispensable part of daily living, allowing patients easier access to health information, contributing to the shift of patient and professional roles in health care (McMullan, 2006), and paving the way for a field named e-health.

1.4. E-health and Patient Involvement

In a 2001 Journal of Medical Internet Research editorial, Eysenbach defined e-health as "an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology" (Eysenbach, 2001). He put up a list of 10 e´s in e-health characterizing "what e-health is all about (or what it *should* be)" (para. 7). Among these e´s were empowerment, encouragement ("of a new relationship between the patient and health professional, towards a true partnership, where decisions are made in a shared manner" (Eysenbach, 2001, para. 12)), and education (of physicians and consumers), indicating links between e-health and patient involvement.

In another editorial in the same volume of the same journal where Eysenbach wrote the words quoted above, Della Mea drew a less enthusiastic picture of e-health: “just medical informatics and telematics on the shop shelves, a fashionable name for something already existing but otherwise difficult to sell” (Della Mea, 2001). Up to today, a comprehensive definition for e-health is missing. Other concerns beside e-health being much about commerce relate to data safety and the “digital” or “cyber divide”[2], meaning that people with lower educational status or literacy might be left behind (Schulz & Nakamoto, 2013; Wyatt & Sullivan, 2005) or mislead by low-quality websites (Eysenbach & Kohler, 2002; Schulz & Nakamoto, 2013). Indeed, the literature suggests that correctness, usefulness and readability of online health information vary greatly (Buultjens, Robinson, & Milgrom, 2012; Eysenbach, Powell, Kuss, & Sa, 2002; Patel & Cobourne, 2011; Scullard, Peacock, & Davies, 2010). Reading levels of online health information are often too high for users with lower health literacy (HL[3]) (Charbonneau, 2012; Lam, Roter, & Cohen, 2013; Sun, 2012), and users mostly rely on a site´s appearance rather than considering its source when assessing website credibility (Eysenbach & Kohler, 2002; Sillence, Briggs, Harris, & Fishwick, 2007; Stanford, Tauber, Fogg, & Marable, 2002).

In the years since these editorials, there has been quite a bit of activity in the field: Looking only at interventions for people with diabetes, various decision aids have been made accessible (http://www.healthwise.net;http://www.mayo.edu; http://effectivehealth-care.ahrq.gov; http://informedmedicaldecisions.org; http://www.healthdialog.com) and in some cases evaluated (Denig, Schuling, Haaijer-Ruskamp, & Voorham, 2014; Lenz & Mühlhauser, 2009; Mullan et al., 2009; Sadowski et al., 2005; Weymiller et al., 2007). Educational self-management interventions (Angeles, Howard, & Dolovich, 2011; Glasgow et al., 2012; Heinrich et al., 2012) for type 2 and type 1 diabetes (T1D) (Grey et al., 2012; Landau et al., 2012; Whittemore et al., 2012) have been developed and evaluated. Results have been mostly favorable, showing effects on knowledge (Heinrich et al., 2012), health behavior (Glasgow et al., 2012; Stellefson et al., 2013; van Vugt, de Wit, Cleijne, & Snoek, 2013), psychosocial (Bond, Burr, Wolf, & Feldt, 2010; Glasgow et al., 2012; Stellefson et al., 2013; van Vugt et al., 2013) and biological outcomes (Angeles et al., 2011; Glasgow et al., 2012; Stellefson et al., 2013; van Vugt et al., 2013).

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[2] The term originally signified the divide between those with Internet access and those without. This gap closing over time, another divide became visible between those who are skilled in using the Web and those who are not (Dewan & Riggins, 2005).

[3] HL as defined by Ishikawa et al. is “the capacity of individuals to access, understand, and use health information to make informed and appropriate health-related decisions” (Ishikawa, Takeuchi, & Yano, 2008, p. 874).

Limitations of the research done have mostly been associated with participants not or not sufficiently using the tools (Heinrich et al., 2012) or effects fading in follow-up (Angeles et al., 2011; Glasgow et al., 2012). These limitations have generated numerous publications discussing the problem of attrition in online trials (Christensen, Griffiths, & Farrer, 2009; Danaher, Boles, Akers, Gordon, & Severson, 2006; Eysenbach, 2005). Among the solutions discussed were study characteristics, like providing incentives for complete datasets, and intervention characteristics, like tailoring interventions to the individual user (Boudreau, Godin, & Poirier, 2011; Brouwer et al., 2011; Brouwer et al., 2010; Christensen et al., 2009; Danaher et al., 2006; Eysenbach, 2005; Fan & Sidani, 2009; Glasgow, 2007; Khadjesari et al., 2011; Leslie, Marshall, Owen, & Bauman, 2005; Noar, Benac, & Harris, 2007; Verheijden, Jans, Hildebrandt, & Hopman-Rock, 2007).

1.5. Summary

Demographic change and technological Progress! are two currents underlying this dissertation: In our ageing society, a growing number of people are affected by chronic disease, and costs explode for a health care system set up to cure acute illness rather than support people with chronic conditions. This raises the question if and how high-quality care can be provided with reduced financial and human resources. Answers have been proposed on the macro, meso and micro level. The present dissertation focuses two possible answers on the micro level: interventions to foster more patient involvement and e-health activities. Both have taken off and spurred each other during the last two decades.

2. AIMS AND RESEARCH QUESTIONS

In the study within which the dissertation is being prepared we have developed an Interactive Health Communication Application (IHCA) for patients with T2D and evaluated it in a randomized controlled trial (RCT). IHCAs are “computer-based, usually web-based, information packages for patients that combine health information with at least one of social support, decision support, or behavior change support” (Murray, Burns, See, Lai, & Nazareth, 2005, p. 1). In their 2005 Cochrane review, Murray and colleagues found that IHCAs can have positive effects on knowledge, social support, clinical and behavioral outcomes (Murray et al., 2005). A more recent Cochrane review on computer-based diabetes self-management interventions for adults with T2D found small effects on knowledge, self-efficacy, and glycated hemoglobin A1C[4] (Pal et al., 2013).

The effectiveness of these systems is limited by attrition (e.g. Cook, Heath, & Thompson, 2000; Eysenbach, 2005; Glasgow, 2007; Leslie et al., 2005), few users visit a health intervention website more than once (Brouwer et al., 2010; Verheijden et al., 2007). Since the effect of online interventions increases with dose (longer stays, repeated website visits, total contact hours) (e.g. Fan & Sidani, 2009; Verheijden et al., 2007), effectiveness is maximized if patients work intensively with the information offered (Danaher et al., 2006; Eysenbach, 2005) and return for repeated visits (Christensen et al., 2009; Norman et al., 2007). Individualization and personalization of information as well as an interactive presentation have been found to effectively increase exposure to and effectiveness of interventions (Boudreau et al., 2011; Brouwer et al., 2011; Noar et al., 2007). These three strategies can be subsumed under the concept of tailoring (Kreuter, 2000).

The overall aim of the present dissertation is to develop an IHCA that is tailored and to test it against a standard website (SW) presenting the same content without tailoring. The notion at the core of the study is therefore that the tailored presentation makes this online health intervention more effective.

The dissertation comprises six publications: a book chapter describing a core aspect of the theoretical basis, two preliminary studies informing the development of the IHCA, a description of the development process, a study protocol of the RCT evaluating the tailored IHCA against the SW, and the RCT itself. There are exploratory research questions related

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[4] The A1C test measures the percentage of the hemoglobin that is covered with glucose, thereby reflecting the average blood glucose level for the past eight to twelve weeks. The higher the A1C, the poorer blood sugar control was during that period.

to the two preliminary studies and research questions and hypotheses to the RCT. The following research questions and hypotheses are therefore grouped according to these three studies.

FIRST PRELIMINARY STUDY: ASSESSMENT OF INFORMATION AND DECISION SUPPORT NEEDS

The aim of the first preliminary study was to assess characteristics and needs of the target audience of the IHCA: people living with T2D in Germany.

RESEARCH QUESTION 1A: How intensively do patients with T2D use the Internet for purposes related to their T2D?

(Exploratory research question)

RESEARCH QUESTION 1B: Which information needs do patients with T2D have?
(Exploratory research question)

RESEARCH QUESTION 1C: Are there differences in Internet use related to age or HL?

(Exploratory research question)

RESEARCH QUESTION 1D: Are there differences in satisfaction with Internet use related to age or HL?

(Exploratory research question)

RESEARCH QUESTION 1E: What are the most frequent medical decisions patients with T2D and their physicians have to make?
(Exploratory research question)

RESEARCH QUESTION 1F: How good is the patients´ HL and knowledge on T2D?

(Exploratory research question)

SECOND PRELIMINARY STUDY: REVIEW OF WEB-BASED HEALTH INFORMATION ON TYPE 2 DIABETES

The aim of the second preliminary study was to explore the quality of the websites that people living with T2D find when searching the Internet for health information.

RESEARCH QUESTION 2A: How good is the formal quality of German and English language websites on T2D?

(Exploratory research question)

RESEARCH QUESTION 2B: How good is the usability of German and English language websites on T2D?

(Exploratory research question)

RESEARCH QUESTION 2C: How good is the quality of decision support in German and English language websites on T2D?

(Exploratory research question)

RESEARCH QUESTION 2D: Are there differences between commercial and non-commercial websites or between websites with and without HON code regarding any of the quality domains?

(Exploratory research question)

RESEARCH QUESTION 2E: Is any of the quality domains associated with website traffic?

(Exploratory research question)

RCT: EVALUATION OF THE INTERACTIVE HEALTH COMMUNICATION APPLICATION.

The aim of the RCT was to evaluate the IHCA (whose development had been informed by the two preliminary studies) against the SW.

RESEARCH QUESTION 3A: Does the tailored presentation of content lead to greater knowledge when compared to presentation in a SW?

Primary hypothesis: The IHCA group will show better diabetes knowledge at t_1 than the SW group.

RESEARCH QUESTION 3B: Does the tailored presentation of content lead to greater empowerment when compared to presentation in a SW?

Primary hypotheses:

The IHCA group will show more empowerment at t_2 than the SW group.

RESEARCH QUESTION 3C: Does the tailored presentation of content lead to better preparation for decision making in users facing a medical decision when compared to presentation in a SW?

Secondary hypothesis: The IHCA group will show better preparation for decision making at t_1 than the SW group.

RESEARCH QUESTION 3D: Does tailored presentation of content lead to reduced decisional conflict in users facing a medical decision when compared to presentation in a SW?

Secondary hypothesis: The IHCA group will show less decisional conflict at t_1 than the SW group.

3. METHODS

The research was done in four steps. In the *first step*, we conducted a needs assessment. Interviews with patients and physicians were conducted. Based on the results of these interviews, a questionnaire was developed. A questionnaire study was performed on a new and larger patient sample. We explored which information and medical decisions are important to people with T2D, to what extent people with T2D in Germany do use the Internet for purposes related to their condition, what they search for, and if they are satisfied with the results (descriptive data analysis). In a subgroup analysis we explored if there are differences in Internet utilization or satisfaction related to age or HL (Pearson´s correlations).

In the *second step*, the quality of information and support available in German and English language websites was explored: The search term "type 2 diabetes" was entered in the two most popular search engines in German and English. The resulting websites were evaluated with respect to formal quality, usability, and quality of decision support. Quality criteria were drawn from previous publications (Abbott, 2000; Eysenbach et al., 2002; Griffiths & Christensen, 2000; Khazaal, Chatton, Cochand, & Zullino, 2008; Khazaal, Fernandez, Cochand, Reboh, & Zullino, 2008; Kim, Eng, Deering, & Maxfield, 1999; Kisely, Ong, & Takyar, 2003; Murphy, Frost, Webster, & Schmidt, 2004; Pealer & Dorman, 1997; Silberg, Lundberg, & Musacchio, 1997) and quality seals (Aktionsforum Gesundheitsinformationssystem (afgis) e.V., Demloh, & Hägele, 2010; International Patient Decision Aid Standards (IPDAS) Collaboration, 2005; University of Oxford & Division of Public Health and Primary Health Care, 2014). Descriptive data was presented. Associations of website quality with affiliation (commercial vs. non-commercial), presence of the HON code[5] quality seal (Mann-Whitney U test), and user acceptance (website traffic according to www.alexa.com[6]; Spearman´s rank correlation) were explored.

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[5] The HON code of conduct is the oldest and most common quality seal for online health information. In order to be certified, site owners have to apply for a review of their site. The medical professionals of the HON review committee check if the site adheres to all eight of the HONcode ethical principles (According to www.hon.ch: "Authority - Give qualifications of authors", "Complementarity - Information to support, not replace", "Confidentiality - Respect the privacy of site users", "Attribution - Cite the sources and dates of medical information", "Justifiability - Justification of claims / balanced and objective claims", "Transparency - Accessibility, provide valid contact details", "Financial disclosure - Provide details of funding", "Advertising - Clearly distinguish advertising from editorial content"). A certified site receives a biennial review, beginning one year after the initial certification, or following user alert.

[6] www.alexa.com is, by its own admission, "the leading provider of free, global web metrics." It ranks websites according to traffic: "The global traffic rank is a measure of how a website is doing relative to all other sites on the web over the past 3 months. The rank is calculated using a combination of the estimated average daily unique visitors to the site and the estimated number of pageviews on the site over the last 3 months" (Alexa - Webpage).

In the *third step*, the web-based IHCA was developed, combining information on T2D with decision support and behavior change support. It was designed in the form of a dialogue, similar to a consultation between patient and professional. Each content block is followed by at least three reply options the user can choose between. The IHCA then answers, tailoring content and tone to the user´s reply. The user characteristics that are mapped in the reply options are the individual user´s T2D knowledge, preferred detail of information, attitudes towards diabetes self-care activities (e.g., foot care, exercise), and fears and hopes associated with insulin treatment. Depending on, for example, the attitude the user expresses towards exercise, the IHCA modifies the next content block. The IHCA was designed as a stand-alone intervention that complements usual care. At the same time, the SW was developed as a control condition, built like a usual website with a content tree and without dialogue or tailoring. The content of both the IHCA and the SW covered basic information on diabetes (pathophysiology, epidemiology, subtypes, symptoms) and its sequelae (neuropathy, nephropathy, retinopathy, heart and vessel problems, sexual dysfunction, and depression), information on health behavior and lifestyle changes, and treatment options. The look of IHCA and SW (colors, typing, figures and pictures) was also identical. Along with the IHCA and SW for T2D, an IHCA and SW for CLBP were developed.

In the *fourth step*, the IHCAs for both conditions (T2D and CLBP) were tested against their respective control counterparts, the SWs. We performed a blinded two-armed randomized controlled trial (RCT) with a parallel design. It was hypothesized that the IHCAs would be more effective regarding patient-centered outcomes than the SWs. Measurements were immediately before the first visit to the intervention (t_0), immediately after (t_1), and three months later (t_2).

Eligibility criteria were age ≥18 years, access to the Internet, sufficient computer / Internet literacy and a self-reported diagnosis of T2D or CLBP. Recruitment took place using a number of pathways in all sectors of health care. Most of them were offline, such as contacting pension funds and health insurance companies, hospitals, practices, and self-help groups. Every person meeting the eligibility criteria could register for the study on the study website. After providing online informed consent and completing the t_0 assessment (T2D: eligibility criteria, demographic data, time since diagnosis, treatment), the participants were randomly assigned to the IHCA or SW. Participants were free to use the intervention as often and as long as they wished.

The primary outcomes were knowledge (assessed on t_1) and patient empowerment (assessed on t_2). T2D knowledge was assessed with 16 items developed to map the IHCA´s and SW´s content that could be answered with true / false / I don´t know. Patient empowerment was measured with the Health Education Impact Questionnaire (heiQ) (Nolte, Elsworth, Sinclair, & Osborne, 2007; Osborne, Elsworth, & Whitfield, 2007). The heiQ includes 42 items and eight dimensions: Positive and Active Engagement in Life, Health Directed Behavior, Skill and Technique Acquisition, Constructive Attitudes and Approaches, Self-Monitoring and Insight, Health Service Navigation, Social Integration and Support, and Emotional Wellbeing. We removed Social Integration and Support from our testing battery because we did not expect an effect of our IHCA on that dimension.

The secondary outcomes were decisional conflict and preparation for decision making, both assessed at t_1. Decisional conflict was assessed with the Decisional Conflict Scale (DCS) by O´Connor (Buchholz, Hölzel, Kriston, Simon, & Härter, 2011; O'Connor, 1995). This questionnaire measures personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making, and effective decision making such as feeling that the choice is informed, values-based, and likely to be implemented and expressing satisfaction with the choice. Preparation for decision making was measured with the Preparation for Decision Making Scale (PDMS) (Buchholz, Simon, & Härter, 2011; Graham & O'Connor, 1996). This 11-item scale assesses a patient´s or participant´s perception of how useful a decision support intervention was in preparing him or her to communicate with his or her practitioner in making a health decision. Both questionnaires were offered only to those participants who had indicated that they were facing a health decision concerning their T2D or CLBP. All outcomes were self-assessed through online questionnaires. Usage data were assessed via log files.

To evaluate the effectiveness of the IHCA, multiple linear regression analyses were performed using the intervention, the condition, and their interaction term as dummy-coded predictors. Intention-to-treat (ITT) and available cases (AC) analyses were performed for all outcomes. In the ITT analysis, all users that had provided data on t_0 were included. Missing values were estimated by a multiple regression approach using all outcomes, demographic data and condition but not intervention information for multiple data imputation (MI). The AC analysis included all users that had provided data on t_1 and/or t_2.

4. OVERVIEW OF PUBLICATIONS

4.1. Publication 1: Partizipative Entscheidungsfindung in der Diabetestherapie: Von der guten Absicht zur guten Tat

Reference: Weymann, N, Dirmaier, J, Härter, M (2013). Partizipative Entscheidungsfindung in der Diabetestherapie: Von der guten Absicht zur guten Tat. In: Petrak F, Herpertz S. Handbuch der Psychodiabetologie. Springer. 281-297.

Aims: This book chapter can be viewed as part of the theoretical background of the dissertation. It gives an overview of theory and practice of SDM in diabetes management, starting with the introduction of SDM as a concept, introducing interventions fostering SDM in diabetes management including web-based interventions, and ending with barriers and facilitators to the implementation of SDM in diabetes care.

4.2. Publication 2: Information and decision support needs in patients with type 2 diabetes

Reference: Weymann N, Härter M, Dirmaier J (2014). Information and decision support needs in patients with type 2 diabetes. Health Informatics Journal, doi:10.1177/1460458214534090.

Aims: to assess the characteristics, information and decision support needs of our target audience: patients with T2D (research questions 1a through f). This original paper is the first of two publications building the empirical backbone of the IHCA´s development and evaluation.

Methods: The needs assessment was performed in two steps. First, we conducted semi-structured interviews with ten patients and seven physicians. In the second step we developed a self-assessment questionnaire based on the results of the interviews and administered it to a new and larger patient sample. The questionnaire comprised four main sections: Internet use and Internet experience, diabetes knowledge and HL, relevant decisions and decision preferences, and online health information needs. Descriptive data analyses and Pearson´s correlations were performed.

Results: In the questionnaire study the patient sample (N=178) was heterogeneous in terms of age, time since diagnosis, and glycaemic control. Research question 1a: Most participants (61.7%) have searched the web for health information at least once. The majority (62%) of those who have used the web use it at least once per month. Research question 1b: The most important information needs concerned sequelae of diabetes, blood glucose control, and basic diabetes information. Research question 1c: Subgroup analyses showed no significant correlation between age and Internet adoption or HL and Internet adoption. Research question 1d: HL and satisfaction with Internet use were negatively and significantly correlated. Age and satisfaction with Internet use were not significantly correlated. Research question 1e: The most relevant treatment decisions concerned glycaemic control, oral medication, and acute complications. The most difficult treatment decision was whether to start insulin treatment. Research question 1f: Diabetes knowledge was scarce: Only a small percentage (1.9%) of the respondents answered all items of the knowledge questionnaire correctly. The overall HL was fairly good (M=2.8, SD=.4), and the sample was quite heterogeneous with HL scores ranging from 1.6 (1 being the minimum score) to the maximum score of 4.

4.3. Publication 3: Quality of online information on type 2 diabetes: a cross-sectional study

Reference: Weymann N, Härter M, Dirmaier J (2014). Quality of online diabetes patient information: a cross-sectional study. Health Promotion International, doi: 10.1093/heapro/dau019.

Aims: to systematically assess formal quality, usability, and quality of decision support of German and English language websites on T2D (research questions 2a through e). This original paper is the second of the two publications building the empirical backbone of the IHCA´s development, exploring the online world the users characterized in publication 2 enter when searching the web for health information.

Methods: The search term “type 2 diabetes” was entered in the two most popular search engines in German and English. Quality was rated by the research team, inter-rater reliability was assessed. Descriptive data analysis was performed. Associations between website quality and affiliation as well as website quality and presence of HON code were tested with a Mann-Whitney U test. Associations of website quality and traffic were tested with a Spearman´s rank correlation.

Results: 46 websites were included. Research question 2a: Most websites met basic formal quality criteria such as disclosure of ownership and copyright information. Still, 12.5% of websites did not disclose ownership. 83% of the websites had been updated less than a year before, but only 4.3% specified a date for the next update. Research question 2b: All sites had a basic structure with headings or subheadings. Hardly any sites declared that patients had been involved in website development, and only 13.6% had evaluation questionnaires for users. Research question 2c: Most websites provided basic information necessary for decision-making while only a minority provided specific information for SDM (e.g., 29% provide information on potential positive and 20% on potential negative outcomes of different treatment options) and only one website provided explicit decision support. Research question 2d: We found no significant difference regarding formal quality, usability, or quality of decision support between sites with commercial or non-commercial affiliation. Websites with a HON code had significantly better formal quality than websites without HON code. Research question 2e: We found a highly significant correlation between usability and website traffic and a significant correlation between formal quality and website traffic. There was no association between quality of decision support and website traffic.

4.4. Publication 4: Health information, behavior change, and decision support for patients with type 2 diabetes: development of a tailored, preference-sensitive health communication application

Reference: Weymann N, Härter M, Petrak F, Dirmaier J (2013). Health information, behavior change, and decision support for patients with type 2 diabetes: development of a tailored, preference-sensitive health communication application. Patient Preference and Adherence. 7:1091-1099.

Aims: to comprehensively describe the development process of the IHCA offering evidence-based, preference-sensitive content and decision support to patients with T2D. There are no specific research questions associated to this paper.

Methods: The content was developed based on the needs assessment and two evidence-based treatment guidelines. Tailoring was realized according to the concepts of personalization ("conveying that the communication is designed specifically for "you""), feedback ("presenting patients with information about themselves"), and content matching. Both content and tailoring were revised by an interdisciplinary advisory committee.

Results: The result of this process is an interactive educational intervention that comprises information on three main topics: What is T2D, how is it diagnosed, and how is it treated. All content fields that were identified as "very important" in the needs assessment are available in more or less detail, depending on the user´s interest and ability, accounting for the great variance of HL found in the needs assessment. There is detailed information on sequelae of diabetes including risk information. Information that is necessary to make the medical decisions identified as relevant in the needs assessment (lifestyle, different forms of glucose monitoring, all oral medication that is available in Germany, different kinds of insulin and treatment regimens) is presented including pros and cons of the treatment options at hand.

Users are encouraged to write down their evaluations of the treatment options in question, as well as questions they might have, and discuss them with their doctors. The delivery format is a dialogue-based, tunneled design tailoring the content and tone of the dialogue to relevant patient characteristics (knowledge, preferred level of detail, attitudes towards self-care, and psychological barriers to insulin treatment).

4.5. Publication 5: A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial.

Reference: Weymann, N, Härter, M, Dirmaier, J (2013). A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial. BMC Medical Informatics and Decision Making, 13:24.

Aims: to clarify aims and procedures of the RCT before conducting it, and to make it transparent and more easily replicable for other researchers. This study protocol can be seen both as a detailed methods section of the dissertation and, when compared with the last paper, the RCT itself, as a document of changes the study underwent after publication of the study protocol.

4.6. Publication 6: Effectiveness of a web-based tailored, interactive health communication application for patients with type 2 diabetes or chronic low back pain: randomized controlled trial

Reference: Weymann N, Dirmaier J, von Wolff A, Kriston L, Härter M (2015). Effectiveness of a web-based tailored, interactive health communication application for patients with type 2 diabetes or chronic low back pain: randomized controlled trial. Journal of Medical Internet Research. 17(3):E53.[7]

Aims: to test the effectiveness of the IHCA combining health information with decision support and behavior change support for patients with T2D or CLBP (research questions 3a through d). This original paper represents the core of the dissertation.

Methods: The effectiveness of the IHCA was tested against a SW with identical content in a single-blinded randomized trial with a parallel design. Participants were blinded to group assignment. Measurements were at baseline (t_0), directly after the first visit (t_1), and at 3-

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[7] N. Weymann and J. Dirmaier contributed equally to this paper.

month follow-up (t_2). In order to keep attrition low, questionnaires were kept short and an incentive was given to participants with complete datasets.

The primary hypothesis was that the tailored IHCA is used more than the SW and thus has larger effects on knowledge and patient empowerment than the SW. Secondary outcomes were preparation for decision making and decisional conflict. All measurements were online self-report questionnaires. Multiple linear regression analyses were performed using intervention, condition, and their interaction term as dummy-coded predictors. An available cases analysis (AC) as well as an intention-to-treat analysis (ITT) were performed for all outcomes.

Results: N = 561 users agreed to participate in the study. Of these, n = 179 (31.9%) had T2D. The mean age was 52.2 years (SD = 13.1) in the IHCA group and 52.7 years (SD = 13.0) in the SW group. Of the participants using the IHCA, 58.5 % (n = 162) were female (SW: 59.1%, n = 162). There were no statistically significant differences in further demographic variables such as marital status, educational level, and working status. At t_2, 52.4% of the sample was retained. The IHCA was used significantly more than the SW ($p<0.001$). In the ITT analysis there was no significant intervention main effect. Research question 3a: In the AC analysis, the IHCA group displayed significantly more knowledge at t_1 ($p = 0.023$). Additionally, in both the ITT an AC analysis, there was a significant interaction between intervention and condition ($p = 0.04$), more strongly favoring the tailored condition over the control condition in CLBP than in T2D. Research question 3b: In the AC analysis, the IHCA group displayed significantly more Emotional Wellbeing (less health-related negative affect like anxiety, anger, and depression) at t_2 ($p = 0.009$). There were no significant effects regarding other subscales of the heiQ. Research questions 3c and d: There were no intervention main effects regarding the two SDM related measures.

5. DISCUSSION

5.1. Summary of results

Exploring the needs and characteristics of people with T2D, we found that our target audience is heterogeneous in terms of demographic variables, health, and HL. Most participants used the Web for health purposes, independently of their age or HL. Those who were more health literate reported less satisfaction with their health-related online activities. The most common treatment decisions were related to glycaemic control, oral medication, and acute complications, while the most difficult treatment decision was whether to start insulin treatment. Information needs were broad, the most important topics being sequelae of diabetes, blood glucose control, and basic diabetes information.

Studying the quality and utilization of diabetes websites we found that websites hardly provided the information necessary for SDM. Better usability and formal quality of websites were associated with more website traffic.

These results informed the development of an IHCA presenting the information identified as important including detailed information for the relevant medical decisions. Special attention was given to usability and formal quality. T2D knowledge, preferred level of detail, attitudes towards self-care activities, and psychological barriers to insulin treatment were chosen as tailoring variables.

The T2D IHCA was evaluated jointly with an IHCA for patients with CLBP. Of the N = 561 users included, N = 179 (31.9%) had T2D. As expected, participants used the IHCA more than the SW. Still, there was no significant intervention main effect in the ITT analysis. In the AC analysis the IHCA group displayed significantly more knowledge immediately after the first visit and significantly more Emotional Wellbeing three months later.

5.2. Strengths and limitations

A main strength of the work presented is that it is a thoroughly built study in which the results of the foregoing step inform the next: A book chapter was written as theory foundation, two preliminary studies were conducted to inform the development of the IHCA, and a study protocol was written to prepare the RCT. Additionally, the dissertation includes several novelties: the first needs assessment among patients with T2D in Germany focusing the Internet as a source for diabetes information, the first assessment of quality of decision support in German and English language diabetes websites, a comprehensive report on two years of development work, and the first trial on a German language IHCA on T2D. Finally, online trials are challenging with regard to attrition (Eysenbach, 2005; Simon et al., 2012), and we managed to keep it comparatively low.

There are some limitations. In the needs assessment (publication 2) we worked with convenience samples which limits generalizability. Some of the measurements we used in the needs assessment and in the RCT were not standardized, and none of the measurements applied online was adapted for online use. With regard to the quality assessment of diabetes websites (publication 3), the major limitation is that the Internet is a dynamic tool that changes at a rapid pace. With the cross-sectional approach we conveniently applied we could only make a snapshot. A limitation of publication 6, the RCT, is the relatively small N for T2D. Thanks to the participants with CLBP, the overall sample was large enough for analysis, but since there were twice as many people with CLBP than with T2D, those had more impact on the results. Also, we did not assess the outcome variables in a pre-test before the intervention, supposing that due randomization there would be no baseline differences with regard to knowledge, empowerment, decisional conflict, or preparation for decision making. Still, we cannot be sure there were no baseline differences with regard to the outcome variables. Thus we cannot be sure either that differences at t_1 or t_2 are caused by the intervention. We did not include quantitative or qualitative feedback on user acceptance. Neither did we assess potential confounders (e.g., which other interventions the participants used while being in the study).

5.3. Comprehensive discussion

The core notion of the study was that tailored presentation of content and support leads to more extensive use of the intervention, thus increases dose and thereby causes greater effects regarding knowledge, empowerment, and SDM-related outcomes in the IHCA than in the non-tailored SW. We did indeed see group differences with regard to use: Users in the IHCA group spent more time using the intervention than users in the SW group. This can be seen as confirmation of the first part supposed mechanism of change, linking tailoring to dose. In the next step of this mechanism, dose is supposed to be linked to effectiveness.

For this link we found only limited evidence: One main result is that we did not see any intervention effects in the ITT analysis. This tells us that looking at all users, including those who dropped out of the study, tailoring does not make a statistically significant difference with regard to our primary or secondary outcomes. In the AC analysis we did not see intervention main effects on six of the seven empowerment scales or any of the SDM measures, but we did see effects on knowledge and Emotional Wellbeing. This tells us that looking only at those users who remained in the study an actually used the interventions, tailoring does make a statistically significant difference with regard to these two outcomes.

The literature suggests that interventions targeting specific outcomes do reliably have effects on these outcomes but less so on related or more distal outcomes (Bond et al., 2010; Schulz et al., 2014; van Bastelaar, Pouwer, Cuijpers, Riper, & Snoek, 2011; van Beugen et al., 2014). The IHCA primarily provided health information. Behavior change support and decision support were additional features. Consequently, our primary outcomes were knowledge and empowerment, and we saw limited effects on these. The two secondary, SDM-related outcomes can be seen as more distal, and we did not see an effect on those. It has been shown that decision aids[8] can have an effect on the two outcomes in question, decisional conflict and preparation for decision making (Stacey et al., 2014). The decision support tools in our IHCA are not strictly decision aids. They do provide users with detailed information on the available options including materials to take to the consultation with their practitioner. They do not provide information on the steps of decision making nor do they guide users through the process. Maybe this mainly information-based approach was not sufficient to impact our SDM-related outcomes. This would be in line with evidence that information alone is often not enough to impact patient decisions (Coulter & Ellins, 2007) and that patients need further support through the process (Coulter & Collins, 2011). Moreover, tailoring was not specific: The decision support tools in the IHCA were not tailored to decision-related patient characteristics, such as risk perception, which has been shown to potentially have an effect on SDM-related outcomes (Trevena et al., 2013).

Similarly, the empowerment scales we did not see any effect on are mainly behavioral and thus more distal outcomes. In their 2005 Cochrane review, Murray et al. proposed a pathway of change for IHCAs (fig. 1) in which

> IHCAs act by combining information with additional services (peer support, decision support or behavior change support) to allow internalization and interpretation of the information by the user. This leads to changes in knowledge, motivation for improved health or health behaviors, affective parameters and self-efficacy. It is likely that these factors interact with each other; for example, understanding the risks of the condition may increase or reduce the user's anxiety levels with subsequent follow-on effect on their motivation to improve health. The combination of enhanced self-efficacy with

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[8] According to Volk et al. (2013) "patient decision aids are tools designed to help people participate in decision making about health care options, with the goal of promoting deliberation between patients, health care providers, and others about those options. They provide information about the options, and help patients to construct, clarify, and communicate the personal values they associate with the different features of the options. Patient decision aids do not advise people to choose one option over another, nor are they meant to replace practitioner consultation. Instead, they provide structured guidance in the steps of decision making and to prepare patients to make informed, values-based decisions with their practitioner" (Volk, Llewellyn-Thomas, Stacey, & Elwyn, 2013).

> motivation and knowledge enables users to change their health behaviors, leading in turn to changes in clinical outcomes. (p.6)

Consequently, according to this postulated pathway the intervention first leads to improved knowledge, followed by changes on an affective and motivational level which are then converted to behavioral and finally clinical and quality of life outcomes.

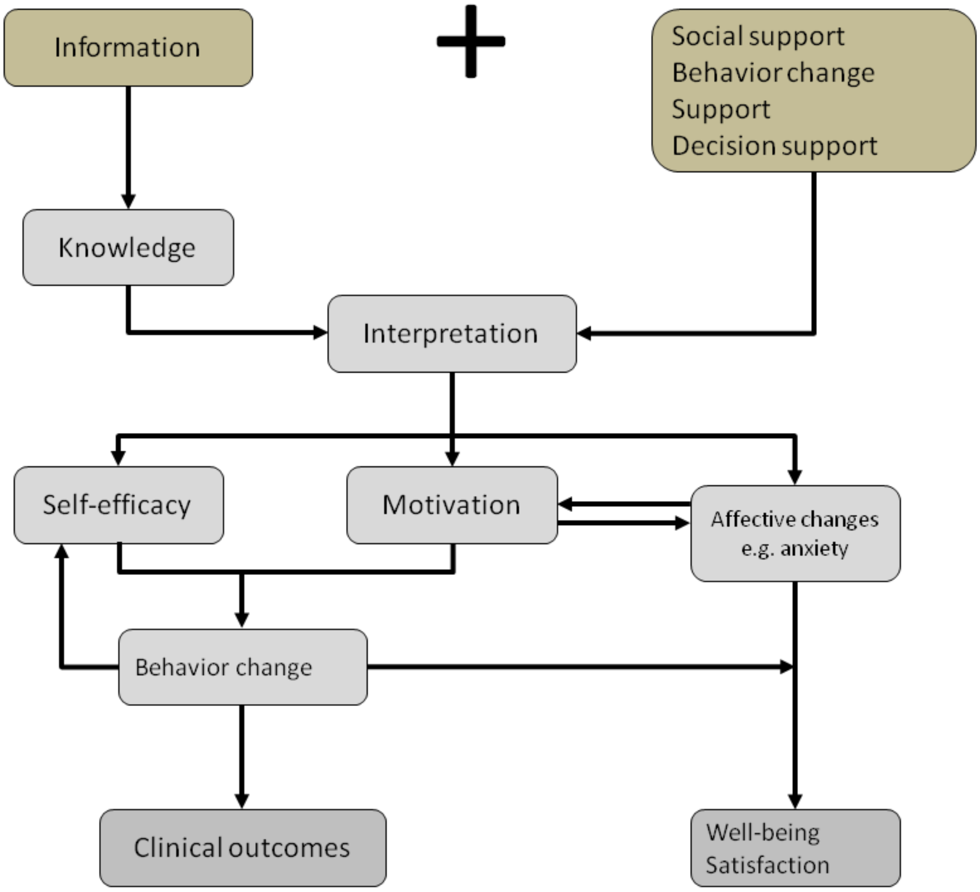

Fig. 1: Postulated pathway of change for IHCAs (adapted from: Murray et al., 2005, p. 7)

In the light of this postulated pathway one could assume that the effects of tailoring in our study reached halfway through the pathway, bringing about changes in knowledge and affect, but did not reach more distal, behavioral outcomes. This can be seen in line with a recent Cochrane review on computer-based diabetes self-management interventions finding that positive effects on cognitive outcomes could not be converted into behavior change (Pal et al., 2013).

Still, there also is recent evidence showing that tailored health interventions can have effects on behavioral outcomes (Broekhuizen, Kroeze, van Poppel, Oenema, & Brug, 2012; Glanz et al., 2015; Redding et al., 2015; Springvloet & Lechner, 2015; van der Wulp & Hoving, 2014). When looking at these interventions, it becomes clear that their development was guided by a comprehensive theory or model, such as the Transtheoretical Model (Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992; Prochaska & Velicer, 1997), Social Cognitive Theory (Bandura, 1977, 1986), or Intervention Mapping (Bartholomew, Parcel, Kok, Gottlieb, & Fernández, 2011).

5.4. Implications

It might be concluded that a clearer and more stringent application of theory could possibly have helped our IHCA reach more distal outcomes. This notion is supported by Webb and colleagues who found in their systematic review on web-based behavior change interventions that a more extensive theoretical basis, as well as incorporation of more behavior change techniques (e.g., goal setting, action planning) led to better effects in terms of behavior change (Webb, Joseph, Yardley, & Michie, 2010).

They found that interventions based on the theory of planned behavior (TPB) (Ajzen, 1991) had the largest effects on behavioral outcomes. Looking at this theory depicted in figure 2, it becomes clear that our IHCA would have become more specific, had it been informed by this theory: We could, for example, have focused on diabetes self-care activities (Toobert, Hampson, & Glasgow, 2000) as target behavior. We did in fact assess attitudes towards diabetes self-care as tailoring variable ("Attitude Toward the Behavior" in figure 2), but did not assess or address the other components when developing the IHCA or designing the study, nor did we select recipients who reportedly had difficulties regarding self-care. When developing an IHCA, targeting one specific behavior or clinical outcome, choosing one theory of change, addressing its components in the intervention, choosing the target population accordingly, assessing the process outcomes according to the theory and testing the supposed mechanisms of change would probably lead to greater effects and to greater advancement of our understanding.

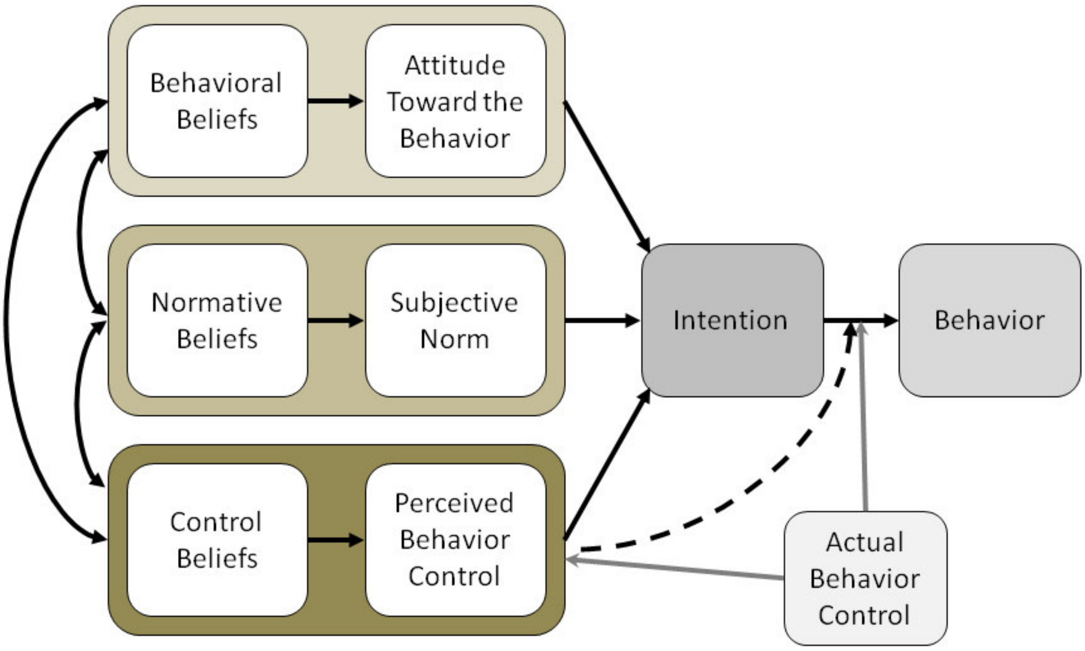

Fig. 2: Theory of Planned Behavior (adapted from: http://people.umass.edu/aizen/tpb.diag.html#null-link, accessed 7 July 2014)

Also, there is research indicating that e-health interventions become more effective if combined with peer support or counselor support via e-mail or phone (Brouwer et al., 2011; Spek et al., 2007; Tate, Jackvony, & Wing, 2006; Webb et al., 2010) while others did not find similar effects (Andersson, Lundstrom, & Strom, 2003; Klein et al., 2009). A recent Cochrane review found computer-based diabetes self-management interventions for adults with T2D to be more effective if the intervention was delivered via mobile phone (Pal et al., 2013). Going mobile and so stepping further into the users´ everyday life would also bring about the opportunity to incorporate applications like tracking of diet, blood sugar, or exercise (Wang et al., 2014) including effective behavior change techniques like feedback (Kristjansdottir et al., 2013) (targeting the TPB component “Perceived Behavioral Control”) or providing normative information about others´ behavior (targeting the TPB component “Subjective Norm”) (Webb et al., 2010). Stellefson et al. (2013) found that more web 2.0[9] leads to larger effects on health-related quality of life and behavioral outcomes (but not so much on biological and health care utilization outcomes).

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[9] Web 2.0 seems to be hard to define even for experts (O'Reilly, 2005). According to Wikipedia, „a Web 2.0 site may allow users to interact and collaborate with each other in a social media dialogue as creators of user-generated content in a virtual community, in contrast to Web sites where people are limited to the passive viewing of content. Examples of Web 2.0 include social networking sites, blogs, wikis, folksonomies, video sharing sites, hosted services, Web applications, and mashups” (Wikipedia). In the cited publication, “web 2.0 was defined as the technical, aesthetic, and functional criteria established to enable collaboration and sharing of information between users on the Internet” (Stellefson et al., 2013, p. 3).

In fact people living with a chronic condition are more actively using the opportunities of web 2.0 (Fox, Purcell, & California Health Care Foundation, 2010) than those without a chronic condition: Numerous blogs inform their readers about the challenges of living with diabetes (Case-Lo, 2014; Köster & Gdanietz), there are diabetes-related facebook groups (Köster & Gdanietz, 2014), and people with diabetes develop diabetes-related apps (mySugr GmbH). Opening the IHCA for users to comment on, generate and share content brings up the question of moderation, and with it come two other issues: On the ethical side, there is the question of how much gate keeping is necessary on the professional (researcher / clinician) side, a question related to the responsibility issue discussed in the patient involvement section (section 1.2).

On the practical side, there is the question of maintenance: As Alpay et al say, “one of the main challenges for e-health is to get past the pilot phase and become financially independent” (Alpay, Henkemans, Otten, Rovekamp, & Dumay, 2010, p. 789). Implementation surely is a challenge inherent in all interventions developed on time-limited grants. In e-health, there is the additional need for hosting, technical support and regular updates and, where applicable, moderation. Speed of technological development is high and sometimes higher than in scientific processes from grant to publication. Glasgow et al. point out that development, maintenance, updating, and testing of e-health interventions “is NOT a linear process, but a cycle of innovation and rapid testing” (Glasgow, Phillips, & Sanchez, 2014, p. 2). Baker et al. (Baker, Gustafson, & Shah, 2014) propose two kinds of strategies: Those that are supposed to improve the efficiency of e-health research, and those that designed to improve its quality. Among both are strategies connecting to problems encountered in the present study, especially “develop models including mediators and moderators: valid models are remarkably generative, and tests of moderation and mediation should elucidate boundary conditions of effects and treatment mechanisms” (Baker et al., 2014, para. 4) and, in line with Glasgow et al. (2014), “continuous quality improvement: researchers need to borrow engineering practices such as the continuous enhancement of interventions to incorporate clinical and technological progress” (Baker et al., 2014, para. 4).

To sum it up, future research should use and test theories of change, designing both the intervention and the study according to a comprehensive model (in the meantime, while we were already working on our IHCA, models for the development and testing of e-health interventions have been proposed) (Crutzen, 2014). Implementation issues should be addressed from the beginning, involving stakeholders in the development of interventions, linking online interventions both to the users´ everyday life (e.g. by adding apps to monitor exercise or blood sugar) and existing health care (e.g. by adding telephone or chat contacts), and considering how to maintain and update the intervention both technically and with regard to contents after the end of funding.

6. CONCLUSIONS

E-Health is a fact, and according to International Telecommunications Union (ITU)[10] secretary general Hamadoun Touré it will become more prominent in the future: “Information and communications technology will play a key role in delivering health care in the future – that´s true in developing and in developed countries. [...] In the developed world the driver is the ageing population. In the developing world it is a rapidly growing young population” (Dumiak, 2012). In 2012, the ITU and the WHO published a toolkit providing guidance to national governments on how to establish a national e-health vision, develop an action plan, and monitor implementation (World Health Organization & International Telecommunications Union, 2012). This being a step towards establishing standards on the macro level, quality seals can be seen as such a step on the meso and micro levels (Risk & Dzenowagis, 2001). The field is comparatively young, and understanding how and for whom e-health interventions work, how they can be implemented, and how quality can be assured are important issues to be addressed. Also, the promise of being more cost-effective than face-to-face interventions has yet to be confirmed (Paul, Carey, Sanson-Fisher, Houlcroft, & Turon, 2013).

What follows with regard to our IHCA? It can be a starting point for a “cycle of innovation and rapid testing” (Baker et al., 2014). Considering the issues discussed so far and drawing on the papers by Pingree et al. (2010), Murray (2012) and Baker et al. (2014) the next cycle should involve (1) delineating an implementation strategy first, which includes a) partnering with someone who has the capacities to technically maintain and update the system after the end of funding, and b) getting in touch with patients and practitioners and finding ways to interconnect everyday life and usual care with the intervention. This, in turn, implies that from this point on there are at least four parties involved. (2) Choosing one target construct or cluster such as, as outlined above, diabetes self-care, or SDM-related variables. (3) Identifying mechanisms known to affect this outcome. (4) Modifying the intervention accordingly (5) Updating the intervention technologically, if applicable, e.g. including mobile or web 2.0 features or chat / phone contacts with the health professional. (6) Identifying relevant patient and context variables. (7) Finding a study design mapping (2), (3), and (6), enabling the research team to determine the active ingredients of the intervention and to find out what works for whom. (8) Finding a study design that is efficient enough to keep up with the pace of progress (e.g., quasi-experimental or fractional-factorial). (9) Generating results

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[10] The ITU is “the United Nations specialized agency for information and communication technologies” (International Telecommunication Union (ITU), 2014)

quickly in order to keep pace and at the same time involving the partners. (10) Entering a new cycle with the results obtained.

Thinking through this cycle it becomes clear that it will probably be hard to both consider implementation from the beginning and at the same time cycling rapidly between innovation and testing. Usually a growing number of parties involved slows down the process. Moreover, which kind of partner would have the interest and the capacities to go through this process with the research team? At this point the issue of commercialization in e-health that was touched on in section 1.3 comes to a full circle: Most research institutions do probably not have the capacities for the technological side of such an intervention or even for the online study testing it, and most of them do not have the capacities to maintain them after funding has ended. As a result, partnering with a private company suggests itself. This does not necessarily have to be a bad thing. After all, besides the intention to foster patient well-being, scientists have scientific interests and political institutions supporting research have political interests. Still, questions of funding and access need to be discussed. In the light of these thoughts it becomes evident that ensuring quality and putting the users in the position to appraise the quality of e-health interventions is another crucial task the field is facing. Independent quality seals (Aktionsforum Gesundheitsinformationssystem (afgis) e.V. et al., 2010; International Patient Decision Aid Standards (IPDAS) Collaboration, 2005; The Health on the Net Foundation Code of Conduct (HONcode); University of Oxford & Division of Public Health and Primary Health Care, 2014) are a good start and an indispensable tool. Still, there is work to be done with regard to standardization and awareness among users. One of the promises at the dawn of e-health was that of democratization and patient involvement, and we are well advised to check from time to time if we are living up to it.

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8. APPENDIX

Curriculum Vitae with publication list

Publication 1

Publication 2

Publication 3

Publication 4

Publication 5

Publication 6

8.1. CV with publication list

Current positions:

Psychotherapist at Marien Gesundheitszentren, Hamburg, Germany

Psychotherapist in own private practice in Hamburg, Germany

Lecturer at the Institute for Behavior Therapy Training Hamburg (Institut für Verhaltenstherapie-Ausbildung Hamburg, IVAH), Germany

Education:

Nov 2010 Certified psychotherapist, Department of Social, Family and Health Affairs and Consumer Protection of the City of Hamburg, Germany

Oct 2005 Graduated psychologist, University of Freiburg, Germany

1999 - 2005 Studies in psychology at the universities of Trier and Freiburg, Germany

Positions:

Since Nov 2013 Psychotherapist at Marien Gesundheitszentren, Hamburg, Germany

Since Aug 2011 Psychotherapist in own private practice

Jul 2013-Oct 2013 Psychotherapist at Asklepios Health Care Center Ulmenstraße, Hamburg, Germany

Feb 2011-Dec 2013 Research associate at the Department of Medical Psychology, University Medical Center Hamburg-Eppendorf, Germany

2010-2011 Research associate at the Gaia AG, Hamburg, Germany

2008-2010 Research associate at the German Center for Addiction Research in Childhood and Adolescence, University Medical Center Hamburg-Eppendorf, Germany

2005-2008 Clinical psychologist at the Albertinen Hospital, Hamburg, Germany

2002-2005 Student research assistant at the University Medical Center Freiburg, Germany

Teaching:

2011-2013 Lecturer for Medical Psychology and Clinical Studies at the University Medical Center Hamburg-Eppendorf, Germany

Since 2012 Lecturer at the Institute for Behavior Therapy Training (Institut für Verhaltenstherapie-Ausbildung Hamburg, IVAH), Hamburg, Germany

Publications

Publications are ordered regarding date, starting with the most recent publication. Publications highlighted in grey are part of the thesis.

Weymann N, Dirmaier J, von Wolff A, Kriston L, Härter M (2015). Effectiveness of a web-based tailored, interactive health communication application for patients with type 2 diabetes or chronic low back pain: randomized controlled trial. Journal of Medical Internet Research. 17(3):E53.

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Dirmaier J, Härter M, **Weymann N** (2013) A tailored, dialogue-based health communication application for patients with chronic low back pain: study protocol of a randomised controlled trial BMC Medical Informatics and Decision Making, 13:66.

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Petersen, KU, **Weymann, N,** Schelb, Y, Thiel, R, Thomasius, R (2009) Pathologischer Internetgebrauch - Epidemiologie, Diagnostik, komorbide Störungen und Behandlungsansätze. Fortschritte der Neurologie und Psychiatrie 77(5), 263-271.

Thomasius, R, **Weymann, N,** Stolle, M, Petersen, KU (2009) Cannabiskonsum und -missbrauch bei Jugendlichen und jungen Erwachsenen. Psychotherapeut 54(3), 170-178.

Conferences – oral presentations and posters

Weymann, N, Härter, M. & Dirmaier, J. (Oktober 2013). Entwicklung und Evaluation eines interaktiven Informationssystems für Patienten/innen mit chronischen Erkrankungen. Kurzvortrag, präsentiert beim Deutschen Kongress für Versorgungsforschung, Berlin.

Steinmann, M, Heddaeus, D, **Weymann, N,** Helms, L, Härter, M & Watzke, B (2013). Telefongestützte Psychotherapie bei Depression: Übersetzung, Adaptation und Weiterentwicklung eines kognitiv-verhaltenstherapeutischen Therapieangebots für den deutschen Sprachraum. Poster, präsentiert beim 8. Workshopkongress der DGPS Fachgruppe Klinische Psychologie, Trier.

Dirmaier, J, **Weymann, N** & Härter, M (Mai 2011). *Entwicklung und Evaluation eines interaktiven Informationssystems für Patienten/innen mit chronischen Erkrankungen.* Poster und Kurzvortrag, präsentiert beim Treffen des Förderschwerpunkts zur versorgungsnahen Forschung Chronische Erkrankungen und Patientenorientierung, Erkner bei Berlin.

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Weymann, N, Baldus, C, Miranda, A, Moré, K, Reis, O & Thomasius, R (November 2009). *CAN Stop – Entwicklung und Evaluation eines indizierten Präventionskonzepts für Jugendliche und junge Erwachsene mit problematischem Cannabiskonsum.* Postersession beim Jahreskongress der Deutschen Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde, Berlin.

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8.2. Publications

Publication 1

WEYMANN, N., DIRMAIER, J., HÄRTER, M. (2013). PARTIZIPATIVE ENTSCHEIDUNGSFINDUNG IN DER DIABETESTHERAPIE: VON DER GUTEN ABSICHT ZUR GUTEN TAT. IN: PETRAK F, HERPERTZ S. HANDBUCH DER PSYCHODIABETOLOGIE. SPRINGER. 281-299.

Partizipative Entscheidungsfindung in der Diabetestherapie – Von der guten Absicht zur guten Tat

N. Weymann, J. Dirmaier, M. Härter

F. Petrak, S. Herpertz (Hrsg.), *Psychodiabetologie*,
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Kurzinfo

Zusammen mit anderen Ansätzen steht die Partizipative Entscheidungsfindung (PEF) für eine aktivere Beteiligung von Patienten an der Gesundheitsversorgung. Im Rahmen der PEF treffen Patient und Behandler im gegenseitigen Austausch eine gemeinsame, „partizipative" Entscheidung, für die sie gemeinsam die Verantwortung tragen.

Gerade bei schwerwiegenden und/oder chronischen Erkrankungen wie Diabetes ist die PEF indiziert, da der Patient die Entscheidung in seinem Alltag im Rahmen seines Selbstmanagements umsetzen und seine Erfahrungen wieder zurück in die Konsultation tragen soll, um die Entscheidung zu reevaluieren. Eine tragfähige, vertrauensvolle Beziehung zwischen Patient und Behandler ist für das Gelingen dieses Prozesses unabdingbare Voraussetzung. PEF-Schulungen für Patienten und Ärzte sowie Entscheidungshilfen als Unterstützung bei konkreten Behandlungsentscheidungen stehen für die Umsetzung der PEF zur Verfügung. Im deutschsprachigen Raum ist die PEF trotz der vor allem patientenseitigen Befürwortung noch nicht flächendeckend im klinischen Alltag angekommen.

22.1 Hintergrund

Die Rolle des Patienten in der Gesundheitsversorgung hat in den vergangenen zwei Dekaden einen grundsätzlichen Wandel durchlaufen. Die noch nicht abgeschlossene Entwicklung wurde maßgeblich von Seiten der Patienten angestoßen, die eine aktivere Rolle für sich einforderten. Auch von politischer Seite wurde vor dem Hintergrund der Zunahme chronischer Erkrankungen verlangt, den Patienten als zentralen, selbstverantwortlichen Akteur stärker in den Mittelpunkt zu stellen. Durch die stärkere Beteiligung sollen das Selbstmanagement gefördert (Forster u. Kranich 2007) und das Gesundheitssystem entlastet werden (Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen 2003). Das Internet mit seinen Informationsmöglichkeiten hat diese Entwicklung weiter beschleunigt (Fox u. Purcell 2010). Viele Patienten erwarten umfassende Aufklärung über ihre Erkrankung und ihre Therapieoptionen (Levinson et al. 2005) sowie Beteiligung bei Entscheidungsfindung und Behandlung (Coulter u. Magee 2003) – und die Zahl der Patienten, die beteiligt werden möchten, ist in den letzten Jahren deutlich gestiegen (Chewning et al. 2012). Forschungsergebnisse untermauern diese Erwartungen. So zeigte sich, dass eine stärkere Beteiligung von Patienten das Wissen über die Erkrankung verbessern, Entscheidungskonflikte reduzieren, die Therapieadhärenz erhöhen (Bieber et al. 2007), Gesundheitsverhalten bzw. Selbstmanagement verbessern (Hibbard et al. 2007) und schließlich zu einem besseren Gesundheitsstatus sowie einer verringerten Inanspruchnahme von Gesundheitsleistungen (Coulter u. Ellins 2007) führen kann.

Eine Möglichkeit, Patienten einen aktiveren Umgang mit ihrer Erkrankung und den Behandlungsempfehlungen zu erleichtern, bietet das Konzept der Partizipativen Entscheidungsfindung (PEF, engl. Shared Decision Making, SDM). Zur Förderung der PEF im deutschen Gesundheitswesen hat das Bundesministerium für Gesundheit von 2001–2007 den Förderschwerpunkt „Patient als Partner im medizinischen Entscheidungsprozess" aufgebaut (Härter et al. 2005). Seit 2008 wird der „Förderschwerpunkt zur versorgungsnahen Forschung Chronische Krankheiten und Patientenorientierung" im Bereich der Forschung zu den drei Bereichen Patienteninformationen, effiziente Schulungsprogramme für chronisch kranke Menschen und partizipative Gestaltung der Versorgung unterstützt (http://www.patient-als-partner.de).

Neben dem Ansatz der PEF existieren weitere Ansätze, die eine Partizipation an der Gesundheitsversorgung auf Seiten des Patienten fokussieren. Eine aktive Beteiligung von Patienten an der Behandlung ihrer chronischen Erkrankung ist beispielsweise explizit im Rahmen des Chronic Care Modells verankert (deutsche Adaptation: Gensichen et al. 2006). Neben Aspekten wie der Verwendung evidenzbasierter Leitlinien, strukturierten Arbeitsabläufen, Vernetzung der Versorgungseinrichtung und dem Einsatz klinischer Informationssysteme soll insbesondere über ein verbessertes Selbstmanagement die aktive Rolle des Patienten im Behandlungsverlauf gestärkt werden (Gensichen et al. 2006). Unter Selbstmanagement wird in diesem Zusammenhang die Hilfe zur Selbsthilfe verstanden, um im Sinne eines Empowerments eine Stärkung der Patientenrolle und -kompetenz zu erreichen und

◘ **Tab. 22.1** Modelle medizinischer Entscheidungsfindung (nach Charles et al. 1999)

		Paternalistisches Modell	**Partizipative Entscheidungsfindung**	**Informationsmodell**
Informationsaustausch	Richtung des Informationsflusses	vom Arzt zum Patienten	vom Arzt zum Patienten und vom Patienten zum Arzt	vom Arzt zum Patienten
	Art der Information	medizinisch	medizinisch und persönlich	medizinisch
	Ausmaß der Information	entsprechend den gesetzlichen Anforderungen	alles für die Entscheidung Relevante	alles für die Entscheidung Relevante
Wer wägt die unterschiedlichen Behandlungen gegeneinander ab?		Arzt alleine	Arzt und Patient	Patient alleine
Wer entscheidet, welche Behandlung durchgeführt wird?		Arzt	Arzt und Patient	Patient

den Patienten zu motivieren, selbstständig Ziele zu setzten, Barrieren und Herausforderungen zu identifizieren und seinen Gesundheitszustand zu überwachen (Gensichen et al. 2006). Selbstmanagement von chronischen Erkrankungen bezieht sich dabei insbesondere auf Bereiche wie Medikamentengebrauch, Lebensstilveränderungen, Verhaltensänderungen zur Prävention von Langzeitkomplikationen oder Adhärenz bezüglich Behandlungsplänen.

Der Beitrag konzentriert sich auf den Teilbereich der PEF. Das Konzept der PEF wird in Abgrenzung zu anderen Modellen medizinischer Entscheidungsfindung dargestellt, die konkrete Umsetzung von PEF im Kontext der Diabetesbehandlung wird vertieft, die Effekte der PEF in der Diabetestherapie werden berichtet sowie Barrieren aufgezeigt, die der Umsetzung im klinischen Alltag entgegenstehen.

22.2 Modelle medizinischer Entscheidungsfindung

Der PEF kommt in Bezug auf das Ausmaß der Verantwortung, die der Patient bei der Entscheidungsfindung übernimmt, eine Mittelstellung zwischen dem Informationsmodell und dem paternalistischen Modell medizinischer Entscheidungsfindung zu (◘ Tab. 22.1).

Im Informationsmodell fließt die Information – beispielsweise zu Behandlungsoptionen und deren Vor- und Nachteilen – ausschließlich oder fast ausschließlich vom Behandler zum Patienten. Der Patient soll durch eine möglichst neutrale Informationsvermittlung in die Lage versetzt werden, die Entscheidung – beispielsweise darüber, welche Behandlung begonnen werden soll – zu treffen. Das Informationsmodell geht davon aus, dass der Patient willens und in der Lage ist, alle relevanten medizinischen Informationen zu verstehen und sie vor dem Hintergrund seiner Lebenssituation zu bewerten (Montori et al. 2006). Am anderen Ende des Kontinuums liegt das paternalistische Modell, bei dem der Behandler als medizinischer Experte die Hauptverantwortung für die Entscheidung trägt. Der Patient ist vorwiegend in der Rolle des passiven Empfängers. Seine Präferenzen werden bei der Entscheidungsfindung nicht explizit erfragt und berücksichtigt (Coulter 1999).

Bei der PEF fließen Informationen in beiden Richtungen – vom Behandler zum Patienten und vom Patienten zum Behandler. Der Behandler als Experte für die Diabetestherapie informiert den Patienten über seine Optionen und deren Vor- und Nachteile. Der Patient als Experte für sich und seine Lebenssituation informiert den Behandler über seine Bedürfnisse, Werte und Emotionen in Bezug auf die aufgezeigten Optionen. Im gegenseitigen Austausch soll so eine gemeinsame, „partizipative" Entscheidung getroffen werden, für die die Verantwortung gemeinsam getragen wird (Bieber et al. 2007).

22.3 Partizipative Entscheidungsfindung: Definition und Konzepte

Eine Definition aus dem deutschsprachigen Raum beschreibt PEF als Interaktionsprozess mit dem Ziel, unter gleichberechtigter aktiver Beteiligung von Patient und Arzt auf Basis geteilter Informationen zu einer gemeinsam verantworteten Übereinkunft zu kommen (Härter 2004). International existieren verschiedene Modelle der PEF nebeneinander, Autoren und Arbeitsgruppen setzen unterschiedliche Schwerpunkte und definieren PEF unterschiedlich weit (Légaré et al. 2010, Stacey et al. 2010).

22.3.1 Indikationen für PEF

Die PEF ist besonders bei schwerwiegenden und/oder chronischen Erkrankungen wie Diabetes indiziert. Sie eignet sich auch besonders, wenn mehr als eine gleichwertige, im besten Fall evidenzbasierte Therapieoption zur Wahl steht. Bei vielen Entscheidungen in der Diabetestherapie geht man davon aus, dass es eine medizinisch überlegene Behandlungsalternative gibt – dass beispielsweise die Blutzuckerselbstkontrolle alternativlos ist. Aktuelle Studien zeigen jedoch, dass die Evidenzlage nicht so klar ist wie oft angenommen (Lenz u. Mühlhauser 2009) und stützen damit einmal mehr die Bedeutung von PEF in der Diabetestherapie.

Außerdem ist PEF geeignet, wenn die Wichtigkeit der Entscheidung und der Konsequenzen für den Patienten hoch ist, d. h., wenn es sich – wie beim Diabetes – um eine lebensbegleitende und -verändernde Erkrankung handelt. Whitney (2004) bezeichnet diese beiden relevanten Variablen als „Entscheidungssicherheit“ und „Bedeutung der medizinischen Entscheidung für den Patienten“ (■ Abb. 22.1). Zweifellos kann man an dieser Stelle darüber diskutieren, inwieweit Patientenpräferenzen ihre Bedeutung mit zunehmender Evidenz verlieren müssen. Konflikte zwischen Patient und Behandler können sich nach Whitneys Modell dann ergeben, wenn sowohl die subjektive Bedeutung der Erkrankung als auch die medizinische Entscheidungssicherheit hoch sind, die Empfehlung des Arztes allerdings mit dem Behandlungswunsch des Patienten nicht übereinstimmt.

PEF sollte natürlich nur in dem Ausmaß stattfinden, das von Patienten in der jeweiligen Situation tatsächlich gewünscht wird. In Krisen- oder Notfallsituationen oder wenn sich Patienten durch eine Beteiligung überfordert fühlen, ist PEF nach Meinung der meisten Autoren weniger oder gar nicht indiziert (Müller-Engelmann et al. 2010).

Hinsichtlich der Patientenpräferenzen hat sich gezeigt, dass vor allem jüngere Patienten mit höherer Bildung und höherem Einkommen stärker an einer Entscheidungsbeteiligung interessiert sind (Say et al. 2006). Bis zu einem Alter von 45 Jahren steigt die Beteiligungspräferenz (Levinson et al. 2005), ältere Patienten bevorzugen eine eher passive Rolle im Rahmen der Behandlung (Bastiaens et al. 2007). Frauen und weniger belastete Patienten bevorzugen im Vergleich zu Männern und stärker belasteten Patienten eine aktivere Rolle in der Entscheidungsfindung (Levinson et al. 2005). Unterschiede in der Beteiligungspräferenz zwischen Patienten mit akuten und chronischen Erkrankungen konnten bisher nicht erhärtet werden (Hamann et al. 2007).

22.3.2 Ablauf der PEF

In der Literatur wird eine Abfolge von Handlungsschritten formuliert (Härter 2004), die als Orientierungshilfe bei der Umsetzung der PEF zu verstehen ist: Zunächst formuliert der Arzt die Notwendigkeit einer Behandlungsentscheidung und das Angebot einer gleichberechtigten Zusammenarbeit beider Partner bei der Entscheidungsfindung. Im nächsten Schritt erfolgt die Beschreibung der Behandlungsoptionen mit ihren jeweiligen Vor- und Nachteilen. Der Arzt erfragt vom Patienten, ob er die Informationen verstanden hat und exploriert seine Erwartungen und Befürchtungen in Bezug auf die Entscheidung. Schließlich werden die unterschiedlichen Präferenzen von Patient und Arzt ermittelt, es erfolgt ein Abwägen der Behandlungsalternativen und es wird ein Plan zur Umsetzung der gewählten Behandlung beschlossen (Loh u. Härter 2005).

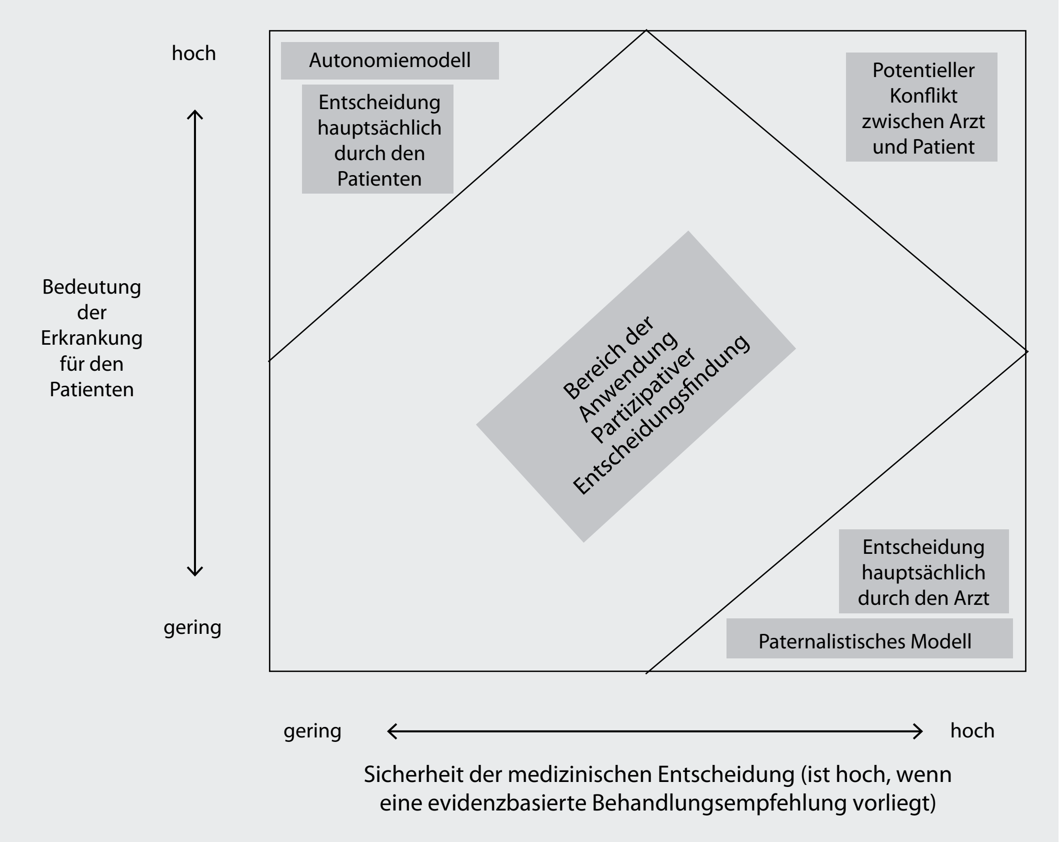


Abb. 22.1 Anwendungsbereiche der PEF (partizipative Entscheidungsfindung) in Abhängigkeit von den Faktoren Bedeutung und Entscheidungsfreiheit. (Adaptiert nach Whitney 2004)

Tipp

Prozessschritte im Rahmen der PEF (nach Härter 2004)
- mitteilen, dass eine Entscheidung ansteht,
- Gleichberechtigung der Partner formulieren,
- über Wahlmöglichkeiten informieren („Equipoise"),
- über Vor- und Nachteile der Optionen informieren,
- Verständnis, Gedanken und Erwartungen erfragen,
- Präferenzen ermitteln,
- aushandeln,
- gemeinsame Entscheidung herbeiführen,
- Vereinbarung zur Umsetzung der Entscheidung treffen.

22.3.3 Besonderheiten der PEF in der Diabetestherapie

Mehr als bei akuten Erkrankungen hat der chronisch kranke Patient eine aktive, verantwortliche Rolle in der Behandlung, denn er soll die Behandlungsentscheidungen über einen langen Zeitraum in seinem Alltag umsetzen und tragen (Adhärenz). Dabei können Entscheidungen – anders als die einmalige Entscheidung beispielsweise für eine Operation – immer wieder hinterfragt, modifiziert und revidiert werden. Die Behandlungsentscheidungen haben auch einen dauerhaften Einfluss auf das soziale Umfeld. Dies gilt für Lebensstiländerungen wie die Umstellung von Ernährung oder Bewegungsverhalten ebenso wie für Insulinschemata. Den Patienten als aktiven Partner auch bei der Entscheidungsfindung zu sehen, hat in der

Diabetesbehandlung aus diesen Gründen einen besonderen Stellenwert. Denn der Patient, der an der Entscheidung für eine Behandlung oder Lebensstilveränderung beteiligt war, wird für die konkrete Umsetzung im Alltag eine höhere Motivation aufbringen und somit adhärenter agieren. Im Rahmen der PEF werden in der Konsultation oder im Therapiegespräch Voraussetzungen dafür geschaffen, dass der Patient auch außerhalb des Behandlungsraums die Entscheidung weiter trägt – und dass er neue Erfahrungen, die seine Einschätzung verändern, aus seinem Alltag zurück in den Behandlungsraum und in die Entscheidungsfindung einbringt (Montori et al. 2006).

Aufbauend auf diesen Eigenheiten der Diabetesbehandlung legen Montori und Kollegen (2006) ein modifiziertes Modell für das Treffen von Behandlungsentscheidungen bei chronischen Erkrankungen vor.

Sie unterscheiden dabei die idealtypischen Phasen:

- Etablieren einer Partnerschaft,
- Informationsaustausch,
- Abwägen von Optionen,
- Entscheidungsfindung und Umsetzung der Entscheidung.

Insbesondere zwei Punkte werden dabei hervorgehoben: Zum einen wird das Etablieren einer von Vertrauen und Respekt geprägten, tragfähigen Partnerschaft zwischen Patient und Behandler, aber auch zwischen „Patiententeam“ (z. B. Freunde, Familie) und Behandlerteam als Basis der Entscheidungsfindung betont. Zum anderen unterstreichen die Autoren den iterativen und prozesshaften Charakter der genannten Phasen. Beispielsweise kann das Treffen und Umsetzen einer Entscheidung die Identifikation von Umsetzungsbarrieren (der Patient berichtet frustriert, er habe sich nicht aufraffen können, wie geplant dreimal pro Woche eine halbe Stunde zu laufen), die Entwicklung und Erprobung von Strategien im Umgang mit diesen Barrieren (Kann er sich mit jemandem zum Laufen verabreden?) oder auch die Reevaluation und Modifikation der Entscheidung (Vielleicht ist Radfahren oder Spazierengehen passender für diesen Patienten?) beinhalten. Der Übergang von PEF zum Krankheitsmanagement scheint hier fließend. Auch von anderen Arbeitsgruppen wird die Bedeutung der tragfähigen Partnerschaft in der Entscheidungsfindung und Behandlung bei Diabetes betont und der Blick von der konkreten Entscheidungssituation auf die Behandler-Patient-Kommunikation erweitert. Als zentral wird dabei das Verstehen der Lebenswelt des Patienten angesehen (Entwistle et al. 2008; Zoffman et al. 2008).

22.4 Praktische Umsetzung von PEF

Verschiedene Maßnahmen stehen zur Verfügung, um PEF stärker im klinischen Alltag zu verankern: Im Rahmen von Schulungen werden Ärzten und Patienten die notwendigen Kompetenzen vermittelt. Entscheidungshilfen bieten Ärzten wie auch Patienten innerhalb oder außerhalb der Konsultation konkrete Unterstützung bei spezifischen Behandlungsentscheidungen.

22.4.1 Fortbildungsmaßnahmen zur Förderung ärztlicher Gesprächs- und Handlungskompetenz

Obwohl einige Ärzte PEF gegenüber anderen Kommunikationsstrategien vorziehen, wird in der Praxis der Diabetestherapie der Großteil der Entscheidungen arztzentriert getroffenen (Heisler et al. 2009). In Ärzteschulungen werden Gesprächskompetenzen vermittelt, die bei der Umsetzung von PEF helfen. Aufbauend auf Erfahrungen aus Großbritannien (Elwyn et al. 2004) und Deutschland (Bieber et al. 2008, Bieber et al. 2006; Loh et al. 2004, 2007). wurde ein deutschsprachiges Trainingsmanual zur PEF entwickelt (Bieber et al. 2007). Das Manual enthält eine Einführung in die theoretischen Grundlagen der PEF, die Vermittlung patientenzentrierter Kommunikationsstrategien und die Umsetzung einer PEF in beispielhaften Indikationen. Eines der Bespiele skizziert die hausärztliche Behandlung eines adipösen Patienten mit neu diagnostiziertem Diabetes mellitus Typ 2.

22.4.2 Patientenschulungen zur Vorbereitung auf eine stärkere Beteiligung am Entscheidungsprozess

Patientenschulungen, die schwerpunktmäßig eine Stärkung von Patientenkompetenzen und die Vermittlung kommunikativer Fertigkeiten für das Gespräch mit dem Arzt zum Ziel haben (Towle u. Godolphin 1999), sind anders als klassische Diabetesschulungen nicht krankheitsspezifisch angelegt und vermitteln entsprechend auch keine diabetesspezifischen Inhalte. Stattdessen sollen sie Patienten dazu ermutigen und befähigen, sich an Entscheidungen im Rahmen ihrer medizinischen Entscheidung zu beteiligen. Die Bandbreite reicht von Checklisten oder Vorbereitungsblättern für die Konsultation über DVDs bis hin zu Trainings zur Vermittlung und zum Üben des Arztgesprächs (Brown et al. 1999).

22.4.3 Entscheidungshilfen

Entscheidungshilfen (engl. Decision Aids) sind „Interventionen, die entwickelt wurden, um Betroffenen beim Treffen konkreter, abwägender Entscheidungen […] zu helfen, indem sie über die Optionen und über die für den Gesundheitsstatus des Betreffenden relevanten Outcomes informieren.“ (O’Connor et al. 2004, zitiert nach Elwyn et al. 2010, S 702).

Entscheidungshilfen können auf Papier, als DVD, als Computersoftware oder online dargereicht werden. Elwyn und Kollegen (2010) unterscheiden drei Kategorien von Entscheidungshilfen:

- Entscheidungshilfen, die von Behandlern in Konsultationen verwendet werden,
- Entscheidungshilfen, die auch außerhalb von Behandlerkonsultationen verwendet werden können,
- Entscheidungshilfen, die interaktive Technologien, z. B. das Internet, verwenden.

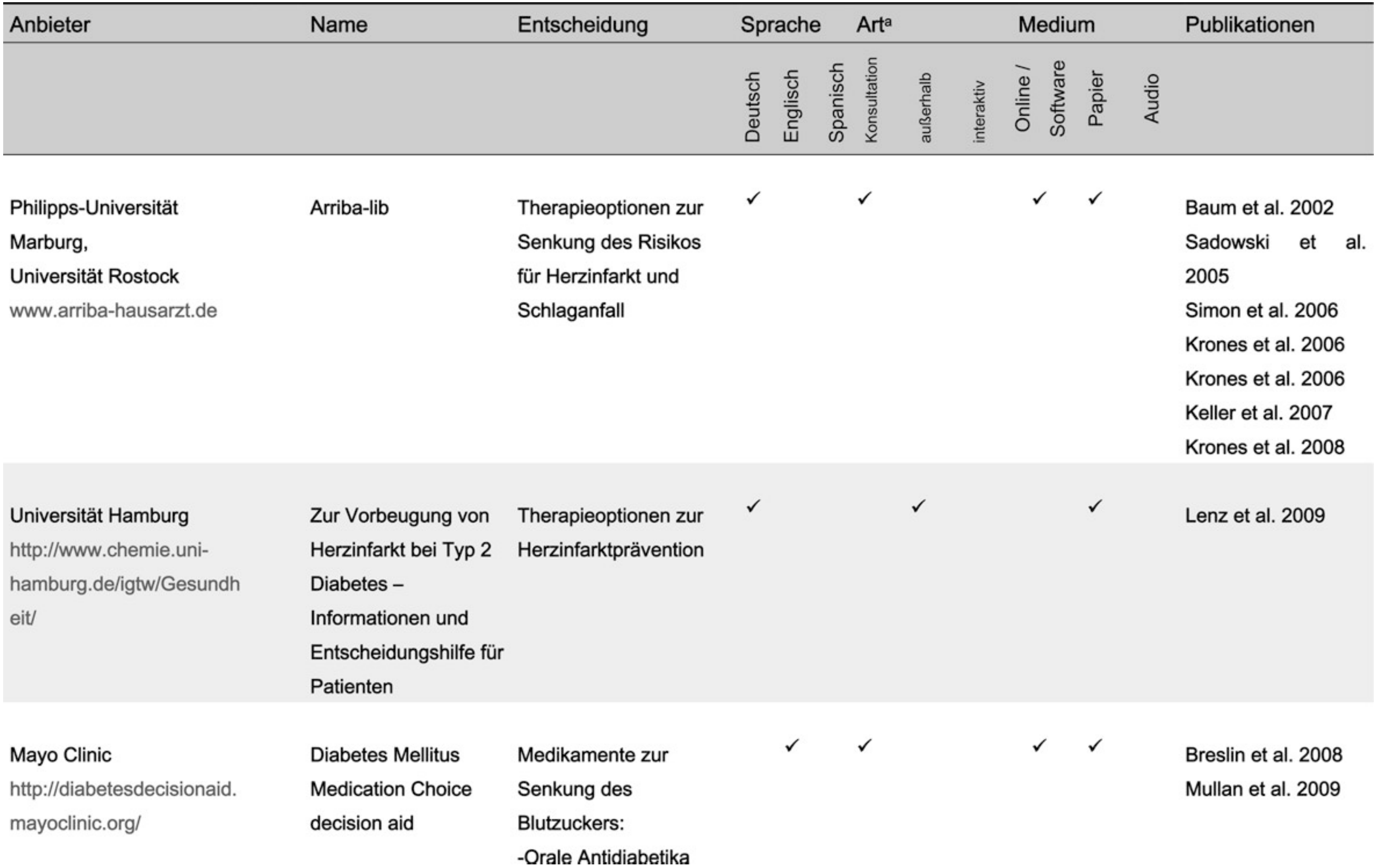
Eine insbesondere in den USA und Kanada mittlerweile häufiger eingesetzte Entscheidungshilfe ist die Unterstützung durch sogenannte „decision coaches“ (Stacey et al. 2012). Decision Coaching wird in der Regel durch speziell geschultes medizinisches Fachpersonal wie Pflegekräfte oder MTA angeboten und zielt darauf ab, die Zuversicht und die Kompetenzen von Patienten hinsichtlich der partizipativen Entscheidungsfindung mit dem Arzt zu erhöhen. Decision Coaching kann persönlich oder über Kommunikationsmedien wie das Telefon erfolgen. Entscheidungshilfen können, müssen dabei aber nicht zum Einsatz kommen (Stacey et al. 2008).

Trotz mittlerweile definierter Qualitätsstandards für die Entwicklung (Elwyn et al. 2006), sind die aktuell verfügbaren Entscheidungshilfen bezogen auf Entwicklungsprozess, Präsentation und Evidenzlage von sehr heterogener Qualität (Elwyn et al. 2006). Gegenstand von Diskussion und Forschung sind gegenwärtig insbesondere Fragen der angemessenen Vermittlung medizinischer Fachinformationen und statistischer Kennwerte (Gigerenzer u. Wegwarth 2008), die Suche nach einer umfassenden theoretischen Grundlage für die Entwicklung von Entscheidungshilfen (Durand et al. 2008; Elwyn u. Miron-Shatz 2010) sowie förderliche bzw. hemmende Faktoren im Rahmen Implementierung in der Routineversorgung. ■ Abb. 22.2 gibt einen Überblick über die aktuell für die Diabetestherapie verfügbaren Entscheidungshilfen.

22.4.4 Diabetesspezifische Ansätze

Für Diabetes liegen zwei englischsprachige Interventionen vor, die jeweils eine Behandlerschulung enthalten, ergänzt durch Arbeitsmaterialien und in einem Fall auch durch eine Patientenschulung.

Die Arbeitsgruppe um Zoffman (Zoffman u. Lauritzen 2006; Zoffman u. Kirkevold 2012) entwickelte eine strukturierte Intervention zur Entscheidungsfindung und Problemlösung (Guided-Self-Determination-Intervention, GSD). Die Behandler – in diesem Fall Diabetesassistentinnen – wurden in Gesprächsführung geschult. Mittels vorgegebener Arbeitsblätter wurden Diabetesassistentinnen und Patienten in fünf Schritten vom Etablieren einer Partnerschaft bis hin zu Verhaltensänderungen und der Entwicklung von Selbstmanagementfertigkeiten geführt.



Anbieter	Name	Entscheidung	Sprache			Art^a			Medium			Publikationen
			Deutsch	Englisch	Spanisch	Konsultation	außerhalb	interaktiv	Online / Software	Papier	Audio	
Philipps-Universität Marburg, Universität Rostock www.arriba-hausarzt.de	Arriba-lib	Therapieoptionen zur Senkung des Risikos für Herzinfarkt und Schlaganfall	✓			✓			✓	✓		Baum et al. 2002 Sadowski et al. 2005 Simon et al. 2006 Krones et al. 2006 Krones et al. 2006 Keller et al. 2007 Krones et al. 2008
Universität Hamburg http://www.chemie.uni-hamburg.de/igtw/Gesundheit/	Zur Vorbeugung von Herzinfarkt bei Typ 2 Diabetes – Informationen und Entscheidungshilfe für Patienten	Therapieoptionen zur Herzinfarktprävention	✓				✓			✓		Lenz et al. 2009
Mayo Clinic http://diabetesdecisionaid.mayoclinic.org/	Diabetes Mellitus Medication Choice decision aid	Medikamente zur Senkung des Blutzuckers: -Orale Antidiabetika		✓		✓			✓	✓		Breslin et al. 2008 Mullan et al. 2009

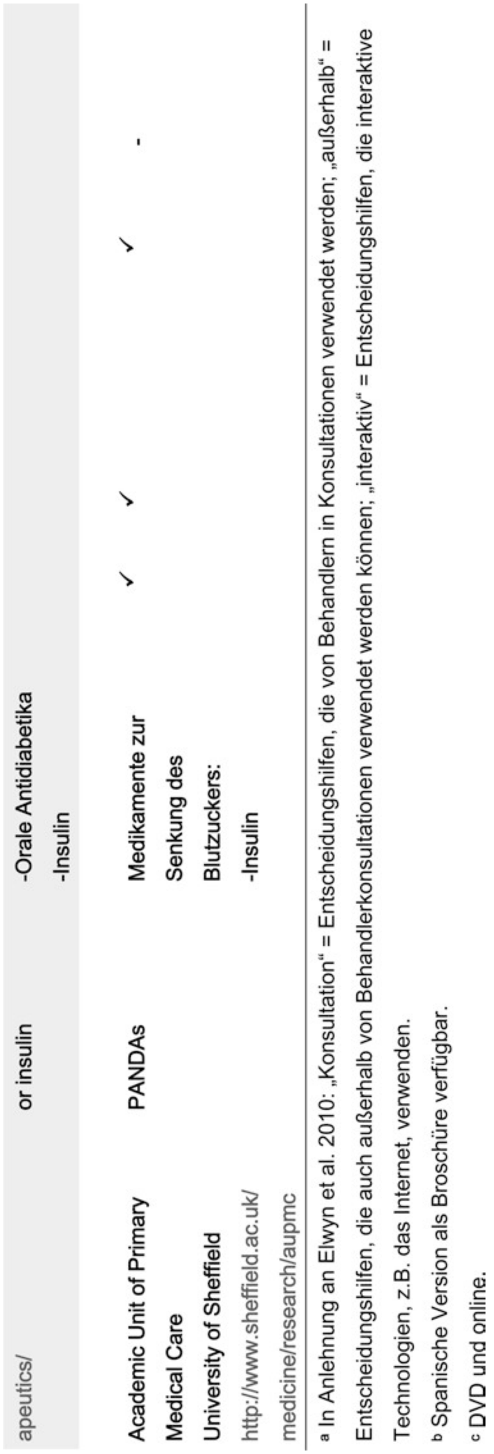
■ **Abb. 22.2** Überblick über vorliegende Entscheidungshilfen

		-Insulin									
Mayo Clinic http://www.mayo.edu/	Statin Choice	Statintherapie	✓	✓	✓				✓		Montori et al. 2007 Weymiller et al. 2007 Mann et al. 2009 Nannenga et al. 2009 Jones et al. 2009 Abadie et al. 2009
Healthwise http://www.healthwise.net	Diabetes: Should I get pregnant?	Schwangerschaft	✓				✓	✓	✓		-
Agency for Healthcare Research and Quality http://effectivehealthcare.ahrq.gov/	Medicines for Type 2 Diabetes: A Review of the Research for Adults	Medikamente zur Senkung des Blutzuckers: -Orale Antidiabetika	✓	✓		✓		✓	✓	✓	
Agency for Healthcare Research and Quality http://effectivehealthcare.ahrq.gov/	Premixed Insulin for Type 2 Diabetes: A Guide for Adults	Medikamente zur Senkung des Blutzuckers: -Insulin	✓	✓		✓		✓	✓	✓	-

Abb. 22.2 (*Fortsetzung*) Überblick über vorliegende Entscheidungshilfen

Healthwise http://www.healthwise.net	Diabetes: Should I get an insulin pump?	Medikamente zur Senkung des Blutzuckers: -Insulin	✓				✓	✓	✓	-
Informed Medical Decisions Foundation http://informedmedicaldecisions.org/ Health Dialog http://www.healthdialog.com/	Living with Diabetes: Making Lifestyle Changes to Last a Lifetime	Lebensstilveränderungen und Medikamente	✓	✓[b]		✓		✓[c]	✓	-
NICE Medicines and Prescribing Centre http://www.npc.nhs.uk/therapeutics/	Blood pressure control	Enge Blutdruckkontrolle	✓		✓				✓	-
NICE Medicines and Prescribing Centre http://www.npc.nhs.uk/therapeutics/	Metformin treatment	Medikamente zur Senkung des Blutzuckers: -Orale Antidiabetika	✓		✓				✓	-
NICE Medicines and Prescribing Centre http://www.npc.nhs.uk/ther	Tight control of blood glucose using sulphonylurea drugs	Medikamente zur Senkung des Blutzuckers:	✓		✓				✓	-

■ **Abb. 22.2** (*Fortsetzung*) Überblick über vorliegende Entscheidungshilfen



apeutics/	or insulin	-Orale Antidiabetika -Insulin					
Academic Unit of Primary Medical Care University of Sheffield http://www.sheffield.ac.uk/medicine/research/aupmc	PANDAs	Medikamente zur Senkung des Blutzuckers: -Insulin	✓	✓		✓	-

[a] In Anlehnung an Elwyn et al. 2010: „Konsultation“ = Entscheidungshilfen, die von Behandlern in Konsultationen verwendet werden; „außerhalb“ = Entscheidungshilfen, die auch außerhalb von Behandlerkonsultationen verwendet werden können; „interaktiv“ = Entscheidungshilfen, die interaktive Technologien, z.B. das Internet, verwenden.

[b] Spanische Version als Broschüre verfügbar.

[c] DVD und online.

Abb. 22.2 (*Fortsetzung*) Überblick über vorliegende Entscheidungshilfen

Corser et al. (2007) stellten eine PEF-Kurzintervention zur Erarbeitung realistischer Behandlungsziele für Patienten mit Typ-2-Diabetes in der Hausarztpraxis vor. Bausteine der Intervention sind ein Patientenarbeitsbuch, an diesem Arbeitsbuch orientierte edukative Termine mit Diabetesassistentinnen, die ärztliche Konsultationen vorbereiten, sowie eine Ärzteschulung zu evidenzbasierter Diabetesbehandlung und PEF.

22.5 Effekte der PEF

Da die Datenbasis für Aussagen über die Effekte von PEF bei Diabetes noch relativ gering ist, werden zunächst Übersichtsarbeiten zu den indikationsübergreifenden Effekten von PEF diskutiert. Unter ► Abschn. 22.5.4 werden Ergebnisse aus dem Bereich Diabetes dargestellt.

22.5.1 Effekte von Fortbildungsmaßnahmen zur Förderung ärztlicher Gesprächs- und Handlungskompetenz

Ein Cochrane-Review aus dem Jahr 2010 (Légaré et al. 2010) fand in zwei von fünf eingeschlossenen Studien zu beim Arzt ansetzenden Interventionen signifikante Effekte auf PEF. In einer dieser beiden Studien wurde die in der ärztlichen Konsultation verwendete Statin Choice Entscheidungshilfe positiv evaluiert (► Abschn. 22.5.4). In der zweiten Studie (Edwards et al. 2004; Elwyn et al. 2004) führte eine Kombination aus Schulungsmaterialien, Schulungstreffen und Feedback für Ärzte zu einer stärkeren Umsetzung von PEF bei einer heterogenen Patientenstichprobe. Weitere Primärstudien zeigen, dass PEF-Schulungen das Wissen der Ärzte über PEF ebenso verbesserten wie ihre Zuversicht, PEF umzusetzen. Die Ärzte gaben an, sich durch die Umsetzung der Fortbildungsinhalte entlastet und zufriedener zu fühlen, und der Umgang mit den Anliegen der Patienten und die Güte der Diagnostik verbesserten sich (Bieber et al. 2008, Bieber et al. 2009). Patienten von geschulten Ärzten sind tatsächlich stärker an Entscheidungen beteiligt, zufriedener mit der Behandlung und adhärenter bezüglich ihrer Behandlung (Loh et al. 2007). Im Hinblick auf die Effekte von Ärzteschulungen auf das klinische Outcome sind die Ergebnisse bislang uneinheitlich (Deinzer et al. 2006; Krones u. Richter 2008).

22.5.2 Effekte von Patientenschulungen zur Vorbereitung auf eine stärkere Beteiligung am Entscheidungsprozess

Eine systematische Übersichtsarbeit (Kinnersley et al. 2008) fand geringfügige Effekte von patientenseitigen Interventionen auf das Frageverhalten der Patienten in der Konsultation. Keine Effekte zeigten sich in den Bereichen Zufriedenheit, erlebte Angst vor oder nach der Konsultation und Wissen. Weitere Primärstudien fanden, dass Patienten nach einer Schulung mehr Fragen in der Konsultation stellten, ein stärkeres Kontrollerleben bezüglich der eigenen Gesundheit haben, sich bei der Entscheidungsfindung autonomer fühlen und ein stärkeres Partizipationsbedürfnis (Kopke et al. 2011; Loh et al. 2007) angeben. Zudem zeigte sich, dass in PEF geschulte Patienten sich besser an Informationen aus der Konsultation erinnern und die Behandlung sowie Behandlungsempfehlungen besser verstehen (Hamann et al. 2005). Kleine positive Effekte wurden in Bezug auf Selbstwirksamkeit, Gesundheitszustand und Inanspruchnahmeverhalten gefunden (Loh et al. 2007).

22.5.3 Effekte von Entscheidungshilfen

Ein aktuelles Cochrane Review (Stacey et al. 2011) fand, dass Entscheidungshilfen in der Behandlung akuter und chronischer Erkrankungen sowie bei Screening-Entscheidungen die Patient-Behandler-Kommunikation verbessern, die Patientenbeteiligung erhöhen, das Wissen vergrößern und zu realistischeren Ergebniserwartungen für die dargestellten Therapieoptionen führen.

22.5.4 Effekte von PEF in der Diabetestherapie

Ein systematisches Review zu den Effekten von PEF bei verschiedenen chronischen Erkrankungen fand heterogene Ergebnisse und kam zu dem Schluss, dass PEF für Patienten mit chronischen Erkrankungen und bei Behandlungen, die mehr als einen Termin oder eine einzelne Konsultation umfassen, gut geeignet sei (Joosten et al. 2008). Primärstudien zu Effekten bei chronischen Erkrankungen lassen den Schluss zu, dass PEF zu größerem Wissenszuwachs, höherer Patientenzufriedenheit, einer verbesserten Qualität der Behandler-Patient-Interaktion und verbesserter Adhärenz in der medikamentösen Therapie führen kann. Die Ergebnisse in Bezug auf das klinische Outcome sind uneinheitlich (Bieber et al. 2008; Deinzer et al. 2006; Loh et al. 2007; Wilson et al. 2010). Deinzer und Kollegen (2006) fanden in ihrer Arbeit über PEF mit Bluthochdruckpatienten nur bei Patienten mit einem höheren Bedürfnis nach Partizipation einen direkten Zusammenhang zwischen der Zunahme von PEF und dem klinischen Outcome.

Eine Übersichtsarbeit zum Effekt partizipativer Entscheidungsfindung in der Diabetestherapie steht noch aus. Zur randomisiert-kontrollierten Untersuchung der Statin-Choice-Entscheidungshilfe liegen mehrere Publikationen mit unterschiedlichen Schwerpunktsetzungen vor. Im Vergleich zu einer Informationsbroschüre wurde die Entscheidungshilfe von den Patienten als hilfreicher gewertet und führte zu stärkerem Wissenszuwachs, reduziertem Entscheidungskonflikt und zu einem reduzierten kardiovaskulären Risiko (Weymiller et al. 2007). Patienten, die die Entscheidungshilfe genutzt hatten, schätzten ihr kardiovaskuläres Risiko mit und ohne Statineinnahme korrekter ein als Patienten in der Kontrollgruppe. Weder zum 3- noch zum 6-Monats-Follow-Up zeigten sich Effekte bezüglich der Adhärenz (Mann et al. 2010). Nannenga et al. (2009) fanden, dass die Nutzung der Entscheidungshilfe das Vertrauen in den Arzt leicht erhöhte.

Die ebenfalls randomisiert-kontrollierte Evaluation des Diabetes Mellitus Medication Choice Decision Aid (Mullan et al. 2009) zeigte, dass die Entscheidungshilfe von den Patienten als hilfreich bewertet wurde und zu mehr Wissen und einer stärkeren Beteiligung bei der Entscheidungsfindung führte als treatment as usual (TAU). Beim 6-Monats-Follow-Up war die Adhärenz in der TAU-Gruppe besser als in der Gruppe, die die Entscheidungshilfe genutzt hatte. Bezüglich des mittleren Blutzuckerwerts der letzten acht Wochen (HbA_{1c}) und des Gesundheitsstatus zeigten sich keine Unterschiede.

22.6 Barrieren bei der Umsetzung von PEF

Der kürzlich vorgelegte Entwurf für ein neues Patientenrechtegesetz, die Formulierung von Patientenorientierung als ein Qualitätsmerkmal von Krankenhäusern und Arztpraxen und die Förderung entsprechender Forschungsvorhaben durch öffentliche Geldgeber zeigen, dass bereits Schritte unternommen wurden. Dennoch ist es noch ein weiter Weg, bis PEF selbstverständlicher Teil des klinischen Alltags ist (Härter et al. 2011).

Obwohl der Einbezug von Patienten in der Diabetestherapie eine vergleichsweise lange Tradition hat, zeigen Studien nach wie vor deutliche Lücken zwischen der guten Absicht, Patienten einzubeziehen, und der tatsächlichen Patientenorientierung in der Praxis (Entwistle et al. 2008; Paterson 2001). Die Mehrzahl der Ärzte (Heisler et al. 2009) und Patienten (Hamann et al. 2007) bevorzugt PEF vor anderen Modellen der medizinischen Entscheidungsfindung. Die von Ärzten am häufigsten genannten Gründe, die der Umsetzung der PEF entgegenstehen, sind Zeitmangel sowie bestimmte Patienteneigenschaften (z. B. Präferenzen, Kompetenzen) und klinische Situationen (z. B. Notfallsituationen, keine gleichwertigen Therapieoptionen). Die von Ärzten am häufigsten genannten fördernden Bedingungen sind die eigene Motivation sowie positive Effekte auf den klinischen Prozess und das klinische Outcome (Légaré et al. 2008). Von Diabetespatienten werden als größte Barriere auf Seiten des Arztes die Kommunikationskompetenz und das Machtgefälle zwischen Arzt und Patient benannt: Es werde keine Beziehung etabliert, in der der Patient sich trauen könne, Fragen zu stellen, ehrlich Auskunft über seine Adhärenz zu geben und eine abweichende Meinung zu äußern (Peek et al. 2009). Auch Studien, in denen Gespräche aufgezeichnet und Barrieren im Fremdrating identifiziert wurden, nennen das Fehlen eines gemeinsamen Krankheitsverständnisses beider Partner als zentrales Hemmnis (Zoffman u. Kirkevold 2005 u. Zoffman u. Kirkevold 2007; Zoffman et al. 2008).

Auf Seiten des Patienten wird besonders die Gesundheitskompetenz (health literacy) als Einflussgröße diskutiert. Die Weltgesundheitsorganisation (WHO) definiert Gesundheitskompetenz als „die kognitiven und sozialen Fertigkeiten, die die Motivation und Fähigkeit […] bestimmen, Zugang zu Informationen zu erhalten und sie in einer Weise zu verstehen und zu nutzen, die gute Gesundheit fördert und erhält" (WHO 1998, S 10, eigene Übersetzung). Eine eingeschränkte Gesundheitskompetenz ist weit verbreitet (Paasche-Orlow et al. 2005) und kann sich negativ auf die PEF auswirken (Edwards et al. 2009). Neuere Ansätze der PEF tragen dem verstärkt Rechnung (McCaffery et al. 2010). Auch Patienten benennen eine geringe Gesundheitskompetenz als wichtige Barriere. Daneben nennen sie Angst und Verleugnung (z. B. die Verleugnung aversiver Konsequenzen von geringer Adhärenz) sowie fehlende Selbstwirksamkeitserwartung als Hindernisse für PEF (Peek et al. 2009).

Fazit

Mehr als bei Einmalentscheidungen im Rahmen akuter Erkrankungen spielt in der Diabetestherapie die Qualität der Patient-Behandler-Beziehung und die fortwährende Reevaluation und gegebenenfalls auch Modifikation von Behandlungsentscheidungen eine Rolle. Insbesondere aus dem englischsprachigen Raum liegen PEF-Interventionen vor, die übereinstimmend den Aufbau einer tragfähigen, vertrauensvollen Patient-Behandler-Beziehung und das Schaffen eines gemeinsamen Verständnisses der Erkrankung und der relevanten Lebenswelt des Patienten in den Mittelpunkt stellen.

In der klinischen Praxis ist PEF trotz positiver Effekte sowie Befürwortung durch Patienten und Ärzte sowie von wissenschaftlicher und gesundheitspolitischer Seite bislang kein fester Bestandteil des klinischen Alltags. Erste Schritte wurden von politischer und struktureller Seite getan, PEF und Patientenorientierung in der Diabetestherapie sind beispielsweise im Förderschwerpunkt „Chronische Krankheiten und Patientenorientierung" Gegenstand der Forschung.

Möglichkeiten, die PEF besser zu implementieren, liegen in der Aus- bzw. Weiterbildung von medizinischem Fachpersonal, in der Entwicklung konkreter, alltagstauglicher Interventionen (insbesondere Patienteninformationen, Entscheidungshilfen, Behandler- und Patientenschulungen) sowie einer stärkeren Integration in Qualitätsmanagementsysteme, wie es für den Bereich „Patientenorientierung" im Rahmen der KTQ-Zertifizierungen bereits erfolgt ist (s. www.ktq.de). Eine Herausforderung liegt dabei in der Frage, wie eine gelungene Beziehung, wie sie in diabetesspezifischen Ansätzen als zentral erachtet wird, gefördert werden kann. Zentral für die Praxis ist die Entwicklung von Entscheidungshilfen für den deutschsprachigen Raum. Ein pragmatischer Ansatz, der Entscheidungshilfen relativ zeitnah in Deutschland verfügbar machen könnte, wäre die Adaptation vorliegender Entscheidungshilfen aus den USA und Kanada. Ein erster Versuch mit einer videogestützten Entscheidungshilfe zu operativen Möglichkeiten bei Brustkrebs erbrachte hinsichtlich der Akzeptanz durch Patienten, Behandler und Gesundheitsfachleute gemischte Ergebnisse (Albrecht et al. 2011). Das Augenmerk der Forschung sollte darüber hinaus auf der Entwicklung eines einheitlichen PEF-Konzepts sowie einheitlicher Messverfahren liegen, um Forschungsergebnisse vergleichbarer zu machen.

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Publication 2

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Information and decision support needs in patients with type 2 diabetes

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Abstract

Diabetes and its sequelae cause a growing burden of morbidity and mortality. For many patients living with diabetes, the Internet is an important source of health information and support. In the course of the development of an Interactive Health Communication Application, combining evidence-based information with behavior change and decision support, we assessed the characteristics, information, and decision support needs of patients with type 2 diabetes.

The needs assessment was performed in two steps. First, we conducted semi-structured interviews with 10 patients and seven physicians. In the second step, we developed a self-assessment questionnaire based on the results of the interviews and administered it to a new and larger sample of diabetes patients (N = 178). The questionnaire comprised four main sections: (1) Internet use and Internet experience, (2) diabetes knowledge, (3) relevant decisions and decision preferences, and (4) online health information needs. Descriptive data analyses were performed.

In the questionnaire study, the patient sample was heterogeneous in terms of age, time since diagnosis, and glycemic control. (1) Most participants (61.7%) have searched the web for health information at least once. The majority (62%) of those who have used the web use it at least once per month. (2) Diabetes knowledge was scarce: Only a small percentage (1.9%) of the respondents answered all items of the knowledge questionnaire correctly. (3) The most relevant treatment decisions concerned glycemic control, oral medication, and acute complications. The most difficult treatment decision was whether to start insulin treatment. Of the respondents, 69.4 percent thought that medical decisions should be made by them and their doctor together. (4) The most important information needs concerned sequelae of diabetes, blood glucose control, and basic diabetes information.

The Internet seems to be a feasible way to reach people with type 2 diabetes. The heterogeneity of the sample, especially with respect to diabetes knowledge, makes it clear that the projected Interactive Health Communication Application should tailor the content to the individual user, taking account of individual characteristics and preferences. A wide range of topics should be covered. Special attention should be paid to the advantages and disadvantages of insulin treatment and the fears and hopes associated with it. These results were taken into account when developing the Interactive Health Communication Application that is currently being evaluated in a randomized controlled trial (International Clinical Trials Registry DRKS00003322).

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Keywords
decision support, diabetes mellitus, Internet, needs assessment, patient information

Background

Diabetes is a chronic condition with a large and growing impact on the quality of life of many people and health care costs all over the world.[1] Projections expect the prevalence to rise from 2.8 percent of the world's population in the year 2000 to 4.4 percent in 2030.[2] Type 2 diabetes accounts for 90–95 percent of diabetes cases[3] and presents a major challenge for the health care system. Patient empowerment is a key for both the individual patient and for the health care system to cope with these challenges. It is defined as

> helping patients discover and develop the inherent capacity to be responsible for one's own life. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of their decisions. (p. 38)[4]

This makes it clear that health information is one necessary part of empowerment.[5] Patients need to be informed about their disease, its potential course, and the treatment options at hand, including their advantages and disadvantages.[6] Consequently, diabetes education has long been recognized as a cornerstone of diabetes management and implemented in the Standards of Medical Care.[7] However, due to limited resources in health care, large numbers of patients still do not have access to feasible diabetes education.[8,9] The Internet can be an important complementary source for health information and support for people living with diabetes. Wagner et al.[10] found that 52 percent of diabetes patients search the Internet for health information. The information they find influence treatment decisions, coping, health behavior, and decisions on whether a health professional is consulted or not.[11] Trials of systematically developed online health interventions for chronic diseases show small but consistent effects on clinical outcomes[12–15] even in older populations who are generally thought to be less inclined to use the web.[16] However, the correctness, usefulness, and readability of online health information vary greatly.[17–19] Systematic website development might lead to improved quality.[20]

In an ongoing project,[21] we are developing an Interactive Health Communication Application (IHCA) for patients with type 2 diabetes. IHCAs are "computer-based, usually web-based, information packages for patients that combine health information with at least one of social support, decision support, or behaviour change support" (p. 1).[22] They were found to have positive effects on knowledge, social support, clinical, and behavioral outcomes.[22] Needs assessments are a crucial step in the participatory planning of such health interventions[20,23] and a systematic method for identifying and prioritizing the needs of a defined target population.[24] In this study, information and decision support needs of patients with type 2 diabetes in Germany are assessed in order to inform the development of an IHCA offering information and decision support. To our knowledge, this is the first German study researching this target group with a focus on the Internet as a source for diabetes information. Existing studies on Internet use by patients with type 2 diabetes mostly describe US populations; the most comprehensive and recent surveys have been provided by the Pew Research Center.[11,25] Pew reports that people living with a chronic condition in the United States have Internet access significantly less frequently than people with no chronic condition (72% vs 89%). If they do, however, the information they find online has major impact on the treatment decisions they make, whether they see a doctor or not, whether they ask their doctor new questions or get a second opinion, and the way they cope with and manage their condition.[26] Looking at diabetes specifically, there were significant differences between people living with and without diabetes (but potentially another chronic condition) with respect to the topics they looked up online: People with diabetes looked more often for information on a drug they had seen advertised or on medical test results, while they looked less for information on pregnancy and childbirth.[25]

Methods

The process was led by published guidelines to needs assessments in health care.[23,24] The needs assessment was performed in two steps: First, we conducted semi-structured interviews with physicians and patients in order to explore the perspectives and preferences of both groups. In the second step, we developed a self-assessment questionnaire based on the main results of the interviews and administered it to a new and larger patient sample. This two-step procedure was chosen for two reasons: First, qualitative interviews are a good method to explore a field, leaving the interviewees the freedom to bring up topics of their own. Data quality is enhanced if different sources (patients and physicians) are included.[27] Second, by developing the questionnaire from qualitative data obtained from the interviews, we aimed to develop an instrument covering all relevant topics and assessing quantitative data that can serve as a basis for the projected IHCA. The study was approved by the Ethics Committee of the Medical Council of Hamburg (Process number: PV3412).

Preliminary qualitative interviews and questionnaire development

The aim of the interviews was to gain insight into the views of patients with type 2 diabetes and their physicians on information needs, sources used for diabetes information, medical decisions in the management of type 2 diabetes, and the role of the Internet in the search for health information and support. The interviews were semi-structured one-hour face-to-face interviews conducted by two doctoral medical students. In order to leave room for all topics relevant to the interviewees, open-ended questions were used and interviewees were invited to introduce issues that were not originally covered by the interviews. Table 1 displays the questions posed by the interviewers. The interviews were recorded and transcribed.

Interviewees were a convenience sample recruited from the diabetes polyclinic of the University Hospital Hamburg-Eppendorf and pre-existing cooperation with practices. For the analysis, we used conventional content analysis[28] or inductive category development.[29] In a first step, we read the transcripts of the interviews. We developed response categories for each question. In a next step, we counted the number of responses that fell into each category. Each category that was mentioned by more than one interviewee was transformed into an item or response option in the questionnaire study.

Patient interview results. In total, 10 patients were interviewed. They were mostly male (9 out of 10 patients), had a mean age of 62 years (range: 48–83 years), and covered the whole educational range from 9 years of schooling to a university degree (3 patients, respectively). On the average, they had been diagnosed with diabetes 8.6 years ago (range: 3–22 years). The treatment the respondents received following diagnosis ranged from insulin treatment (2 respondents) to the recommendation to change their diet (2 respondents). Only one interviewee reported having received a structured diabetes education and extensive counseling on diabetes right after the diagnosis. At the time of the interview, six respondents received insulin treatment, and nine were on

Table 1. Interview with physicians and patients.

Interview section	Topics and questions (examples): physicians	Interview section	Topics and questions (examples): patients
Assessment of demographic and professional data	How many patients with type 2 diabetes do you treat per week?	Assessment of demographic and disease-related data	Duration of disease
Areas of concern and information needs of patients with type 2 diabetes	What are information needs regarding the following areas? ▪ Diagnosis ▪ Treatment: ○ Basic therapy (sport, weight, beverages, nutrition) ○ Drug therapy (oral antidiabetics, insulin) ○ Complications and sequelae (diabetic retinopathy, diabetic foot, diabetic nephropathy)	Questions on diabetes information needs	Where have you received information about your diabetes previously?
Participation of patients with type 2 diabetes in medical decisions	What role do you have as a physician in the decision-making process?	Questions on relevant treatment decisions	What kind of medical decisions have you made/will you have to make concerning your type 2 diabetes?
Questions on the planned IHCA	How could a website improve knowledge and decision-making for patients concerning their illness/treatment options?	Questions on Internet use when searching for diabetes information	Do you use the Internet to search for information about diabetes and its treatment?
Questions on diabetes education	Do you think complementary programs in addition to diabetes education are necessary? What kind of information do patients need that are not part of diabetes education?	Additional information	Your suggestions regarding the projected IHCA

IHCA: Interactive Health Communication Application.

oral medication. One respondent received no medication at all. The participants' current A1C was 6.9 at mean, ranging from 5.5 to 8.3.

For most patients, their physician is the most important source of information and support. All interviewed patients use complementary sources of information (press, pharmacist, Internet, friends with diabetes, television (TV)) if they do not understand, agree with, or are not satisfied with the information provided by their physician. Patients reported that the most difficult decision in diabetes treatment is whether to start insulin treatment or not. Reasons why this decision was regarded as especially difficult were fear (of weight gain, of reduced life expectancy, of stigmatization, of not being "normal" any more, of depending on insulin shots for the rest of one's life), the subjective feeling of not being ill, and not understanding the information provided. Seven patients felt that their physicians made this treatment decision for them. Two said their physicians had provided them with information and advice so they could make the decision. One said the decision had been shared between him and his physician. Accordingly, seven patients reported not having been informed about treatment alternatives when deciding on insulin treatment. Three said oral antidiabetics, different kinds of insulin, or combining insulin and oral antidiabetics had been presented to them as an alternative. All patients said they would generally like to share decisions with their physicians, and to be able to do this, they needed more recent and understandable information on diabetes, on treatment options, and their risks and benefits. Patients desire the projected IHCA to provide sophisticated and correct, understandable, and individual education.

Physician interview results. Of the seven physicians interviewed, three were female. They were 60 years old at mean. All were internists; two of them had specialized in diabetology. One worked as a general practitioner. Five had their own practice, and two worked in a diabetes polyclinic in the University Hospital Hamburg-Eppendorf.

The physicians agreed with the patients that the most difficult decision in diabetes treatment is whether to start insulin treatment or not. Perceived reasons for the difficulty were that patients were overstrained by the amount of information given to them on insulin therapy, that they were not sufficiently motivated for the lifestyle changes that should accompany insulin treatment, and that patients got wrong information from the pharmaceutical industry. As remedies they suggested independent, profound, understandable patient information; individual patient education; and making it clear to patients that they are responsible for a good part of their diabetes management.

The physicians also agreed with the patients that they mostly made the treatment decisions for them. Physicians said this was necessary due to lacking and misleading information on the patients' side. Consequently, they suggested informing patients about insulin treatment, especially the aspects that frighten patients, and generally fostering health literacy (HL) as steps toward more patient-centered decision-making. While patients feel uncomfortable with the amount of responsibility given to them by their physicians for their disease and its treatment, the physicians would like their patients to take more responsibility. Like the patients, the physicians too desire the projected IHCA to provide sophisticated and correct, understandable, and individually tailored education and so disburden the consultation.

Questionnaire study

Data collection. The questionnaire study aimed at quantifying the patients' perspective and identifying relevant content for the projected IHCA. Items on diabetes knowledge were added in order to become acquainted with the target group. The resulting questionnaire comprised four main sections: (1) Internet use and Internet experience, (2) diabetes knowledge, (3) relevant decisions and decision preferences, and (4) online health information needs.

In contrast to the interviews, closed-ended questions offering between 2 and 10 response options were used. Where feasible, multiple responses were possible. Internet use was assessed using the following questions: Have you ever searched for diabetes information on the Internet (yes/no format)? When was the last time (<3 months, 3–12 months, >12 months)? How often have you searched the Internet for diabetes information during the last 3 months (5 response options ranging from "(almost) daily" to "never")? Why did you decide to use the Internet (4 options including the option for a free answer)? Which kind of diabetes information have you looked for (10 options including the option for a free answer)? Participants were then asked to evaluate the usefulness of their online searches using 13 items (e.g. "The diabetes information on the Internet was credible.")

on a 5-point Likert scale. Diabetes knowledge was measured with six true/false items assessing knowledge on fasting blood sugar, A1C, insulin treatment, diet, sequelae, and hypoglycemia. With respect to decision-making and information needs, a scale adapted from Man-Son-Hing et al.[30] assessed the extent to which a participant wishes to participate in medical decision-making. Relevant decisions were identified asking in which of seven decision areas (e.g. oral antidiabetics) a treatment decision had to be made during the last 2 years (yes/no response format). Finally, participants were asked to rate the importance of 14 topics on a diabetes website using a 4-point scale ranging from 1 (very important) to 4 (very unimportant).

In addition, participant characteristics such as demographics and HL were assessed. HL as defined by Ishikawa et al.[31] is "the capacity of individuals to access, understand, and use health information to make informed and appropriate health-related decisions" (p. 874). The authors developed an instrument (HL Scales) measuring the three subscales functional HL, communicative HL, and critical HL in patients with type 2 diabetes. A total HL score can be formed. The subdomains are defined as follows:[32] Functional or basic HL means having "sufficient basic skills in reading and writing to be able to function effectively in everyday situations" (p. 263). Communicative or interactive HL comprises "more advanced cognitive and literacy skills which, together with social skills, can be used to actively participate in everyday activities, to extract information and derive meaning from different forms of communication, and to apply new information to changing circumstances" (pp. 263f.). Critical HL is defined as "more advanced cognitive skills which, together with social skills, can be applied to critically analyze information, and to use this information to exert greater control over life events and situations" (p. 264). There is no suggested hierarchy or structure among the three subscales. The instrument contains five items for functional and communicative HL, respectively, and four items for critical HL. Each item is rated on a 4-point scale. Construct validity and internal consistency of the three scales (functional HL: $\alpha = 0.84$, communicative HL: $\alpha = 0.77$, critical HL: $\alpha = 0.65$) are satisfactory.[31] The questionnaire was available in a paper-and-pencil format and an online format using QuestBack Survey Software.[33] Patients could choose which format they preferred to answer.

Participants. The patient sample for the questionnaire study was again recruited via the pathways described above. In addition, we searched the Internet for diabetes self-help groups. To those groups that had an email address on the website, we mailed a request for cooperation, a link to the online questionnaire, and the offer to provide paper-and-pencil questionnaires. We asked relevant German diabetes self-help associations, for example, Deutscher Diabetiker Bund (DDB) and diabeteDE, whether they were willing to place a short invitation and the link to our online questionnaire on their websites.

Data analysis. Descriptive data analysis (M, standard deviation (SD), min/max, %) and Pearson's correlations were performed using PASW Statistics 18 (SPSS Inc., Chicago, IL, USA).

Results

Sample characteristics

In total, 178 patients with type 2 diabetes completed the questionnaire. The sample characteristics are displayed in Table 2. Of the participants, 41 percent were treated with insulin, 52.7 percent were on oral medication, 18.2 percent combined both, and 5.5 percent reported taking neither insulin nor oral medication. The overall HL was fairly good (M = 2.8, SD = 0.4), and the sample was quite heterogeneous with HL scores ranging from 1.6 to the maximum score of 4. The scores on all

Table 2. Sample characteristics.

Variables	
n	178
Sex	
Female	44%
Male	56%
Mean age	62 years Min: 36 years; Max: 86 years (SD: 10.8 years)
Family status	
Single	12.3%
Married	63.8%
Divorced/widowed	23.8%
Working status	
Working	29.7%
Retired	60.2%
Mean duration since diagnosis	11.8 years Min: 0 years; Max: 40 years (SD: 10.1 years)
HbA1c	
Tight control (≤6.5%)	24.4%
Fair control (6.6%–7.9%)	58.5%
Poor control (≥8%)	17.1%

three subscales ranged from 1.0 to 4.0, covering the whole range of possible scores. Communicative HL had was highest (M = 3.2, SD = 0.6), followed by critical (M = 2.9, SD = 0.7) and functional HL (M = 2.4, SD = 0.7).

Internet use

Of the participants, 61.7 percent reported having looked for health information online. Of the respondents who reported never having looked for health information online, 35.1 percent said they did not have Internet access, 31.5 percent said they preferred asking their doctor for information on health and diseases, 15.8 percent said they were not used to using the Internet, and 8.8 percent reported having no trust in the Internet as a source for this kind of information. Of the respondents who reported having looked for health information online, 68.5 percent had performed their last search less than 3 months ago. The majority of respondents (62%) said they searched the web for diabetes information at least once a month. A significant proportion of respondents reported some difficulties with online search: 48.5 percent judged the information they found to be of low quality, 32.4 percent found it not credible, 25.8 percent said the information was too extensive, and 47.9 percent reported difficulties of comprehension (see Figure 1). When asked for the reasons why they used the web for diabetes information, 28.2 percent said the information they received from their physicians was not sufficient and 11.7 percent said that the information they received from their physicians was too hard to understand or that they did not agree with them. The most frequently searched topics were general information on diabetes, diet and exercise (42.7%, respectively), treatment options (39.8%), sequelae (34%), self-help groups and patient forums (32%), risks and side effects of specific treatment options (30.1%), and acute complications (24.3%).

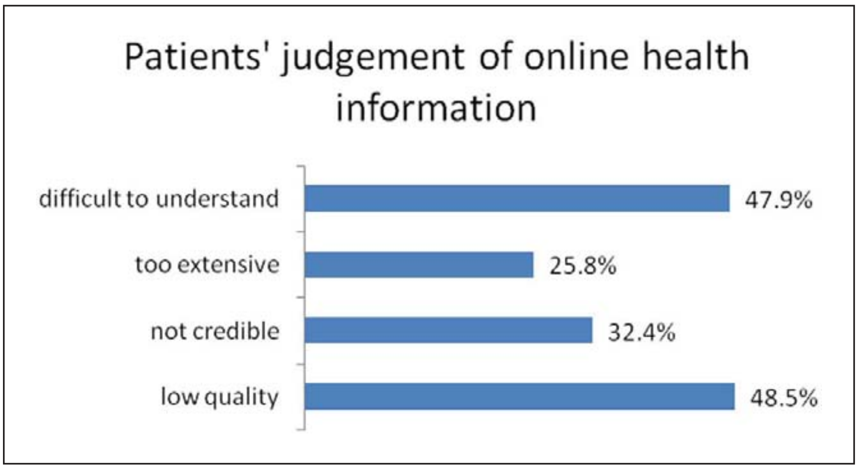

Figure 1. How do you evaluate the health information you found online?

Diabetes knowledge

Only two (1.9%) of the respondents answered all six items assessing diabetes knowledge correctly. One respondent (1%) had only one correct answer. Especially difficult was the item asking for the optimal fasting blood glucose (answered correctly by 9.2%), while "A healthy diabetes diet is …" was the easiest item (answered correctly by 95.8%).

Decision-making needs

Most respondents thought that medical decisions should be made by them and their doctor together (69.4%, see Figure 2). Among the most frequent treatment decisions respondents and their doctors made during the last 2 years were decisions concerning glycemic control (68%), oral medication (56.7%), acute complications (48.4%), health behavior changes (46.2%), insulin treatment (44.2%), and treatment of sequelae (35.5%, see Figure 3).

Health information needs

Almost every topic that was offered in the questionnaire was rated "very important" by more than half of the interviewees. The topic that was considered very important by the biggest proportion of participants was sequelae of diabetes, followed by blood glucose control, basic information on diabetes, effectiveness of treatment options, and risks and side effects of treatment options. The topic that was considered least important was combination therapy (see Figure 4).

Subgroup analysis

Since the prevalence of type 2 diabetes increases with age, while international and German studies found that Internet use declines with age,[34–36] we examined whether Internet use and satisfaction with Internet use are correlated with age in this sample. Another relevant moderator could be HL. It has been reported that reading levels of online patient materials are often too high for the average user,[37] which might lead to lower Internet use in people with lower HL.[38]

Age, Internet use, and satisfaction with Internet use. For further descriptive analysis, we split the sample into three age groups (<55 years, 55–69 years, ≥70 years). In total, 54 participants (30.3%)

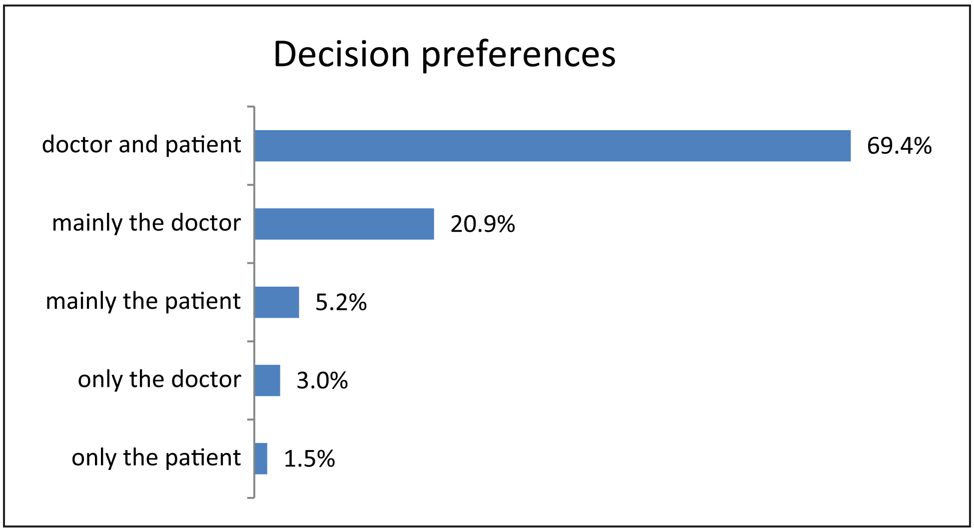

Figure 2. Who should generally make medical decisions regarding your condition?

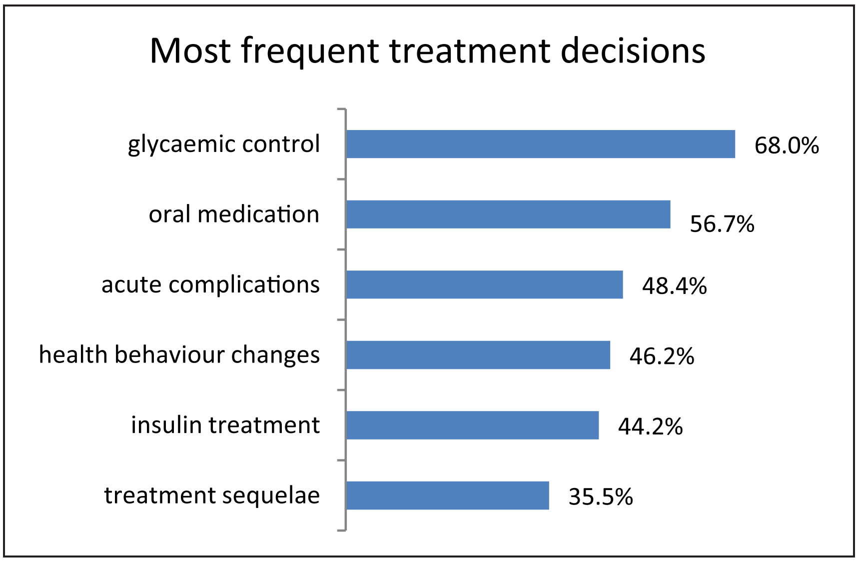

Figure 3. Did you or your doctor have to make a decision on the following options?

were younger than 55 years, 27 (15.2%) were aged between 55 and 69 years, and 31 (17.4%) were aged 70 years or older. And 66 participants (37.1%) did not report their age. Looking at frequency of Internet use in these three groups, we found that 55.1 percent of the youngest group had ever searched for diabetes information online, 57.7 percent of the group between 55 and 69 years, and 40.9 percent of the oldest group. The fact that these numbers are all lower than the overall Internet adoption in our sample (61.7%) suggests that there are systematic missings.

There was no significant correlation ($r = -1.4$, $p = 0.16$) between age and Internet adoption ("Have you ever looked for diabetes information online?"). Pearson's correlation between age and satisfaction with Internet use ("How was the overall usefulness of your online search for diabetes information?") was also not significant ($r = -0.06$, $p = 0.64$).

HL, Internet use, and satisfaction with Internet use. For further descriptive analysis, we split the sample into two groups (median split: $HL \leq 2.8$, $HL > 2.8$). In all, 68 participants (38.2%) had an

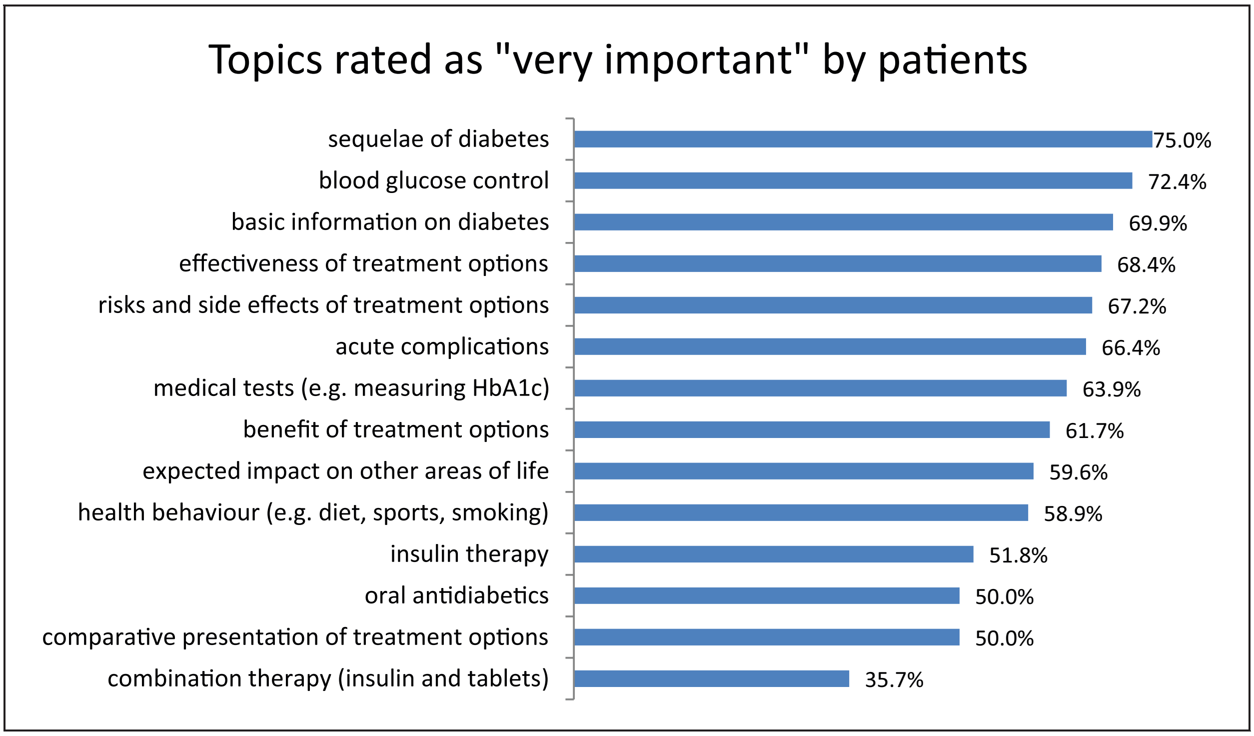

Figure 4. How important are the following topics for you on a diabetes website?

overall HL of 2.8 or lower and 72 participants (40.4%) had a HL higher than 2.8. The HL score was missing for 38 participants (21.3%). Looking at frequency of Internet use in these two groups, we found that 55.7% of the lower HL group and 57.8% of the higher HL group had ever searched for diabetes information online. Again, the fact that these numbers are all lower than the overall Internet adoption in our sample (61.7%) suggests that there are systematic missings.

There was no significant correlation ($r = -0.01$, $p = 0.25$) between overall HL and Internet use. HL and satisfaction with Internet use were negatively and significantly correlated ($r = -0.24$, $p = 0.03$).

Discussion

This study is the first needs assessment among patients with type 2 diabetes in Germany, focusing on the Internet as a source for diabetes information. In order to develop an IHCA that meets the specific needs of patients with type 2 diabetes, we undertook a cross-sectional assessment in two steps, conducting interviews with patients and physicians and deepening our understanding of the patients' view in a questionnaire study.

The majority of participants have used the web when searching for health information. Of these, the majority performs diabetes-related searches at least once a month on a wide variety of topics. Still, the Internet adoption rate of 61.7 percent found in our sample is relatively small compared to the German general population: A 2013 representative survey of Internet adoption found that 77.2 percent of the population aged 18 years and older used the web.[36] This difference might be due to the fact that we did not ask for Internet adoption itself but for searching the Internet for health information. It is possible that some participants do use the web but not for health purposes. As an orientation, the Pew Internet & American Life Project found that 86 percent of the chronically ill who do use the web at all also use it for health purposes. The authors also report that less people living with a chronic condition go online (51%) than do those without a chronic condition (74%)

in the United States and that this is due to higher age and lower educational status in the chronically ill subgroup, as well as to being chronically ill itself.[26] These factors might also contribute to the low Internet adoption rate in our sample compared to the general population.

Looking at the older age groups, we found higher adoption rates in our sample than in the general population. Even though the increase in Internet adoption over the last years is mostly due to the age group over 50 years, older Germans still are not avid Internet users: while 82.7 percent of those between 50 and 59 years of age reported being online, only 42.9 percent of those aged 60 years or older and 30.4 percent of those over 70 years of age have ever used the web.[36] In our sample, 40.9 percent of those over 70 years of age have searched the web for diabetes information. This gap might be due to a bias in our sample: It is possible that those who are willing and interested in taking part in a scientific study are also more interested in new technologies. This might also explain why we, in contrast to prior national and international studies,[34–36] did not find a significant correlation between age and Internet use or age and satisfaction with Internet use.

Neither did we find a correlation between HL and Internet adoption, even though the literature suggests that reading levels of online health information are often too high for users with lower HL.[39–41] As Schulz and Nakamoto[42] suggest in their recent article, lower HL might not lead to less Internet use but to more misunderstandings and dangers related to wrong or biased information found online. This concern was also uttered by the physicians in our interviews. Schulz and Nakamoto claim that patients, especially those with lower HL, need guidance from their health professionals when using the Internet for health purposes. Our finding that HL is negatively correlated with satisfaction with Internet use might thus reflect the capability of more health-literate patients to critically reflect on the information they find. Further research should explore Internet adoption as well as use and understanding of health information found online in patients with different levels of HL.

In summary, the Internet can be regarded as a feasible supplementary medium to provide patients with type 2 diabetes in Germany with information and support, but its low adoption rate emphasizes the need to maintain traditional sources of information. In our sample, both patients and physicians would welcome the development of evidence-based, readable online diabetes information. The wide range of diabetes knowledge found in the sample should be addressed by the IHCA. Both patients and physicians said that not understanding the information provided or a lack of knowledge is among the most important reasons why medical decisions are difficult to make. Knowledge gaps result in anxiety (in some cases, even unnecessary fears like being afraid of a loss-of-life expectancy if starting insulin treatment) and helplessness on the patients' side. The most important topics when it comes to information needs and treatment decisions are basic diabetes information, lifestyle topics, treatment options, sequelae, and self-help. These content areas should be covered by the IHCA. While the questionnaire study shows that starting insulin treatment is not among the most frequent decisions that patients with type 2 diabetes have to make, it was pointed out as the hardest decision by patients and physicians in the interviews. The decision on insulin treatment should, therefore, receive special attention.

The vast majority of respondents wish to share the decision with their physicians. Both patients and physicians state that this is not yet reality: usually the physicians make decisions. This finding corresponds to the literature.[43,44] In our study, knowledge gaps and communication problems (too little time, information not understandable) between patient and physician are named as the main reasons why decisions are not shared. This, too, corresponds to findings reported in the literature. Time pressure and communication problems like the absence of a shared understanding of the disease are named as key impediments to shared decision-making on the physicians' side, while low HL, fear, and denial are barriers on the patients' side.[45–48]

Throughout the IHCA, patients should be encouraged to share the information and support they received from the IHCA with their physician and use the IHCA as a preparation for consultations and shared decision-making.

There are some limitations to the work presented. Since we worked with convenience samples, we cannot know whether the results of our needs assessment are representative for the population of people with type 2 diabetes in Germany. When compared to data from other studies,[49–51] we found similar results with respect to age, gender, treatment, and glycemic control. To our knowledge, there are no data available on HL, health locus of control, or diabetes knowledge of people with type 2 diabetes in Germany. Additionally, it might have broadened our perspective if we had interviewed not only patients and physicians but also caregivers of diabetes patients and diabetes educators. With regard to the target group of the IHCA, we also could have included caregivers who are even more actively searching the web for health information than the patients themselves.[11,52] Moreover, the measurements we used were only partly standardized and partly developed or adapted for our purposes. Strengths of the study are the inclusion of qualitative and quantitative data from two sources (patients and physicians) as well as the broad range of data assessed.

Sample characteristics as well as the concerns expressed by the patients and physicians in this study are consistent with findings in the international literature. This confirms that the data obtained are a valid base for the development of an IHCA. Needs regarding content and structure could clearly be identified. Within a randomized controlled trial, we are currently evaluating the IHCA we developed based on the needs assessment.

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Quality of online information on type 2 diabetes: a cross-sectional study

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SUMMARY

Evidence-based health information is a prerequisite for patients with type 2 diabetes to engage in self-management and to make informed medical decisions. The Internet is an important source of health information. In the present study, we systematically assessed formal quality, quality of decision support and usability of German and English language websites on type 2 diabetes. The search term 'type 2 diabetes' was entered in the two most popular search engines. Descriptive data on website quality are presented. Additionally, associations between website quality and affiliation (commercial vs. non-commercial), presence of the HON code quality seal and website traffic were explored. Forty-six websites were included. Most websites provided basic information necessary for decision-making, while only one website also provided decision support. Websites with a HON code had significantly better formal quality than websites without HON code. We found a highly significant correlation between usability and website traffic and a significant correlation between formal quality and website traffic. Most websites do not provide sufficient information to support patients in medical decision-making. Our finding that usability and website traffic are tightly associated is consistent with previous research indicating that design is the most important cue for users assessing website credibility.

Key words: diabetes; health information; internet; medical decision-making

PRIMARY OBJECTIVES

Diabetes and its sequelae are a major and still growing cause of morbidity and mortality in many countries. In the last three decades, the number of people living with diabetes more than doubled (Danaei *et al.*, 2011). In the year 2000, it was estimated that 2.8% of the world's population live with diabetes. Projections for the year 2030 expect the prevalence to rise to 4.4% (Wild *et al.*, 2004). Type 2 diabetes accounts for 90–95% of diabetes cases (American Diabetes Association, 2012).

Patients, practitioners, scientists and politicians have called for more patient involvement in the making of medical decisions as well as in the management of their diseases in order to reduce the burden on patients and society. Patient involvement in diabetes management (especially in watching one's diet and exercising regularly) was shown to reduce fasting blood glucose levels, A1C and the need for diabetes medication (Deakin *et al.*, 2005). Two main aspects of patient involvement are self-management and shared decision-making (SDM). Self-management means that the patient successfully copes with the challenges of living with and treating diabetes. This may involve that the patient autonomously sets goals, identifies barriers and challenges and monitors his or her health (Wagner *et al.*, 1996, 2001). SDM means '(1) that at least two participants—physician and patient be involved; (2) that both parties share information; (3) that both parties take steps to build a consensus about the preferred treatment; and (4) that an agreement is reached on the treatment to implement' (Charles *et al.*, 1997). Both for SDM and for self-management patients need to be informed about their disease, its course and the treatment options at hand, including their advantages and disadvantages.

In times of rapidly growing Internet adoption and limited resources in the health care system, many patients turn to the World Wide Web in search for diabetes information: The Pew Internet and American Life Project found that 51% of people living with one or more chronic conditions search the Internet for health information (Fox and Purcell, 2010). Similarly, Wagner and colleagues (Wagner *et al.*, 2004) found that 52% of patients with diabetes used the Internet for health information. For the chronically ill, the Internet offers the opportunity to gather health information at their own pace and become experts of their disease (Kerr *et al.*, 2006). According to Shuyler and Knight (Shuyler and Knight, 2003), most visitors search websites for information about a condition, treatment or symptoms, or for advice about symptoms or treatment. According to Fox and Duggan (Fox and Duggan, 2013), the self-management topic that is searched most by people living with diabetes is weight loss/weight control. Topics that people with diabetes search significantly more often than people with no diabetes are information about drugs they saw advertised and medical test results. The information they find online have an impact on coping, health behaviour, decisions on whether a health professional is consulted or not, and choice of treatment and provider (Wagner *et al.*, 2004; Fox and Purcell, 2010).

However, the correctness, usefulness and readability of online health information vary greatly (Eysenbach *et al.*, 2002; Scullard *et al.*, 2010; Patel and Cobourne, 2011; Buultjens *et al.*, 2012). Only a minority of websites offer enough information to support patients in medical decision-making (Smart and Burling, 2001). For users, it can be difficult to distinguish high-quality from low-quality online health information: In a study by Eysenbach and Köhler (Eysenbach and Köhler, 2002), participants claimed that the source, a professional design, a scientific or official touch, the language used and ease of use were the main criteria when assessing the credibility of a website. When these participants were observed while searching the web for health information, they did not check the source of the information. These findings are consistent with other studies reporting that design/look are the most important clues for users when assessing website credibility and quality (Stanford *et al.*, 2002; Sillence *et al.*, 2007).

The latest evaluations of the quality and content of online patient information on diabetes date from the mid-2000s (Thakurdesai *et al.*, 2004; Bull *et al.*, 2005; van Esch *et al.*, 2006). Two recent studies researched diabetes online social networks and also found variable quality (Greene *et al.*, 2011; Weitzman *et al.*, 2011). To our knowledge, there is no current study systematically assessing the quality of online patient information on type 2 diabetes in Germany, and there is no study assessing the content quality of web-based information on type 2 diabetes with a focus on the information needed for informed medical decision-making. Therefore, in our cross-sectional study, we aimed to systematically assess formal quality, quality of decision support and usability of web-based information on type 2 diabetes, using a set of instruments based on previously published work researching quality of online information (Abbott, 2000; Griffiths and Christensen, 2000; Khazaal, 2008a, b). We further explore whether website quality is associated with website affiliation, presence of HON code, a quality seal for health websites and higher website traffic. We hope that our work can make a small contribution to the elaboration and implementation of core criteria for online patient information. There are labels, codes and criteria that overlap in many aspects. Still, we believe that most patients or even health care professionals are not familiar with them, and that the transfer from science to practice is still in its infancy.

RESEARCH DESIGN

In January 2012, we systematically searched for English and German language online information on type 2 diabetes. Rating of websites was performed between February and December 2012. The present study thus is a cross-sectional study reflecting the situation in 2012.

Methods and procedures

We were interested in a sample that is representative for what the average user finds when performing an online search for diabetes information. Consequently, we aimed at evaluating websites across types (commercial, not-for-profit organization, government, etc.) that are accessible by anyone with Internet access.

The two most popular search engines of the year 2012 were determined using alexa.com which is, by the provider's own admission, 'the leading provider of free, global web metrics' (www.alexa.com). What we know about how 'most popular' is operationalized by alexa.com is the following: 'The global traffic rank is a measure of how a website is doing relative to all other sites on the web over the past 3 months. The rank is calculated using a combination of the estimated average daily unique visitors to the site and the estimated number of pageviews on the site over the past 3 months. The site with the highest combination of unique visitors and pageviews is ranked #1.' (http://www.alexa.com/help/traffic-learn-more). In the 'top sites' tab, the top 500 sites on the web are displayed. The first two search engines that are on the list are www.google.com (#1) and yahoo.com (#4).

The search term 'type 2 diabetes' was entered in English and German language in Google.de (German)/Google.com (English), and Yahoo.de (German)/Yahoo.com (English). Our goal was to imitate searches performed by lay users looking for health information. For this reason, each search engine was searched only once. All searches were conducted by the same person who was based in Germany. The search was conducted with the single search term 'type 2 diabetes' because according to Eysenbach and Köhler (Eysenbach and Köhler, 2002), 65% of the searches performed by users looking for health information consist of only one phrase. The same authors report that users primarily search among the first 20 hits of a keyword search. In order to imitate this user behaviour, we included the first 20 hits from each search engine. Hits that contained no information on type 2 diabetes, that were accessible only via login or requiring user fees, that were not accessible due to other (e.g., technical) reasons, that were duplicates of websites we had already included or that were not websites but YouTube videos, links, books, articles or online forums were excluded from the sample. Website affiliations were divided into seven categories: nonprofit organization, commercial, governmental, university, private, insurance company and other according to the declaration of affiliation. If no affiliation was declared, we performed a WHOIS request on www.denic.de for German websites and on http://domains.whois.com/ for English websites. A WHOIS search provides information regarding a domain name, such as domain ownership, where and when registered, expiration date and the nameservers assigned to the domain. The information on domain ownership helped us determine the website's affiliation. In order to find out how much traffic each website has, we assessed the rank of the included websites on www.alexa.com.

Measures

Given the lack of a standard instrument or procedure that is applied for the evaluation of health websites, we turned to the literature and found that over the years a core set of quality criteria has been established: Around the turn of the century, three articles were published reviewing the quality criteria that had been applied in the literature on quality of health web sites so far. All three reviews state that page aesthetics/design/ease of use and content/currency and accuracy of information are major quality domains that are usually evaluated. There is also agreement that disclosure of authorship/sponsors are key criteria. These three quality domains are also repeatedly found in later publications on the quality of health websites, including a core set of criteria operationalizing them (Pealer and Dorman, 1997; Silberg *et al.*, 1997; Kim *et al.*, 1999; Abbott, 2000; Griffiths and Christensen, 2000; Eysenbach *et al.*, 2002; Kisely *et al.*, 2003; Murphy *et al.*, 2004; Khazaal, 2008a, b). We reviewed this body of literature, extracted the core criteria and erased duplications. Additionally, the DISCERN instrument (www.discern.org.uk, 2012), the International Patient Decision Aid Standards Patient Decision Aid Checklist for Users (IPDAS, 2005) and the German Action forum for health information systems (Aktionsforum Gesundheitsinformation ssystem (Afgis), 2012) were used as sources.

The DISCERN Project was originally funded by The British Library and the NHS Executive Research & Development Program. The DISCERN instrument can be used by consumers or producers of information on treatment choices. The International Patient Decision Aid Standards (IPDAS) Collaboration is an international group of researchers, practitioners and stakeholders aiming to establish an international standard for the evaluation of patient decision aids. The IPDAS Patient Decision Aid Checklist for Users is a summary of these standards. Afgis is a network that was originally funded by the German Federal Ministry of Health aiming at improving and assuring quality of health information. There is considerable overlap between these publications and instruments so we extracted a list of core criteria. Table 1 shows the

Table 1: Quality criteria (all except the one string variable are coded as present (1) or absent (0))

Formal quality (fq) (Silberg *et al.*, 1997; Griffiths and Christensen, 2000; Murphy *et al.*, 2004; Khazaal, 2008a, b; Afgis, 2012; IPDAS, 2005; DISCERN, 2012)	Usability (u) (Abbott, 2000; Kisely *et al.*, 2003; Khazaal, 2008a, b; Afgis, 2012)	Quality of decision support (qds) (DISCERN, 2012; IPDAS, 2005)
(1) Authors are identified	(1) Document has a distinguishable header, body and footer	(1) Does the website describe the health condition?
(2) Affiliations are identified	(2) Presence of headings or subheadings	(2) Does it describe the procedures relevant for decision-making?
(3) Credentials are identified	(3) Major headings and subheadings are easily identifiable	(3) Does it describe the treatment options?
(4) Co-operations are identified	(4) Presence of diagrams	(4) Does it include the option of doing nothing?
(5) Declaration of conflicts of interest	(5) Presence of hyperlinks to external sites	(5) Does it describe how each treatment works?
(6) Ownership of the site is disclosed	(6) Absence of advertising	(6) Does it describe the benefits of each treatment?
(7) Sponsoring is disclosed	(7) If there is advertising, it is not placed within the body of the text	(7) Does it describe the risks of each treatment?
(8) If there is advertising, it is disclosed	(8) Presence of a within site search engine	(8) Does it include the chances of the risks and benefits?
(9) Sources are mentioned	(9) Audio or video support	(9) Does it provide probabilities of outcomes in an unbiased and understandable way? (a) Does it use event rates specifying the population and time period? (b) Does it compare outcome probabilities using the same denominator, time period, scale? (c) Does it use diagrams? (d) Does it use multiple methods to view probabilities (words, numbers, diagrams)? (e) Does it allow the patient to select a way of viewing probabilities? (f) Does it allow the patient to view probabilities based on their own situation? (g) Does it place probabilities in the context of other events? (h) Does it use both positive and negative frames (e.g. showing both death and survival rates)?
(10) References/links are provided	(10) Supporting bodies (forums and discussion rooms)	(10) Does it describe what would happen if no treatment is used (natural course of the condition)?
(11) Relevant copyright information is noted	(11) Opportunity to send queries to the webmaster or authors	(11) Does it provide support for shared decision-making? (a) If decision aids are provided: Which ones? (string variable)
(12) Date of the creation and latest modification of the site has been specified	(12) Satisfaction and knowledge evaluation questionnaires for users	
(13) Site has been modified in the past month and year		
(14) Date of the next update of the site has been specified		
(15) Statement declaring that information provided on the site is meant to complement and not replace any advice or information from a health professional is clearly provided		
(16) Patients were involved in website development		
(17) Development of the website is described		
(18) Quality of scientific evidence is explained		
(19) Information on self-help and support is provided		
(20) Aims of the website are clear		

quality criteria that were applied. They can be subsumed under the three quality domains formal quality criteria, usability and quality of decision support. In the following paragraphs, the contributions of all relevant sources are discussed by table column/quality domain. Items will be named according to quality domain (fq, formal quality; u, usability; qds, quality of decision support) and numeration as displayed in Table 1. For example, the first item in the column 'formal quality', 'authors are identified', will be named 'fq1'.

Formal quality

Silberg *et al.* (Silberg *et al.*, 1997) contributed to items fq1–4 and fq6–12. Kim *et al.* (Kim *et al.*, 1999) contributed to Griffiths and Christensen (Griffiths and Christensen, 2000) contributed to fq1–3,fq6–7, fq9–10 and fq12–13. Murphy *et al.* (Murphy *et al.*, 2004) contributed to items fq1–4 and fq6–12. Khazaal (Khazaal, 2008a,b) contributed to fq1–4, fq6–10 and fq12. Afgis (Afgis, 2012) contributed to fq7, fq9–10 and fq12. IPDAS (IPDAS, 2005) contributed to fq 3, fq5, fq10, fq14 and fq16–18. DISCERN (DISCERN, 2012) contributed to fq 9, fq12 and fq18–20.

Usability

Abbott (Abbott, 2000) contributed to u1, u3–7 and u11. Kisely *et al.* (Kisely *et al.*, 2003) contributed to u2 and u4–6. Khazaal (Khazaal, 2008a,b) contributed to u2, u4–6 and u8–12. Afgis (Afgis, 2012) contributed to u8.

Quality of decision support

DISCERN (DISCERN, 2012) contributed to qd4–7 and qd18. IPDAS (IPDAS, 2005) contributed to all qd items.

We additionally assessed the presence of a Health on the Net (HON) code (HONcode, 2012). The HON foundation is a non-profit, non-governmental organization based in Switzerland that promotes reliable online health information. According to the foundation's web site www.hon.ch, the HON code of conduct is the oldest and most common quality seal for online health information. In order to be certified, site owners have to apply for a review of their site. The medical professionals of the HON review committee check if the site adheres to all eight of the HONcode ethical principles (According to www.hon.ch: 'Authority—Give qualifications of authors,' 'Complementarity—Information to sup-port, not replace,' 'Confidentiality—Respect the privacy of site users,' 'Attribution—Cite the sources and dates of medical information,' 'Justifiability—Justification of claims/balanced and objective claims,' 'Transparency—Accessibility, provide valid contact details,' 'Financial disclosure—Provide details of funding,' 'Advertising—Clearly distinguish advertising from editorial content).' A certified site receives a biennial review, beginning 1 year after the initial certification, or following user alert.

The resulting coding sheet has 44 items. 43 are numeric items, 1 is an open-ended question (string variable). All numeric items were rated as present (1) or absent (0).

The included websites were rated by four members of the research team under NWs supervision (see Acknowledgements). A codebook was developed by NW and one of the coders (IE). It contained operationalization of the items and the way the coders should search for the information. For example, for the item 'Sponsoring is disclosed,' the tabs 'about', 'about us', 'imprint', 'editorial policy' on English web sites and 'Impressum', 'über uns' on German web sites were searched. If there was an on-site search engine, the search terms 'sponsor', 'partner' and 'fund(ing)' were entered. The item was only achieved if it was either clearly stated that there was no sponsoring or if sponsoring was explicitly disclosed. The item was not achieved if it was stated that there was sponsoring but without disclosing by whom. The coders were trained in coding according to the codebook using three web sites that were results of the above-mentioned searches but not among the first 20 hits. If there were disagreements, they were discussed under NWs supervision, and the respective section in the codebook was modified accordingly (e.g. clearer wording). Inter-rater reliability was assessed based on full codings (all items) of a random sample of 10 sites. The median of Cohen's κ was 0.6 (interquartile range $Q3-Q1 = 0.6$, $\min = -0.4$, $\max = 1$). This corresponds to a good inter-rater reliability (Wirtz and Caspar, 2002). Due to a lack of variation in the ratings of one or both raters Cohen's κ could not be calculated for 19 items. Consequently, absolute correspondence of ratings (percentage of items that were rated correspondingly by both raters) was calculated as an additional measure of inter-rater reliability. The median was 84.5% (SD = 24.3%, min = 0%, max = 100%).

Analyses

For descriptive analysis, sum scores for total quality and quality domains (formal quality, usability, quality of decision support) were calculated. All criteria were weighted equally as in previous publications (Griffiths and Christensen, 2000; Kisely *et al.*, 2003). The criterion 'Does it provide probabilities of outcomes in an unbiased and understandable way?' was operationalized by eight items (e.g. 'Does it use event rates specifying the population and time period?'). The mean of these eight items constituted the value for the criterion. For each sum score, the percentage of quality criteria met was calculated (e.g. if a website met 9 out of 43 quality criteria, the percentage was 20%). The quality dimension (formal quality, usability, quality of decision support) that was achieved most often (highest mean percentage reached by websites) and most achieved least often (lowest mean percentage reached by websites) were identified. For each dimension, the two quality criteria that were achieved most often (met by the highest percentage of websites) and the two that were achieved least often (met by the lowest percentage of websites) were identified.

Additionally, associations between aspects of website quality (percentage reached on one or more of the quality domains) presence of HON code, affiliation (commercial vs. non-commercial) and website traffic (rank on alexa.com) are explored. Due to different scale levels of the variables, separate analyses are applied: Associations between website quality and presence of HON code as well as associations between website quality and affiliation are tested with a Mann–Whitney *U*-test. Associations of website quality and website traffic are tested with a Spearman's rank correlation. All analyses are two-tailed. For all analyses, a significance level of $p \leq 0.05$ was used. Data analysis was performed using PASW Statistics 18 (SPSS Inc., Chicago, IL, USA).

MAIN OUTCOME AND RESULTS

Of the 80 hits, 26 were excluded because they were duplicates of already included websites. Two were not accessible or not accessible without login. Three were YouTube videos or articles. Another three were excluded because they had no content on type 2 diabetes. In total, 46 websites were included in the study. Of these, 23 were in German and 23 were in English language. All sites had been set up between 1995 and 2011. Most of them (83%) had been last updated in 2011 or 2012. Table 2 shows the URLs of the included websites.

Descriptive analyses

Forty-three numeric quality criteria were rated, one was a string variable ('If decision aids are provided, which ones?') and was therefore not included in the calculation. Since all criteria were weighted equally, a maximum score of 43 could be reached for total quality. The highest score that was reached by two websites was 27 (62.8% of quality criteria met, see Table 3). The lowest score was 7 (16.3%, http://www.diabetessymptome.com/). The quality subdomain where the most criteria were met at mean (49.6%) was quality of decision support. The quality domain where the least criteria were met at mean (35.0%) was formal quality. There were two quality criteria that were met by all of the included websites. One was 'Presence of headings or subheadings' (usability), and the other 'Does the website describe the health condition?' (quality of decision support). The quality of decision support criterion 'Does it provide probabilities of outcomes in an unbiased and understandable way?' was met by none of the included websites. Table 3 shows the 10 websites with the highest scores.

Quality of decision support

In the quality domain 'Quality of decision support', the criteria that were achieved most often were 'Does the website describe the health condition?' (100%) and 'Does it describe what would happen if no treatment is used (natural course of the condition)?' (82.6%), the criteria that were achieved least often were 'Does it provide support for shared decision-making?' (2.5%) and 'Does it provide probabilities of outcomes in an unbiased and understandable way?' (0%). Thus, within the domain quality of decision support the whole range from the item that was achieved most often to the one that was achieved least often is covered. There are items on both extremes of the range but hardly any in the middle. Only one website (https://www.edgepark.com/information/education/diabetes/diabetes-information/type-2-diabetes-symptom) provided a decision aid. The website owner is a

Table 2: URLs of included websites

http://www.myhandicap.de/diabetes-deutschland.html?gclid=CILOs8ufyK0CFUG-zAodtRcAgw
http://www.netdoktor.de/Krankheiten/Diabetes/Wissen/Diabetes-mellitus-Typ-2-Zuckerk-119.html
http://de.wikipedia.org/wiki/Diabetes_mellitus
http://www.onmeda.de/krankheiten/diabetes.html
http://www.diabetes-ratgeber.net/Diabetes-Typ-2
http://www.lilly-diabetes.de/patienten/startseite.html
http://www.eesom.com/go/867V2C6UVVPORPXB5XAY3R3ORYWXGMZS
http://www.akdae.de/Arzneimitteltherapie/Patientenratgeber/Diabetes.pdf
http://www.gesundheitsinformation.de/diabetes.518.56.de.html
http://www.blutzuckerwert-senken.de/
http://www.hausmed.de/krankheiten/diabetes-mellitus-typ-2-zuckerkrankheit
http://www.versorgungsleitlinien.de/themen/diabetes2/dm2_therapie/pdf/nvl-t2d-therapie-kurz-1.1.pdf
http://diabetes.webmd.com/guide/type-2-diabetes
http://www.mayoclinic.com/health/type-2-diabetes/DS00585/
http://diabetesaustralia.com.au/Understanding-Diabetes/What-is-Diabetes/Type-2-Diabetes/
http://bodyandhealth.canada.com/channel_condition_info_details.asp?disease_id=214&channel_id=1055&re
http://www.nlm.nih.gov/medlineplus/ency/article/000313.htm
http://www.medicinenet.com/diabetes_mellitus/article.htm
http://www.bupa.co.uk/individuals/health-information/directory/t/type-2-diabetes
http://www.dlife.com/diabetes/type-2
http://en.wikipedia.org/wiki/Diabetes_mellitus_type_2
http://www.patient.co.uk/health/Diabetes-Type-2.htm
http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Diabetes_Type_2
http://www.emedicinehealth.com/diabetes/article_em.htm
http://diabetes.about.com/
http://www.thirdage.com/hc/c/type-2-diabetes
http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/diabete-eng.php
http://diabetes.niddk.nih.gov/dm/ez.aspx?control=Pubs
http://www.diabetes24.at/
http://www.diabetessymptome.com/
http://www.diabetes-typ-2.info/
http://www.diabetes-typ2.com/
http://www.1-diabetes.de/symptome/
http://www.typ2-diabetiker.com/
http://www.diabetesmellitus.net/
http://www.navigator-medizin.de/diabetes/
http://diabetesmedizinische.com/
http://www.curado.de/Diabetes-mellitus-26/
http://www.ellviva.de/Gesundheit/Diabetes-mellitus.html
http://www.diabetes.org/
https://www.edgepark.com/information/education/diabetes/learn/diabetes-information.cfm
http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001356/
http://www.rightdiagnosis.com/d/diab2/intro.htm
http://www.diabeticseniors.com/type-2-diabetes/
http://www.pdrhealth.com/diseases/diabetes-type-2
http://www.isletsofhope.com/diabetes/symptoms/type_2_pg_1.html

company selling medical supplies, and the decision aid was on the decision whether or not to switch to insulin pump therapy.

Usability

The usability criteria that were achieved most often were ‘Presence of headings or subheadings’ (100%) and ‘Document has a distinguishable header, body, footer’ (90.7%), the ones that were achieved least often were ‘Audio or video support,’ ‘Presence of diagrams’ (20.5% respectively) and ‘Satisfaction and knowledge evaluation questionnaires for users’ (13.6%).

Formal quality

The formal quality criteria that were achieved most often were ‘Ownership of the site is disclosed’ (87.5%) and ‘Relevant copyright information is noted’ (80.0%), the ones that were achieved least often were ‘Patients were involved in website development’ (4.9%) and ‘Date of the next update of the site has been specified’ (4.3%).

Table 3: Top ten websites

URL	Affiliation	Percentage of quality criteria that were met
http://www.netdoktor.de/Krankheiten/Diabetes/Wissen/Diabetes-mellitus-Typ-2-Zuckerk-119.html	Commercial	62.8%
http://www.medicinenet.com/diabetes_mellitus/article.htm	Commercial	62.8%
http://www.nlm.nih.gov/medlineplus/ency/article/000313.htm	Non-commercial	60.5%
http://www.versorgungsleitlinien.de/themen/diabetes2/dm2_therapie/pdf/nvl-t2d-therapie-kurz-1.1.pdf	Non-commercial	58.1%
http://www.dlife.com/diabetes/type-2	Commercial	58.1%
http://www.patient.co.uk/health/Diabetes-Type-2.htm	Non-commercial	55.8%
http://www.emedicinehealth.com/diabetes/article_em.htm	Commercial	55.8%
http://de.wikipedia.org/wiki/Diabetes_mellitus	Commercial	53.5%
http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001356/	Non-commercial	53.5%
http://diabetes.about.com/	Commercial	53.5%

Associations of website quality and website characteristics

Associations of website quality and website affiliation:

Almost half (48.8%) of the sites had commercial funding (e.g. pharmaceutical industry). Non-commercial sites were a heterogeneous group. Most non-commercial sites were government sites (12.2%) or run by private persons (9.8%). There was no significant difference between sites with commercial or non-commercial affiliation regarding any of the quality domains.

Associations of website quality and presence of HON code

23.1% of the included websites had a HON code. Websites with a HON code had significantly better formal quality (Sig. = 0.001). There was no significant difference regarding usability or quality of decision support.

Associations of website quality and website traffic

The traffic on the included sites ranged from highly frequented sites (http://en.wikipedia.org/wiki/Diabetes_mellitus_type_2, Alexa.com rank 6) to much less frequented sites (http://www.diabetesmellitus.net/, rank 8461523). There was a highly significant correlation ($r = -0.47$, $p = 0.002$) between usability and website traffic and a significant ($r = -0.38$, $p = 0.014$) correlation between formal quality and Alexa.com rank. Negative correlations are due to lower numbers signifying higher ranks. We also found a highly significant correlation ($r = 0.45$, $p = 0.002$) between two quality domains usability and formal quality. There was no significant correlation between presence/quality of decision support and website traffic.

CONCLUSION

We assessed formal quality, usability and quality of decision support in English and German language websites on type 2 diabetes. Most websites met basic formal quality criteria such as disclosure of ownership and copyright information. Still, 12.5% of websites did not disclose ownership. 83% of the websites had been updated 2011 or 2012, but only 4.3% specified a date for the next update.

Hardly any sites declared that patients had been involved in website development, and only 13.6% had evaluation questionnaires for users. This lack of user involvement might be due to the effort that is necessary when different stakeholders such as patients and experts are involved. Not involving patients harbours the risk of developing a website that does not meet the users' needs. The fact that Wikipedia, the embodiment of user generated content, was the website with the most traffic in this study, might be the harbinger of a trend towards more user involvement in the generation of online health information.

This study is the first to assess quality of decision support in German and English language diabetes websites. We found that most websites provide basic information necessary for decision-making (such as a description of the natural course of the disease), while only a minority provides specific information for SDM (e.g. 29% provide information on potential positive and 20% on potential negative outcomes of different treatment options). Content that is required for veritable decision aids [e.g. detailed risk communication using numbers and diagrams (Trevena *et al.*, 2012)] is not present in any of the included websites. This might be due to the effort that is required to construct a veritable decision aid (Coulter *et al.*, 2012) and to meet the quality criteria the IPDAS Collaboration put up for decision aids (IPDAS, 2005). In order to provide probabilities of outcomes in an unbiased and understandable way, one needs to have the numbers required to do so and the capacities to convert highly complex and contradictory data into helpful and understandable information. We found only one other study researching the quality of decision support in online health information on radiological procedures. The authors of that study also conclude that only few sites provide sufficient information for medical decision-making (Smart and Burling, 2001).

We found no significant difference regarding formal quality, usability or quality of decision support between sites with commercial or non-commercial affiliation. This finding is consistent with the literature (Khazaal, 2008a,b) and might be due to the heterogeneity of non-commercial sites. This category comprises websites that are run by private persons or non-profit organizations as well as government or university sites and is heterogeneous with respect to financial and personnel capacities, aims and scope. There was a significant difference between websites with and without HON code: Websites with a HON code had significantly better formal quality. There was no difference regarding usability and quality of decision support. This might be explained by the considerable overlap of the formal quality criteria used in this study and the HON code principles. Both put an emphasis on accountability and transparency (Boyer *et al.*, 2011). Earlier studies found that the presence of HON code was associated with accountability, which is one aspect of formal quality. There were mixed results regarding the association between presence of HON code and content quality (Khazaal, 2008a, b).

In the present study, we also assessed whether there are associations between the three quality domains and website traffic as reported on Alexa.com. There is hardly any literature on associations of website quality and traffic. We found a highly significant correlation between usability and website traffic. This is consistent with findings that design and looks of a website are the most important cues for users (Stanford *et al.*, 2002; Sillence *et al.*, 2007) when assessing website quality. Our finding that formal quality and website traffic are significantly correlated might be seen as contrary to an earlier finding (Eysenbach and Köhler, 2002; Stanford *et al.*, 2002; Sillence *et al.*, 2007) that users do not consider the source of a health website when assessing its quality. Still, declaration of ownership and authorship are only 2 out of 20 criteria assessing formal quality in our study. Further research is needed in order to explore whether formal quality is taken into consideration by users and which aspects are important to their assessment of website quality. Since we also found a highly significant correlation between the two quality domains usability and formal quality, we cannot say how much each of these two domains contributes to the association with website traffic. The fact that they are associated might be due to common underlying principles such as clarity of the website, or both might be associated to a third factor like the degree of professionalism of the website author(s). We did not find an association between quality of decision support and website traffic. This might be interpreted as a hint that detailed information on probabilities of risks and benefits of different treatment options are, at least up to the present date, not a central concern of most users.

Various quality labels and instruments are used in practice. In the scientific community, a set of quality criteria has been developed and established that has been applied in various publications. There is considerable overlap between the labels and instruments used in practice and the quality criteria applied in research. We do not know if users are aware of these labels, instruments and criteria, and we do not know if quality in the sense of these labels and instruments play a role in users' approach to health websites. Further research is needed to address these questions.

There are some limitations to the work presented. First, the Internet is a dynamic tool that changes at a rapid pace. With the cross-sectional approach, we conveniently applied we can only capture one moment in the ever changing flow of information. Similarly, the location of the authors might have influenced the search results. All searches were based in Germany, and the results might have been different had we been based somewhere else on the globe. Both of these points limit replicability of our results.

AUTHORS' CONTRIBUTIONS

N.W. participated in the conception and design of the study and drafted the manuscript. M.H. participated in the conception and design of the study and revised the manuscript. J.D. participated in the conception and design of the study and revised the manuscript. All authors read and approved the final manuscript.

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PERSPECTIVES

Health information, behavior change, and decision support for patients with type 2 diabetes: development of a tailored, preference-sensitive health communication application

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Purpose: Patient involvement in diabetes treatment such as shared decision-making and patient self-management has significant effects on clinical parameters. As a prerequisite for active involvement, patients need to be informed in an adequate and preference-sensitive way. Interactive Health Communication Applications (IHCAs) that combine web-based health information for patients with additional support offer the opportunity to reach great numbers of patients at low cost and provide them with high-quality information and support at the time, place, and learning speed they prefer. Still, web-based interventions often suffer from high attrition. Tailoring the intervention to patients' needs and preferences might reduce attrition and should thereby increase effectiveness. The purpose of this study was to develop a tailored IHCA offering evidence-based, preference-sensitive content and treatment decision support to patients with type 2 diabetes. The content was developed based on a needs assessment and two evidence-based treatment guidelines. The delivery format is a dialogue-based, tunneled design tailoring the content and tone of the dialogue to relevant patient characteristics (health literacy, attitudes toward self-care, and psychological barriers to insulin treatment). Both content and tailoring were revised by an interdisciplinary advisory committee.

Conclusion: The World Wide Web holds great potential for patient information and self-management interventions. With the development and evaluation of a tailored IHCA, we complement face-to-face consultations of patients with their health care practitioners and make them more efficient and satisfying for both sides. Effects of the application are currently being tested within a randomized controlled trial.

Keywords: type 2 diabetes, interactive health communication application, development, Internet

Introduction

Patients, practitioners, scientists, and politicians have called for more patient involvement in the making of medical decisions as well as in the management of their diseases in order to reduce the burden on both sides. Patient involvement in diabetes management has been shown to reduce fasting blood glucose levels, A_{1C}, and the need for diabetes medication.[1]

Two main aspects of patient involvement are self-management and shared decision-making (SDM). Self-management means that the patient successfully copes with the challenges of living with and treating diabetes. This may involve that the patient autonomously sets goals, identifies barriers and challenges, and monitors his or her health.[2,3]

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SDM means '(1) that at least two participants – physician and patient be involved; (2) that both parties share information; (3) that both parties take steps to build a consensus about the preferred treatment; and (4) that an agreement is reached on the treatment to implement.'[4] Both for shared decision-making and for self-management, patients need to be informed about their disease, its course, and the treatment options at hand, including their advantages and disadvantages. Face-to-face diabetes education is one way to inform and empower patients. Research has shown the effects of diabetes education on relevant patient outcomes like knowledge, self-management behaviors, and glycemic control.[5–7] However, due to limited resources in health care, large numbers of patients still do not have access to feasible diabetes education.[8–10] New forms of fostering patient involvement are needed to complement the established formats and to supply information at the time and pace that is suitable for the individual patient.

The Internet is widely regarded as an effective complementary source for addressing these topics. In times of rapidly growing Internet penetration, it holds the opportunity to deliver interactive, personalized, and individualized content to large numbers of users on comparatively low costs and at the time, place, and learning speed the individual user prefers. Consequently, people increasingly take advantage of these opportunities: The Pew Internet and American Life Project found that 51% of people living with one or more chronic conditions such as diabetes search the Internet for health information. The information they find there influences treatment decisions, coping, health behavior, and decisions on whether a health professional is consulted or not.[11] However, the quality and usability of diabetes health information on the World Wide Web is limited – in their review, Thakurdesai et al[12] found that quality, transparency, presentation, and broadness of content was deficient in the vast majority of the 53 diabetes patient education websites included in the study. Our own pilot study updates and corroborates this finding. Additionally, reading levels of patient materials on the web are often too high for the average user, not taking into account the great variance of health literacy in the population.[13] Consequently, despite the abundance of information available on the web, patient materials might be inaccessible to users with lower health literacy.

Studies of systematically and thoroughly developed web-based health information show small but consistent effects on clinical outcomes,[14–16] even in older populations that are often thought to use the web less frequently.[17] Murray et al[18] found that Interactive Health Communication Applications (IHCAs), a computer-based format combining health information with social support, decision support, or behavior change support, have positive effects on knowledge, social support, clinical, and behavioral outcomes. Still, the effectiveness of online applications is limited by high attrition rates,[19–22] and few users visit a health intervention website more than once.[23,24] Since the effect of online interventions increases with dose,[5,24] effectiveness is increased if users work intensively with the provided content[21,25] and return for repeated visits.[26,27] Several studies have reviewed strategies to enhance website usage. Individualization and personalization of information as well as an interactive presentation have been found to effectively reduce attrition rates and increase effectiveness of web-based interventions.[28–30] These three strategies can be subsumed under the concept of tailoring.[31] Tailoring information to individual needs and characteristics including different levels of health literacy has the potential to make health information accessible to a greater number of users.

The present work describes the development of a web-based tailored IHCA for patients with type 2 diabetes, offering diabetes information and support for medical decisions. The resulting IHCA is designed to improve user acceptance and adherence; it should increase the users' knowledge and empower them to be active partners in medical decisions and diabetes management. We are currently evaluating the IHCA in a randomized controlled trial.[32] The primary hypothesis is that the tailored IHCA has larger effects on diabetes knowledge and patient empowerment (primary outcomes) than a standard website with identical content but without tailoring. Secondary outcomes are website usage as well as decisional conflict and preparation for decision making.

Development work

The basic assumptions were that the projected IHCA should be tailored, and that the content should comprise information, decision support, and behavior change support for people with type 2 diabetes. Consequently, three questions guided the planning of the IHCA: (1) Which content is relevant for the target group?, (2) How can the content be adequately tailored to the users' preferences?, and (3) Which technical design is feasible?

The result of the development process is an interactive educational intervention that contains general information on diabetes, information on health behavior and lifestyle changes, and treatment options. It incorporates educational, behavioral, and psychological intervention elements in our IHCA and combines didactic and interactive methods. This mix was found to have a greater effect on patient knowledge than interventions focusing on one aspect or method.[5]

Content

Quality criteria for content

Before the actual development work, we looked for a framework that could guide us through the process. There are international (Health On the Net code of conduct [HONcode], DISCERN)[33,34] as well as German (Aktionsforum Gesundeitsinformations-system [afgis])[35] quality criteria for medical information on the Internet. These criteria can and did serve as an orientation during the content development but did not offer detailed advice on the process itself. A manual on the development process is provided by the German Agency for Quality in Medicine (ÄZQ).[36] The manual on the development of evidence-based patient information[36] that is offered on the ÄZQ's website is based on a checklist of quality criteria that was developed on the basis of DISCERN[37] and Appraisal of Guidelines for Research and Evaluation (AGREE)[38] (Table 1). The development process followed the steps proposed in this manual where appropriate. Whenever the advice did not match the project (eg, because of specifics of the Internet or because of financial restrictions), the primary author and editor of the manual was consulted.

Table 1 Quality criteria for patient health information

Scope and purpose
- Is the goal of the publication clearly defined?
- Is the target group of the publication clearly defined?

Stakeholder involvement
- Are the names of the authors stated?
- Are the qualifications of the authors stated?
- Is it stated whether patients or self-help organizations were involved in the development of the publication?

Accuracy
- Is it stated if the publication is based on scientific sources?
- Are the kinds of scientific sources stated?
- Is the date of creation stated?
- Is it stated how long the publication remains valid?
- Is a revision date stated?
- Is it stated whether the publication was developed following certain quality criteria (eg, DISCERN)?
- Is it stated whether the website holding the information participates in a quality initiative (eg, AFGIS, HON code, MedCIRCLE)?
- Does the publication contain sufficient information on additional information and literature?
- Are the modes of action of the medical procedures described sufficiently?
- Are the benefits of the medical procedures described sufficiently?
- Are potential risks of the medical procedures described sufficiently?
- Is it stated whether the medical procedures affect daily life?
- Is it stated whether there are contradicting results or experiences with respect to the medical procedures' effects and side effects?
- Is it explicitly stated whether all known medical procedures for the problem in question are named?
- Is the natural course of the condition (without treatment) described?

Editorial independence
- Is the publication independent and unbiased?

Clarity of design
- Is it easy to identify the most important content?
- Is the content comprehensible?

Additional criteria for online health information
- Is it stated who operates the website?
- Is there a data security statement?
- Can the author and the webmaster be contacted directly?
- Is access unlimited?
- Can the content be printed in a single document?

Notes: Translated with permission from http://www.afgis.de/.[35]
Abbreviations: afgis, Aktionsforum Gesundeitsinformationssystem; HON, Health On the Net;

Needs assessment

Since self-management education interventions that cover more than one diabetes-related topic produce larger effects than those focusing on one topic,[5] the projected IHCA should include a variety of topics. In order to find out which topics are relevant to patients with type 2 diabetes, a needs assessment with two steps was performed. Firstly, semi-structured interviews with physicians and patients were conducted. Secondly, a self-assessment questionnaire for patients was developed, based on the main results of the interviews, which was administered to a larger patient sample. The questionnaire comprised four main sections: (1) health literacy and health locus of control; (2) Internet use and Internet experience; (3) relevant treatment decisions, decision preferences, and online health information needs; and (4) diabetes knowledge. The needs assessment and its results will be described in more detail elsewhere.

Guidelines

In order to ensure that the content is evidence-based, treatment guidelines were used as primary sources. For reasons of consistency only, guidelines that covered the whole range of diabetes management were included while guidelines that focused on distinguished aspects or sequelae of diabetes were excluded. In Germany, the development of such a comprehensive guideline was still underway when the information system was developed. Therefore, the British[39] and the American[40] guidelines were chosen as bases for the contents of the IHCA based on review articles,[41,42] expert advice, and up-to-dateness. Their content was adapted to the German disease management program (DMP) with the help of German treatment professionals and researchers.

Based on the results of needs assessment and selected guidelines, a first draft of the content was created. The application comprises information on three main topics: what is type 2 diabetes?; how is it diagnosed?; and how is it treated? Information that is necessary to make the treatment decisions identified as relevant in the needs assessment includes the risks and benefits of the treatment options at hand (lifestyle, different forms of glucose monitoring, all oral medication that is available in Germany, different kinds of insulin and treatment regimens). Users are encouraged to write down their evaluations of the treatment options in question, as well as questions they might have, and discuss them with their doctors. Moreover, detailed risk information is given for various diabetes-related complications and common comorbidities (angiopathy, polyneuropathy, retinopathy, diabetic nephropathy, diabetic foot, depression, skin diseases, and sexual problems). Table 2 shows the subsections available within each of the main topics.

Tailoring

In a clinical consultation, the professional has the disease- and treatment-specific information and matches the information given and the way it is provided to the knowledge, interests, and other characteristics of the patient. The developed IHCA works accordingly, guiding the user through the information and selecting or modifying the information in a way that matches the individual patient. This corresponds to the concept of tailoring.

Kreuter et al[31] define tailoring as 'any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment' (p277). Individualized messages are supposed to be perceived as more relevant, interesting, and informative by the recipient.[30] Results on the effectiveness of tailoring have been promising, but not consistently so. Some researchers have tried to identify key components that distinguish effective from less effective tailoring.[43–45] Hawkins et al[46] describe three key strategies for effective tailoring: personalization ('conveying that the communication is designed specifically for 'you''), feedback ('presenting patients with information about themselves'), and content matching ('forming messages according to the patient's status on determinants of the behavior of interest', eg, knowledge, attitudes/outcome expectancies). Further studies support the effectiveness of these three strategies.[43,44]

Table 2 Overview of the IHCA's content

Chapters and sections
1. Introduction: What is this website?
1.1. Where does the information on this site come from?
2. Basics
2.1. Different diabetes types
2.2. How do I know I have type 2 diabetes?
2.3. What causes type 2 diabetes?
2.4. How many people live with type 2 diabetes?
2.5. How is type 2 diabetes diagnosed?
2.6. Diabetes ABCs
2.7. Blood sugar control
3. How is type 2 diabetes treated?
3.1. What are the goals of diabetes treatment?
3.2. What can you do to treat your diabetes?
3.3. When should you consider taking pills?
3.4. Insulin treatment
3.5. Summary and overview over the treatment options
4. Acute complications and sequelae
4.1. Which acute complications can occur?
4.2. Which sequelae can occur?
5. Additional information and literature
5.1. Associations and self-help
5.2. Websites
5.3. Journals
5.4. Books
6. Glossary
7. Legal notice
8. References

Notes: Modified from Weymann N, Harter M, Dirmaier J. A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial. *BMC Med Inform Decis Mak*. 2013;13(1):24.[32]
Abbreviation: IHCA, Interactive Health Communication Application.

Personalization

Personalization is thought to enhance message processing by increasing attention and motivation.[46] It can be realized by identifying the recipient by name ('identification') or by overtly claiming that the information offered is customized especially for the individual user ('raising expectation of customization'). This information can have a placebo effect even if there is no actual tailoring.[47] Taking advantage of the placebo effect without fulfilling the promise of customization seems ethically questionable, but explicitly informing the user that tailoring is taking place seemed an appealing concept to us. A third personalization strategy is contextualization. Contextualization means framing information in a way that fits into the user's subjective reality (eg, starting from the user's attitude toward self-care when explaining the concept of self-care). In the tailored IHCA, the user is identified by his or her name, and the user is informed that the content is tailored to his or her individual characteristics. The personalized answers mirror what the user has said, convey esteem and empathy, and build an individualized bridge to the next content block. Whenever possible, content is contextualized according to the individual user's viewpoint (eg, 'As you said before …'). These three personalization strategies are realized within a dialogue format (see 'technical design').

Feedback

Feedback means presenting users with information about themselves. Besides increasing attention, feedback usually directly targets psychosocial determinants of the outcomes of interest. Hawkins et al[46] described three forms of feedback: descriptive feedback ('reports what is known about the recipient based upon his or her data', p461), comparative feedback ('contrasts what is known about the recipient with what is known about others', p461), and evaluative feedback ('makes interpretations or judgments based on what is known about the recipient', p461). In the tailored IHCA, descriptive and evaluative feedback are performed. Feedback is given on the data the IHCA receives when the user answers questions on his or her diabetes knowledge, attitudes towards self-care, or hopes and fears related to insulin treatment. The IHCA mirrors the user's answers and provides tailored advice.

Content matching

Content matching, often thought of as the essence of tailoring, attempts to direct messages to individuals' status on key theoretical determinants (knowledge, outcome expectations, normative beliefs, efficacy and/or skills) of the behavior of interest (p462).[46] Content matching on theoretical concepts such as attitudes was found to be especially effective.[30] Content matching (as well as feedback) is performed on three determinants of successful self-management: health literacy, attitudes towards self-care, and barriers to insulin treatment[48] were chosen as tailoring constructs.

The decision to tailor on health literacy was driven by the great variance of health literacy that was found in the needs assessment. Health literacy is operationalized by the user's pre-existing diabetes knowledge and the complexity of information he or she prefers. Knowledge tailoring is performed in two steps. Firstly, knowledge is assessed using a questionnaire based on the brief diabetes knowledge test.[49] The original questionnaire was adapted to the text: one item on the pathophysiology of type 2 diabetes was added. Items were deleted for the following reasons: they aimed at messages that are not clearly evidence-based (one item); because they did not seem to fit German eating habits (two items); because the matching text passage was covered by self-care tailoring (two items); or because there were too many items for too short a text passage (three items). After each item, feedback is given on the result. If the answer was correct, this is reinforced, and the user can choose if he/she wants to learn more about the topic in question or proceed to the next content section. If the answer was wrong, the correct answer is explained and more information on the topic in question is provided before the user proceeds to the next content section. With respect to the complexity of information, all content that was identified as very important in the needs assessment was available in more or less detail, depending on the user's interest and ability. For each of these topics, the user can choose if he or she would like to have more detailed information or to move on to the next topic. Table 3 shows an example of knowledge tailoring.

Attitude toward self-care (diet, exercise, blood sugar testing, foot care, smoking) is assessed with a questionnaire that we developed based on the Summary of Diabetes Self Care Activities Questionnaire (SDSCA).[50] Motivation to perform the self-care activities is assessed on a 3-point Likert scale. Low motivation in self-care leads to answers that comply with the principles of motivational interviewing (expressing empathy, developing discrepancy, rolling with resistance, supporting self-efficacy).[51] High motivation is reinforced and specific steps for action are proposed. Table 4 shows an example of self-care tailoring.

Psychological barriers to insulin treatment are assessed using the Barriers to Insulin Treatment Questionnaire (BIT).[52] The BIT assesses the following expectations regarding insulin treatment: fear of injection and self-testing; expectations regarding positive insulin-related outcomes; expected hardship from insulin treatment; stigmatization by insulin injections; and fear of hypoglycemia. There are two or three items per subscale. In every item, a certain hope or fear with respect to insulin treatment is expressed (eg, 'I am afraid of the pain when injecting insulin.'). The user is asked to rate his or her agreement on a scale from 1 ('completely disagree') to 10 ('completely agree'). A score from 1 to 10 can be calculated for each subscale. A validating and understanding (if a fear was expressed) or reinforcing (if a hope was expressed) answer is given. If the score is over 1, further information on the topic in question is provided. Table 5 shows an example of tailoring to psychological barriers to insulin treatment.

Table 3 Tailoring to knowledge on symptoms of hyperglycemia

Item	If you feel thirsty and urinate frequently, it usually means your blood sugar is:		
Response options	**High (correct answer)**	**Low (wrong answer)**	**I don't know**
Reply	That's correct! If you want to learn more about what happens in the body and how you know that you have type 2 diabetes, you can go into more detail. Otherwise you can proceed to the next question. • I'd like to learn more about that topic. • I'd like to proceed to the next question.	No, that's not correct. Actually it's the other way round: When you have type 2 diabetes, there is too much sugar in your blood. Unfortunately, you don't realize it in the beginning. But there are warning signs. The most important signs are […]	That's ok, [name], that's what we are here for: to learn, for example, what high blood sugar does to your body. When you have type 2 diabetes, there is too much sugar in your blood. Unfortunately, you don't realize it in the beginning. But there are warning signs. The most important signs are […]

Table 4 Tailoring to attitudes toward foot care

Item	People with diabetes are advised to regularly check their feet and the inside of their shoes. People differ a lot with respect to the importance they attach to 'good advice' of this kind. How important is this advice for you personally?		
Reply options	**Unimportant**	**A little important**	**Important or very important**
	OK, so this recommendation is not important for you. Maybe you are very aware of the inconvenience of daily foot care. You are right there; it takes some effort in the beginning. At the same time, it helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet. For many people, the first step is the hardest. Once you get used to it, the effort does not seem so great anymore.	OK, so this recommendation is a little important for you. Maybe you are aware of the inconvenience of daily foot care. At the same time, it helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet. For many people, the first step is the hardest. Once you get used to it, the effort does not seem so great anymore.	You are right, this recommendation is really important. Looking after your feet can be inconvenient but helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet.

Notes: Modified from Weymann N, Harter M, Dirmaier J. A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial. *BMC Med Inform Decis Mak*. 2013;13(1):24.[32]

When a draft of the written content and the items and structure for tailoring were completed, they were sent to four experts from different related areas (internal medicine, diabetology, health education/medical journalism, and psycho-diabetology) who revised content and tailoring in an iterative process. They provided advice on correctness and completeness of the content, appropriateness with respect to the German health care system, comprehensible communication of complex and controversial medical issues, and psychosocial and motivational aspects. Special attention was given to appropriate reading levels of the texts.

Technical design

The system was developed in the format of a written dialogue, simulating a consultation or chat with a professional. The 'professional' or the tailored IHCA provides information or asks a question, the user replies, and the IHCA gives an answer that starts from what the user has said. For the user's side of the dialogue, three or more answers were created to every text passage that is provided by the IHCA. The user chooses one of the three options and receives a personalized answer. The technical design of the IHCA is tunneled in the sense that the user is guided through the content; the 'professional' has an agenda in mind of what might be helpful for the individual patient. Tunneled designs were found to increase website use and knowledge gained from a website when compared to a website without guidance.[53] Even though being guided can be helpful when confronted with complex information, it can also annoy the user and evoke resistance;[54] the patient might have an agenda on his or her own that differs from the professional's. The dialogue strikes a balance between guidance (suggestions made by the IHCA) and user control (reply options). This dialogue format has been found to be effective in depression and acute low back pain,[55–58] but has not been applied to diabetes websites so far.

Table 5 Tailoring to an expressed fear of hypoglycemia

Items	1. An overdose of insulin can lead to extremely low blood sugar (hypoglycemia). I am afraid of disagreeable symptoms.									
	Completely disagree								Completely agree	
	1	2	3	4	5	6	7	8	9	10
	2. An overdose of insulin can lead to extremely low blood sugar (hypoglycemia). I am afraid of resulting health damages.									
	Completely disagree								Completely agree	
	1	2	3	4	5	6	7	8	9	10
Reply*	Having slightly low blood sugar is hard to avoid when your blood sugar is in tight control. Usually, this can be handled easily. As long as you reliably notice the first symptoms of such a slight hypoglycemia, it is no serious problem. They are an annoying but harmless side effect of insulin treatment. Most people with diabetes notice these warning signs very well, at the start of hypoglycemia so they can counteract them (eg, by taking glucose). A minority of people with diabetes suffer from hypoglycemia unawareness. That means that you have difficulties noticing these helpful warning signs. Mostly people who have been living with diabetes for a longer time suffer from hypoglycemia unawareness. There are things you can do to improve hypoglycemia awareness, for example, by taking part in blood glucose awareness training. If slight hypoglycemia occurs frequently or if you have severe hypoglycemia you should talk to your doctor about adapting your therapy.									

Note: *The reply is given if a user reaches a sum score >1 in the two items.

Programming and graphic design were performed by the Gaia AG (Hamburg, Germany), a subcontractor specializing in web-based health interventions. When content, structure, tailoring, and cornerstones of graphic design were completed by the research team and the advisory committee, they were handed over to the subcontractor for programming. Further elaboration of graphic design was coordinated in meetings between the research team and the subcontractor. A serious, medical style was agreed on. Labeled, partly interactive drawings were added to the complex content in order to make them more comprehensible[59] and to enhance acceptance, especially in older users.[60] Less complex text passages were complemented by photographs conveying positive affects in order to enhance recall of contents.[61] When the first version of the IHCA was completed, it went through a phase of technical testing. Due to individualization, there are many paths that a user can take going through the system. Many of these paths were systematically tested by the subcontractor and the research team with respect to logic and functioning. Given the high complexity of the system, it was not possible to test all paths.

Conclusion

IHCAs that match the medical care situation can complement in-person education if patients have a high interest in and/or need for extensive or repeated information, live in underserved areas, and have access to the Internet. Practitioners might make use of IHCAs for eligible patients in order to improve diabetes knowledge and self-management. IHCAs are supposed to complement in-person counseling, and they work better for patients if they are combined with other forms of support; Brouwer et al[28] found that peer support, counselor support, email, and phone contact increased exposure to web-based interventions. The integration of IHCAs into diabetes education could be especially effective if combined with the offer to discuss the content in telephone, chat, or in-person sessions. Offering IHCAs not only to patients but also to caregivers could be an asset both for the patients and for the caregivers. Studies show that caregivers search the web even more actively than the patients themselves.[11,62] Another potential target group for the present IHCA are people at risk for developing type 2 diabetes. Current guidelines addressing the prevention of type 2 diabetes recommend similar behavioral changes regarding exercise, diet, and smoking cessation as presented in the IHCA. Target populations are people with impaired glucose tolerance, impaired fasting glucose, and/or metabolic syndrome.[63–65]

Web 2.0 features might further increase the attractiveness of IHCAs. According to the Pew Internet and American Life Project,[11] Americans living with a chronic condition are more active members of the web community than healthy people. They use more social media, read user-generated content and generate content themselves, blog and chat about experiences with doctors, hospitals, medication, and/or offer emotional support. Inviting patients to share information and experience might enhance attractiveness and patient-centeredness of IHCAs. Other possible features would be online tracking of diet, blood sugar, or exercise, preferably with an app so that the patient can record his activities and blood sugar, and get the information they need in real-time. Finally, tailoring might become more effective if it was not static (assessed at only one point in time), but dynamically adapting to the user's present state.[16] Further research and practical tests are needed to better understand how IHCAs can best support patients and professionals.

The opportunities created by technical progress can only be helpful to patients who know how to use them. This could be a challenge for older patients, while younger patients may take a liking to IHCAs and technical devices. While personal support and a good relationship between practitioners, patient, and caregivers is the basis for successful diabetes management, IHCAs could add new opportunities of education and self-management.

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Disclosure

The authors report no conflicts of interest in this work.

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Publication 5

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STUDY PROTOCOL **Open Access**

A tailored, interactive health communication application for patients with type 2 diabetes: study protocol of a randomised controlled trial

Nina Weymann*, Martin Härter and Jörg Dirmaier

Abstract

Background: Type 2 diabetes is an increasingly common chronic condition whose prognosis can be improved by patient involvement and self-management. Patient involvement can be fostered by web-based Interactive Health Communication Applications (IHCAs) combining health information with decision support, social support and/or behaviour change support. They reach great numbers of patients at low cost and provide high-quality information and support at the time, place and learning speed patients prefer. Still, online tools often suffer from high attrition. Tailoring content and tone of IHCAs to the individual patient´s needs might improve their effectiveness. This study aims to test the effectiveness and usage of a tailored IHCA combining health information with decision support and behaviour change support for patients with type 2 diabetes.

Methods/design: The effectiveness and usage of the tailored IHCA will be tested against a standard website with identical content in a single-blinded randomized trial with a parallel design. The content covers information on type 2 diabetes, its complications and sequelae, and its treatment options including health behaviour. In the intervention group the content is delivered in dialogue form, tailored to relevant patient characteristics (health literacy, attitudes towards self-care, and barriers to insulin treatment). In the control group the different sections are presented in a content tree, without any tailoring. Participants are blinded to group assignment. Eligibility criteria are age ≥ 18 years, self-reported type 2 diabetes, and Internet access. The study aims to include 414 participants in order to detect the expected small effect (Cohen's d=0.2), with measurements at baseline, directly after the first visit, and at 3-month follow-up. The primary hypothesis is that the tailored IHCA has larger effects on diabetes knowledge and patient empowerment (primary outcomes) than the standard website. Secondary outcomes are website usage as well as decisional conflict and preparation for decision making. All measurements are online self-report questionnaires.

Discussion: IHCAs are a promising way to foster diabetes knowledge and self-management competencies. The present trial tries to increase the knowledge on how to develop more effective IHCAs for patients with type 2 diabetes.

Trial registration: International Clinical Trials Registry DRKS00003322

Keywords: Type 2 diabetes mellitus, Randomized controlled trial, Study protocol, Patient information, Web

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Background

Diabetes and its secondary diseases are a leading cause of morbidity and mortality in many countries. The number of people living with diabetes more than doubled during the last three decades [1]. Projections expect the prevalence to rise from 2.8% in 2000 to 4.4% in 2030 [2]. Type 2 diabetes accounts for 90 to 95% of diabetes cases [3]. Patients, practitioners, scientists and politicians have called for more active patient involvement in the making of medical decisions as well as in the management of diabetes. Patient involvement has been shown to reduce fasting blood glucose levels, glycated hemoglobin levels, and the need for diabetes medication [4]. Two main aspects of patient involvement are self-management and shared decision-making (SDM). Both for shared decision-making and for self-management patients need to be informed about their disease, its course, and the treatment options at hand, including their advantages and disadvantages. However, due to limited resources in health care, large numbers of patients still do not have access to feasible diabetes education [5,6].

In times of rapidly growing Internet penetration, the web holds the opportunity to deliver health information and support to large numbers of participants on comparatively low cost and at the time, place and learning speed the individual users prefer. Trials of systematically and thoroughly developed online health interventions show small but consistent effects on clinical outcomes [7-9] even in older populations that are generally thought to be less inclined to use the web [10]. Murray et al. [11] reviewed the effects of a format that combines health information with at least one other type of support, e.g., social support, decision support, or behaviour change support (= “Interactive Health Communication Applications”, IHCAs) [11]. They found that IHCAs can have positive effects on knowledge, social support, clinical, and behavioural outcomes.

Still, the effectiveness of those online applications is limited by high attrition rates [12,13], and few users visit a health intervention website more than once [14,15]. Since the effect of online interventions increases with dose (longer stays, repeated website visits, total contact hours) [15,16], effectiveness is maximized if patients work intensively with the information offered [17,18] and return for repeated visits [19,20]. Individualization and personalization of information as well as an interactive presentation have been found to effectively increase exposure to and effectiveness of interventions [21,22]. These three strategies can be subsumed under the concept of tailoring [23].

Aims of the trial

This trial tests an IHCA presenting diabetes information, self-management education and decision support in a dialogue-based, tailored format against a website presenting the same information in a content tree without dialogue or tailoring. The primary hypothesis is that the interactive and individualized delivery format has larger effects on diabetes knowledge and patient empowerment than the standard website. Exploratory research questions are if usage is higher for the interactive and individualized delivery format and whether users facing a health decision experience less decisional conflict and feel better prepared for the consultation after using the interactive and individualized site rather than the standard website.

Methods/Design

Study design

We chose a single-blinded two-armed randomised controlled trial (RCT) with a parallel design. We aim to include N=414 participants. Measurements are scheduled immediately before the first use of the system, immediately after and at three month follow-up. Diabetes knowledge (primary outcome), decisional conflict, and preparation for decision making (secondary outcomes) are assessed immediately after the first visit. Patient empowerment (secondary outcome) is assessed three months after the first visit (see figure 1).

Study procedures

After providing an informed consent and completing the pre-assessment (eligibility criteria, demographic data, time since diagnosis, treatment) the participants are randomly assigned to the tailored IHCA or the standard website with the content tree. In the intervention group, the questions used for tailoring are presented during the dialogue. Participants assigned to the control condition where no tailoring takes place fill in these questionnaires immediately before visiting the website in order to control for baseline disparities between intervention and control group. Immediately after their first visit to the IHCA or the standard website all participants are asked to fill in the post-assessment.

All participants receive an e-mail three months after their first visit asking them to fill in the follow-up online questionnaire. Because non-monetary incentives have been shown to reduce attrition in online trials [24,25], participants who have answered all questionnaires receive a 10 € amazon gift voucher. The voucher code is sent to them by e-mail at the end of the study. Figure 1 gives an overview of the study procedures.

Participants are free to use the intervention as often and as long as they wish, also between the post and follow-up assessment. Information on frequency and duration of usage is gathered via server registrations. Usage data, data from the self-assessment questionnaires, and personal data such as name and e-mail address are saved

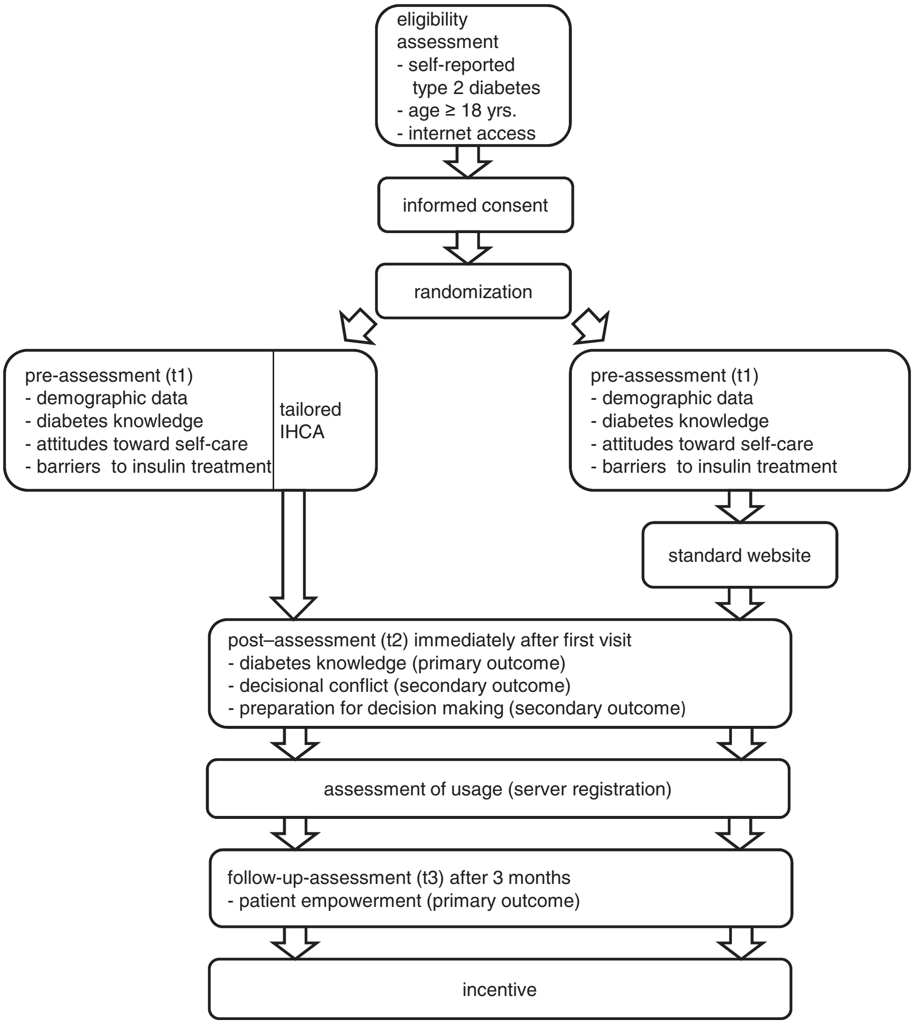


Figure 1 **Study procedures.**

separately. Data are pseudonymesed. After data collection, personal data will be deleted. If a participant withdraws his or her informed consent to study participation his or her data shall be erased immediately. All data will be erased five years after the end of the study. The study was approved by the Hamburg Medical Chamber ethics committee.

Treatment allocation

The informed consent informs participants that they will be randomly assigned to one of two presentation formats holding the same content. The two formats are not further elucidated so participants do not know whether they are in the intervention or control group. Randomisation is performed by computer.

Recruitment

In Germany, health care for chronically ill patients is organized in different sectors, mainly in acute-care clinics and rehabilitation centres for in-patient care, and primary care and diabetology practices for out-patient care. Treatment in acute-care clinics, in primary care practices, and in diabetology practices is funded by health insurance while rehabilitation in rehabilitation centres is usually funded by pension funds. Study aim is to include patients from all sectors. Recruitment takes place via support from different health insurance companies, pension funds, primary care practices and diabetology practices, hospitals and rehabilitation centres, and self-help groups. The study is advertised in various media such as newspapers, magazines, patient websites, and flyers. Information on the study is available on the study website www.entscheidungshilfe.info.

Study Population

Eligibility criteria are age ≥ 18 years, access to the Internet, and a self-reported diagnosis of type 2 diabetes. According to the American Diabetes Association [3,26], type 2 diabetes should be diagnosed if a fasting plasma glucose of ≥ 126 mg/dl or a non-fasting plasma glucose of ≥ 200 mg/dl or a plasma glucose of ≥ 200 mg/dl two hours after oral intake of 75g glucose (oral Glucose Tolerance Test, oGTT) is measured. Supposing that most patients cannot give these exact numbers and that self-reported diagnoses are a valid criterion [27], we decided to rely on self-reported diagnosis of type 2 diabetes as inclusion criterion.

Description of the intervention and control condition

The content of both the tailored IHCA and the standard website covers basic information on diabetes (pathophysiology, epidemiology, subtypes, symptoms) and its sequelae (neuropathy, nephropathy, retinopathy, heart and vessel problems, sexual dysfunction, and depression), information on health behaviour and lifestyle changes, and treatment options (see section Chapters and sections). The look of the website (colours, typing, figures and pictures) is identical in both conditions. After registration, each participant receives a password via e-mail with which he/she can log into the system as often as he/she wishes.

Chapters and sections

1. Introduction: What is this website?
    - 1.1. Where does the information on this site come from?
        - 1.1.1. What are treatment guidelines?
        - 1.1.2. What are disease management programmes?
2. Basics
    - 2.1. Different diabetes types
        - 2.1.1. Type 1
        - 2.1.2. Type 2
        - 2.1.3. Other types of diabetes
    - 2.2. How do I know I have type 2 diabetes?
        - 2.2.1. The most important signs
        - 2.2.2. Other signs
    - 2.3. What causes type 2 diabetes?
        - 2.3.2. Risk factors
        - 2.3.1. What causes insulin resistance?
    - 2.4. How many people live with type 2 diabetes?
        - 2.4.1. Diabetes is on the rise
    - 2.5. How is type 2 diabetes diagnosed?
        - 2.5.1. Fasting plasma glucose
        - 2.5.2. Oral glucose tolerance test (oGTT)
        - 2.5.3. Measurement units for blood sugar
        - 2.5.4. HbA1c
        - 2.5.5. Urine analysis
    - 2.6. Diabetes ABCs
        - 2.6.1. „A“ is for HbA1c
        - 2.6.2. “B” is for blood pressure
        - 2.6.3. „C“ is for cholesterol
    - 2.7. Blood sugar control
        - 2.7.1. What is it good for?
        - 2.7.2. How to do it
            - 2.7.2.1. At the doctors´ practice
            - 2.7.2.2. At home
3. How is type 2 diabetes treated?
    - 3.1. What are the goals of diabetes treatment?
    - 3.2. What can you do to treat your diabetes?
        - 3.2.1. How do I keep a healthy diet?
        - 3.2.2. Why is exercise important?
        - 3.2.3. Why is smoking so bad if you have diabetes?
    - 3.3. When should you consider taking pills?
        - 3.3.1. Pills to treat type 2 diabetes
        - 3.3.2. How much do they lower blood sugar levels?
        - 3.3.3. Biguanide /metformin
        - 3.3.4. Sulphonylureas
        - 3.3.5. Glinides (repaglinide, nateglinide)
        - 3.3.6. Glitazone
        - 3.3.7. α-glucosidase inhibitor (AGI)
        - 3.3.8. Dipeptidyl peptidase-4 inhibitor
        - 3.3.9. Exenatide, liraglutide
    - 3.4. Insulin treatment
        - 3.4.1. Human insulin and insulin analogues
        - 3.4.2. When is insulin treatment initiated?
        - 3.4.3. Hopes and fears when starting insulin treatment
        - 3.4.4. How is insulin administered?
        - 3.4.5. Different types of insulin and their effects
        - 3.4.6. How does insulin act in the body?
        - 3.4.7. Insulins with different durations of action
        - 3.4.8. Insulin treatment and blood sugar control
        - 3.4.9. Combining pills and insulin
    - 3.5. Summary and overview of the treatment options
4. Acute complications and sequelae
    - 4.1. Which acute complications can occur?
        - 4.1.1. Low blood sugar
        - 4.1.2. High blood sugar
    - 4.2. Which sequelae can occur?
        - 4.2.1. Coronary heart disease and stroke
        - 4.2.2. Neuropathy
        - 4.2.3. Nephropathy
        - 4.2.4. Retinopathy
        - 4.2.5. Diabetic foot
        - 4.2.6. Skin diseases
        - 4.2.7. Sexual health
        - 4.2.8. Depression
5. Additional information and literature
    - 5.1. Associations and self-help
    - 5.2. Web sites

Intervention condition

In the intervention the delivery format is a dialogue-based, tunnelled design tailoring the content and tone of the dialogue to relevant patient characteristics. A tunnelled design where the user is guided through the content was found to increase website use and knowledge gained from a website more than a design with more user control [28]. Still, it might also annoy the user and evoke resistance [29]. Consequently we decided to give the user some control over the path he/she takes through the dialogue. At the end of each text passage the user chooses one of at least three reply options and receives a tailored answer. The answers mirror what the user has said, convey esteem and empathy and build an individualized bridge to the next content block.

Tailoring is performed on the following patient characteristics: health literacy, attitudes towards self-care, and, if insulin treatment is a relevant topic, psychological barriers to it. The questionnaires that assess patient characteristics are presented during the dialogue: In the beginning of the respective section (e.g. diabetic foot), the participant is asked about his or her knowledge or attitude toward the topic. The following section is then modified according to his/her answer. Figure 2 shows a dialogue window.

The user´s attitudes towards self-care are assessed with items that we adapted from the Summary of Diabetes Self-care Activities Measure (SDSCA) [30] to match the respective content section (see Table 1). The question is always how important a certain self-care activity or advice is for the individual user. Every item has three reply options: “important or very important”, “a little important”, and “not important”. The goal and techniques are inspired by Motivational Interviewing [31]. Motivational interviewing is a counseling method for addressing ambivalence about change.

For example, if a user attaches great importance to the self-care behavior in question, this is reinforced, positive consequences of the self-care behavior are stressed, and/or ideas are provided on how to keep up motivation. If a user finds the self-care behavior in question “a little important”, understanding for the users´ ambivalence is uttered, and the importance the user attaches to the self-care behavior – little as it might be – is stressed and reinforced. Finally, if a user rates the self-care behavior as not important, the autonomy expressed in this answer is respected in order not to elicit resistance.

Control condition

On the standard website, the content is not tailored and is not presented in a dialogue format. In contrast to the tailored, interactive version, it is not tunnelled; there is no guidance through the content. On the right of each page a content tree displays a menu of all content sections that the participant can click on to get to the content of interest (see Figure 3).

Potential risk for participants

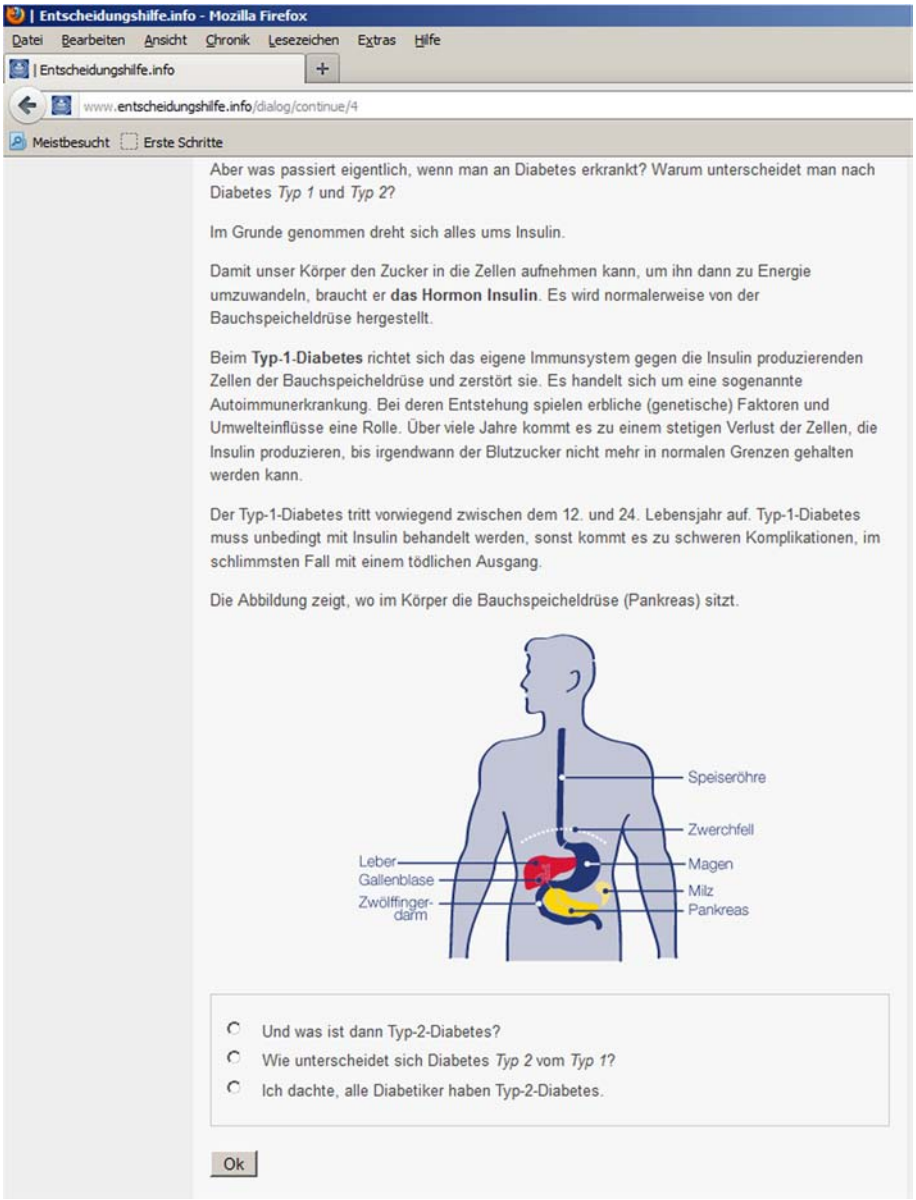
Contraindications or side effects of IHCAs are not known.

Intervention development and trial design

The development process was user-oriented, evidence-based and peer reviewed. In order to find out which topics are relevant to patients with type 2 diabetes, we performed a needs assessment with two steps: First, semi-structured interviews with seven physicians (all internists, 1 working as a general practitioner, 2 specialized in diabetology) and ten patients with type 2 diabetes were conducted. In the second step, a self-

Table 1 Example of self-care tailoring

Item	People with diabetes are advised to regularly check their feet and the inside of their shoes. People differ a lot with respect to the importance they attach to “good advice“ of this kind. How important is this advice for you personally?		
Reply options	not important	a little important	important or very important
Tailored answer	OK, so this recommendation is not important for you. Maybe you are very aware of the inconvenience of daily foot care. You are right there; it takes some effort in the beginning. At the same time it helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet. For many people the first step is the hardest. Once you get used to it, the effort does not seem so great anymore.	OK, so this recommendation is a little important for you. Maybe you are aware of the inconvenience of daily foot care. At the same time it helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet. For many people the first step is the hardest. Once you get used to it, the effort does not seem so great anymore.	You are right, this recommendation is really important. Looking after your feet can be inconvenient but helps a lot to prevent diabetic foot syndrome. A diabetic foot can be painful and can lead to amputation. There is a great benefit for the comparatively small effort of taking care of your feet.



Aber was passiert eigentlich, wenn man an Diabetes erkrankt? Warum unterscheidet man nach Diabetes *Typ 1* und *Typ 2*?

Im Grunde genommen dreht sich alles ums Insulin.

Damit unser Körper den Zucker in die Zellen aufnehmen kann, um ihn dann zu Energie umzuwandeln, braucht er **das Hormon Insulin**. Es wird normalerweise von der Bauchspeicheldrüse hergestellt.

Beim **Typ-1-Diabetes** richtet sich das eigene Immunsystem gegen die Insulin produzierenden Zellen der Bauchspeicheldrüse und zerstört sie. Es handelt sich um eine sogenannte Autoimmunerkrankung. Bei deren Entstehung spielen erbliche (genetische) Faktoren und Umwelteinflüsse eine Rolle. Über viele Jahre kommt es zu einem stetigen Verlust der Zellen, die Insulin produzieren, bis irgendwann der Blutzucker nicht mehr in normalen Grenzen gehalten werden kann.

Der Typ-1-Diabetes tritt vorwiegend zwischen dem 12. und 24. Lebensjahr auf. Typ-1-Diabetes muss unbedingt mit Insulin behandelt werden, sonst kommt es zu schweren Komplikationen, im schlimmsten Fall mit einem tödlichen Ausgang.

Die Abbildung zeigt, wo im Körper die Bauchspeicheldrüse (Pankreas) sitzt.

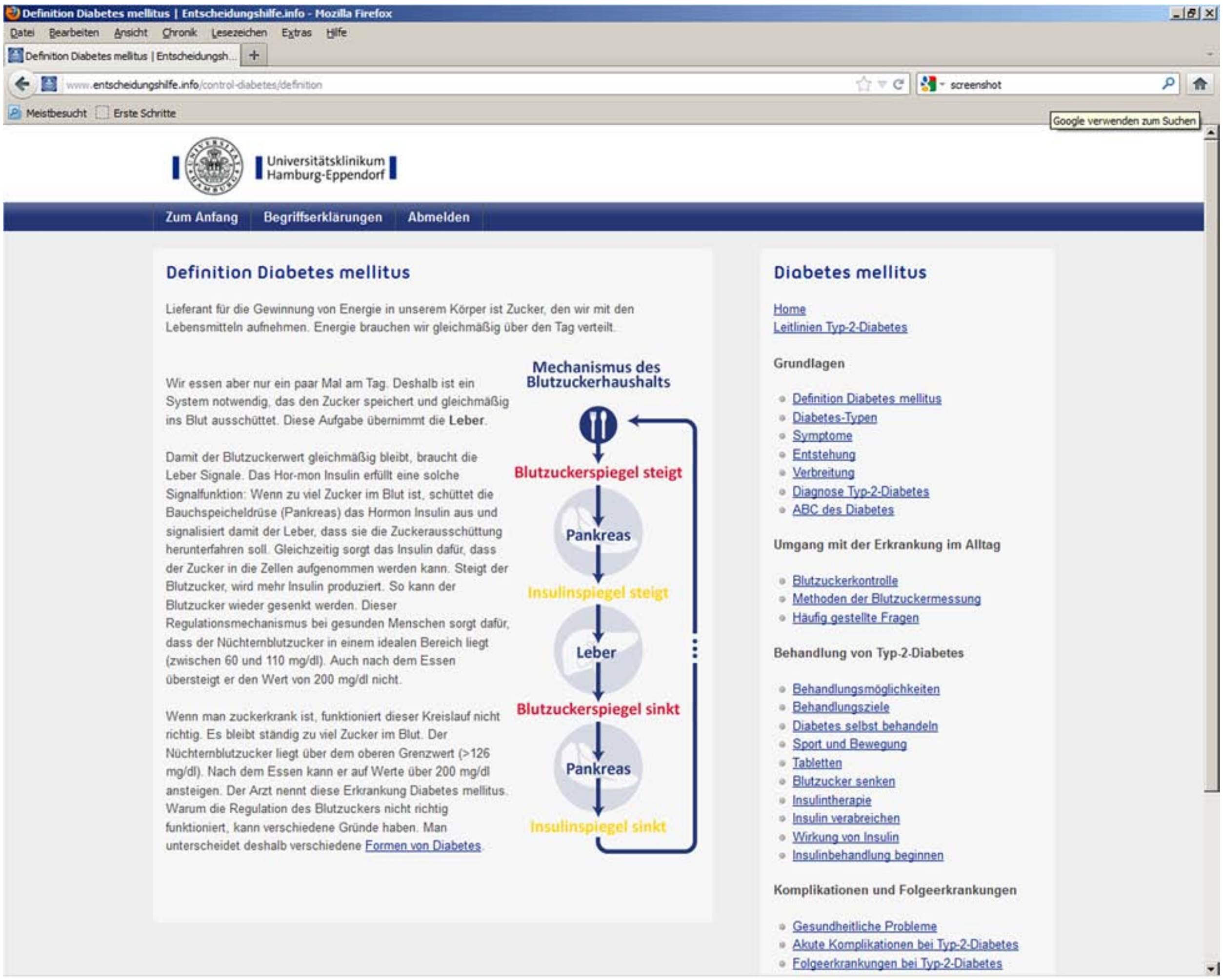
○ Und was ist dann Typ-2-Diabetes?
○ Wie unterscheidet sich Diabetes *Typ 2* vom *Typ 1*?
○ Ich dachte, alle Diabetiker haben Typ-2-Diabetes.

Figure 2 Dialogue window.

assessment questionnaire was developed based on the main results of the interviews, and it was administered to a new and larger patient sample (N=178). The needs assessment will be described in more detail elsewhere. In order to ensure that information is evidence-based treatment guidelines were used as primary sources. Based on review articles [32,33], expert advice and up-to-dateness, the British [34] and the American [26] guidelines were chosen. Throughout the development, the content was revised by an interdisciplinary advisory committee in an iterative process. The development will be described in more detail elsewhere.

Outcome assessment

The primary outcomes are diabetes knowledge (assessed immediately after the first visit) and patient empowerment (assessed at three month follow-up). Diabetes knowledge is assessed with 16 multiple-choice questions we developed according to the IHCA´s content. Patient empowerment is measured with the Health Education Impact Questionnaire (HeiQ) [35,36]. The HeiQ includes 42 items and eight dimensions: Positive and Active Engagement in Life, Health Directed Behavior, Skill and Technique Acquisition, Constructive Attitudes and Approaches, Self-Monitoring and Insight, Health Service Navigation, Social Integration and



Definition Diabetes mellitus

Lieferant für die Gewinnung von Energie in unserem Körper ist Zucker, den wir mit den Lebensmitteln aufnehmen. Energie brauchen wir gleichmäßig über den Tag verteilt.

Wir essen aber nur ein paar Mal am Tag. Deshalb ist ein System notwendig, das den Zucker speichert und gleichmäßig ins Blut ausschüttet. Diese Aufgabe übernimmt die **Leber**.

Damit der Blutzuckerwert gleichmäßig bleibt, braucht die Leber Signale. Das Hor-mon Insulin erfüllt eine solche Signalfunktion: Wenn zu viel Zucker im Blut ist, schüttet die Bauchspeicheldrüse (Pankreas) das Hormon Insulin aus und signalisiert damit der Leber, dass sie die Zuckerausschüttung herunterfahren soll. Gleichzeitig sorgt das Insulin dafür, dass der Zucker in die Zellen aufgenommen werden kann. Steigt der Blutzucker, wird mehr Insulin produziert. So kann der Blutzucker wieder gesenkt werden. Dieser Regulationsmechanismus bei gesunden Menschen sorgt dafür, dass der Nüchternblutzucker in einem idealen Bereich liegt (zwischen 60 und 110 mg/dl). Auch nach dem Essen übersteigt er den Wert von 200 mg/dl nicht.

Wenn man zuckerkrank ist, funktioniert dieser Kreislauf nicht richtig. Es bleibt ständig zu viel Zucker im Blut. Der Nüchternblutzucker liegt über dem oberen Grenzwert (>126 mg/dl). Nach dem Essen kann er auf Werte über 200 mg/dl ansteigen. Der Arzt nennt diese Erkrankung Diabetes mellitus. Warum die Regulation des Blutzuckers nicht richtig funktioniert, kann verschiedene Gründe haben. Man unterscheidet deshalb verschiedene Formen von Diabetes.

Diabetes mellitus

Home
Leitlinien Typ-2-Diabetes

Grundlagen

- Definition Diabetes mellitus
- Diabetes-Typen
- Symptome
- Entstehung
- Verbreitung
- Diagnose Typ-2-Diabetes
- ABC des Diabetes

Umgang mit der Erkrankung im Alltag

- Blutzuckerkontrolle
- Methoden der Blutzuckermessung
- Häufig gestellte Fragen

Behandlung von Typ-2-Diabetes

- Behandlungsmöglichkeiten
- Behandlungsziele
- Diabetes selbst behandeln
- Sport und Bewegung
- Tabletten
- Blutzucker senken
- Insulintherapie
- Insulin verabreichen
- Wirkung von Insulin
- Insulinbehandlung beginnen

Komplikationen und Folgeerkrankungen

- Gesundheitliche Probleme
- Akute Komplikationen bei Typ-2-Diabetes
- Folgeerkrankungen bei Typ-2-Diabetes

Figure 3 Control window.

Support, and Emotional Wellbeing. Schuler and colleagues [37] translated the questionnaire into German and evaluated its psychometric properties (Raykov's Composite Reliability Coefficient, factorial and concurrent validity). They were able to replicate the structure of the eight scales and found the questionnaire to be a reliable and valid measure. We removed Social Integration and Support from our testing battery since we did not expect an effect of our IHCA on that dimension.

Secondary outcomes are decisional conflict and preparation for decision making. Decisional conflict is assessed with the Decisional Conflict Scale (DCS) by O´Connor [38]. This questionnaire measures personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making, and effective decision making such as feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice. Reliability is good with a Cronbach´s α between 0.78 and 0.92 [38]. Discriminant validity is acceptable.

Preparation for decision making is measured with the Preparation for Decision Making Scale (PDMS) [39]. This 11 item scale assesses a patient´s or participant´s perception of how useful a decision aid or decision support intervention was in preparing him or her to communicate with his or her practitioner in making a health decision. Reliability is very good ranging from α=.92 to α=.94. Both questionnaires are offered only to those participants who have indicated that they are facing a health decision concerning their type 2 diabetes. In order to avoid missing data, all questionnaires include validation checks that alert participants when their answers are implausible or items are skipped.

Statistical analyses

T-tests for independent samples will be performed to test the hypotheses. Due to randomization and the supposed structural equality of the groups we do not expect confounding factors. If we detect baseline disparities between the control and intervention group they will be included in an analysis of covariance (ANCOVA) as confounding variables. Following the intention-to-treat approach we will include all randomized participants in the analyses in order to avoid biases such as non-random attrition of participants. Additionally we will perform a sensitivity analysis following the per-protocol approach including only participants that have filled in all the questionnaires. For all analyses $\alpha \leq 0.05$ will be the critical value for statistical significance. We expect only small sample sizes with respect to the exploratory research questions because only a fraction of the participants will be facing a health decision and will therefore be asked to fill in the DCS and PDMS. For all parameters 95% confidence intervals will be defined so we will be able to appraise the exactitude of testing.

Power calculation

On the basis of the Cochrane review by Murray et al. [11] we expect a small effect on the primary outcomes (Cohen's d=0.2). To detect a small effect with an α of 0.05 and a power of 0.80 (one-tailed t-test), a sample size of N=310 (155 per group) is required. Expecting a rate of dropout 20% between registration and follow-up (3 months), we aim at including a sample of N=414 at baseline.

Discussion

In an on-going RCT, we are testing a web-based, tailored, dialogue-based information system that contains information on type 2 diabetes and its sequelae, health behaviour, and treatment options, against a standard website providing identical information without dialogue structure, tailoring or interactive elements. Both websites were thoroughly developed based on a needs assessment and two evidence-based guidelines, and reviewed by an interdisciplinary advisory committee. The primary outcomes of the trial are diabetes knowledge and patient empowerment. Secondary outcomes are decisional conflict, preparation for decision making, and website usage. The present study is the first trial on a German language IHCA on type 2 diabetes.

There are some limitations to the work presented. The most obvious limitation is that only people with Internet access can be included in the study. 73% of the German general population use the Internet [40], but of the population over 50 years of age, 47% are online. Since the prevalence of type 2 diabetes increases strongly with age [41] we run the risk of excluding a part of our target group. This is a limitation both with respect to implementation and reach, and as a source of selection bias.

There are some disadvantages of online questionnaires, namely the relatively high nonresponse rates and concerns regarding data quality [42,43]. With regard to the quality of the data obtained online, there are indications that the psychometric properties are equivalent with data obtained from paper pencil questionnaires or even better [44,45]. Quality can be improved by validation checks that alert participants when their answers are implausible or items are skipped [44]. Furthermore, online assessments seem to be less prone to social desirability [46]. With respect to non-responders we try to reduce attrition by keeping the questionnaires as short as possible, making the intervention itself attractive, and offering an incentive for answering all questionnaires. Another limitation concerning our measurements is that only some of them are standardized (DCS, PDMS, BIT) while others are adapted (attitudes toward self-care) or developed (diabetes knowledge) for our purposes. None of the measurements have been adapted for online use which puts their comparability to results obtained from paper pencil tests into question [47].

Abbreviations

SDM: Shared decision-making; IHCA: Interactive Health Communication Application; RCT: Randomized controlled trial; PDMS: Preparation for Decision Making Scale; DCS: Decisional Conflict Scale; HeiQ: Health Education Impact Questionnaire; ADA: American Diabetes Association; oGTT: Oral Glucose Tolerance Test; ANCOVA: Analysis of covariance.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

NW participated in the conception and design of the study and drafted the manuscript. MH participated in the conception and design of the study and revised the manuscript. JD participated in the conception and design of the study and revised the manuscript. All authors read and approved the final manuscript.

Authors' information

NW is a certified psychotherapist and a research associate at the Department of Medical Psychology. MH is a medical doctor, a certified psychotherapist and head of the Department of Medical Psychology. JD is a certified psychotherapist and a research associate at the Department of Medical Psychology.

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Publication 6

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Original Paper

Effectiveness of a Web-Based Tailored Interactive Health Communication Application for Patients With Type 2 Diabetes or Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract

Background: The prevalence of chronic diseases such as type 2 diabetes and chronic low back pain is rising. Patient empowerment is a key strategy in the management of chronic diseases. Patient empowerment can be fostered by Web-based interactive health communication applications (IHCAs) that combine health information with decision support, social support, and/or behavioral change support. Tailoring the content and tone of IHCAs to the needs of individual patients might improve their effectiveness.

Objective: The main objective was to test the effectiveness of a Web-based, tailored, fully automated IHCA for patients with type 2 diabetes or chronic low back pain against a standard website with identical content without tailoring (control condition) on patients' knowledge and empowerment.

Methods: We performed a blinded randomized trial with a parallel design. In the intervention group, the content was delivered in dialogue form, tailored to relevant patient characteristics. In the control group, the sections of the text were presented in a content tree without any tailoring. Participants were recruited online and offline and were blinded to their group assignments. Measurements were taken at baseline, directly after the first visit, and at 3-month follow-up. The primary hypothesis was that the tailored IHCA would have larger effects on knowledge and patient empowerment (primary outcomes) than the control website. The secondary outcomes were decisional conflict and preparation for decision making. All measurements were conducted by online self-report questionnaires. Intention-to-treat (ITT) and available cases (AC) analyses were performed for all outcomes.

Results: A total of 561 users agreed to participate in the study. Of these, 179 (31.9%) had type 2 diabetes and 382 (68.1%) had chronic low back pain. Usage was significantly higher in the tailored system (mean 51.2 minutes) than in the control system (mean 37.6 minutes; $P<.001$). Three months after system use, 52.4% of the sample was retained. There was no significant intervention effect in the ITT analysis. In the AC analysis, participants using the tailored system displayed significantly more knowledge at t1 ($P=.02$) and more emotional well-being (subscale of empowerment) at t2 ($P=.009$). The estimated mean difference between the groups was 3.9 (95% CI 0.5-7.3) points for knowledge and 25.4 (95% CI 6.3-44.5) points for emotional well-being on a 0-100 points scale.

Conclusions: The primary analysis did not support the study hypothesis. However, content tailoring and interactivity may increase knowledge and reduce health-related negative effects in persons who use IHCAs. There were no main effects of the intervention on other dimensions of patient empowerment or decision-related outcomes. This might be due to our tailored IHCA being, at its core, an educational intervention offering health information in a personalized, empathic fashion that merely additionally provides decision support. Tailoring and interactivity may not make a difference with regard to these outcomes.

Trial Registration: International Clinical Trials Registry: DRKS00003322; http://apps.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00003322 (Archived by WebCite at http://www.webcitation.org/6WPO0lJwE)

(J Med Internet Res 2015;17(3):e53) doi:10.2196/jmir.3904

KEYWORDS

Type 2 diabetes mellitus; back pain; randomized controlled trial; health communication; Internet

Introduction

Long-term conditions such as type 2 diabetes (T2D) and chronic low back pain (CLBP) are chronic diseases with high and still rising prevalence [1,2], which causes a significant burden on individuals as well as negative social and economic effects [3-8]. Thus, there is a strong need for cost-effective ways to improve the care of these long-term conditions.

To improve care of long-term conditions, patients, practitioners, scientists, and politicians have called for a greater empowerment of patients in the management of their chronic diseases [9]. Patient empowerment can be observed as a motivational construct reflecting the ability to positively influence self-management and health behavior. The main aspects of patient empowerment are knowledge of the disease, its course and treatment options, the ability to be involved in making medical decisions and relate to health care providers [10], and to manage one's health behavior and treatment regimens [11,12]. Schulz and Nakamoto additionally stressed that these factors must be accompanied by a volitional component to better predict changes in individuals' behavior [13]. The most popular definition of patient empowerment is probably that of Funnell et al [14] who defined patient empowerment as "the discovery and development of one's inherent capacity to be responsible for one's own life. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control, and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of their decisions". Patient empowerment and health-related knowledge can be considered as predictors of improved self-management and health outcomes [15,16].

In times of rapidly growing Internet adoption, the Web holds the opportunity to deliver health information [17] and self-management support [18] to large numbers of participants at a comparatively low cost and at the preferred time, place, and learning speed of the individuals. Existing systematic reviews and meta-analyses of Internet interventions in somatic diseases aimed at improving lifestyles (smoking, alcohol consumption, diet, physical exercise) show promising effects on either health- or cost-related outcome measures [19]. More specifically, recent reviews and studies on Internet interventions for adults with T2D [20,21] and CLBP [22-24] also found effects on knowledge, self-efficacy, health behavioral changes, and clinical outcomes. Evidence for Internet interventions can also be found with regard to effects on more proximal outcomes such as patient empowerment [22,25,26] or specific antecedents and mediators of patient empowerment [27].

A specific application of Internet interventions combines health information with at least one other type of support, for example, social support, decision support, or behavior change support: interactive health communication applications (IHCAs). These Internet interventions are expected to improve the knowledge, involvement in decision making, motivation, and self-efficacy of users, resulting in enhanced patient empowerment [28]. This improved empowerment can then enable users to initiate changes in health behaviors, which might result in improved clinical outcomes [28,29]. A Cochrane review found that IHCAs could have positive effects on knowledge, self-efficacy, and behavioral and clinical outcomes. However, the authors demanded more evidence regarding the most suitable application and delivery approaches of IHCAs and the effects of IHCAs for different chronic diseases [28].

Still, the effectiveness of those online applications is limited by high attrition rates [30,31], and users often visit a health intervention website only once [32-34]. A major body of evidence suggests that the effect of online interventions increases with the dose (longer stays, repeated website visits, total contact hours) [35,36], and the effectiveness is maximized if patients intensively work with the information offered [37-39] and return for repeated visits [40,41].

Computer tailoring strategies such as the individualization and personalization of information, as well as an interactive presentation, have been found to effectively increase the exposure to [42] and effectiveness of Web-delivered interventions [43,44]. However, these previous studies predominantly focused on tailoring in health behavior change interventions, with great variability in how the tailoring was carried out. In addition to the question of which elements of the intervention work, one remaining challenge of research with regard to Internet interventions is finding out which delivery methods (interactivity, tailoring, individualization) are effective [45]. Therefore, evidence is especially needed with regard to disease-specific tailoring and individualization strategies in IHCAs for T2D and CLBP, focusing on more proximal outcomes such as health-related empowerment and knowledge.

In this randomized controlled trial, we compared a tailored IHCA presenting information on T2D and CLBP, self-management education, and decision support to a website presenting the same information in a content tree without tailoring. The primary hypothesis was that the tailored and individualized delivery format has a greater effect on knowledge and patient empowerment than the control website. The secondary hypothesis was that users, when facing a health decision, experience less decisional conflict and feel better prepared for the consultation after using the tailored rather than the control website. This paper reports on the trial using the two guidelines that were published in 2011 on designing and reporting Internet intervention research [18,46].

Methods

Study Design

We performed a blinded two-armed randomized controlled trial with a parallel design. Measurements were scheduled immediately before the first use of the system, immediately after use, and at 3-months follow-up. Knowledge (primary outcome) and decisional conflict and preparation for decision making (secondary outcomes) were assessed immediately after the first visit. Patient empowerment (primary outcome) was assessed 3 months after the first visit. All measurements were online self-assessment questionnaires. The study design and procedures have been published in two study protocols [47,48]. There were no important changes to the study design, methods, or trial outcomes after trial commencement. Data collection took place between August 2012 and April 2013.

Study Population

The eligibility criteria were age ≥18 years, access to the Internet, sufficient computer/Internet literacy, and a self-reported diagnosis of T2D or CLBP. CLBP was defined as pain in the lower back almost every day for more than 12 weeks [49].

Recruitment

In general, based on the Cochrane review by Murray et al [28], we expected a small effect (Cohen's d=0.2) of the IHCA. Based on the review by van Vugt et al [20] for diabetes, and based on a similar previous study [23] for patients with back pain, we did expect that the tailored intervention would perform better (d=0.2) than the control on the primary outcome knowledge for both patient groups. Based on the meta-analysis by Samoocha et al [25], we also expected a small effect with regard to the primary outcome empowerment for patients with T2D and CLBP. To detect a small effect with an alpha of .05 and a power of 0.80 (one-tailed t test), a sample size of 310 (155 per group) was required. Due to the experiences of other Internet trials [40] and the effect of incentives [50], we expected a dropout rate of 20% between registration and immediately after the first visit. Thus, we aimed to include a sample of 414 at baseline. Because we were not aware of differences in the dropout rates between T2D and CLBP patients, we calculated with the same expected dropout rate for both groups.

Recruitment took place using a number of pathways. Two pension funds and six health insurance companies were contacted to request whether they were interested in informing their insurants about the study (eg, via their website, magazine, or newsletter). Three outpatient treatment networks (in which mainly primary care and specialized practices are organized), 15 diabetology practices, 15 practices specialized in CLBP, 87 primary care practices, six rehabilitation centers and hospitals, seven patient associations, and 192 self-help groups were contacted and asked whether they were interested in displaying flyers. Additionally, information on the study and a link to it were disseminated via the mailing list of a population-representative online panel of the University of Münster. Information on the study was also available on the study website. Information and links were placed on the website of the University Medical Centre Hamburg-Eppendorf, as well as on websites that are structurally connected to the work group, one external private diabetes information website, and the website of a doctors' and therapists' CLBP network. An article was also published in a regional newspaper (Hamburger Abendblatt).

Study Procedures

In this purely Web-based trial without any face-to-face component, every person meeting the eligibility criteria could register for the study on the study website (open survey on a site created exclusively for the study) by providing a unique email address and choosing a password for login. After providing online informed consent and completing the pre-assessment (T2D: eligibility criteria, demographic data, time since diagnosis, treatment; CLBP: eligibility criteria, demographic data, chronic pain grade [51]), the participants were randomly assigned to the tailored system or the control system with the content tree. The informed consent was the first page entered after login. The participants were told the approximate length of time of the survey, where data were stored and for how long, who the investigators were, and the purpose of the study. Consent was provided via checkbox. Pre-assessments were completed after providing informed consent and before randomization. Only users who had filled in the pre-assessment were allowed to use the intervention (mandatory survey). In the control condition, tailoring variables (T2D: diabetes self-care [52], barriers to insulin treatment (BIT) [53], knowledge; CLBP: coping style [54], knowledge) were assessed immediately after randomization and before the intervention. In the tailored version, coping style (CLBP) was also assessed immediately after randomization and before the intervention, whereas knowledge, diabetes self-care, and barriers to insulin treatment were assessed throughout the intervention. The reason for this is that when tailoring to coping style, the user's coping type is determined in the beginning. At different places throughout the intervention, messages are tailored to this pre-assessed type. However, when tailoring to knowledge, diabetes self-care, and barriers to insulin treatment, there is no typology. Instead, individual items are assessed at different places throughout the intervention, and at that assessment point, one single message is tailored to the user's answer to the single item. Immediately after their first visit to the tailored IHCA or the control website, all participants were asked to fill in the post-assessment.

All participants received an email 3 months after their first visit asking them to fill in the online follow-up questionnaire. Participants were reminded by email twice, at 2 weeks and 4 weeks after the first email. Because non-monetary incentives have been shown to reduce attrition in online trials [50,55], participants who had answered all questionnaires received a €10 Amazon gift voucher. The voucher code was sent to them by email at the end of the study.

Participants were free to use the intervention as often and as long as they wished. Between the post and follow-up assessments, no prompts or reminders were used. No recommendations were provided regarding the duration or frequency of use, but the IHCA was designed to be used in one "go". Consequently, there were no prompts to use the interventions. No payment was required. Information on the frequency and duration of usage was gathered via server registrations. Usage data, data from the self-assessment questionnaires, and personal data such as name and email address were saved separately. Data were pseudonymized. After data collection, personal data were deleted. If a participant withdrew their informed consent to study participation, their data were immediately erased. All data will be erased 5 years after the end of the study.

The study was approved by the Hamburg Medical Chamber ethics committee.

Treatment Allocation

The informed consent outlined that participants would be randomly assigned in consecutive order (50:50) to one of two presentation formats holding the same content. The random allocation (simple randomization) of the participants was automatically performed by the software program, which also provided the website and triggered automatic emails to participants. This centralized, software-driven, computerized, simple randomization procedure to the intervention or control group assured the concealment of allocation, so that randomization could not be subverted by the team of researchers. The two formats were not further elucidated, so participants did not know whether they were in the intervention or control group.

Description of the Intervention and Control Conditions

The tailored IHCA is designed as a stand-alone intervention that complements usual care. The T2D content of both the tailored IHCA and the control website covered basic information on diabetes (pathophysiology, epidemiology, subtypes, symptoms) and its sequelae (neuropathy, nephropathy, retinopathy, heart and vessel problems, sexual dysfunction, and depression), information on health behavior and lifestyle changes, and treatment options (see Table 1). The CLBP content covered essential information on CLBP (physiology of pain, acute vs chronic pain, chronification, epidemiology, psychological aspects, coping and pain management) and related psychological problems (depression, anxiety), diagnostic procedures, and treatment options (pharmacological and non-pharmacological; see Table 1). The look of the website (colors, font, figures, and pictures) was identical in both conditions. After registration, each participant received a password via email with which they could log onto the system as often as they wished.

Table 1. Overview over the IHCA contents.

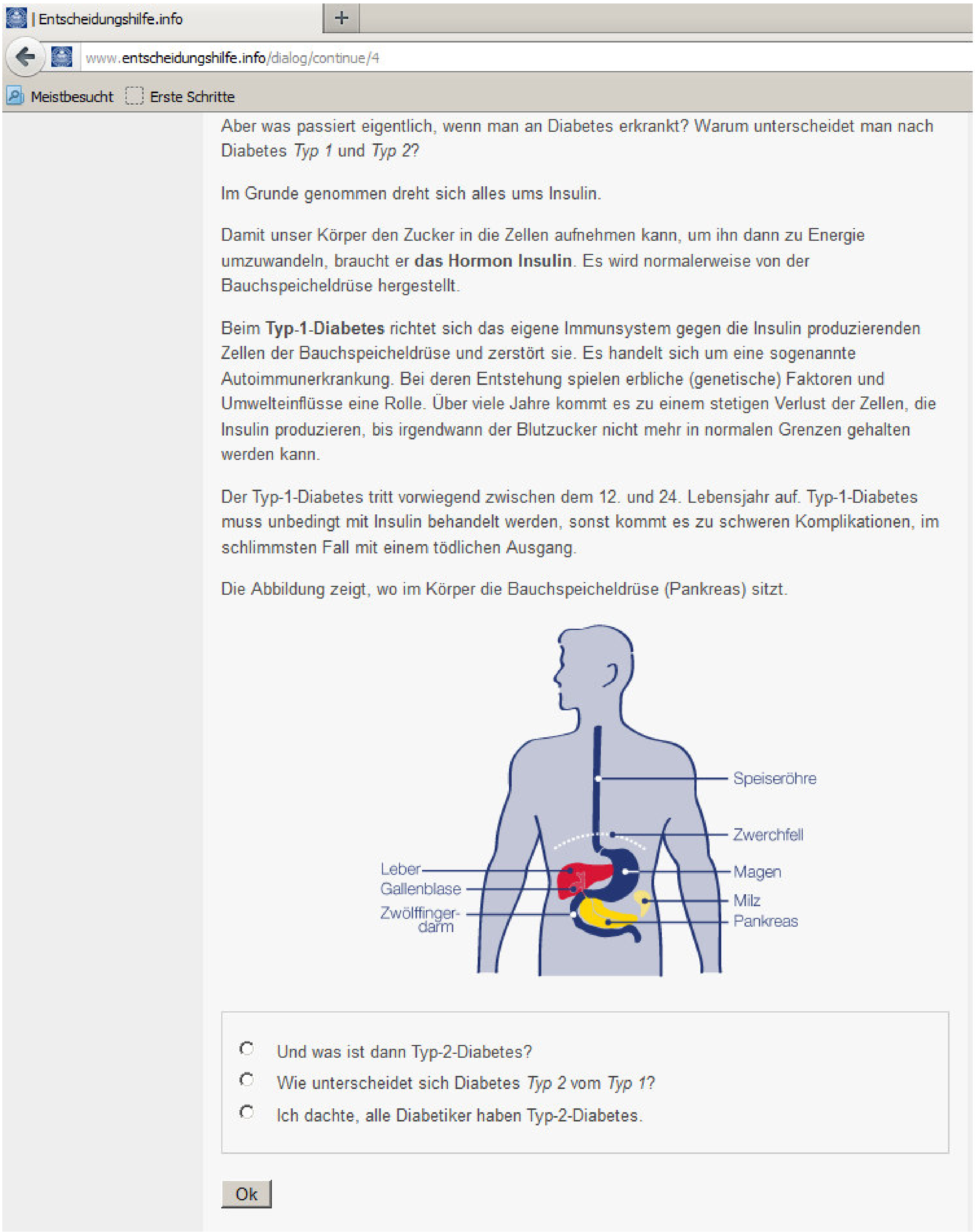
Type 2 diabetes	Chronic low back pain
1. Introduction: What is this website?	1. Introduction: What is this website?
1.1. Where does the information on this site come from?	1.1. Where does the information on this site come from?
2. Basics	2. CLBP Basics
2.1. Different diabetes types	2.1. Physiological basics: back, spine, and intervertebral discs
2.2. How do I know I have type 2 diabetes?	2.2. What exactly is pain?
2.3. What causes type 2 diabetes?	2.3. What is the difference between acute and chronic pain?
2.4. How many people live with type 2 diabetes?	2.4. Why does the pain stay when the physical injury heals?
2.5. How is type 2 diabetes diagnosed?	2.5. How many people live with CLBP?
2.6. Diabetes ABCs	2.6. Managing CLBP in everyday life
2.7. Blood sugar control	3. How is CLBP diagnosed?
3. How is type 2 diabetes treated?	3.1. How much diagnostics makes sense and at which point?
3.1. What are the goals of diabetes treatment?	3.2. Diagnostic options
3.2. What can you do to treat your diabetes?	4. How is CLBP treated?
3.3. When should you consider taking pills?	4.1. How much treatment makes sense and at which point?
3.4. Insulin treatment	4.2. What is the natural, untreated course of CLBP?
3.5. Summary and overview of the treatment options	5. Are there accompanying conditions or sequelae of CLBP?
4. Acute complications and sequelae	6. Treatment options
4.1. Which acute complications can occur?	6.1. How do I recognize good treatment?
4.2. Which sequelae can occur?	7. Summary
5. Additional information and literature	8. Additional information and literature
5.1. Associations and self-help	8.1. Associations and self-help
5.2. Websites	8.2. Websites
5.3. Journals	8.3. Journals
5.4. Books	8.4. Books
6. Glossary	9. Glossary
7. Legal notice	10. Legal notice
8. References	11. References

Tailored Condition

In the tailored condition, the delivery format was a dialogue-based, tunneled design tailoring the content and tone of the dialogue to relevant patient characteristics. It was developed based on two preliminary studies exploring the quality of existing websites [56] and assessing patient needs [57]. A tunneled design, in which the user is guided through the content, has been found to increase website use and knowledge gained from a website more than a design with more user control [58]. Still, it might annoy the user and evoke resistance [59]. Consequently, we decided to give the user some control over the path they take through the dialogue: at the end of each text passage, the user chose one of at least three reply options. These options always included at least one answer that expressed disagreement or doubt. The user then received a tailored answer that mirrored what the user had said, respected disagreement, conveyed esteem, and empathy and built an individualized bridge to the next content block. It was not possible to skip a whole content block (meaning the subheadings in Table 1), but it was possible to view the content in more or less detail.

Tailoring was performed using the following characteristics for diabetes patients: current T2D knowledge and preferred level of detail, attitudes toward self-care, and, if insulin treatment was a relevant topic, psychological barriers to it. The questionnaires that assessed patient characteristics were presented during the dialogue. In the beginning of the respective section (eg, diabetic foot), the participant was asked about their knowledge or attitude toward the topic, and the following section was then modified according to their answer. Figure 1 shows such a dialogue window.

Figure 1. Dialogue window.



Aber was passiert eigentlich, wenn man an Diabetes erkrankt? Warum unterscheidet man nach Diabetes *Typ 1* und *Typ 2*?

Im Grunde genommen dreht sich alles ums Insulin.

Damit unser Körper den Zucker in die Zellen aufnehmen kann, um ihn dann zu Energie umzuwandeln, braucht er **das Hormon Insulin**. Es wird normalerweise von der Bauchspeicheldrüse hergestellt.

Beim **Typ-1-Diabetes** richtet sich das eigene Immunsystem gegen die Insulin produzierenden Zellen der Bauchspeicheldrüse und zerstört sie. Es handelt sich um eine sogenannte Autoimmunerkrankung. Bei deren Entstehung spielen erbliche (genetische) Faktoren und Umwelteinflüsse eine Rolle. Über viele Jahre kommt es zu einem stetigen Verlust der Zellen, die Insulin produzieren, bis irgendwann der Blutzucker nicht mehr in normalen Grenzen gehalten werden kann.

Der Typ-1-Diabetes tritt vorwiegend zwischen dem 12. und 24. Lebensjahr auf. Typ-1-Diabetes muss unbedingt mit Insulin behandelt werden, sonst kommt es zu schweren Komplikationen, im schlimmsten Fall mit einem tödlichen Ausgang.

Die Abbildung zeigt, wo im Körper die Bauchspeicheldrüse (Pankreas) sitzt.

○ Und was ist dann Typ-2-Diabetes?
○ Wie unterscheidet sich Diabetes *Typ 2* vom *Typ 1*?
○ Ich dachte, alle Diabetiker haben Typ-2-Diabetes.

Diabetes Section and its Tailoring

Users' attitudes toward self-care were assessed with items that we adapted from the Summary of Diabetes Self-care Activities Measure (SDSCA) [52] to match the respective content section (see Table 2). Users were asked how important a certain self-care activity or piece of advice is for them. Every item had three reply options: "important or very important", "a little important", and "not important". The goal and techniques were inspired by Motivational Interviewing, a counseling method for addressing ambivalence about change [60].

For example, if a user attached great importance to the self-care behavior in question, this behavior was reinforced, positive consequences of the self-care behavior were stressed, and/or ideas were provided on how to keep up motivation. If a user found the self-care behavior in question “a little important”, an understanding of the users’ ambivalence was expressed, and the importance the user attached to the self-care behavior (little as it might be) was stressed and reinforced. Finally, if a user rated the self-care behavior as not important, the autonomy expressed in this answer was respected in order not to elicit resistance. Table 2 shows an example of self-care tailoring.

Table 2. Example of self-care tailoring: Response to “If you feel thirsty and urinate frequently, it usually means your blood sugar is…”.

Response options	Reply
High (correct answer)	That’s correct! If you want to learn more about what happens in the body and how you know that you have type 2 diabetes, you can go into more detail. Otherwise you can proceed to the next question. • I’d like to learn more about that topic. • I’d like to proceed to the next question.
Low (wrong answer)	No, that’s not correct. Actually, it’s the other way around: When you have type 2 diabetes, there is too much sugar in your blood. Unfortunately, you don’t realize it in the beginning. However, there are warning signs. The most important signs are […]
I don’t know	That’s ok, [name], that’s what we are here for: to learn, for example, what high blood sugar does to your body. When you have type 2 diabetes, there is too much sugar in your blood. Unfortunately, you don’t realize it in the beginning. However, there are warning signs. The most important signs are […]

Psychological barriers to insulin treatment were assessed using the BIT questionnaire [53]. The BIT assesses the following expectations regarding insulin treatment: fear of injection and self-testing; expectations regarding positive insulin-related outcomes; expected hardships from insulin treatment; stigmatization by insulin injections; and fear of hypoglycemia. There are two or three items per subscale. In every item, a certain hope or fear with respect to insulin treatment is expressed (eg, “I am afraid of the pain when injecting insulin”). The user is asked to rate their agreement on a scale from 1 (completely disagree) to 10 (completely agree). A score from 1-10 can be calculated for each subscale. A validating and understanding (if a fear was expressed) or reinforcing (if a hope was expressed) answer was given. If there was a sign of fear (score >1), further information on the topic in question was provided.

Chronic Low Back Pain Section and its Tailoring

For CLBP, the concepts of coping style according to the avoidance endurance model (AEM) [37] and current CLBP knowledge and preferred level of detail were used for tailoring the provided information to the individual preferences of the users. The individual coping style was assessed using a questionnaire, which was presented before starting the dialogue. There are four AEM subtypes: the “depressed endurer”, which is high endurance coping (EC) and high depressiveness (D), the “happy endurer”, which is high EC and low D, the “depressed avoider”, which means low EC and high D, and the “adaptive coper”, which means low EC and low D (see Table 3). During the virtual conversation, the content, tone, and messages were tailored to the coping style of the individual user. The items that assess CLBP knowledge were presented during the dialogue. In the beginning of the respective section (eg, physiological basics), the user was asked about their level of knowledge on this subject. Depending on the response, the subsequent section was accordingly amended.

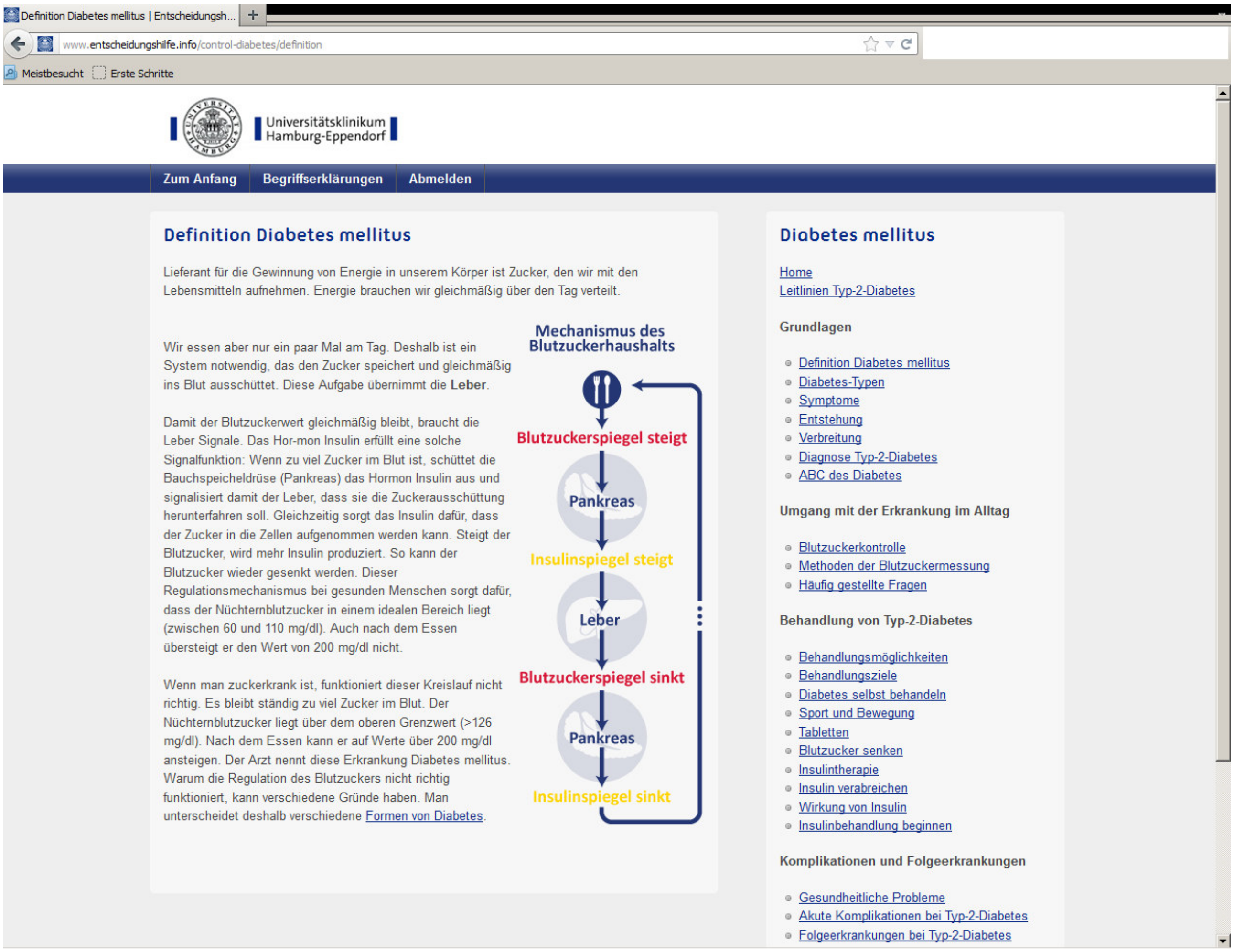
Table 3. Example of tailoring to coping style (CLBP).

Coping type	Adaptive coper	Happy endurer	Depressed endurer	Depressed avoider
Description of coping style	You go about your pain in a matter-of-fact manner. You know that on one hand, there is no serious disease behind it but that on the other hand, it can signal to you physical strain. You are good at taking short breaks at the right time to keep up your daily routine – maybe temporarily a little slower than usual.	You tend to keep going in your daily routine even if the pain is strong. This is, on one hand, a personal strength. However, at the same time, you run the risk of actually straining your muscles, ligaments, joints, and intervertebral discs.	You are a multi-tasker. Saying “No” to someone or not getting things done is hard on you. To meet requirements and get things done, you push yourself to your limits and beyond. Often, you don’t listen to your body before it is overstrained.	You are unsettled by your pain. You are worried that there might be a serious disease behind it, and / or you avoid activities that might increase the pain.
Take home message	Keep on like that! Make exercise part of your routine if you haven´t yet. Choose something fun and back-friendly. If you strengthen your muscles and stick to your relaxing breaks, the pain should soon vanish.	Even if it’s hard, try to pay more attention to your pain and take breaks early enough. Keep working, do things that are pleasant and fun, and keep moving – but remember to pause when you might need to!	Reconsider what you are asking from yourself: do you really have to demand so much? Maybe there are times when it is possible to leave something undone, to do it o.k. instead of perfectly, or to ask for assistance. These things are closely related to your pain.	Pain is unpleasant but not dangerous. Don’t let it suffocate you. Expand your limits step by step, and make pleasant activities a part of your everyday life.

Control Condition

On the control website, the content was not tailored and was not presented in a dialogue format. In contrast to the tailored, interactive version, the control website was not tunneled, and there was no guidance through the content. On the right side of each page, a content tree displayed a menu of all content sections that the participant could click on to get to the content of interest (see Figure 2). On both the intervention and control websites, the institutional affiliation of the University Medical Center Hamburg-Eppendorf was displayed at the top of each webpage.

Figure 2. Control window.



Definition Diabetes mellitus

Lieferant für die Gewinnung von Energie in unserem Körper ist Zucker, den wir mit den Lebensmitteln aufnehmen. Energie brauchen wir gleichmäßig über den Tag verteilt.

Wir essen aber nur ein paar Mal am Tag. Deshalb ist ein System notwendig, das den Zucker speichert und gleichmäßig ins Blut ausschüttet. Diese Aufgabe übernimmt die **Leber**.

Damit der Blutzuckerwert gleichmäßig bleibt, braucht die Leber Signale. Das Hor-mon Insulin erfüllt eine solche Signalfunktion: Wenn zu viel Zucker im Blut ist, schüttet die Bauchspeicheldrüse (Pankreas) das Hormon Insulin aus und signalisiert damit der Leber, dass sie die Zuckerausschüttung herunterfahren soll. Gleichzeitig sorgt das Insulin dafür, dass der Zucker in die Zellen aufgenommen werden kann. Steigt der Blutzucker, wird mehr Insulin produziert. So kann der Blutzucker wieder gesenkt werden. Dieser Regulationsmechanismus bei gesunden Menschen sorgt dafür, dass der Nüchternblutzucker in einem idealen Bereich liegt (zwischen 60 und 110 mg/dl). Auch nach dem Essen übersteigt er den Wert von 200 mg/dl nicht.

Wenn man zuckerkrank ist, funktioniert dieser Kreislauf nicht richtig. Es bleibt ständig zu viel Zucker im Blut. Der Nüchternblutzucker liegt über dem oberen Grenzwert (>126 mg/dl). Nach dem Essen kann er auf Werte über 200 mg/dl ansteigen. Der Arzt nennt diese Erkrankung Diabetes mellitus. Warum die Regulation des Blutzuckers nicht richtig funktioniert, kann verschiedene Gründe haben. Man unterscheidet deshalb verschiedene Formen von Diabetes.

Potential Risks for Participants

Research focusing on the negative effects of Internet interventions is scarce. One recent study on the side effects of Internet interventions for social anxiety disorder found that 14% of participants experienced negative effects, of which the most frequent was the emergence of new symptoms [61]. Concerning long-term conditions like T2D or CLBP, possible negative effects on cognitive or emotional variables such as self-efficacy or anxiety should be considered, because of high demands concerning self-management tasks or fear-inducing information. However, several recent reviews did not find any contraindications or negative side effects of IHCAs [21,28].

Intervention Development and Trial Design

The development process was user-oriented, evidence-based, and peer-reviewed. Two preliminary studies were conducted informing intervention development. To find out which topics are relevant to patients with T2D or CLBP, we performed a needs assessment with two steps. First, we conducted semistructured interviews with 12 physicians (T2D: 7 internists, 2 of whom were specialized in diabetology; CLBP: 5 physicians specialized in orthopedics) and 19 patients (10 with T2D, 9 with CLBP). In the second step, a self-assessment questionnaire was developed based on the main results of the interviews, and it was administered to a new and larger patient sample (T2D: N=178, CLBP: N=117). The needs assessment for T2D is described in more detail elsewhere [57]. We then conducted a cross-sectional study on the information and support available online, evaluating the formal quality, usability, and presence and quality of decision support of websites for CLBP or T2D. The results on T2D have been published elsewhere [56]. To ensure that the information is evidence-based, selected treatment guidelines were used as primary sources. Based on review articles [62,63] and up-to-dateness, the British [64] and the American [65] T2D guidelines were chosen. For CLBP, certain guidelines [49,66,67] and Cochrane reviews [68-73] were chosen. The theoretical foundations and the development of the T2D IHCA are described in more detail elsewhere [74]. Programming and graphic design were performed by the Gaia AG, a subcontractor specializing in Web-based health interventions. The intervention was not changed during the trial.

Outcomes Assessment

The primary outcomes were knowledge (assessed immediately after the first visit) and patient empowerment (assessed at 3-months follow-up).

T2D knowledge was assessed immediately after the first visit with 16 items, and CLBP knowledge was assessed with 29 items. The items were developed to map the content covered in the sections of the tailored IHCA and could be answered with true/false/I don’t know.

For the context of long-term conditions, patient empowerment was defined as a feeling of confidence and the ability to manage the challenges resulting from the chronic disease [10]. An empowered patient can better understand and participate in care processes, use resources, and measures to reduce negative emotions, and enhance strategies to cope with chronic disease. Consequently, patient empowerment includes intrapersonal and behavioral dimensions [75]. However, at the time this study started, we could not identify a generic, adequately validated questionnaire of empowerment for general use in long-term conditions as reported by a systematic review [76]. Patient empowerment was therefore measured with the Health Education Impact Questionnaire (heiQ) [77,78]. The heiQ includes 42 items and eight dimensions: Positive and Active Engagement in Life, Health Directed Behavior, Skill and Technique Acquisition, Constructive Attitudes and Approaches, Self-Monitoring and Insight, Health Service Navigation, Social Integration and Support, and Emotional Well-being. Schuler et al [79] translated the questionnaire into German and evaluated its psychometric properties (Raykov's Composite Reliability Coefficient, factorial and concurrent validity). They were able to replicate the structure of the eight scales and found the questionnaire to be a reliable and valid measure. We removed Social Integration and Support from our testing battery because we did not expect an effect of our IHCA on that dimension. Although these 7 heiQ scales may not comprehensively measure the multidimensional construct of empowerment given, the selected scales do cover the intrapersonal and behavioral dimensions that are part of health-related empowerment. Patient empowerment was assessed only at 3-months follow-up because we expected changes on the heiQ to take more time.

The secondary outcomes were decisional conflict and preparation for decision making, assessed immediately after the first visit. Decisional conflict was assessed with the Decisional Conflict Scale (DCS) by O'Connor [80,81]. This questionnaire measures personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values, and unsupported in decision making, and effective decision making such as feeling that the choice is informed, values-based, and likely to be implemented and expressing satisfaction with the choice. Reliability is good, with a Cronbach alpha between .78 and .92 [80]. The discriminant validity is acceptable.

Preparation for decision making was measured with the Preparation for Decision Making Scale (PDMS) [82,83]. This 11-item scale assesses a patient's or participant's perception of how useful a decision aid or decision support intervention was in preparing them to communicate with their practitioner in making a health decision. The reliability is very good, ranging from alpha=.92 to alpha=.94. Both questionnaires were offered only to those participants who had indicated that they were facing a health decision concerning their T2D or CLBP. To avoid missing data, all questionnaires included validation checks that alerted participants when their answers were implausible or when items were skipped. Usage data were assessed via log files. Before going online, the usability and technical functionality of the electronic questionnaire was tested by members of the research team. All outcomes were self-assessed through online questionnaires. The questionnaires were not validated for online use.

Statistical Analysis

Baseline Data

Data on sample characteristics were analyzed using *t* tests (for metric data) and chi-square tests (for categorical data) to test for differences between treatment groups. A dropout analysis was performed to test for possible attrition bias. The effects of the intervention (tailored vs control condition), disease (T2D vs CLBP), gender, age, education, family status, and employment status on attrition were evaluated using *t* tests (for metric data) and chi-square tests (for categorical data).

Intention-to-Treat Analysis

To evaluate the effectiveness of the tailored IHCA, multiple linear regression analyses were performed using the intervention, the disease, and their interaction term as dummy-coded predictors. Intention-to-treat (ITT) and available cases (AC) analyses were performed for all outcomes. The ITT approach pooled 10 analyses, estimating missing values by a multiple regression approach using all outcomes, demographic data, and diseases but not intervention information for multiple data imputation (MI). In the primary ITT analysis, a corrected level of significance was used for testing the eight primary outcomes (Bonferroni adjustment); thus, the results with a type I error rate of $P<.001$ were considered statistically significant. For secondary outcomes, $P<.05$ was used.

Sensitivity Analysis (Available Cases)

The AC analysis included all of the available participants providing valid data on $t_1$and/or t_2. In both analyses, estimated marginal means with standard errors for both the tailored and control conditions were calculated with analysis of variance (ANOVA). Additionally, these parameters were also retained for subgroups stratified by condition. In all AC analyses, results with a type I error rate of $P<.05$ were considered statistically significant. All analyses were performed using SPSS 18.0.

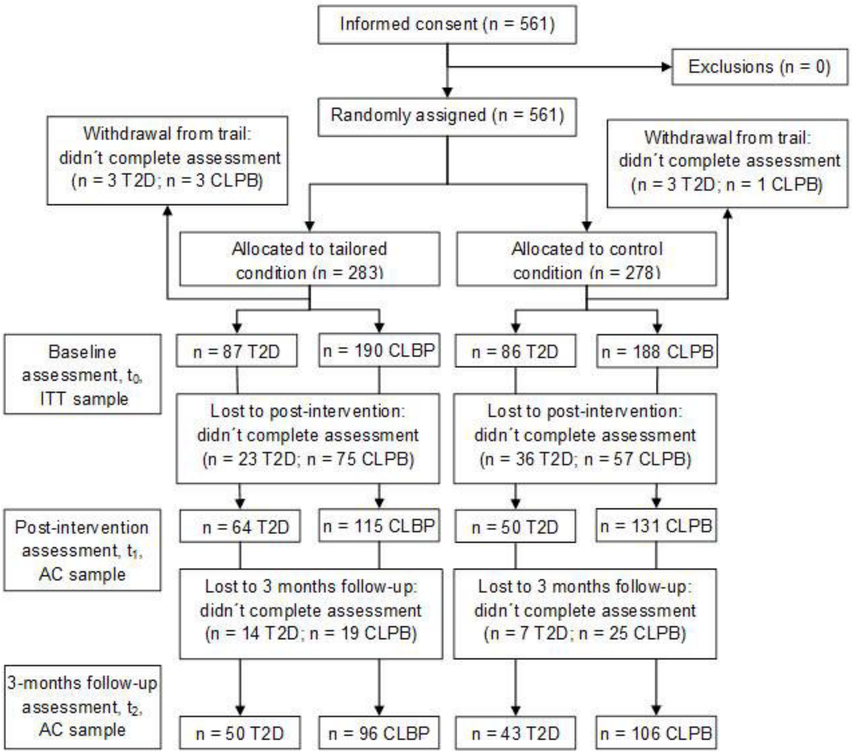
Results

Participant Flow

A total of 561 users agreed to participate in the study. Of these, 179 (31.9%) had T2D, and 382 (68.1%) had CLBP. Analyzable data (availability of at least basic demographic information such as age and gender) at $t_0$were available from 551 users. For data analysis at t_1, data for 360 participants was available (availability of data for at least one of the outcomes of t_1). Three months after system use, the questionnaires of 295 participants contained data on at least one of the three outcomes at $t_2$and could thus be used for analyses (Figure 3). There were no significant differences with regard to gender, age, family status, educational level, or working status between those participants who provided all questionnaires and those who dropped out of the study after providing at least demographic data. Participants with T2D who were treated with oral anti-diabetics provided data at $t_1$significantly more often than those who were treated with dietary changes or insulin. Those participants who provided data at t_1 spent significantly more time using the system, and participants in the tailored condition spent significantly more time in the IHCA than participants in the control condition spent in the control website (see Table 4).

There was also selective dropout between t_0 and t_1 among participants with CLBP. At t_1, participants with CLBP were significantly (*P*=.015) younger in the tailored condition (mean 48.0; SD 12.9) than in the control condition (mean 52.0; SD 12.7). Additionally, there are significantly (*P*=.021) more participants with higher education in the tailored condition (62.6%) than in the control condition (48.9%). Among the participants with T2D, there was no selective dropout between t_0 and t_1. At t_2, there were no significant differences in either of the two diseases (T2D or CLBP).

Figure 3. Flow of participants after randomization (ITT=intention-to-treat, AC=available cases).



Baseline Data

The mean age was 52.2 years (SD 13.1) in the tailored condition and 52.7 years (SD 13.0) in the control condition. Of the participants using the IHCA, 58.5% (162/277) were female (control condition: 59.1%, 162/274). There were no statistically significant differences in further demographic variables such as marital status, educational level, and working status. Sample characteristics are shown in Table 4.

Table 4. Sample characteristics[a].

	Tailored condition t_0 (n=277)	Control condition t_0 (n=274)	Baseline differences (tailored vs control condition), *P* value	Total t_1 (n=360)	Dropout analysis ($t_1$available vs $t_1$not available), *P* value
Female, n (%)	162 (58.5)	162 (59.1)	.474	216 (60.0)	.467
Age in years, mean (SD)	52.2 (13.1)	52.7 (13.0)	.668	51.8 (13.1)	.116
Family status, n (%)					
Single	67 (24.2)	77 (28.1)	.742	100 (27.8)	.341
Married	162 (58.5)	150 (54.7)		194 (53.9)	
Divorced	39 (14.1)	37 (13.5)		52 (14.4)	
Widowed	9 (3.2)	10 (3.6)		14 (3.9)	
Educational level, high[b], n (%)	148 (53.4)	140 (51.1)	.322	198 (55.0)	.089
Working status, employed, n (%)	145 (55.6)	160 (58.4)	.282	207 (57.5)	.786
Years since diagnosis[c], mean (SD)	11.1 (7.6)	10.5 (8.0)	.649	10.7 (8.2)	.858
Current diabetes treatment [a]					
Dietary change	40 (44.4)	46 (51.7)	.371	57 (50.0)	.535
Insulin	35 (38.9)	25 (28.1)	.154	43 (37.7)	.139
Oral anti-diabetics	59 (65.6)	55 (61.8)	.643	80 (70.2)	.023
Disability score[d], mean (SD)	41.4 (22.5)	42.7 (22.8)	.573	42.2 (20.9)	.855
System usage in minutes, mean (SD)	51.16 (39.7)	37.6 (35.0)	<.001	49.7 (35.1)	<.001

[a] t_0=demographic data available (ITT population); t_1= at least one outcome after intervention reported.

[b] more than 10 years of education.

[c] for patients with diabetes.

[d] for patients with back pain.

Intention-to-Treat Analysis

The following results were obtained using the ITT approach including all randomized participants. The results of the sensitivity analysis using the available cases approach are reported in a separate section. Table 5 shows all of the results in detail.

Knowledge Immediately After the First Visit (t1)

With regard to knowledge of T2D or CLBP users in the tailored condition had a mean score of 77.9 (SE 1.2) compared with 76.3 (SE 1.3) in the control condition. There were no significant differences between groups (*P*=.53). There was, however, a significant difference between users with T2D and CLBP (*P*<.001), indicating higher knowledge scores in the T2D group. In addition, we observed a significant interaction effect between intervention and disease (*P*=.04), more strongly favoring the tailored condition over the control condition in CLBP (estimated mean difference of 4.6 [95% CI 1.0-8.2] points on a 0-100 points scale) than in T2D participants (estimated mean difference of -1.6 points [95% CI -7.4 to 4.2] on a 0-100 points scale).

Patient Empowerment at 3-Month Follow-Up (t2)

The heiQ does not provide a total score for patient empowerment. Table 5 shows the results for the seven included dimensions. There was no significant intervention main effect or interaction. However, there was a significant disease main effect on the dimensions Skill and Technique Acquisition (*P*=.01) and Self-Monitoring and Insight (*P*=.04), both indicating higher scores for users with T2D.

Decisional Conflict Immediately After the First Visit (t1)

There was a highly significant disease main effect. After the first use of the system, decisional conflict was lower in the CLBP group than in the T2D group (*P*<.001). There was no significant intervention main effect and no significant interaction.

Preparation for Decision Making Immediately After the First Visit (t1)

There was no significant main effect or interaction.

Table 5. Results of ITT and AC analyses.

	N	Tailored condition			Control condition			Intervention main effect P	Disease main effect P	Intervention x disease P
		T2D,M (SE)	CLBP,M (SE)	Total, M (SE)	T2D, M (SE)	CLBP, M (SE)	Total, M (SE)			
Intention-to-treat analysis										
Primary outcomes										
Knowledge	551	81.3 (1.9)	74.4 (1.2)	77.9 (1.2)	82.9 (2.3)	69.8 (1.4)	76.3 (1.3)	.53	<.001	.04
Positive and active engagement in life	551	71.9 (2.5)	69.7 (1.8)	70.8 (1.4)	71.4 (2.3)	70.9 (1.8)	71.2 (1.4)	.88	.86	.43
Health directed behavior	551	63.5 (3.9)	68.7 (2.4)	66.1 (2.4)	63.7 (3.3)	68.3 (2.4)	66.0 (2.0)	.97	.28	.92
Emotional well-being	551	68.8 (3.9)	63.2 (2.8)	66.0 (2.6)	62.6 (3.7)	60.2 (2.8)	61.4 (2.3)	.28	.60	.66
Constructive attitudes and approaches	551	78.3 (2.9)	75.4 (2.1)	76.8 (1.9)	75.8 (2.5)	75.6 (1.9)	75.7 (1.6)	.498	.95	.59
Skill and technique acquisition	551	77.6 (2.6)	65.1 (1.7)	71. 4 (1.5)	75.8 (2.9)	67.6 (1.7)	71.7 (1.8)	.62	.01	.36
Self-monitoring and insight	551	80.1 (2.1)	70.8 (1.4)	75.4 (1.4)	79.5 (2.2)	73.4 (1.3)	76.5 (1.2)	.85	.04	.52
Health service navigation	551	77.9 (3.1)	70.0 (2.1)	73.9 (2.0)	74.0 (2.9)	69.7 (1.8)	71.8 (1.6)	.32	.24	.44
Secondary outcomes										
Decisional conflict	551	79.7 (2.3)	61.3 (1.6)	70.5 (1.5)	75.5 (2.3)	60.3 (1.7)	67.9 (1.4)	.15	<.001	.33
Preparation for decision making	551	60.5 (3.4)	53.8 (2.5)	56.7 (2.1)	57.6 (3.7)	51.2 (2.3)	54.4 (2.2)	.57	.14	.85
Available cases analysis										
Primary outcome										
Knowledge	330	81.1 (1.9)	77.1 (1.4)	79.1 (1.2)	81.8 (2.1)	68.7 (1.3)	75.2 (1.2)	.02	<.001	.008
Positive and active engagement in life	295	71.8 (2.6)	69.9 (1.8)	70.9 (1.6)	71.3 (2.8)	71.3 (1.8)	71.3 (1.6)	.86	.68	.68
Health directed behavior	295	63.0 (3.4)	69.4 (2.5)	66.2 (2.1)	64.9 (3.7)	68.7 (2.4)	66.8 (2.2)	.84	.10	.68
Emotional well-being	295	70.8 (3.7)	66.1 (2.6)	68.5 (2.3)	60.7 (3.9)	59.3 (2.5)	60.0 (2.3)	.009	.35	.60
Constructive attitudes and approaches	295	78.8 (2.8)	76.1 (2.0)	77.5 (1.7)	3.2 (0.09)	74.5 (3.0)	75.2 (1.9)	.30	.68	.51
Skill and technique acquisition	295	78.3 (2.4)	64.3 (1.7)	71.3 (1.5)	75.0 (2.6)	68.8 (1.6)	71.9 (1.5)	.78	<.001	.06
Self-monitoring and insight	295	80.3 (1.9)	70.0 (1.3)	75.2 (1.2)	79.3 (2.0)	74.7 (1.3)	77.0 (1.2)	.27	<.001	.09
Health service navigation	295	79.1 (2.7)	71.2 (1.9)	75.2 (1.6)	73.4 (2.9)	69.8 (1.8)	71.6 (1.7)	.13	.02	.37
Secondary outcomes										
Decisional conflict	324	79.9 (2.4)	61.9 (1.8)	70.9 (1.5)	74.8 (2.7)	60.4 (1.7)	67.6 (1.6)	.13	<.001	.47
Preparation for decision making	324	61.0 (3.3)	52.1 (2.4)	56.4 (2.0)	55.7 (3.6)	51.2 (2.2)	53.5 (2.1)	.29	.02	.47

Sensitivity Analysis (Available Cases)

In addition to the ITT approach, we performed all calculations following the AC approach, including only participants who filled in all of the questionnaires. The aim of this procedure was to determine the extent to which missing data impacted the results reported above (sensitivity analysis).

Knowledge Immediately After the First Visit (t1)

The AC analysis showed a significant intervention main effect for knowledge (*P*=.02) indicating higher scores for the tailored condition (mean 79.1, SE 1.2) than for the control condition (mean 75.2, SE 1.2). The estimated mean difference between groups was 3.9 (95% CI 0.5-7.3) points on a 0-100 points scale. There was a significant disease x intervention interaction (*P*=.008) for knowledge, indicating the superiority of the tailored condition over the control condition in CLBP (estimated mean difference of 8.4 [95% CI 4.7-12.1] points on a 0-100 points scale) but not in T2D participants (estimated mean difference of -0.7 [95% CI -6.5 to 5.1] points on a 0-100 points scale). Additionally, there was a significant disease main effect for knowledge favoring the T2D group.

Patient Empowerment at 3-Month Follow-Up (t2)

We found a significant intervention main effect for Emotional Well-being (meaning less health-related negative effects such as anxiety, anger, and depression [78]) (*P*=.009) favoring the tailored condition (mean 68.5, SE 2.3) over the control condition (mean 60.0, SE 2.3). The estimated mean difference between groups was 25.4 (95% CI 6.3-44.5) points on a 0-100 points scale. Finally, there were significant disease main effects for Skill and Technique Acquisition (*P*<.001), Self-Monitoring and Insight (*P*<.001), and Health Service Navigation (*P*=.02) favoring the T2D group.

Decisional Conflict Immediately After the First Visit (t1)

We found a significant disease main effect (*P*<.001) showing more decisional conflict in the T2D group.

Preparation for Decision Making Immediately After the First Visit (t1)

There was a significant disease main effect (*P*=.02) indicating higher scores for the T2D compared with the CLBP group.

Discussion

Principal Findings

In a randomized controlled trial, we compared a Web-based, tailored, dialogue-based information system containing information on T2D or CLBP (tailored condition) with a website providing identical information without dialogue structure, tailoring, or interactive elements (control condition). The primary outcomes of the trial were knowledge and patient empowerment. Secondary outcomes were decisional conflict and preparation for decision making.

We expected that the tailored IHCA would be more attractive than the control website, be used more, and would thus lead to more knowledge and more empowerment. Indeed, participants spent significantly more time with the tailored website than the control website. Still, this did not lead to more knowledge or empowerment in the primary ITT analysis. In the AC analysis, the participants in the tailored condition displayed more knowledge at $t_1$and more Emotional Well-being at t_2. This indicates that the tailored IHCA was more effective on these two dimensions than the control website. This was not the case for all users included; this was only the case for those who remained in the study and thus spent more time using the system. Contrary to the hypothesis, the tailored IHCA did not result in higher scores on the other six heiQ scales. It is possible that the effect was limited to the emotional level and could not be transferred to the cognitive or behavior level. This is in line with the results of Pal et al, who found that positive effects on cognitive outcomes could not be converted into behavioral changes [21]. There was a significant intervention x disease interaction favoring the tailored condition over the control condition more strongly in CLBP than in T2D participants. This superiority might indicate that tailoring in the CLBP IHCA may be more effective than tailoring in the T2D IHCA.

Other recent studies aimed directly at behavioral changes found effects on behavioral outcomes [24], and a meta-analysis on Internet-based cognitive behavioral therapy for patients with chronic somatic diseases found effects on psychological and physical outcomes [84]. A Web-based intervention aimed at psychosocial well-being in older adults with diabetes found improvements in depression, quality of life, social support, and self-efficacy [85], and a Web-based depression treatment for people with diabetes was found to reduce diabetes-specific emotional distress but had no beneficial effect on glycemic control [86]. Taken together, these results suggest that interventions aimed specifically at certain outcomes reliably have effects on these outcomes but have fewer effects on related or more distal outcomes. Consequently, our IHCA, as an educational intervention providing health information and adding behavioral change and decision support, has more consistent effects on knowledge (in persons who actually use it) than on cognitive or behavioral outcomes.

There were no significant effects regarding decisional conflict or preparation for decision making. A recent Cochrane review found that decision aids have, among other outcomes, an impact on knowledge and decisional conflict [87]. Again, the fact that we did find an impact on knowledge in the AC analysis but not on decisional conflict or preparation for decision making might be due to our IHCA being more of an educational intervention, providing the information necessary for shared decision making, than a classical decision tool.

Users with T2D yielded significantly better results regarding knowledge, preparation for decision making (only AC), and three (ITT: two) dimensions of the heiQ than participants with CLBP. One possible explanation might be that education and empowerment are traditionally cornerstones of diabetes management [88], which is not as explicitly true for the treatment of CLBP. Still, this result should be interpreted cautiously, because the instruments used to measure knowledge were different in both groups.

Strengths and Limitations

The work presented is the first trial on a German language IHCA on T2D or CLBP. The intervention was designed carefully based on two preliminary studies. There are some limitations to the work. One limitation concerns the representativeness of the sample. Only people with Internet access could be included in the study. Of the German general population, 73% are online [89], but of the population over 50, only 47% use the Internet. Because the prevalence of both T2D [90] and CLBP increases with age [91,92], there might be a selection bias in our sample. The diagnosis was self-assessed. In addition, this presents a limitation regarding the implementation and reach of online support for these diseases. Still, attrition was comparatively low for an online trial [23]. At t_2, 52.4% of the sample was retained. The comparatively low attrition rate in the tailored and control conditions might be due to the incentive given for complete datasets. Because none of the outcome criteria were assessed at t_0, we cannot know whether the differences between conditions at t_1 were caused by the intervention or had been there from the beginning.

We did not include quantitative or qualitative feedback on user acceptance. We also did not assess potential confounders (eg, which other interventions the participants used while enrolled in the study). These variables might have added to our understanding of the IHCA effects. Going beyond the scope of our study, investigating the effectiveness of the tested intervention, further research should focus on the mechanisms of change and the role of context variables through analyzing potential mediators and moderators [93]. Although the participants were blinded to the group assignment, it might be possible that participants identified the intervention group due to the unusual dialogue-based delivery format used in the intervention group. However, the design and content of both groups were nearly identical.

Another limitation arises from the measures used. First, there are concerns regarding data quality and response rates in online questionnaires [94,95]. Psychometric properties have been found to be equivalent to or even better than data obtained from paper pencil questionnaires [96,97]. There are also advantages of online assessment: data quality can additionally be improved by validation checks that alert participants if their answers are implausible or if items are skipped [96]. Furthermore, online assessment seems to be less prone to social desirability [98]. Second, only some of the measures used in this trial are standardized (DCS, PDMS, BIT), whereas others are adapted (attitudes toward self-care) for our purposes. The measure to assess the primary outcome of diabetes/CLBP knowledge was developed for the purpose of this study and has not been validated. Different versions of this outcome measure with different numbers of items for T2D and CLBP are used. None of the measures have been adapted for online use, which limits their comparability to results obtained from paper pencil tests [99].

Finally, the intervention had multiple components. We cannot know which component resulted in which effect. Future research should determine which components are effective and which are not.

Conclusions

The tailored IHCA enhanced knowledge and empowerment in persons who actually used it but failed to have effects in the total study population and on more distal outcomes. It might be concluded that tailoring and interactivity do not have effects with regard to these outcomes. Intervention components more specifically targeting cognitive and behavioral outcomes might enhance the effects. Pathways of change connecting intervention components and effects should be explored.

With regard to implementation, the IHCA could function outside of the study without major changes. Still, it would require some resources for updates and maintenance. Involving sponsors from the beginning might facilitate implementation. If our IHCA had made it to this stage, there would have been steps taken to extend its reach and effectiveness. In addition to being more specific, adaptability to tablets and mobile phones might have been an asset [21]. Another feature could be blended care to more explicitly integrate personal contacts, telephone, and online support [100]. The opportunity to share information and experiences with peers might be an especially attractive and important feature. The Pew Internet and American Life Project [101] found that people living with a chronic disease are more actively using the opportunities of Web 2.0: they generate and share content on their disease, use social media, blog, and chat more than people with no chronic conditions. Stepping into a multimedia dialogue with the users and letting expert-generated content and user-generated content spur each other might be the next step toward patient-centeredness in online support.

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Authors' Contributions

NW participated in the conception and design of the study, interpreted the findings, and drafted the manuscript. JD participated in the conception and design of the study, interpreted the findings, and revised the manuscript. AW analyzed the data, interpreted the findings, and participated in drafting and revising the manuscript. LK participated in the conception and design of the study, analyzed the data, interpreted the findings, and participated in revising the manuscript. MH was awarded the grant, participated in the conception and design of the study and the interpretation of the findings, and revised the manuscript.
All authors read and approved the final manuscript.

Conflicts of Interest

NW, JD, and MH were among the developers of the intervention.

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Abbreviations

ADA: American Diabetes Association
AEM: avoidance endurance model
ANCOVA: analysis of covariance
DCS: Decisional Conflict Scale
heiQ: Health Education Impact Questionnaire
IHCA: Interactive Health Communication Application
PDMS: Preparation for Decision Making Scale

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