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BOOK OF ABSTRACTS

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Systematic use of tools to facilitate dialogue on psychological matters in diabetes consultations

Clea Bruun Johansen, R. Torenholt, E. Hommel, M. Wittrup, I. Willaing
Steno Diabetes Center, Steno Health Promotion Center

Background and Aims	Diabetes is associated with an increased risk of diabetes distress, depression, anxiety and eating disorders. Apart from being important in their own right, psychological problems are associated with poor glycemic control and increased mortality. However, health professionals working with diabetes fail to identify two out of three patients with serious psychological problems. Hospital-based diabetologists are situated in the core of diabetes treatment and thus play an agenda-setting role for patients as well as other group of health professionals. The diabetes consultation therefore seems a promising context for identifying psychological problems and for legitimising such problems for persons living with diabetes. Accordingly, this study explores the potential of systematically using a dialogue tool to address psychological matters in diabetes consultations. We have chosen the Brief Diabetes Distress scale (DDS2) as a possible tool due to its promising properties. Firstly DDS2 is a well validated instrument when used for screening purposes, and secondly its short form is expected to fit well with the tight schedule of diabetes consultations. Our primary aim is to study the potential of systematically using a dialogue tool to address psychological matters in diabetologists consultations with diabetes patients.
Design/Methods	We conducted a qualitative interview study of Danish diabetologists. Participants were eight diabetologists working in three different specialist diabetes clinics in Danish hospitals, six consultants and two junior doctors in specialist training. Initially we had an individual dialogue with each diabetologist in which the diabetologists positioned themselves on the role of psychological matters in consultations and were introduced to the dialogue tool. We encouraged the diabetologists to find their own way to employ the tool, e.g. hand out the questions prior to consultation or ask them during consultation. The diabetologists tested the dialogue tool on around 10 patients each and subsequently the diabetologists were interviewed individually about their experiences. Interviews were semi-structured; they each lasted 40-60 minutes and were audio taped. The interviews were transcribed verbatim.
Planned Analysis	We plan to analyse the interview transcripts using meaning condensation and meaning interpretation inspired by the methods of Kvale and Georgi. We will follow four stages of analysis: 1) a thorough reading of all material to obtain an overall impression of important themes, 2) identification and condensation of units of meaning relevant to previously identified themes, 3) reorganization of the condensed meanings and identification of new themes and 4) interpretation and contextualisation of findings.
Expected Outcomes	Based on the interview experience itself and on a tentative reading of the transcripts we have identified some main themes for further analysis. The diabetologists expressed quite different views on using a dialogue tool such as the DDS2, some were very positive, some were moderate and some were negative. Perceived strengths of the tool were for example the potential for providing new information relevant for medical treatment, an experience of patients appreciating it when you ask about their problems and a feeling that the two questions can easily be integrated in a consultation. Perceived weaknesses were for example the limited time available for applying the tool, the fact that it is not already a part of medical routine, and the two questions not being relevant for all group of patients. The diabetologists chose differing ways to employ the specific dialogue tool: they used it orally, in writing, literally, reformulated, in the beginning of their consultation, in the end of consultation, on patients in sequence or on selected patients. None of the diabetologists had handed out the questions prior to consultation. Those who found the instrument useful had different perspectives on how to best employ it in the future: on some patients, on all patients, as a dialogue tool during consultation, as screening questions ticked off before consultation or as a ‘one question tool’. Further analysis of the data will provide us a deeper knowledge of the strengths and weaknesses of using a dialogue tool to facilitate dialogue on psychological matters.
Questions	Dialogue on psychological matters is not an area of priority within the limited diabetes consultation

time in Danish settings as defined by the established health care system. How can this be addressed?

1) on a structural/ management level
2) on a concrete consultation level

MY NOTES:

Development study in youth with type 1 diabetes (DESTINY): Finding a balance

Maartje de Wit, M.M.A. Eilander, & F.J. Snoek
VU Medical Center Amsterdam

Aims	The DCCT/EDIC study has shown that strict glycaemic control during adolescence decreases the risk of developing complications later in life, even if this level of control is not maintained afterwards. However, the majority of adolescents with type 1 diabetes are in poor control and so far medical or psychological interventions have shown limited success. Adolescence is characterized by major biological, cognitive, psychological and social role changes and the complex interaction between these developmental trajectories, and its impact on health outcomes, is still poorly understood. A specific topic of interest in this context is the timing of diagnosis. Objective: The proposed longitudinal study aims to examine: 1) if the onset of type 1 diabetes before vs. during puberty results in different outcomes of glycaemic control, self management, psychological functioning and diabetes-related QoL 2) how the development of cognitive skills of adolescents with type 1 diabetes relates to their diabetes self management tasks and how this affects diabetes outcomes.
Design/Methods	We propose a prospective multi-centre cohort study, based on a bio-psychosocial model of diabetes, conducted in youth with type 1 diabetes in the age range 8-15 years. Sample size analysis indicates we should include at least 200 children. The children will be divided into two subgroups: A) pre-pubertal children (Tanner stage 1) and B) pubertal children (from Tanner stage 2 onwards). Both groups will be followed for 3 years with measurements based on the bio-psychosocial model once to twice a year. Outcomes are: Glycaemic control (HbA1c, Hospitalizations, DKA's, Severe hypo's), Psychological functioning (SDQ) and Diabetes QoL (MY-Q). Developmental changes to be assessed: Biological/Puberty (Tanner stage, Blood pressure, BMI, Complication status), Neuropsychological battery, Self Esteem (KINDL), Autonomy (KIDSCREEN & DFRQ). Of course demographic and clinical variables will be assessed as well.
Planned Analysis	Longitudinal linear regression analyses, using GEE, enables us to examine the association between the developmental trajectories in relation to diabetes onset and outcomes. Latent class growth analysis will be used to identify developmental trajectories of glycaemic control and psychological and cognitive functioning.
Expected Outcomes	A better understanding of how the onset of diabetes during puberty affects glycaemic as well as psychological outcomes could help to develop more effective care pathways for distinct groups, with subsequent benefits on health outcomes.
Questions	How do we keep the children in the study? Tips, tricks?

MY NOTES:

Development of a mentoring program for adult patients with type 1 diabetes

Lene Eide Joensen & I. Willaing
Steno Health Promotion Center, Steno Diabetes Center, Gentofte, Denmark

Background and Aims

To live well with diabetes requires a large degree of self-management. Diabetes can be a heavy burden and psychological problems are highly prevalent among patients with diabetes. A large survey among persons with type 1 diabetes conducted at Steno Diabetes Center (N=2419, 67%) showed that social network and social support are significantly associated with self-management behaviours, psychological wellbeing and glycaemic control: living without a partner was associated with poor psychological health, unhealthy self-management behaviours, and poor glycaemic control. Perceived poor social support was associated with poor psychological health, unhealthy self-management behaviours and poor glycaemic control (unpublished data). The present study concerns the development of an adequate and effective intervention aimed at providing social support for patients with type 1 diabetes, based on results from the survey.

We expect peer support to be a useful method to assist patients with behavioural and affective aspects of diabetes. Peer support can provide support through sharing of experiential knowledge. One rather unexplored approach in diabetes peer support is mentoring. The aim of this study is to explore how a mentoring program can be designed to meet individual needs for social support among patients with type 1 diabetes in order to approve quality of life, self-management behaviours and perhaps glycaemic control in the long perspective.

Design/Methods

An action research approach will be used to develop a mentoring program in collaboration with persons with type 1 diabetes. Action Research is a research approach that seeks to generate solutions rather than descriptions of practice and problems as more traditional research does. Action research is *future oriented* and focuses on *bringing about changes and generating theory* that is *grounded in practice*. Action research is *systematic and rigorous* in the process and the researcher *evaluates continuously* during the development.

A variety of methods will be used to develop and try out the format of a mentoring program, e.g. individual and focus group interviewing, story dialogue/narratives and workshops. At workshops, customized participatory tools will be used to generate dialogue about patients' need and perspectives on mentoring. The workshops and interviewing will be (video) recorded. Analytic outcomes of the interviews and workshops will continuously be presented to and evaluated by persons with type 1 diabetes.

We expect data to consist of videos, photos, written material, transcriptions and field notes.

Planned Analysis

Data from interviews and workshops etc. will be analysed using a thematic approach focusing on coding, constant comparison, conceptualization, and discovery of categories. The data material will be coded and comparisons of statements from participants across types of material and themes will be made. Comparing statements and condensing meaning will reveal differences and similarities in the categories, thereby identifying main patterns and ensuring that categories represent collective experiences and thoughts. Categories and insights regarding needs for support and for a mentoring program/model will be further developed and refined through discussion in workshops with persons with type 1 diabetes and in the research team. A theoretical analytical approach based on social learning theory and health pedagogical concepts will broaden the perspective of the identified needs for support and the mentoring program.

Expected Outcomes

Preliminary results from our first workshop with 11 persons with type 1 diabetes showed that a mentoring program is highly relevant. Four men and seven women (age 35 to 62) with diabetes duration of 7 months to 40 years participated in the workshop. The majority of participants expressed a substantial need of getting experiential knowledge from persons with type 1 diabetes as a supplement to treatment and guidance from health care professionals and called this "a missing link". Participants suggested relevant topics of mentoring connected to specific situations in relation to their diabetes, e.g. getting diagnosed with diabetes, having an insulin pump, being pregnant and having children, travelling, practicing specific sports and how to start new everyday

	routines, e.g. as a consequence of retirement. Participants also expressed the relevance of support from a mentor in relation to feeling distress. Participants stated the importance of matching mentees and mentors in respect to the mentees' needs and the mentors' competences and experiences. In relation to this, participants also suggested that mentors could choose specific mentoring topics, corresponding to both qualifications and wishes of the mentor. Furthermore participants suggested sharing of experiences between mentors, to have ethical and practical guidelines for mentors and mentees, and supervision for mentors. The expected outcome of this study is an intervention model of social support for persons with type 1 diabetes ready for feasibility test and evaluation in 2014.
Questions	Any experiences or knowledge of studies about mentoring in diabetes? Any suggestions based on presentation as to the platform for such a mentoring network? e.g. patient associations or diabetes clinics?

MY NOTES:

Self-management needs during life transitions among younger people with type 2 diabetes: An Australian and Danish Cohort Comparison

Bodil Rasmussen[1], T. Dunning[1], T. Livingston[1], V. Lorentzen[2], B. Hedegaard-Larsen[2], H. Terkildsen Maindal[3]
[1] Deakin University, Australia;
[2] Centre for Clinical Nursing Research, VIA Viborg, Denmark;
[3] Aarhus University, Denmark

Background and Aims

The primary aim of this pilot study is to provide cross-cultural and detailed insights into how psychological and social factors impact on younger people with type 2 diabetes (T2DM) and self-management skills (20-40 years). The specific objectives are to:

- Identify self-management strategies used by younger people with T2DM during life transitions in the period from 20 – 40 years of age
- Investigate participants' perception of self-management to identify the specific needs of younger people with T2DM

Young people with T2DM's self-management strategies appear to be influenced by varied social and psychological factors. Findings indicate that this group is at high risk for developing diabetes complications later in life signify the importance of providing well-targeted diabetes education programs that motivates people to self-manage their diabetes. Findings also indicate that this group feel they are placed 'in-between' younger and older groups of people with diabetes when receiving diabetes education. It is therefore pertinent for positive clinical outcomes that social, psychological and cultural needs among this group are identified. In provision of targeted educational programs it is also pertinent to understand how young people with T2DM access, use and process information as well as how they navigate the health system. Young adulthood represents a period in people's life in which major transitions occur, at times more than one transition concurrently. This research will provide health professionals with insights to the specific needs for young adults with T2DM and will add ground breaking innovative information by investigating cultural comparison between Australia and Denmark.

Design/Methods

This study will employ a, descriptive, cross sectional prospective cohort study design with mix-methods data collection including semi-structured interviews and survey methods to achieve the study aim and objectives.

1. Participant information
Demographic data and information about:

- Socio -demographic characteristics (age, gender, level of education, living arrangement, children, work, exercise, diet, smoking, alcohol)
- Clinical data (duration of illness, complications, combination, family history, diabetes history, Diabetes Distress, depression, medication).

2. Life Transition information by semi-structured interviews (10 participants in each Australian and Danish site)

The purpose of the interviews is to identify specific issues experienced during life transitions and identify key management strategies.

3. Instruments

a. *The Diabetes Distress Screening (DDS)*

The DDS17 yields a total diabetes distress scale score plus 4 sub scale scores, each addressing a different kind of distress (emotional burden, physician-related distress, regimen-related distress and interpersonal distress). (Polonsky et al., 2005).

b. *The Patient Activation Measure*

The Patient Activation Measure® (PAM®) assessment gauges the knowledge, skills and confidence essential to managing one's own health and healthcare. The PAM assessment segments consumers into one of four progressively higher activation levels. Each level addresses a broad array of self-care behaviors and offers deep insight into the characteristics that drive health activation.

The data collection will occur via two methods.

a. Semi-structured interviews with 10 eligible patients in each Australian and Danish agency. Equal numbers of women and men will be important to ensure self-management strategies based on gender are identified. A semi-structured interview guide will be used.
b. Based on above validated instruments; a questionnaire will be developed including questions on perception of problems related to diabetes management, distress associated with a diabetes diagnosis, patient activation. The questionnaires will be available on Diabetes Australia-Vic web site and at the diabetes clinics on IPADs.

Inclusion criteria:

- A diagnose with Type 2 diabetes for a minimum of 12 months
- Aged 20-40 years
- Able to provide written informed consent to participate

Planned Analysis

a. Qualitative analysis of participant responses
The patient responses to the qualitative questions in the interview will be recorded using a Dictaphone and transcribed in full. Transcriptions will be subjected to thematic analysis where major concepts will be categorised, and findings compared to identify cross-cultural issues between the two countries (in progress March-May 2013)

b. Statistical Analysis
Patient demographic and disease related characteristics will be described using descriptive statistics. Patient symptom profiles (presence, frequency, intensity and distress) will be explored using frequency distributions. Means and standard deviation data for symptom frequency, intensity, and distress will be mapped as repeated measures. Overall survey data will be also analysed using inferential statistics using parametric and non-parametric tests, factor analysis and regression. The calculation of sum scores for each scale, the missing data and the extreme outliers will be handled according to the guidelines for the respective scales.

Data Management

a. The results obtained from the questionnaire will predominantly be analysed quantitatively using SPSS version 19.
b. Qualitative data will be managed by NVivo version 9

Expected Outcomes

This research aim to provide health professionals with insights to the specific needs for young adults with T2DM and will add ground breaking innovative information by investigating cultural comparison between Australia and Denmark in developing well targeted educational programs.

Questions

1. The research team consider including a health literacy component as a part of the questionnaire. During the qualitative data collection is comes apparent that many participants have difficulties reading and to comprehend educational material and navigating the health system. What would the group's experiences be in relation to this?

2. Do the planned methods seem reasonable?

3. Have any important and relevant factors been missed?

MY NOTES:

Providing our best guess of true relative effectiveness of therapy X for the treatment of type 2 diabetes in clinical practice

Matthew Reaney, J. Johnston, D. Faries
Eli Lilly

Aims

A Randomised Clinical Trial (RCT) of a new type 2 diabetes treatment will commonly recruit a stringent group of well-defined patients for the comparison to active comparators and/or placebo. While treatment efficacy relative to active comparators and/or placebo is often sufficient for regulatory decision making, the extent to which the data from the RCTs can be generalised to the real-world clinical population is unclear; expected real-world comparative effectiveness (i.e. the anticipated incremental benefit derived from the new treatment relative to existing standards of care in patients who will receive treatment in routine, real-world treatment environments) is not known. There is therefore an increasing interest in "observational" research studies to better understand the patient population prescribed the therapy in clinical practice and to provide a more definitive assessment of real-world comparative effectiveness. However, the analysis of observational studies is complex, and although many forms of bias adjustment exist, there is no simple algorithm for estimating treatment effectiveness accounting for treatment switching (common in the management of type 2 diabetes), and the magnitude of "observation effects" (the process of participation in an observational study, whereby the patient is knowingly being observed and monitored, may change behaviour and result in improved clinical outcomes) is unknown and as such our estimates of treatment effectiveness cannot be appropriately adjusted.

This study aims to answer the question "what is your best guess of true treatment effect with therapy X relative to best standard of care in a clinical practice environment?" In order to achieve this aim, the study will incorporate the following aims:

(1) assess the representativeness of RCT & observational study populations (relative to expected/actual clinical practice populations);
(2) quantify the extent to which any observed non-representativeness of the RCT population contributes to efficacy and effectiveness differences observed from RCT and observational studies, respectively;
(3) develop an algorithm for dealing with "switching behaviour" in observational studies when establishing treatment effect;
(4) understand and quantify the magnitude of "observation effects" (behavioural) in prospective observational trials of a given therapy

Design/Methods

(1) Population characteristics of patients participating in RCTs and prospective observational studies, as well as those prescribed therapy in a retrospective database will be summarised, and generalizability will be evaluated by looking for statistical similarities and differences on key clinical and psychosocial parameters.
(2) Statistical models will be developed to understand the impact of certain decisions on a given variable in an RCT on the generalizability of the data to clinical practice (using observational study data).
(3) To understand the potential impact of switching behaviour on effectiveness estimates in prospective observational studies, an algorithm will be developed based on UKPDS (or similar) data.
(4) To calculate a quantitative estimate for the "observation effects", data from a completed prospective observational study will be used. The population will be matched to retrospective database and RCT populations using a propensity score approach, or on individual variables.

Planned Analysis

To answer the question "what is your best guess of true treatment effect with therapy x relative to best standard of care in a clinical practice environment?" from RCT data, the design characteristics of a proposed RCT and/or efficacy data from completed RCTs will be adjusted, according to the most appropriate method following completion of aims 1 & 2 (methods 1 & 2), to produce an estimate of real-world effectiveness. To answer the same question from prospective observational data, the observed effectiveness will be corrected for switching behaviour and the

	observation effects following completion of aims 3 & 4 (methods 3 & 4). The final outputs would represent our best guess in the two data sets – RCTs and prospective observational studies.
Expected Outcomes	It is hypothesised that there will be clinically relevant differences between participants in RCTs and prospective observational studies of therapy x, and clinical practice populations using therapy x. Understanding the generalizability of RCT & Prospective Observational study populations (relative to expected clinical practice populations) will assist clinical teams in developing meaningful research. It is hypothesised that the "observation effects" are significant. Generating a hypothesis for the magnitude of this effect will enhance understanding of observed effectiveness data, and improve our understanding of the nuances in interpreting data from prospective observational research.
Questions	(1) Do you believe that efficacy results from RCTs are generalisable to clinical practice? (2) What psychosocial variables in type 2 diabetes should be considered in this study, as potentially differing between study participants (RCTs, prospective observational studies) and clinical practice? (3) What known and hypothesised effects may impact on behaviour in a research study (ie what makes up the "observation effects")?

MY NOTES:

Depressive symptoms, cardiovascular disease and all-cause mortality in people with type 2 diabetes: a focus on depression symptom clusters and potential mechanisms

Giesje Nefs, F. Pouwer, J. Denollet, & V. Pop

Center of Research on Psychology in Somatic diseases (C*o*RPS), Department of Medical and Clinical Psychology, Tilburg University, Tilburg, The Netherlands

Aims	Depression has been associated with the development of macrovascular disease and all-cause mortality in people with type 2 diabetes. We examined whether symptoms related to the two core features of depression – dysphoria and anhedonia – and anxiety are differentially associated with these end points and whether there are symptom-specific behavioral or pathophysiological mechanisms in play.
Methods and participants	1,465 people completed the Edinburgh Depression Scale (EDS – including subscales measuring dysphoria, anhedonia and anxiety) in 2005 and were followed until first cardiovascular hospitalization during follow-up, death, or the end of the study period (December 31, 2010). Cox regression analyses were used to determine whether there was a difference in time to a cardiovascular event or to all-cause mortality between people with a low versus a high dysphoria/anhedonia/anxiety score at baseline (adjusting for meaningful demographic and clinical confounders) and to identify mediating mechanisms.
Results	The prevalence of depression (EDS≥12) was 12% (n=182). At the end of follow-up, 191 people had experienced a cardiovascular event and 139 had died. Depression was associated with survival time (adjusted HR=1.93, 95% CI 1.10-3.41), but not with time to cardiovascular event. Dysphoria predicted a shorter time to first cardiovascular event during follow-up in univariable analysis only (unadjusted HR=1.49, 1.02-2.17), while anxiety was associated with a longer time to event in the multivariable model (adjusted HR=0.52, 0.29-0.92). Dysphoria and anxiety were not associated with survival time. However, at all time points people with anhedonia had an almost 2-fold increased risk to die compared to their counterparts without anhedonia, also after taking potential confounders into account. Physical activity met criteria for mediation, attenuating the HR for anhedonia by approximately 20%.
Conclusions	Symptom-clusters of negative emotions predicted time to first cardiovascular event during follow-up, while symptoms of anhedonia were associated with shorter survival time. Mechanistic pathways, in particular physical activity, should be explored further.

MY NOTES:

The intensity of initial depressive symptoms predicts short-term efficacy of behavioural treatments in type 2 diabetes patients

Dea Ajduković[1], J. Kos[1], I. Poljak[1], M. Prašek[1], M. Šekerija[2], & M. Pibernik-Okanović[1]

[1] Vuk Vrhovac University Clinic, Merkur Teaching Hospital
[2] Croatian National Institute of Public Health

Aims	This paper aimed to examine the associations between changes in depressive symptoms and in other psychosocial and biological indicators in diabetes, and to explore the predictors of change of the clinical category of depressive symptoms in patients who participated in behavioural programs for the treatment of subsyndromal depression.
Methods and participants	Depressive symptoms (CES-D), diabetes distress (PAID), health-related quality of life (HRQoL; SF-12), diabetes self-care behaviours (SDSCA) and metabolic indicators (HbA1c, cholesterol) were assessed at baseline and after 8 weeks in patients who were randomized to psychoeducation, physical exercise or minimal diabetes education. Data were analyzed by mixed ANOVA and logistic regressions. Type 2 diabetes patients (N = 197, 54.8% women, mean age 58.2±5.53 years) participated in the interventions. Based on baseline and follow-up CES-D scores (cut-off=16), they were classified into 4 groups: persistently low, non-clinical symptoms (”LL”, n = 57), change from low, non-clinical to high, clinical symptoms (”LH”, n=10), change from high, clinical symptoms to low, non-clinical symptoms (”HL”, n=48) and persistently high, clinical symptoms of depression (”HH”, n=82).
Results	Improvements in the LL group included total (p<.001) and emotional diabetes distress (p=.040); the frequency of following a diabetes diet (p=.004), healthy diet (p=.009) and exercise (p=.017); physical (p=.031) and emotional role limitations (p=.018) and mental health (p=.011), and their mental health component score (p=.008) of HRQoL; and HbA1c (p=.022). In the LH group, food-related diabetes distress (p=.046), the frequency of SMBG (p=.002) and foot self-examinations (p=.06) increased, while the decrease in their total cholesterol was statistically borderline (p=.052). The HL group improved in total (p<.001), emotional (p<.001), food (p=.007) and treatment-related (p=.013) diabetes distress; following a diabetes diet (p<.001), exercise (p=.001) and foot self-examinations (p=.002); the mental component score (p<.001), as well as self-rated general health (p<.001), emotional role limitations (p=.001), mental health (p<.001), vitality (pp=.001) and social functioning (p=.012); and their total (p=.014) and LDL cholesterol (p=.046). In the HH group, there were improvements in depressive symptoms and in total diabetes distress (p<.001); the frequency of diabetes diet (p=.015), exercise (p=.007), SMBG (p=.017), and foot care (p=.004); bodily pain (p=.012) and mental health (p=.020); and HbA1c (p=.014). The multivariate predictors of the change from clinically elevated to clinically acceptable depressive symptoms were lower initial depressive symptoms (OR=.91, 95%CI=.84-.99, p=.030), while lower initial diabetes distress (OR=.98, 95%CI=.95-1.00, p=.051) and mental component scores of HRQoL (OR=1.04, 95%CI=1.00-1.10, p=.059) were statistically borderline. The bivariate predictors of the change from clinically acceptable to clinically elevated depressive symptoms were higher initial depressive symptoms (OR=1.37, 95%CI=1.02-1.86, p=.039), higher social diabetes distress (OR=1.03, 95%CI=1.00-1.06, p=.023) and more emotional role limitations (OR=.96, 95%CI=.92-1.00, p=.049).
Conclusions	Participating in behavioural interventions for subsyndromal depression in diabetes was beneficial for most patients, including those whose depressive symptoms were significantly elevated. Diabetes distress, self-care, HRQoL and metabolic outcomes of the illness improved along with depressive symptoms. The intensity of initial depressive symptoms may be an important predictor of patient response to such interventions. Implications for research and clinical interventions will be discussed.

MY NOTES:

Effect of a group programme for treatment of elevated depressive symptoms and diabetes related distress in people with diabetes: results of a randomized controlled trial

Norbert Hermanns, B. Kulzer, A. Schmitt, A. Gahr, J. Kruse, & T. Haak

Research Institute of the Diabetes Academy Mergentheim (FIDAM), Diabetes Centre Mergentheim, University Clinic Giessen, Department of Psychosomatic Medicine.

Aims	Approximately two thirds of depressed diabetic patients are suffering from elevated depressive symptoms, whereas only one third is affected by major depression according to ICD-10 or DSM IV criteria. A negative impact of even mild depressive symptoms on the prognosis of diabetes with regard to morbidity and mortality and it's negative impact on quality of life is well known. In spite of these negative consequences of elevated depressive symptoms in people diabetes, there are no interventions available for the treatment of mild or subclinical depression. Another problem is that elevated depressive symptoms in people with diabetes may indicate rather a high level of diabetes related distress than a "pre-stage" of major depression. We developed therefore a group intervention for diabetic patients with elevated depressive symptoms (DIAMOS – Strengthen Diabetes Motivation). This intervention concept is based on cognitive behaviour therapy (CBT), but focuses primary on coping with diabetes related distress rather than on depression-specific topics. DIAMOS was evaluated in a randomized controlled trial in a 12 month follow up. Standard diabetes education was the control group (CG). This paper presents key findings of the evaluation trial.
Methods and participants	DIAMOS consists of 5 lessons (a´90 minutes). 214 patients were randomized to DIAMOS or to the CG. Patients completed at baseline and at 12 month follow up several questionnaires to assess depressive symptoms (CES-D), diabetes related distress (PAID), psychological well-being (WHO 5) und quality of life (SF 36).
Results	After one year data of 181 patients could be assessed (age: 45 ±14 yrs..; 57% female; BMI: 29 ±7 kg/m², 63% Type 1 diabetes, diabetes duration 15 ±11 yrs. 51% diagnosed with at least 1 complication, HbA1c: 8,8 ±1,7%; CES-D: 23,3 ±8,1; PAID: 39,5 ±18,4; WHO-5: 8,9 ±4,5; SF-36-PSK: 35,0 ±10,4). Drop out rate was 15%. After one year depressive symptoms could be significantly reduced in DIAMOS compared to CG (CES-D: -7,4 ±11,4 vs. -2,7 ±11,7; p< 0,01) as well as diabetes related distress (PAID: -13,0 ±18,9 vs. -4,2 ±16,9; p< 0,01): Also psychological well being improved significantly more in DIAMOS than in CG (WHO 5: +4,5 ±6,1 vs. +2,5 ±6,3; p=0,03). In both groups was a comparable improvement of mental aspects of health related quality of life (Mental composite Score of SF 36: +7,5 ±13,3 vs. +6,1 ±14,8; p=0,51) and overall glycaemic control (HbA1c:-0,5 ±2,0 vs. -0,8 ±1,7%; p=0,41) demonstrated.
Conclusions	Results indicate that DIAMOS is an effective intervention programme for people with diabetes and elevated depressive symptoms. Participation in DIAMOS was associated with a significant reduction of depressive symptoms and diabetes-related distress and with a significant improvement of psychological well-being. Interestingly was glycaemic control improved in DIAMOS as well as in CG. This study showed the efficacy of a cognitive behavioural intervention concept for the large group of people with diabetes and mild depression.

This study was supported by a grant of the Federal Ministry of Education and Research within the competence network: Diabetes mellitus (FKZ 01GI0809).

MY NOTES:

Living with diabetes and Charcot foot: Assessment of anxiety and depression

Jörg W. Huber & Z. Chapman
University of Northampton

Background and Aims	Little research is available on the psychological impact of Charcot foot. The aim was to investigate psychological morbidity associated with Charcot foot in Type 2 diabetes patients and the moderating effects of socio-demographic factors.
Methods and participants	Cross-sectional questionnaire data using the Hospital Anxiety and Depression Scale (HADS) and demographic background were collected from 100 patients with diabetes and foot complaints (males 62%; mean age 62.2 ± 8.5 years), 50 each with Charcot foot and without acute foot problems, in a secondary care facility in London.
Results	Demographic characteristics of both groups were similar. Anxiety and depression levels were generally high, but no difference was observed between patients with and without Charcot foot (increased anxiety risk: 42 vs 46%; increased depression risk: 42 vs 44%; p-values > 0.50). These findings remained stable after adding demographics and duration of diabetes as additional factors to the analysis. Additional findings indicate that anxiety levels were higher in females than males, and both anxiety and depression levels were elevated in ethnic minority compared to white patients (p-values < 0.05); age, work and marital status were not associated with anxiety or depression.
Conclusions	The lack of difference between the Charcot foot and the non-Charcot foot patients with a history of ulceration was probably because they both suffer from different psychological vulnerabilities which result in equally high levels of anxiety and depression. The study should be repeated with additional comparison groups (no history of foot problems) in a multi-centre sample.

MY NOTES:

Preliminary findings from the 2nd Diabetes Attitudes Wishes and Needs (DAWN2) Study

Mark Peyrot, on Behalf of the Global DAWN2 Study Group
Loyola University Maryland

Aims	The 2nd Diabetes Attitudes Wishes and Needs (DAWN2) Study aims to provide a holistic assessment of diabetes care and management among people with diabetes (PWD), family members (FM), and healthcare professionals (HCPs) and explores potential drivers leading to active management. DAWN2 aims to build on the original 2001 DAWN study to identify new avenues for improving diabetes care.
Methods and participants	DAWN2 surveys over 16,000 individuals (~9,000 PWD, ~2,000 FM of PWD, and ~5,000HCPs) in 17 countries across 4 continents. Respondents complete a sample-specific questionnaire; items are carefully designed to allow cross-sample comparisons on common topics. The questionnaires comprise elements from the original DAWN study, as well as psychometrically validated instruments and novel questions developed for this study to assess self-management, attitudes/beliefs, disease impact/burden, psychosocial distress, health-related quality of life, healthcare provision/receipt, social support and priorities for improvement in the future. The questionnaires are completed predominantly online or by telephone interview, supplemented by face-to-face interviews in countries with low internet access. In each country, recruitment ensures representation of the diabetes population in terms of geographical distribution, age, gender, education and disease status.
Results	People with diabetes and their families experience impaired quality of life and wellbeing, although some are able to derive meaningful benefits from living with diabetes. Psychosocial care and support are lacking, as are the resources for providing them. Active diabetes self-management is sub-optimal, but people with diabetes, families and healthcare providers want to collaborate in improving it. Diabetes self-management education and other sources of information are beneficial but underutilised. People with diabetes and their families experience discrimination, intolerance and lack of support, and need to become more involved in affecting relevant societal changes.
Conclusions	Results from DAWN2 will be used by national investigators and policymakers in the 17 participating countries to identify shortfalls in the provision of patient-centered diabetes care and policies affecting quality of life for those living with diabetes, and to identify models for improving these policies and procedures. Particular attention will be plaed on the benchmarking process in which cross-country comparisons and longitudinal assessment can help drive and evaluate change.

MY NOTES:

Depression and anxiety in young people with diabetes type 1: How big is the problem?

Per Winterdijk, H.J. Aanstoot, & F. Pouwer

Diabeter Center for Pediatric and Adolescent Diabetes Care and Research, Rotterdam, The Netherlands

Aims	Since the implementation of intensive treatment therapies and the advocacy of self management in diabetes care, there have not been any major improvements in diabetes outcome.[1] As shown by the Hvidoere study group the mean A_1c has been remarkably consistent over a decade; 1995: 8.6%; 1998: 8.6%; 2005: 8.7%.[2-4] There are several barriers that hamper further improvements in pediatric diabetes care. Firstly: any (new, more intensive) treatment regimen can only lead to an improvement of glycemic control in children if consistency of goals in the healthcare team, coping skills of the patient, family functioning and also psychopathology are addressed first.[5] Secondly: The application of a diabetes regimen is only as good as the ability of the patient and parent(s) to apply or manage it. The ability to adhere to a treatment is strongly influenced by psychosocial factors.[6] Depression is reported to have a prevalence of 18 - 28% in diabetic adolescent patients.[7-10] Anxiety in the same age group has a prevalence of 17-20%.[8, 9] Symptoms of depression are very similar to symptoms of poor metabolic control.[11, 12] Therefore under-diagnosis of depression in adolescents with diabetes should be considered. The studies that have been conducted in the area of psychosocial functioning of adolescent with diabetes have important limitations. The majority of the studies relied on self-report questionnaires for the assessment of depression and anxiety, while the psychiatric diagnostic interview is the gold standard. The few studies that have used a diagnostic psychiatric interview in diabetic adolescents have been conducted in the USA.[7, 8, 13, 14], except two studies.[15, 16] So, European data on depression in young people with diabetes are scarce. This could possibly result in a cultural bias. Most studies reporting prevalence of depression have included a rather small number of patients from selected groups. Selection bias could have affected the results of many studies. For example, there is no description of the number of patients who refused to participate in the study of Blanz.[15] Longitudinal studies on this important topic are also scarce.[8, 9, 14] Another important limitation is that most studies focused only on depression, ignoring symptoms of anxiety and diabetes specific emotional distress (such as fear of hypoglycemia). These symptoms are closely related to depression.[17] Aims: To assess the prevalence, incidence and recurrence of depression, anxiety and diabetes specific emotional distress in young people with type 1 diabetes and their parents/caregivers.
Design/Methods	Locations: The study will be conducted in paediatric clinics located in Europe. In total, we aim to include 1200 young patients, aged 12-18 years) with T1D. Questionnaires CDI-2 and GAD-7, and the Composite International Diagnostic Interview (CIDI), will be used. Demographic patient data, along with detailed data from self-monitoring and glucose metabolism will be collected.
Planned Analysis	In order to determine the prevalence and course of depression and anxiety, a sample of 1200 young patients with T1D will be included in a cohort study with at least two assessments: baseline and 1-year follow up. All patients will complete the CDI and the GAD-7, those with an elevated score will be invited for a psychiatric diagnostic interview.
Expected Outcomes	Prevalence and incidence of depression in young people with T1D. The relation of self care and glucose metabolism (A_1c) in T1D adolescents with depression and anxiety.
Questions	1. Choice of questionnaires? 2. Can we avoid differences in interview techniques / or how can we compensate for that. 3. How do we compensate for recurrence of depression?

MY NOTES:

Psychosocial problem in depresion in diabetes - Comparison of patients who developed diabetes in course of depression and those who developed depression in the course of diabetes

Andrzej Kokoszka & A. Papasz-Siemieniuk
II. Department of Psychiatry, Medical University of Warsaw

Aims	Results of meta-analyses indicate that depression is related with 30% increase of risk of diabetes (Knol, al., 2007), whereas diabetes is related to 24% increase of risk of depression (Nouwen, at al, 2010). A variety of hypotheses about possibly bidirectional interaction between depression and diabetes was formulated. However, there are no studies comparing psychological characteristics of patients with co-morbid diabetes and depression differing in the order of appearance of the diseases. It seems possible that primarily depressed patients have weaker psychological resources than patients primarily suffering from diabetes. Aims: A comparison of these two group of patients including: - clinical history (type of treatment, number of hospitalizations, diabetes complications and health behaviours) - level of glycemic control - quality of life - problem areas in diabetes and knowledge about diabetes - style of coping with the disease - perception of self-influence on the course of the disease and ability of self-determination - depressive symptoms and the presence of other mental disorders - differences in depression characteristics - personality traits
Design/Methods	60 consecutive patients of the psychiatric outpatient clinic, who developed diabetes in the course of depression and 60 consecutive patients of the diabetic outpatient clinic, who developed depression in the course of diabetes will be assessed with the following methods: - HbA1C blood level - WHOQOL-BREF - quality of life questionnaire - MINI-plus Neuropsychiatric Interview - HAM-D - PAID (problematic areas in depression) Questionnaire - NEO-FFI – psychological personality inventory - A short method of assessment the perception of self-influence on the course of the disease (Kokoszka 2005), - Brief method of evaluating coping with the disease (Kokoszka, Radzio, Kot 2008) - Empowerment Scale (Rogers, 1997) - Inventory measuring attitude to depression and to self-management with diabetes
Planned Analysis	The comparison of the results in two groups.
Expected Outcomes	- lower scores of all measured parameters among primarily depressed patients with exception of acceptance of depression - differences in characteristics of depression in both groups - the need for modified approach to management with diabetes in both groups
Questions	- clinical experience with differentiated groups - final choice of measures - realistic choice of characteristics of those groups that have to be controlled

MY NOTES:

How to modify eating rate? A mindfulness-based approach

Karin Kanc Hanzel et al.
jazindiabetes (Diabetes&Me), Židovska ulica 1, 1000 Ljubljana; Slovenia

Background and Aims	In medical nutrition it has always been recommended that one should eat slowly in order to chew food properly and enable optimal digestion. The recommendation of slow eating is valid for people with diabetes. However, there is only one very recent evidence from 7275 subjects from Japan, that there is an impact of eating rate on obesity and cardiovascular risk factors according to glucose tolerance status. The aim of our pilot study is twofold: - to investigate the eating behaviour of people with type 2 diabetes - to apply a mindfulness-based intervention to the group of fast eaters in order to modify their eating rate
Design/Methods	100 type 2 diabetes patients aged 40 and above (half of them insulin-treated and others OAD-treated), visiting our centre for a routine check-up on a Tuesday and Wednesday of 2 (if needed, 4) clinical weeks will be asked to fill-in a one-item questionnaire: What is your eating rate? They will choose among the answers: slow, medium, fast and the WHO-5 questionnaire. Then, in the intervention part of the study, the fast eaters will be divided in two equally numbered groups. Each group will have 2 sessions on nutrition in diabetes: 'classical' nutrition sessions in one group and mindfulness-oriented sessions in the other group (mindful eating; 3-step breathing space). 4 weeks after the sessions they will get both questionnaires as in the beginning of the study, by post 8 weeks after the sessions they will be called for a clinical visit, where clinical parameters will be measured and the questionnaires applied again.
Planned Analysis	Descriptive statistics of usual diabetes clinical parameters on different time-points (HbA1c, BMI, BP etc.) – to be discussed in the group.
Expected Outcomes	The mindfulness-oriented group will adopt a slower eating rate that might have significant implications, such as: change of eating behaviour, improvement of general well-being, weight reduction, better metabolic control, etc.
Questions	1. Do we have to test the one question questionnaire on eating rate in general population first and is the scale of 3 too little? 2. There are several ideas for the up-grade of the study, depending on the outcome of the pilot, like: testing the eating rate with a test meal served on a special plate; applying the continuous glucose sensor during the time of eating and following the glucose excursion in relation to eating rate. 3. Spontaneous comments from the group are welcome.

MY NOTES:

Development and evaluation of a tailored internet-based intervention to improve psychological receptiveness to insulin in people with type 2 diabetes

Elizabeth Holmes-Truscott,[1, 2] D. Austin,[2] & J. Speight[1,2,3]

[1] The Australian Centre for Behavioural Research in Diabetes, Diabetes Australia–Vic, Melbourne, VIC, Australia.
[2] Centre for Mental Health and Wellbeing Research, School of Psychology, Deakin University, Burwood, VIC, Australia
[3] AHP Research, Hornchurch, Essex, UK.

Background and Aims

Negative appraisals of insulin treatment, known as psychological insulin resistance (PIR), can lead to delays in the initiation of insulin and/or suboptimal insulin taking behaviours after insulin initiation. Consistent with previous research, preliminary data from the Diabetes MILES – Australia survey indicate that people with non-insulin-treated type 2 diabetes (T2D) believe that insulin initiation would mean their diabetes has become much worse (80%), they had failed to manage their diabetes (59%), as well as having negative implications for their lifestyle (67%). A number of recommendations for lowering PIR have been proposed, often reactive in nature, focusing primarily on communication by healthcare professionals (HCPs). Positive reframing of messages about insulin may have a positive impact on attitude formation but this has not been investigated. Furthermore, no recommendations to improve receptiveness to insulin have been empirically tested.

Aims: To develop and pilot an internet-based individualised intervention specifically designed to improve receptiveness to insulin in people with non-insulin-treated T2D.

Design/Methods

Participants: A minimum of 50 participants will be recruited via the local diabetes association membership register. Inclusion criteria will include T2D diagnosis, no previous insulin use, ≥18 years of age, and English speaking.

Procedure: Upon visiting the resource website, participants will be invited to read study information and provide informed consent. If eligible, participants will complete pre-intervention, post-intervention and 3-month follow up questionnaires. The internet-based resource will be accessible by participants on any internet-enabled device of their choosing.

The intervention will comprise a series of video clips designed to acknowledge and normalise concerns about insulin use, followed by the recounting of positive experiences of insulin. Video clip scripting and content will be informed by qualitative interviews exploring concerns about insulin prior to initiation, and how these concerns were alleviated for individuals now using insulin. Participants will view clips that relate to the negative aspects of insulin most highly endorsed (e.g. top 5) in their pre-intervention questionnaire.

The evaluation: Both the pre-intervention and 3-month follow-up questionnaire will include a measure of 'willingness to initiate insulin' and the Insulin Treatment Appraisal Scale (ITAS); a 20-item measure of perceived barriers to insulin initiation. In addition, known correlates of PIR will be assessed, including diabetes-related distress (DDS17) and beliefs about current medication (Beliefs about Medication Questionnaire Specific; BMQ). The pre-intervention questionnaire will also include demographics, diabetes diagnosis among family/friends, relationship with (and frequency of visits to) HCPs, diabetes treatment, last known HbA1c level, and whether insulin has been recommended. The 3-month follow-up questionnaire will include whether participants have since met with their HCP and whether insulin initiation has been discussed. Participants will be invited to access the follow-up questionnaire through a scheduled email at 3 months. Immediately post-intervention, participants will complete a short questionnaire including study-specific items addressing attitudes about insulin and willingness to use insulin as well as a user evaluation of the suitability and acceptability of the internet-based resource.

Planned Analysis

Analysis will include descriptive statistics of the intervention acceptability ratings and trends in pre-and-post intervention attitudes towards insulin. The effect of the intervention on attitudes towards insulin (ITAS) and other variables of interest will be examined through repeated measures inferential statistics. Secondary analyses will explore change trends and user acceptability for

	particular participant sub-groups (i.e., differentiated by demographic/ psychosocial variables) and investigate which attitudes towards insulin are most responsive to the resource. The results of this pilot will inform resource re-design and power/sample size estimations for a future randomised controlled trial (RCT).
Expected Outcomes	The proposed study will be the first to our knowledge that involves development and evaluation of an internet-based intervention specifically designed to improve receptiveness to insulin use in people with non-insulin-treated T2D. This study will provide preliminary evidence about (1) the extent to which acknowledgement and normalisation of concerns about insulin followed by positively-framed messages about actual experience of insulin use can reduce PIR, and (2) the feasibility and acceptability of internet-based interventions for this purpose. It is expected that this pilot will provide a sustainable and translational intervention, which could be embedded in (or accessed via) diabetes association websites and made widely available. This pilot study will also inform a full-scale RCT.
Questions	1) Qualitative studies highlight the importance of significant others, such as family/friends and health professionals, in formulating attitudes towards insulin. However, recommendations for reducing PIR generally focus upon HCPs' communication techniques. Who should introduce, appear in, or narrate the video clips? 2) Some individuals continue to hold negative attitudes towards insulin after insulin initiation. How do we best assist these people? Could an internet-based intervention be targeted to this group? 3) Diabetes-related distress and beliefs about current medications are associated with PIR. Assuming the proposed intervention leads to a reduction in PIR, should we expect improvements in DDS and BMQ scores? Should the intervention include elements tackling these broader concepts?

MY NOTES:

Development and pilot study of *Hypobewust*: a psycho-educational group intervention with internet for adult insulin dependent type 1 and 2 diabetes patients and elevated fear of hypoglycaemia

Stefanie M.P.A. Rondags, M. de Wit M, F.J. Snoek

Department of Medical Psychology, VU University Medical Center, Amsterdam, The Netherlands

Aims	The main objective of this study was to develop a psycho-educational intervention aimed at adult type 1 (T1DM) and type 2 diabetes (T2DM) patients on intensive insulin regimen with elevated fear of hypoglycaemia and to evaluate the programme in terms of feasibility, acceptability and trends in outcome measures of interest.
Methods and participants	Our intervention HypoBewust (in English: HypoAware) is based on elements of the Blood Glucose Awareness Training (BGAT). This programme aims to improve patients' hypoglycaemia symptom and risk awareness and preventive and problem-solving strategies. Adaptations were based on input from: 1) interviews in eight centres where the Dutch BGAT (Hypoglykemie Preventie Training: HPT) was implemented, 2) expert meetings with a clinical psychologist, diabetes nurse, diabetes dietitian and an endocrinologist, 3) critical evaluation of HPT by our project members (five researchers with expertise in diabetes and psychology), and 4) evaluations derived from a beta-version pilot-test within our medical centre (n=4) and from our multi-centre pilot-study (7 centres, n=37). We assessed feasibility and acceptability by observations, questionnaires and evaluations from our beta-version and multi-centre pilot-test. Trends in pre-post outcome measures were examined in the pilot study: self-reported frequency of hypoglycaemia, hypoglycaemia awareness, fear of hypoglycaemia (HFS-II), diabetes distress (PAID-5), subjective health (EQ-5D VAS), psychological distress (K10) and emotional well-being (WHO-5). Paired t-tests were used to examine changes.
Results	Main adaptations were: from 6 to 3 group meetings, elements that were perceived as difficult or labour-intensive were fully automated in internet modules (www.hypobewust.nl; built in collaboration with a multimedia company with expertise in educational health programmes), reach was broadened by adding T2DM patients, attention for coping with fear of hypoglycaemia was added, referral to the programme was structured by means of a 5-item checklist (frequent or unexplainable hypoglycaemia, elevated fear of hypoglycaemia in terms of worries or avoidance behaviours and impaired hypoglycaemia awareness), the programme was imbedded in ongoing care, and method of delivery was changed from health-professional directed to a patient empowerment approach. Patient recruitment and delivery of the programme in the pilot study was unproblematic. 52 patients were enrolled in the programme after pre-screening; 4 patients didn't complete the programme. We obtained pre-post measurements from 37 adult insulin dependent T1DM and T2DM patients. Baseline characteristics: mean age 55 years±13, 58% male, education=lower: 32%, middle: 46%, higher: 22%, 85% T1DM, mean HbA1c=60 mmol/mol ± 13, mean diabetes duration=25 years±13, 71% reported frequent mild hypoglycaemia, 15% recent episode of severe hypoglycaemia with hospitalization, 73% ever experienced severe hypoglycaemia, and 60% reported impaired hypoglycaemia awareness. The evaluation showed that trainers as well as patients where very satisfied with the programme. We observed a positive trend in all outcome measures, with significant improvements in worries about hypoglycaemia (mean 21.05 to 18.05, p=.031) and diabetes distress (mean 6.98 to 6.08, p=.023).
Conclusions	HypoBewust is a new highly feasible and acceptable intervention aimed at patients with elevated fear of hypoglycaemia. The trends in outcome measures of interest are promising and need to be further explored in a RCT.

MY NOTES:

Evaluation of the implementation of quality of life in routine paediatric care for adolescents with type 1 diabetes in the Netherlands

Minke M. A. Eilander, M. de Wit & F.J. Snoek
VU University Medical Centre

Aims	The Quality of Life (QoL) method aims to improve the paediatric care for youngsters with type 1 diabetes. Prior to their consultation with the diabetes team, adolescents complete the MIND Youth Questionnaire (MY-Q) regarding their psychosocial wellbeing. Outcomes are discussed in the subsequent consultation. Additionally the parents' wellbeing can be examined. In a pilot study, we implemented the QoL method in routine care by 11 hospitals in the Netherlands. The experiences of the diabetes teams, the adolescents and their parents were studied to be able to increase the usage of this method nationwide.
Methods and participants	The diabetes team members completed an online survey regarding their overall experience with the QoL method and the implementation of the method. Also a semi structured interview was conducted. A selection of adolescents and parents where approached to complete an online survey considering the MY-Q and the subsequent conversation. Additionally the parents whose wellbeing was examined where asked about this part of the QoL method.
Results	Of 65 team members recruited 36 completed the online survey. 10 diabetes teams were interviewed. Of the 69 adolescents approached, 29 completed the online survey and 66 of the 89 parents did. Diabetes teams: 2 out of 10 interviewed diabetes teams successfully implemented the QoL method. The method is often used as a screening tool (by 94.1%); teams appreciate the possibility to discuss their feelings about adolescents and make them concrete (85.3%). Even though 91.2% reported the method as a high valued addition to the routine care, interviews reveal that most hospitals did not continued the usage due to logistical problems. Resulting in time pressure what makes it difficult to discuss both the QoL and physical aspects of diabetes with the adolescents. However, all teams want the QoL method to be a part of the routine care in the nearby future. Adolescents and parents: 78.8% of parents and 41.4% of adolescents appreciate the usage of the MY-Q. An additional 41.4% of adolescents provided a neutral opinion. For 86.2% of adolescents and 80.3% of parents the method is no waste of time. 51.9% of adolescents is neutral about the added value of subsequent conversation. 85.2% feel themselves heard by the diabetes team. The wellbeing of 40 participating parents was examined by the diabetes teams. 87.5% of these parents found this useful and according to 80% it contributed to the paediatric diabetes care. With 9 of these parents their wellbeing was discussed. All of these parents found this beneficial and felt themselves heard. 62.1% of adolescents and 78.8% of parents consider it a good idea if the method is used in more hospitals in the Netherlands.
Conclusions	Implementation of the QoL method in routine care seems difficult, although almost all diabetes team members highly appreciate the method. Adolescents themselves are neutral to positive about the usage; parents are overall positive. It seems worthwhile to continue the usage and further implementation of the QoL method in de paediatric diabetes care. More effort should be made to solve logistic problems.

MY NOTES:

The Diabetes Self-Management Questionnaire (DSMQ): Evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control.

Andreas Schmitt[1], A. Gahr[1], N. Herrmanns[1], B. Kulzer[1], J. Huber[2], & T. Haak[1]

[1] Research Institute of the Diabetes Academy Mergentheim (FIDAM)
[2] University of Northampton, England

Aims	Though a number of questionnaires of self-care and regimen adherence have been introduced, the evaluations do not always succeed to report consistent and substantial correlations with measures of glycaemic control. Small ability to explain variance in HbA1c constitutes a major limitation of such instrument's use for scientific purposes as well as clinical practice. In order to measure self-care activities with association to glycaemic outcomes, the Diabetes Self-Management Questionnaire (DSMQ) was designed.
Methods and participants	The DSMQ is a 16 item questionnaire which assesses self-care activities with regard to the previous eight weeks. Besides the sum scale as global measure of self-care the four subscales 'glucose management' (5 items), 'dietary control' (4 items), 'physical activity' (3 items), and 'health-care use' (3 items) can be estimated (1 item is included in the sum score exclusively). To evaluate its psychometric quality, 261 diabetic patients (age: 52 ± 15 y.; 42% female; BMI: 30 ± 7 kg/m2; 58% type 1 DM; diabetes duration: 17 ± 10 y.; 92% with insulin; HbA1c: 8.6 ± 1.5%; 51% with late complications) were assessed with the DSMQ and the Summary of Diabetes Self-Care Activities Measure (SDSCA). The DSMQ's item and scale characteristics as well as factorial and convergent validity were estimated.
Results	The questionnaire showed good item characteristics (mean difficulty: 47 ± 25; mean corrected item-total-correlation: r = 0.46 ± 0.12; homogeneity: r = 0.25) and internal consistency (α = 0.84). Consistencies of the subscales were acceptable (mean α = .72 ± .08). Principal component analysis indicated a four factor structure (60% explained variance), and the items' factor loadings confirmed the designed scale structure. The DSMQ scales showed convergent correlations with the parallel SDSCA scales (between r = .52 and .58, all P < .01) and with HbA1c ('glucose management': r = -0.39; 'dietary control': r = -0.30; 'physical activity': r = -0.15; 'health-care use': r = -0.22; sum scale: r = -0.40; all P ≤ 0.01). However, all correlations with HbA1c were significantly higher than the equivalent ones of the SDSCA (all P ≤ 0.02).
Conclusions	The study provides preliminary evidence that the DSMQ is a reliable and valid instrument and enables an efficient assessment of self-care behaviours associated with HbA1c. The questionnaire should be valuable particularly for scientific analyses but also clinical work and may be used in both type 1 and type 2 diabetic patients.

MY NOTES:

Evaluation of a structured treatment and education programme (PRIMAS) for type 1 diabetic patients. a randomised controlled trial

Dominic Ehrmann, N. Hermanns, B. Kulzer, N. Bergis-Jurgan & T. Haak

Research Institute of the Diabetes Academy Mergentheim (FIDAM)

Aims	PRIMAS is a newly developed structured treatment and education programme for patients with type 1 diabetes. It is a self-management oriented programme which consists of 12 lessons focusing on patients' daily living with diabetes. Besides educating and empowering patients, PRIMAS monitors relevant parameters of insulin therapy (basal insulin dose, carbohydrate factors, correction rules). PRIMAS was compared to an established education programme which focuses rather on the conveyance of knowledge. In a randomised, multi-centre trial, the efficacy of PRIMAS was compared with the established education programme as control group (CG). Primary outcome was the effect on glycaemic control in a six month follow-up. Secondary outcomes were the impact on emotional aspects, self-management related aspects and hypoglycaemia problems.
Methods and participants	160 participants were randomised either to PRIMAS or the control programme. The study was conducted in an outpatient setting. Baseline characteristics in PRIMAS and CG were similar (age 45.1 ± 13.5 vs. 45.9 ± 13.1 yrs, p=.716; diabetes duration 18.8 ± 12.3 vs. 19.8 ± 13.4 yrs, p=.615; BMI 26.5 ± 4.6 vs. 27.5 ± 5.0 kg/m², p=.236; HbA1c 8.3 ± 1.1 vs. 8.1 ± 1.0%, p=.236).
Results	The PRIMAS group achieved a significant 0.4 percentage points greater reduction of HbA1c at follow-up compared to CG (Δ -0.4 ± 1.0% vs. Δ 0.0 ± 0.6%; p=.012). Furthermore, diabetes-related distress (Δ -0.3 ± 0.7 vs. -0.1 ± 0.4; p=.032) and dissatisfaction with diabetes treatment (Δ -3.3 ± 6.9 vs. -1.9 ± 5.6; p=.024) decreased significantly more in PRIMAS. Diabetes empowerment (Δ 2.6 ± 5.9 vs. 0.8 ± 5.1; p=.037) and diabetes self-efficacy (Δ 1.4 ± 3.6 vs. 0.2 ± 4.0; p=.013) increased significantly more in PRIMAS. Incidence of severe hypoglycaemia, hypoglycaemia awareness, diabetes knowledge, and self-care behaviour improved in both groups with no significant differences between groups.
Conclusions	PRIMAS is significantly more effective in lowering HbA1c than the established education programme. Regarding emotional and self-management related aspects, PRIMAS also showed superiority in reducing diabetes-related distress and increasing diabetes empowerment, diabetes self-efficacy and satisfaction with insulin therapy. Reducing HbA1c was not at the expense of increasing hypoglycaemic problems. Thus, PRIMAS can be regarded as an effective alternative for educating type 1 diabetic patients.
	Trial registration: ClinicalTrials.gov NCT01220557

MY NOTES:

The patients' experience in attending their consultations with diabetes specialist nurses

Robert Priharjo, J. Smith, A. McVicar

Faculty of Health, Social Care and Education, Anglia Ruskin University, Cambridge, Chelmsford, Peterborough, United Kingdom

Aims	The role of diabetes specialist nurses in delivering diabetes consultations in the United Kingdom has been recognised for more than one decade, particularly since the publication of the PREP handbook (UKCC, 2001). However, evidence on how the consultation was delivered, together with patients' experiences, was somewhat limited. This study examined the patients' experience in attending their consultations with diabetes specialist nurses It also investigated how the nurse-patient interaction could contribute to patients' outcome.
Methods and participants	This research was part of a bigger project utilised a sequential mixed methods single approach design: QUAL- QUAN involving patients with diabetes and diabetes specialist nurses. In the qualitative stage (QUAL), 7 patients were interviewed individually (in a separated project, seven nurses were also interviewed and their consultations were also observed and analysed). The data from the patients' interviews were analysed thematically. The study continued with quantitative investigation (QUAN), where the questionnaires had been developed based on the findings from QUAL and adaptation of the Consultation Quality Index/ CQI-2. Following on from a pilot study, the questionnaires were sent to adult patients with diabetes (n=150) and 40 completed questionnaires were returned. The analysis was conducted to reveal patients' biography, partnership, information giving, and length of consultation, empathy and outcome. The associations of these variables were measured
Results	Thematic analysis from the patients' interviews produced five themes which were: '*I don't like living with diabetes*', '*Daily problems*', '*Coping with my diabetes*', '*How the nurses approach Me*' and '*My expectations toward the DSNs*'. The statistical analysis showed the ages of the participants ranged from 18 to 65 or older, and nearly 70 per cent of these were in the 25-64 years old age group. Nearly 75 per cent of the respondents' ethnicity was White. The majority of respondents had either secondary (38 per cent) or further education (35 per cent) and only 5 per cent of them had primary education. The types of diabetes of the respondents were nearly equally distributed, with 45per cent living with Type 2 and 42.5per cent with type 1 diabetes. 67 per cent of the respondents had been living with diabetes more than 5 years the majority of patients were already on anti-hyperglycaemic drugs either tablets (36 per cent), insulin (37 per cent) or a combination of tablets and insulin (26 per cent). Further analysis showed nearly half of the respondents (45 per cent) said that the information supplied was sufficient, but some of them highlighted that the information was too much (25 per cent). The majority of the patients (80 per cent) spent between 15-30 minutes with their DSNs in each consultation. Ten statements indicated the quality of DSN's empathy from 'very good' to 'excellent'. The majority of participants felt their condition was the same following their consultations, only a few of them mentioned a slightly increase in self-help (32.5 per cent). Inferential statistic test found an association between empathy with age (P= 0.004), ethnicity (P= 0.016) and marital status (P= 0, 001). Parametric correlation suggested a significant correlation at the 0.01 (level (2-tailed) between partnership and information giving, empathy and consultation time (P=427). However, only empathy associated with outcome (correlation significant at the level 0.05 2-tailed).
Conclusions	Nursing diabetes consultation has been closely established within the community diabetes service. Overall, the patients have expressed their positive experiences. The development of nurse-patient partnership seemed to be influenced by the ability of the DSNs to give information to the patient, to show their empathy as well as to spend sufficient time with the patients. Empathy was likely to promote information giving. Consultation time was likely to promote partnership and information giving. Further study is needed to explore the empathetic understanding amongst nurses and long term outcome of diabetes consultation conducted by specialist nurses.

MY NOTES: