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- Abstract booklet -

Title: Patient empowerment: Myths and misconceptions

Author: Anderson B

Institute: Diabetes Research and Training Center, University of Michigan, Michigan, USA

The purpose of this presentation is to clarify the concept of empowerment and to correct common misconceptions about its use in diabetes care and education.

The patient empowerment approach is well suited to helping patients make self-selected changes related to weight, nutrition, and physical activity. Although the concept of patient empowerment has become an integral part of diabetes education, an accurate understanding and authentic application of empowerment has not occurred as readily.

Embracing empowerment means making a paradigm shift that is often difficult because the traditional approach to care is embedded in the training and socialization of most health care professionals (HCP). Unlike the traditional approach, empowerment is not something one does to patients. Rather, empowerment begins when HCPs acknowledge that patients are in control of their daily diabetes care. Empowerment occurs when the HCPs goal is to increase the capacity of patients to think critically and make autonomous, informed decisions. Empowerment also occurs when patients are actually making autonomous, informed decisions about their diabetes self-management.

Clarity about all aspects of the empowerment approach is essential if it is to be used effectively.

Title: Depression is associated with the metabolic syndrome among patients with type 1 diabetes

Authors: Ahola AJ [1,2], Thorn LM [1,2], Saraheimo M [1,2], Forsblom C [1,2], Groop PH [1,2] on behalf of the FinnDiane Study Group

Institute: [1] Folkhälsan Institute of Genetics, Folkhälsan Research Center, Biomedicum Helsinki, Finland
[2] Division of Nephrology, Department of Medicine, Helsinki University Central Hospital, Finland

Aims: Research evidence suggests that there is an association between the metabolic syndrome and depression. The results are not, however, conclusive. There are studies suggesting that the association is rather gender specific. We have previously shown that metabolic syndrome exists also among patients with type 1 diabetes. In the current study, we aimed to assess the relationship between the metabolic syndrome and depression among patients with type 1 diabetes.

Methods and patients: A total of 1198 patients (44% men, mean age 45±12 years, diabetes duration 28±13 years) participating in the Finnish Diabetic Nephropathy Study were included. Depression was defined as regular use of antidepressive medication or Beck Depression Inventory (BDI) score ≥16. The metabolic syndrome was defined using the National Cholesterol Education Program (NCEP) diagnostic criteria. Co-existence of at least three of the criteria indicate the presence of the metabolic syndrome: waist circumference >102 cm in men and >88 cm in women, triglycerides ≥1.70 mmol/l, HDL cholesterol <1.00 mmol/l in men and <1.30 mmol/l in women, blood pressure ≥130/85 mmHg or antihypertensive medication, and fasting glucose ≥6.11 mmol/l. All patients were defined to fulfill the criterion for hyperglycemia while lipid-lowering treatment was not an inclusion criteria.

Results: A total of 196 (16%) patients were depressed. The results for men and women were comparable, and are thus presented pooled. The metabolic syndrome was more frequently observed among those depressed (49% vs. 35%, p=0.001). The BDI score increased with the number of the metabolic syndrome components present (p<0.001). Of the individual components of the metabolic syndrome, the waist and triglyceride components were more frequently fulfilled among patients with depression. Depressed patients had higher serum triglyceride concentrations and were more frequently using antihypertensive medication. In logistic regression analyses, the BDI score was independently associated with the metabolic syndrome (odds ratio 1.027, 95% confidence interval 1.008–1.047), waist component (OR 1.034, 95% CI 1.013–1.056), and triglyceride component (OR 1.024, 95% CI 1.001–1.048) when each were adjusted for gender, age and socioeconomic status. In a further adjustment with the use of antidepressive medication, the BDI score remained associated with the waist and triglyceride components, but not the metabolic syndrome.

Conclusions and discussion: The metabolic syndrome is frequently found among depressed patients with type 1 diabetes. Our results are in concordance with many other studies conducted among other patient groups. However, while a number of studies have suggested that the association between depression and metabolic syndrome or its components is mainly present in women, this distinction was not observed in the present study. Both physiological and behavioral pathways could explain the association between depression and metabolic syndrome. Whether depression increases the risks of long term complications via the components of the metabolic syndrome needs to be elucidated.

Title: Psychological correlates with metabolic control in type 2 diabetes patients in Brazil

Authors: Gross CC [1,2], Rodrigues TC [2], Goldim JR [3], Consoli ÉA [2], Rados DV [2], Gross JL [2]

Institute: [1] Institute of Communication and Health, Faculty of Communication Sciences, Università della Svizzera italiana, Switzerland

[2] Endocrine Division, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil

[3] Bioethics Laboratory, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil

Aims: To assess psychological aspects in a cohort of type 2 diabetes patients and to analyze a possible association with the degree of metabolic control and presence of chronic complications.

Methods and patients: Consecutive literate patients with type 2 diabetes attending the outpatient diabetes clinic of a Brazilian university hospital were invited to complete the following questionnaires: Hospital Anxiety and Depression Scale (HADS), Eating Disorder Examination (EDE-Q), Problem Areas in Diabetes Scale (PAID), Resilience and the Perceived Coercion. The presence of micro- and macrovascular complications was obtained according to a standardized protocol. A1C was measured by a high-performance liquid chromatography system.

Results: A total of 154 patients was included and 30.6% reported mild to moderate symptoms of anxiety and 29.6% of depression (≥ 8 score on HADS anxiety and depression, respectively). A1C was negatively associated with symptoms of anxiety ($r = -0.194$, $P < 0.05$) assessed by HADS anxiety. In a multiple regression analysis diabetic retinopathy (DR) was associated with PAID [OR: 1.01 (95% CI: 1.00-1.03), P=0.04] and diabetic nephropathy (DN) was also associated with PAID [OR: 0.97 (95% CI: 0.95-0.99), P=0.007].

Conclusions and discussion: Patients with type 2 diabetes frequently presented symptoms of anxiety and depression. Furthermore, patients with diabetic retinopathy show an increased diabetes related distress. Patients with mild to moderate symptoms of anxiety were more frequently female and sedentary than non-anxious. It is important to properly assess and address the psychological well being of patients with type 2 diabetes.

Title: Reduced worry about hypoglycaemia following insulin initiation in suboptimally controlled Dutch type 2 diabetes patients

Authors: Hajos T, Pouwer F, de Grooth R, Twisk J, Holleman F, Diamant M, Snoek F

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

Aims: Striving for strict glycaemic control by means of insulin therapy may induce anxiety about hypoglycaemia, negatively affecting patients' well-being and complicating self-management. We studied the impact of improved glycaemic control following initiation of long-acting insulin (insulin glargine) on worries about hypoglycaemia in insulin naïve Type 2 diabetes patients.

Methods: Therapy with the long-acting insulin analog was initiated in 1021 insulin-naïve, suboptimally controlled (HbA1c>7%) T2DM patients from 363 Dutch primary care practices. Patient characteristics, HbA1c, self-reported hypoglycaemic episodes during the past month, worries about hypoglycaemia (HFS-Worry scale), and emotional well-being (WHO-5) were assessed, before and 3 and 6 months after insulin initiation. Data were analyzed using Generalized Estimating Equations analysis. Multiple imputation was used for missing data.

Results: Patients had a mean age of 62.3±10.9 years, diabetes duration 6.7±5.5 years; 49% was female, 55% was lower educated. Mean HbA1c improved from 8.5±1.6% to 7.6±1.0% at 3 and 7.3±1.0% at 6 months follow-up ($p<0.001$). A downward trend was observed in symptomatic hypoglycaemic episodes, from 2.7±6.7/month at baseline to 2.4±5.4 at 3, and 1.9±3.7 at 6 months follow-up ($p=0.090$). A small, yet statistically significant decrease in nocturnal hypoglycaemic events was observed (from 0.7±2.6/month to 0.6±3.0 and 0.5±2.1 respectively; $p=0.032$). Frequency of severe hypoglycaemic events did not change. Mean HFS-w score was already low at baseline (7.3±8.6), yet decreased to 6.1±8.6 and 6.0±9.2 at 3 and 6 months respectively ($p<0.001$). To study the impact of the glycaemic improvement on HFS-w HbA1c was added as a possible confounder, but the improvement in HFS-w score did not change. When correcting for age, sex, diabetes duration, educational level, BMI, co-morbidities, diabetes complications and WHO-5 score, change in HbA1c was not associated with the HFS-w score ($p=0.211$). Four percent reported high HFS-w scores at baseline, defined as 2 standard deviations above the mean (32.1±6.3) that decreased to 17.5±14.8 at 6 month follow-up ($p<0.001$).

Conclusions and discussion: Improving glycaemic control in Type 2 diabetes patients by initiating a long-acting insulin analog does not go at the expense of increased worry about hypoglycaemia. A small minority of patients report high levels of hypoglycaemia fear warranting clinical attention. However, they showed a significant decrease after initiating insulin glargine.

Title: Structure of pediatric diabetes care in Germany 1998-2008: Increased centralization and qualification of multidisciplinary teams

Authors: Lange K [1], Gocz A [1], Neu A [2] on behalf of the German working group for paediatric diabetes (AGPD)

Institute: [1] Hannover Medical School, Medical Psychology, Germany;
[2] Universitätsklinik für Kinder- und Jugendmedizin, Tübingen, Germany

Introduction: Current German paediatric diabetes guidelines recommend an integrated in- and outpatient paediatric diabetes care through a multidisciplinary team including a psychologist and a social worker. The objective of the third nationwide survey (relating to 2008) was to analyze the recent changes in structure and process quality of care.

Aims: To analyze the recent changes in structure and process quality of multidisciplinary paediatric diabetes care.

Methods: Three representative surveys were carried out in 1998, 2003 and 2008 via standardized questionnaire mailed to all paediatric units in Germany. Data with respect to personnel for diabetes care, educational programs, number of treated children in out- and inpatient paediatric diabetes care for the respective year were collected.

Results: The response rate in 2008 was 80% (n= 268 units) (1998: 79%; 2003: 80%). 225 of these units cared for children and adolescents with diabetes (164 in- and outpatient, 48 only inpatient and 13 only outpatient). In 2008 a total of 2.534 newly onset patients were reported. While in 1998 only 44% of the newly onset patients were treated by a team with a certified paediatric diabetologist and a certified diabetes educator, this was the case in 64% in 2003 and in 72% of the patients in 2008. Such a team was present in 52 units (1998), in 94 units (2003) and in 111 units (2008). 86% of the new onset patients were treated by a team with a psychologist, 79% with a social worker. While in 1998 65% of the newly onset patients were treated in units with at least 10 new cases a year, this increased to 79% in 2008. In 1998 a total of 71% of the children were followed in outpatient units with more than 60 patients in long-term care. In 2008 this increased to 88% of the 16.827 reported patients. An outpatient team of certified paediatric diabetologist, certified diabetes educator, psychologist and other allied health professionals took care of 57% of the reported patients in 1998, of 73% in 2003 and of 81% in 2008. On average the patients were seen 5.5 times per year. Compared to inpatient teams there were fewer psychologists (71 % of patients) and social workers (58%) in outpatient teams due to deficient funding.

Conclusions and discussion: The representative nationwide survey related on 2008 shows nearly a doubling in the number of paediatric diabetes units with a structure quality according to the national guidelines within ten years, including an increasing number of psychologists being an integral part of the multidisciplinary teams.

Title: Dietary self-care in Type 1 Diabetes: perceptions of young people and their parents

Authors: Nouwen A, Queralt V, Law G

Institute: School of Psychology, University of Birmingham, Birmingham, UK

Aims:

1. To examine the role of three constructs, namely motivation (Deci & Ryan, 2000), self-efficacy (Bandura, 1997), and illness representations (Leventhal, et al. 1984) in relation to dietary self-care, metabolic control (HbA1c levels) and diabetes related distress in adolescents with type 1 diabetes mellitus (T1DM).
2. To bring the cognitive theories into a social context, family responsibility, and the perceptions of parents and their distress levels were also evaluated.

Methods: 85 adolescents, aged 12-18 years, and 80 parents/carers completed self-report questionnaires regarding demographics, diabetes responsibility, illness representations, dietary self-efficacy, motivation toward dietary self-care activities, dietary self-care and problem areas in diabetes. HbA1c was obtained through medical files.

Results: Multiple regression analysis identified that parents' perceptions of adolescent motivation and parent-child discrepancies in self-efficacy accounted for 18% of the variance in HbA1c levels. Age moderated the relationship between no responsibility and HbA1c levels. The relationship between motivation and dietary self-care was mediated by dietary self-efficacy. Adolescent consequence beliefs, motivation and self-efficacy accounted for 36% of the variance in adolescents' distress levels. Parents' perceived consequences and perception of adolescent motivation accounted for 14% of the variance in parent diabetes related distress.

Conclusions and discussion: Adolescent and parent perceptions of motivation, self-efficacy and consequences, are important variables to consider when assessing diabetes outcomes. The data seems to suggest that that low levels of family responsibility are detrimental to young adolescents. However, for adolescents aged over 14 years, family responsibility was found not to relate to HbA1c levels. Parents can facilitate adolescent independence in diabetes tasks during mid-adolescence, and when parents and adolescents are in tune with the adolescent feeling intrinsically motivated and competent.

Title: Diabetes and healthy eating: A systematic review of dietary interventions

Authors: Povey R, Clark-Carter D

Institute: Centre for Health Psychology, Staffordshire University, Stoke-on-Trent, UK

Aims: The objective was to review the literature on healthy eating interventions within diabetes care as the state of evidence exists.

Methods: The databases PubMed, Cumulative Index to Nursing and Allied Health Literature, and PsycINFO were searched for the terms "("healthy eating" or "dietary") and intervention and diabetes" in the abstracts. In addition, electronic searches of the contents of the specific journals Diabetes, Clinical Diabetes, Diabetes Care, Diabetes Spectrum and Diabetic Medicine were conducted. Papers were included in the review if the participants were diagnosed with type 1 or type 2 diabetes; results from an intervention to promote dietary change were reported; measurements were taken from two time points: pre- and post-intervention; at least one outcome measured eating behaviour; and the articles had been published between 1990 and the present date. Data were extracted from eligible studies. Each paper included in the review was scrutinized thoroughly and methodically by two independent reviewers, and the relevant data extracted. During this process, two articles were removed, as under closer scrutiny it was found that they did not meet all the inclusion criteria. The total number of articles which were reviewed was 23.

Results: Studies included a wide range of outcome measures, making direct comparison between studies difficult. To complicate the issue further, studies varied in how the outcome was assessed or reported. However, results from studies were compared by examining the characteristics of those studies which produced a statistically significant result, with those which did not for the different outcome measures. To make the task more manageable this process was limited to those outcomes which had been measured by at least six studies. Studies were compared in terms of sample types and sizes, duration, and type and content of intervention.

Comparisons between significant and non-significant studies revealed some interesting differences between them, although there did not appear to be any clear patterns across the different outcomes, making it difficult to identify any clear distinctions. However, for studies measuring the outcomes of weight, fat intake saturated fat intake, and carbohydrates, there was a tendency for successful interventions to include an exercise dimension, and group work. There was no clear pattern for sample size or duration of studies. However, it is interesting that some outcomes were more likely to show significant changes in studies of longer duration (e.g. serum cholesterol); whereas others were more likely to show significant changes in studies of shorter duration (e.g. weight, fibre), suggesting that certain behavioural outcomes may be more difficult to maintain.

Conclusions and discussion: Future research would benefit by ensuring sample sizes are adequate to give sufficient power, and also by including outcomes in the four different areas of learning, behaviour, clinical improvement and health status. In addition, interventions should be designed which focus on the maintenance, in addition to the initiation of eating behaviour change.

Title: Are people with negative screening tests falsely reassured? A parallel group cohort study embedded in the ADDITION (Cambridge) randomised controlled trial

Authors: Paddison C [1], Eborall HC, Sutton SR, French DP, Vasconcelos J, Prevost AT, Kinmonth AL, Griffin SJ

Institute: [1] General Practice & Primary Care Research Unit, University of Cambridge, Cambridge, UK

Background: Studies have shown limited evidence of adverse psychological effects associated with diabetes screening programmes in terms of increased anxiety and depression. However it is uncertain whether people with a negative diabetes screening test result may be falsely reassured.

Aims: To assess whether receiving a negative test result at primary care-based stepwise diabetes screening results in false reassurance.

Methods: A parallel group cohort study embedded in the ADDITION (Cambridge) randomised controlled trial included 5334 participants aged 40-69 (964 controls and 4370 screening attenders) who were in the top quartile for risk of having undiagnosed type 2 diabetes. Screening attenders completed questionnaires after an initial random blood glucose test and at 3-6 and 12-15 months later, and controls were sent questionnaires at equivalent time points. The main outcomes measures were: perceived personal and comparative risk of diabetes; intentions for behavioural change; and self-rated health.

Results: A linear mixed effects model controlling for clustering by practice showed no significant differences between controls and screen negatives on perceived personal risk, behavioural intentions, or self-rated health after first appointment, at 3-6 months or 12-15 months later. After the initial test those who screened negative reported significantly (but slightly) lower perceived comparative risk (mean difference = -0.16, 95% confidence interval -0.30 to -0.02, p = 0.04) than the control group at the equivalent time point; no differences were evident at 3-6 and 12-15 months.

Conclusions and discussion: A negative test result at diabetes screening does not appear to promote false reassurance. Implementing a widespread programme of primary-care based stepwise screening for type 2 diabetes is unlikely to cause an adverse shift in the population distribution of plasma glucose and cardiovascular risk due to an increase in unhealthy behaviours arising from false reassurance among those who screen negative.

Title: The treatment of co-morbid emotional problems in people with diabetes type 2: Evaluation of a mindfulness-based psychological intervention (DIAMIND)

Authors: van Son J, Nyklicek I, Pouwer F, Pop V

Institute: Center of Research on Psychology in Somatic diseases (CoRPS), University of Tilburg, The Netherlands

Background: A considerable proportion of the patients with type 2 diabetes (T2D) experience emotional problems, varying from disease-specific worries to general symptoms of anxiety and depression. This emotional well-being is related to other unfavorable outcomes, like reduced quality of life, worse self-care, reduced glycemic control, complications, and mortality. A mindfulness-based psychological intervention may increase the emotional well-being in patients with diabetes, since the intervention has proven to be successful in various other patient populations earlier.

Aims: the purpose of this study is first to test the effectivity of a mindfulness-based psychological intervention (MBSR) aimed at increasing the emotional well-being and quality of life of patients with T2D. Second, to examine which group of patients, with which characteristics (like the extent of complications and personality) will benefit most from the intervention. Third, to investigate the effect of the intervention on self-care, health care consumption behavior, glycemic control, blood pressure, and heart rate variability.

Design and methods: The study is a randomized controlled trial (RCT). Dutch speaking patients with T2DM with self reported emotional problems recruited from hospitals, primary care organizations, and a patients' association will be randomized in an intervention group or a wait-list (usual care) control group. The intervention group will receive the MBSR program directly, while the control group will receive the program six months later. The MBSR will be given in eight weekly sessions (including one booster session) to groups of eight to ten persons. The intervention will be based on a combination of existing protocols with an emphasis on practicing mindfulness and will be given by a psychologist. The number of patients necessary will be 160, taking into account a medium effect size, a power of 0.80, an alpha of .05 and patient attrition. Data on anxiety, stress, depressive symptoms and diabetes stress will be collected at baseline, after four weeks, at post intervention and after six months. Data on personality, diabetes acceptance, self-care, mindfulness, quality of life, health care consumption, complications, glycemic control, blood pressure and heart rate will be collected at baseline, post intervention and after six months. The study is supported by grants from the Dutch Diabetes Research Foundation (Diabetesfonds) and Tilburg University and has been approved by the medical ethical committee.

Planned Analysis: Repeated measures analysis of variance ((M)ANCOVA) will be used to test the hypotheses concerning the differences between groups on the dependent variable over time. In these tests age, sex, education, and co morbidity will be included as covariates. The analyses concerning the subgroup effects will be conducted on the sample as a whole, whereby possible moderating variables, like complications and personality will be included in the analyses as between-subjects factors. All analyses will be based on the intention-to-treat approach.

Discussion: It is hypothesized that the MBSR will be effective in improving the emotional well-being, quality of life and self-care of patients with T2D. Results of this study will contribute to a better care for patients with T2DM with emotional problems. The first results will become available in 2012.

Problems and questions:

Which type of patient (in terms of personality, extent of complication or other characteristics) is likely to benefit most from a mindfulness-based intervention? What would you expect?

Do you believe it is possible that this intervention could positively influence the diabetes regulation in a direct (next to an indirect) manner?

Title: Development of the psychological treatment program for young patients with diabetes type 1 and comorbid eating disorder

Authors: Primožič S, Gorenc M, Bratin N, Bratanič N, Battelino T

Institute: Department of Endocrinology, Diabetes and Metabolic Diseases, University Children's Hospital Ljubljana, University Medical Center Ljubljana, Slovenia

Aims: Eating disorders and their subthreshold variants are approximately twice as common in adolescent females with type I diabetes as in their peers without diabetes. These eating disorders fall largely into the categories of full-syndrome bulimia nervosa and its subthreshold variants, and eating disorders not otherwise specified (ED-NOS; binge-purge variety). The outcome of this combination is often catastrophic, with recurrent episodes of hypoglycaemia precipitated by food restriction despite insulin administration, poor metabolic control, recurrent diabetic ketoacidosis, earlier-than-expected onset of diabetes-related complications, and early mortality.

There is an increased risk of eating disorders in adolescents with diabetes type I, likely due to multiple interacting factors associated with diabetes and its treatment. The following diabetes-specific factors interact with other individual, familial and sociocultural vulnerabilities to lower the threshold for expression of an eating disorder, namely weight gain by introducing the insulin therapy, body dissatisfaction, the drive for thinness and dietary restraint. Deliberate insulin omission or dose manipulation is the most common way to weight control by inducing hyperglycemia and glucosuria. Binge eating has been reported in as many as 55-80% of young women with diabetes. Eating disorders are often accompanied by depression and anxiety.

Our main aim is to develop psychological treatment program based on cognitive behavioral therapy to provide appropriate help for above mentioned population. The goal is to reduce patient's symptoms of inappropriate eating behavior, symptoms of depression and anxiety, and improve their wellbeing. The purpose of study is also to find out which of the symptoms of eating disorders are the most common or expressed in studied population and some other characteristics of s studied population.

Design and methods: Adolescent girls with Type 1 diabetes with suspected eating disorder will be referred to psychologist from pediatric diabetologist at regular outpatient visits. Patients with severe ketoacidosis admitted to the hospital will be also referred to psychologist who will provide diagnostic interview and offer the psychological treatment to the patient. Specific treatment program will be held in groups of 8-12 patients, with two CBT therapists during 10 sessions focused on specific topics. Topics will cover the following areas: education about eating disorders, motivation for treatment, self-image,

self-esteem, healthy life style, self-control techniques, relaxation, planning exercise and pleasure activities, emotional regulation and restructuration of distorted negative thoughts.

The treatment process will be evaluated with questionnaires that measure symptoms of eating disorders (DEPS, EDI), depression (CDI, HDI), anxiety (RCMAS), wellbeing (RPWB), coping (COPE), diabetes related distress (PAID, DDS) and diabetes self-management (SDSC-A).

Data about duration of eating disorder and of diabetes, presence of diabetic complications, episodes of hypoglycemia (number of serious episodes in last six months), glycosylated hemoglobin values (HbA1c), diabetes therapy (insulin pump or multiple daily injections), and BMI will be interceded by pediatric diabetologist. Sociodemographic data (gender, age, data about family functioning, parent's education, academic performance and alcohol or drug abuse) will be collected. All data will be collected before treatment, after six months and at the end of the treatment. Patients on the waiting list will be used as control group, so they will be asked to fill the same questionnaires twice in similar time interval as treatment will last.

Planned analysis: Collected data will be analyzed with SPSS 15.0 statistics. T-test, Wilcoxon matched pairs test, $\chi 2$ or analysis of variance will be used besides descriptive statistic parameters. The linear regression and Spearman's or Pearson's correlation coefficient will be applied to estimate to relationship between different variables.

Expected outcomes: We expect that by the end of the group treatment the symptomatology of eating disorder would subside or at least reduce, that there would be reduction in dieting, binge eating, insulin omissions, body dissatisfaction and preoccupation with thinness and eating. Additionally improvement of wellbeing is expected, decline in depressive and anxiety symptoms. Changes in better self-management of diabetes, improvement in diabetic control and lower scores of diabetes distress are also expected.

Problems, questions for group discussion:

1) May individual therapy be more appropriate?

2) Are the patients on a waiting list suitable for control group?

3) How many subjects should be included in the study?

4) How much should be treatment focused on topics related to diabetes (insulin omissions, hyperglycemias)?

Title: Longitudinal associations between depression, type D personality and micro- and macrovascular outcomes in primary care patients with type 2 diabetes: rationale and design of the DiaDDZOB Study

Authors: Nefs G, Pouwer F, Denollet J, Pop V

Institute: Center of Research on Psychology in Somatic diseases (CoRPS), University of Tilburg, The Netherlands

Aims: Depression is a common complication of diabetes, but longitudinal studies into the natural course and the consequences of depressive symptoms in primary care patients with type 2 diabetes are scarce. Meta-analyses have shown that depression is associated with poor glycemic control and increases the risk for macrovascular disease. However, the association between depression and the development of microvascular complications remains understudied. The predictive role of other aspects of emotional distress and the mechanisms that link emotional distress with poor vascular outcomes are also not fully understood. The DiaDDZOB Study (Diabetes, Depression, Type D Personality Zuidoost Brabant) will therefore examine: (1) the course (prevalence, incidence, recurrence, remission) of depressive symptoms in primary care patients with type 2 diabetes, (2) whether depressive symptoms and Type D (distressed, socially inhibited) personality are risk factors for the development of both microvascular and macrovascular complications in this group; (3) whether these types of emotional distress also increase the risk of all-cause or vascular mortality; and (4) the behavioural and biomedical mechanisms that may mediate these associations.

Design and methods: The DiaDDZOB Study is a prospective cohort study that is embedded within the larger DiaZOB Primary Care Diabetes Study, which covers a comprehensive cohort of type 2 diabetes patients treated by over 200 primary care physicians in South-East Brabant, The Netherlands. These patients will be followed during their lifetime and are assessed annually for several demographic, clinical, lifestyle and psychosocial factors. Measurements include an interviewer-administered and self-report questionnaire, results from regular care laboratory tests and physical examinations, and pharmacy medication records. The DiaDDZOB Study uses data that have been collected during the original baseline assessment (M0; N = 2,460) and the 2007 (M1; N = 2,225) and 2008 (M2; N = 2,032) follow-up occasions.

Planned analyses: For question #1: Frequencies will be provided for (1) the prevalence, (2) incidence (with / without prior history of depression), (3) recurrence (high score across at least two assessments) and (4) other patterns of relapse and remission of high depressive symptoms (EDS-score of 12 or more). Logistic regression analyses will be used to determine significant predictors of these different course patterns. For question #2: To evaluate the vascular risk associated with emotional distress, we will perform

logistic regression analyses for (a) the development of each separate micro- and macrovascular complication and (b) a composite measure of vascular disease (the development of any vascular condition) during the two year follow-up period. For question #3: Similar analyses will be used for mortality, with the dependent variable defined as (a) all-cause or (b) (cardio)vascular mortality, as registered in primary care medical records up until December 2008. For question #4: Before proceeding to the multivariate statistics in question #2 and #3, several study variables will be evaluated for their potential as confounders or mediators in the association between emotional distress and the onset / progression of complications. We will adopt a > 5 % change in the effect size (odds ratio) for emotional distress before and after adjustment for the variable in question as the criterion to identify suitable mediating or confounding factors. All variables satisfying these conditions will be included in the final logistic regression models in question #2 and #3.

Expected outcomes: Based on the current literature, we hypothesize the following: Approximately one fifth of our sample will have an increased level of depressive symptoms at each separate measurement occasion (prevalence). In the group of patients without a history of depression, incident depression will be low (< 5 %). In the patients with a history of depression, recurrence rates will be relatively high (at least 25 %). Significant risk factors for depression most likely will be (1) psychosocial factors such as stressful life events and loneliness and (2) the presence (onset or progression) of vascular complications. We also hypothesize that patients with co-morbid distress (either depressive symptoms or Type D) will be at increased risk for the development of micro- and macrovascular conditions; these associations are (partly) explained by behavioural (smoking behaviour, alcohol consumption, physical activity) and biomedical (cardiovascular disease history, characteristics of the metabolic syndrome) mechanisms.

Problems, questions for group discussion:

#1: Are there any questions / remarks / suggestions about the study?

#2: Will Type D personality have a unique clinical prognostic value beyond that of depressive symptoms?

#3: In the present study, we consider several health behaviours (smoking, alcohol use, physical activity) and biomedical characteristics (medical history, treatment characteristics, results from laboratory tests / physical examinations) as potential mediators of the association between emotional distress and disease outcomes. Are there any other interesting candidate mechanisms that could be included in follow-up assessments, bearing in mind that all measurements take place during regular care procedures?

Title: DiAlert: A Lifestyle intervention in Dutch and Turkish Dutch 1st degree relatives of persons with type 2 diabetes. A randomised controlled trial

Authors: Heideman WH, Stronks K, van Middelkoop BJC, Twisk JWR, Snoek FJ

Institute: VU University Medical Center, Department of medical psychology, Amsterdam, The Netherlands

Background: Family history (FHi) is a known risk factor for T2DM, and more so in the presence of overweight. Prevention trials (e.g. Diabetes Prevention Program) in overweight persons with IGT have demonstrated that the risk of developing type 2 diabetes (T2DM) can significantly be reduced by weight reduction. In the Netherlands persons from Turkish origin are known to be at increased risk for type 2 diabetes and cardiovascular disease, but so far received little attention.

Aims: The main objective of this study is to test and compare the effectiveness of a lifestyle-oriented intervention in Dutch and Dutch-Turkish 1st degree relatives of type 2 diabetes patients with overweight.

Design and methods: In this RCT, participants will be allocated to either the intervention or wait-list control group. Recruitment occurs via general practitioners and outpatient clinics in the Amsterdam region. Eligible are overweight persons from Dutch or Turkish origin with a first degree relative with type 2 diabetes, aged between 29 and 55 years.
The intervention aims to promote diabetes awareness and intrinsic motivation to change lifestyle. Two interactive group sessions and one booster session are offered. The follow-up program aims to sustain achieved behaviour changes. The wait-list control group receives the intervention 3 months after baseline. Basic content and learning principles of the program are derived from existing behaviour change interventions in the field with an emphasis on self-management. Unique features of the program are the review of own family history of T2DM, diabetes risk assessment and family communication on diabetes prevention. A culturally appropriate Turkish version of the program will be made available. The main endpoint is to achieve and maintain body weight loss. Secondary outcomes include anthropometric, medical and psychological indices, along with process indicators. Changes in outcomes are tested between intervention and control group at 3 months; effects over time are tested within and between both ethnic groups at 3, 6 and 9 months.

Planned analysis: By means of t-tests and chi-square tests, baseline variables will be compared for the different groups. Linear and logistic regression models will be used to examine the effect of the intervention on each of the outcome measurements at 3 months cross-sectionally. Separate analysis of predictors will be performed to examine which participants benefit the most of the intervention.
To determine the effect of the intervention on weight loss and to follow individual change over the total follow-up time we will use a Generalized Estimating Equation (GEE) approach.

Expected outcomes: We hypothesize that the intervention will prove to be more effective than the control condition in achieving significant body weight loss at 3 months. We expect to observe significant changes in metabolic, psychological and behavioural parameters 3, 6 and 9 months following the intervention in both ethnic groups, resulting in reduced risk of developing type 2 diabetes and cardiovascular disease.

Problems and questions:
The challenge in offering an intervention in a community setting is to find the right balance between efficacy (intensity, follow-ups) and feasibility. What could contribute to the personal lifestyle changes of the participants with minimal contact moments.
We expect heterogeneity within the group sessions (e.g. age, SES). How could we address all participants in the groups?

Title: The effects of a self-efficacy based exercise intervention on physical activity, cardiovascular risk factors and health status in inactive people with type 2 diabetes mellitus

Authors: van der Heijden M, Pouwer F, de Bie R, Pop V

Institute: Center of Research on Psychology in Somatic diseases (CoRPS), University of Tilburg, The Netherlands

Aims: Sufficient exercise is important for people with Type 2 Diabetes Mellitus, as it can prevent future health problems. Although the knowledge about the effects of physical activity and the number of diabetes-exercise programs is increasing, still a substantial number of people with type 2 Diabetes Mellitus do not exercise enough. Therefore, we have developed DIAFYZOB, a new diabetes-exercise program that takes into account the patients' level of exercise-self-efficacy (the confidence that one can independently increase their amount of physical activity).

The aims of the DIAFYZOB study are: (1) To test whether the intervention increases the level of physical activity of participants; (2) Examine which determinants contribute to a successful change of the amount of physical activity (3) Examine the effects of the intervention on health status; and (4) Examine the effect on cardiovascular risk factors. Secondary aims focus on patient satisfaction and the effects on diabetes self-efficacy, depressive symptoms and quality of sleep.

Design and methods: This study is a Non-randomised Controlled Clinical Trial with 400 (2x200) intervention participants and 200 control participants. The intervention consists of a 6 months physiotherapist guided exercise program, with both resistance and aerobic exercise. Intervention: Participants who are confident that they can independently increase their amount of physical activity (represented by a high exercise-self-efficacy score), receive a patient-tailored exercise plan: After an intake, the participant is supposed to exercise at home (at least 3 times a week). Progression is evaluated in four individual consultations.

Participants who are less convinced that they can increase their amount of physical activity independently (represented by a low exercise-self-efficacy score) receive a more intensive exercise intervention: Group training sessions supervised by a physiotherapist (first 8 weeks: 2x/week, 1 hour each time; next 8 weeks: 1x/week, 1 hour each time) and at-home exercise (first 8 weeks: 1x/week; next 8 weeks: 2x/week; last 8 weeks: 3x/week). Progression is evaluated in four individual consultations.

Both intervention programs will be compared to a matched control group that receives 'care as usual'. Measurements include (among other things) amount of physical activity,

cardiovascular risk factors, health status, diabetes self-efficacy, depressive symptoms, quality of sleep and satisfaction. Assessments take place at baseline, after 24 weeks and after 1 year for both intervention- and control group. The intervention group has additional assessments after 12 and 36 weeks.

Planned analyses: Participants of the 'exercise-plan' intervention group will be compared with control group participants with a high exercise self-efficacy score. Participants of the 'intensive' intervention group will be compared control group participants with a low exercise self-efficacy score.

Major analysis for study aims 1 and 4 will be an independent t-test/Man Whitney test. Major analysis for study aim 2 will be logistic regression. Major analysis for study aim 3 will be a MANOVA. Secondarily, multi-level analyses will be done as participants are clustered in seven regions/physiotherapists.

Expected outcomes:

1 Effect on physical activity: It is hypothesized that both interventions will significantly and clinically increase the amount of physical activity compared to care-as-usual.

2 Successful change of the amount of physical activity: It is hypothesized that particularly a high level of exercise self-efficacy, high social support, low BMI, and low depression at baseline are related to a successful change of the amount of physical activity after 1 year.

3 Effect on health status/mood: It is hypothesized that health status (both the physical and mental component) will improve significantly en clinically.

4 Effects on cardiovascular risk factors: It is hypothesized that BMI, waist-hip ratio and blood pressure will improve significantly en clinically.

Problems, questions for group discussion:

1: Any suggestions for improvements?

2: How can we make sure that participants stay active after the intervention?

3: Limitation: This study is non-randomised. How serious a problem is this?

Title: Development and evaluation of a self-management oriented diabetes education programme for the initiation of intensive insulin therapy in type 2 diabetes (MEDIAS 2 ICT)

Authors: Mahr M, Maier B, Hermanns N, Kulzer B

Institute: FIDAM - Research Institute of the Diabetes Academy Mergentheim, Bad Mergentheim, Germany

Background: A large percentage of patients with type 2 diabetes will need insulin injections at some point in the course of the disease in order to achieve and maintain recommended targets for metabolic control. Despite the knowledge that insulin therapy can be effective in achieving this control, and at the same time, insulin therapy has no adverse effect on the patient's quality of life, often patients with type 2 diabetes are reluctant to go onto insulin therapy. Multiple factors are involved in the refusal of insulin, referred to as "psychological insulin resistance". Education programmes addressing the specific attitudes towards insulin therapy and aiming at an improvement of self-management could be a source for a better acceptance and a safe transition to insulin therapy.

Aims: Against this background we developed a new self-management oriented education programme for the initiation of insulin therapy in type 2 diabetes, named MEDIAS 2 ICT. It is intended for patients with multiple daily injections (MDI) and consists of ten lessons. Each lesson lasts for approximately 90 min and takes place biweekly.

MEDIAS 2 ICT targets - methodical and didactical - at supporting patients in the development of (1) general self-management skills necessary for the effective management of a chronic condition (e.g. goal setting, action planning and problem solving), (2) diabetesspecific self-management skills necessary for the effective management of type 2 diabetes (e.g. management of hypo- and hyperglycaemia, foot care, cardiovascular risk, etc), and (3) insulin therapy-specific self-management skills necessary for the effective management of insulintherapy (e.g. insulin dose adaptation, assessment of carbohydrate intake, etc.). Each lesson includes a training of practical capabilities (e.g. insulin injection, self-monitoring, etc.). Specific insulin-related topics are discussed in group (e.g. concerns about insulin therapy, insulin related weight-gain, injection in public, etc.). It is expected that an education programme which targets at an improvement of selfmanagement and accounts for the individual lifestyle and personal experience in the programme will be more effective than the current education.

The aim of this randomized controlled trial is to evaluate the efficacy of MEDIAS 2 ICT. The primary outcome variable after a 6 month follow-up is improvement of glycaemic control. Secondary efficacy variables are change of attitudes towards insulin therapy and improvement of diabetes self care behaviour, diabetes knowledge, diabetes related distress, quality of life and metabolic variables.

Design and methods: In a randomized controlled prospective trial MEDIAS 2 ICT is compared with a control group (CG) whose members received a current education programme combining an insulin education programme with a hypertension programme.

Inclusion criteria are type 2 diabetes, two years diabetes duration with oral treatment, indication of insulin therapy, HbA1c > 7.0%, age 18-75 years, BMI < 40 kg/m2, no participation in a structured education programme during the past 2 years and the ability to read and understand German. All patients have to give informed consent. Exclusion criteria are current psychiatric disease, dementia or other severe cognitive impairment, severe diabetes complications or other severe somatic diseases (e.g., cancer) and gestational diabetes. The study was approved by the ethics committee in February 2009.

The study's primary outcome is improvement of glycaemic control. As a parameter of glycaemic control, A1c values are measured in central laboratory. Secondary outcomes are attitudes towards insulin therapy, diabetes self care behaviour, diabetes knowledge, diabetes related distress, quality of life and metabolic variables (lipids, weight). Attitudes towards insulin therapy are assessed using ITEQ. Diabetes self care behaviour and diabetes knowledge are assessed using questionnaires. Diabetes related distress is measured using the PAID questionnaire and quality of life is measured using the WHO-5 and the EuroQol questionnaire.

The recruiting of study participants started in April 2009 in outpatient study centres. If patients who met the inclusion criteria gave informed consent, they were invited to a baseline assessment. After baseline assessment a centrally block randomization of the patients of one study center (8 to 16 patients) took place. A total of 164 participants were randomized either to the CG or to MEDIAS 2 ICT. A second assessment took place immediately after termination of the programmes, the final and decisive assessment 6 months later.

Planned analysis: Normally distributed and continuous variables will be analyzed by a two-factor ANCOVA with the factors "treatment" (MEDIAS 2 ICT vs CG) and "measurement" as independent variables. To control for baseline differences, the baseline values will be integrated as covariates.

Expected outcomes: It is expected that the new developed programme can demonstrate non-inferiority with regard to the main outcome variable glycaemic control. If non-inferiority can be demonstrated superiority of the programme will be tested. Secondary efficacy variables are change of attitudes towards insulin therapy, improvement of diabetes self care behaviour, diabetes knowledge, diabetes related distress, quality of life and metabolic variables.

Problems, questions for group discussion:

1. Is psychological insulin resistance appropriately addressed with the new education programme?
2. How can the effect of the education programme on glycaemic control be separated from the effect of insulin?

Title: Parental anxiety and avoidance of acute hypoglycaemia

Authors: Barnard K 1; Royle P [2]; Thomas S [2]; Waugh NR [2]

Institute: [1] University of Southampton, [2] University of Aberdeen

Background: Many children with type 1 diabetes have poor glycaemic control. Since the Diabetes Control and Complications Trial (DCCT) showed that tighter control reduces complication rates, there has been more emphasis on intensified insulin therapy. We know that patients and families are scared of hypoglycaemia. We hypothesised that fear of hypoglycaemia might take precedence over concern about long-term complications, and that behaviour to avoid hypoglycaemia might be at the cost of poorer control, and sought to explore if there were effective interventions to prevent that.

Aims: To systematically review studies concerning the extent and consequences of fear of hypoglycaemia in parents of children under 12 years of age with type 1 diabetes, and interventions to reduce it.

Data Sources: MEDLINE, EMBASE, PsycINFO, The Cochrane Library, Web of Science, meeting abstracts of EASD, ADA and Diabetes UK, Current Controlled Trials, ClinicalTrials.gov, UK CRN, scrutiny of bibliographies of retrieved papers and contact with experts in the field.

Inclusions: We used relevant studies of any design. The key outcomes were the extent and impact of fear, hypoglycaemia avoidance behaviour in parents due parental fear of hypoglycaemia in their children, the effect on diabetes control, and the impact of interventions to reduce this fear and hypoglycaemia avoidance behaviour.

Results: Eight articles from six studies met the inclusion criteria for question. All were cross sectional studies and most were of good quality. Parental fear of hypoglycaemia, anxiety and depression were reported to be common. Evidence on behaviour to avoid hypoglycaemia was sparse, but there were some suggestions that higher than desirable blood glucose levels might be permitted in order to avoid hypos. No studies reporting interventions to reduce parental fear of hypoglycaemia were found.

Conclusions and discussion: The evidence base was sparse. Parental fear of hypoglycaemia in their children with Type 1 diabetes is considerable, affecting both parental health and quality of life. There is some evidence of hypoglycaemia avoidance behaviours by parents which adversely affects glycaemic control. Trials of interventions to reduce parent anxiety and hypoglycaemia avoidance behaviour are needed. We suggest that there should be a trial of structured education for parents of young children with Type 1 diabetes.

Title: Depression, alexithymia and the endocrine-metabolic and clinical profile in Type II diabetic patients

Authors: Braude M, Alvarez A

Institute: Department of Psychiatry, Diabetes Section of the Department of Metabolism, Endocrinology and Nuclear Medicine of the Italian Hospital of Buenos Aires, Argentina

Introduction: The coexistence of depression and diabetes is a very serious medical situation. Moreover, depression and diabetes are associated with higher mortality and morbidity. Despite these facts, depression is not frequently diagnosed. The incidence of alexithymic features can explain this sub-diagnosis.

Objectives: To study the relation between Type II diabetes, depression and alexithymia. To study the relation between diabetes, depression, alexithymia and the endocrine-metabolic and clinical profile of Type II diabetic patients.

Methods: We studied a sample of 59 Type II diabetic patients, aged 17 to 70 years old. Patients had been attended at the Diabetes Section of our hospital for the last 12 months. Diagnoses were made during a psychiatric interview and MINI (Mini International Neuropsychiatric Interview), according to DSM IV criteria. Patients depression features were evaluated with the Hamilton Depression Scale. Patients also fulfilled Beck Depression Inventory and TAS 26 for Alexithymia. Faster blood sample were obtained for glycemia, etc. Finally BMI, waist circumference and blood pressure were also included.

Results: Correlation was positive between results of Hamilton Scale for Depression and alexithymia features in TAS 26. Both measures also correlate positively to higher glycemia and CLU.

Correlation between Hamilton and TAS and between Hamilton and CLU

	Alexithymia	N	Media	Deviation	Probability
Hamilton	Positive	27	18,85	8,61	P=0;003
	Negative	32	12,19	8,11	

Significant variables	Hamilton	N	Media	Deviation	Probability
CLU	Normal	19	52,16	17,7	0,01
	Depression	35	68,53	27,26	

Conclusions and discussion: Type II Diabetic patients with higher score in the Hamilton Depression Scale suffer from a more severe depression and also present a higher score in Alexithymia (TAS 26). This patients are more exposed to a much torpid evolution, with cardiovascular diseases, several morbidities and mortality. On the other hand, patients less depressed are not alexithymic. The alexithymic condition may contribute to the underdiagnosis of Depression in patients with Type II Diabetes.

Title: First administration of Hypoglycaemia Fear Survey and Problem Areas in Diabetes questionnaire in Slovenian type 1 and type 2 diabetes subjects – A pilot study

Authors: Kanc K [1], Kastrin A [2], Kastrin M [1], Gonder-Frederick L [3]

Institute: [1] IandDiabetes, Private Diabetes Centre, Ljubljana, Slovenia
[2] Institute of Medical Genetics, University Medical Centre, Ljubljana, Slovenia
[3] Behavioral Medicine Center, University of Virginia Health System, USA

Background: Recurrent episodes of hypoglycemia in diabetic patients may lead to psychomotor abnormalities, cognitive impairment, and behavioral changes. Consequently, patients may develop fear of hypoglycemia, which reduces the quality of life and may lead to unsatisfactory diabetes management. Extensive literature review and own clinical experience suggest that psychological screening should become a more routine part when evaluating medical, psychological, and educational interventions for diabetes patients. Therefore, the importance of psychological aspects in diabetes management suggest extensive clinical application of reliable and valid psychometric instruments. Two different self-report instruments, the Hypoglycemic Fear Survey (HFS) and the Problem Areas in Diabetes Survey (PAID), are currently used worldwide to assess specific behaviors and situations related to diabetes patients.

Aims: The objective of the present pilot study was two-fold: (i) translation and linguistic adaptation of the HFS and PAID questionnaires for use among Slovene-speaking patients with diabetes, and (ii) evaluate metric properties of the adapted questionnaires.

Methods: All insulin-treated patients (N = 138) registered with private medical centre at the time of survey, were contacted and 103 agreed to participate. Self-reported demographic and clinical characteristics of the participants were collected. Forward and backward translation of the HFS and PAID questionnaires was performed by two independent Slovene native speakers fluent in English. All participants responded to the questionnaires. There were 50 males and 53 females, aged 15 to 88 years (M = 54, SD = 19 years). The sample included 45 patients with type 1 diabetes and 58 patients with type 2 diabetes. Missing values were handled with the EM algorithm. Internal consistency of the scales was estimated by Cronbach's α coefficients. Factorial validity was examined using factor analysis.

Results: Cronbach's coefficients indicated high reliability (α = 0.92) for the whole HFS scale, with α = 0.82 and α = 0.93 for the Behavior and Worry Subscale respectively. Factor analysis indicated that two-factor structure is reasonable. Internal consistency of the PAID was high (α = 0.95). Factor analysis suggested one common factor. Small sample size made it difficult to interpret both factor solutions. Convergent validity was confirmed by strong correlation ($r = 0.70$, $p < 0.001$) between the total scores on the HFS and PAID scales, respectively. Further validation including clinical characteristics as covariates revealed statistically significant difference in HFS score according to type of diabetes ($t = 2.87$, $p = 0.005$). Type 1 patients reported significantly higher fear of hypoglycemia.

Conclusions and discussion: We performed the first systematic adaptation and administration of HFS and PAID scales in Slovenia. Results of this study support the high reliability of the adapted versions of the HFS and PAID scales in patients with type 1 and type 2 diabetes in this pilot patient sample. Coefficients of internal consistency in Slovene sample are comparable with those reported in similar adaptation studies. The factor structure should be re-analyzed on a larger sample size. A feasible goal is to expand our research including other biological (e.g., HbA1c level) and psychological (e.g., personality traits) characteristics.

Title: Ethnic differences in the prevalence and recognition of depression in a UK primary care population with and without type 2 diabetes

Authors: Ali S (1), Taub NA, Stone MA, Skinner TC, Davies MJ, Khunti K

Institute: (1) University of Warwick, (2) University of Leicester, (3) Combined Universities Centre for Rural Health

Aims: Results from meta-analyses suggest that the prevalence of depression is higher in people with type 2 diabetes compared to those without. However a number of methodological limitations in the literature remain including the use of inadequate control groups and a failure to control potentially confounding factors. Furthermore there is a paucity of data from the UK. The present study aimed to determine the prevalence of depression in a multiethnic primary care population with and without type 2 diabetes in the UK. In addition the study aimed to examine ethnic differences in the prevalence of depression between South Asian and White European people with type 2 diabetes and to assess the recognition of depression in Primary Care.

Methods and patients: Consecutive general practice attenders were screened for depression using the depression subscale of the Hospital Anxiety and Depression Scale (HADS-D) during routine appointments in primary care. Demographic and medical data were also extracted from participants' general practice records.

Results: Complete data were available for 860 adults with type 2 diabetes (560 South Asian and 300 White European). No significant difference in the prevalence of depressive symptoms were observed between people with and without type 2 diabetes (HADS-D > 8 =28% vs.29%, P=0.68; HADS-D >11 = 17.4 vs 17.3, P=0.99). Higher rates of probable and/ or major depression were observed in SA people with type 2 diabetes compared to WE's; 32% vs. 22%, P = 0.006 (HADS-D >8) and 13% vs. 10%, P = 0.166 (HADS-D >11). Using a cut-off of >8 on the HADS-D, the ethnic difference also persisted when controlling for age, gender, deprivation and the presence of one or more co-morbidity or diabetes-related complication. Controlling for the effects of selected socio-demographic and clinical factors, the corresponding estimate of currently recognised depression as noted in patient records demonstrated much lower rates of depression in SAs compared to WEs (1% vs. 4%, OR 0.339; 95% CI 0.116-0.989, P = 0.006). Higher rates of recognition were also associated with younger age (P<0.05) and the presence of one or more diabetes related complications (P<0.01).

Conclusions and discussion: In contrast to previous research, the findings showed no significant difference in risk for depression in those with diabetes vs. controls, suggesting that the association between depression and diabetes may be less robust than previously acknowledged. However, Depression is seriously under-diagnosed in people with type 2 diabetes, most acutely in South Asians, suggesting a need to improve methods of identifying depression in these patients.

Title: Releasing knowledge empowers people. Grounded theory from qualitative evaluation of guided self-determination in one-to-one contexts

Authors: Zoffmann V

Institute: PCC, Steno Diabetes Center, Gentofte, Danmark

Aims: To present the grounded theory of Releasing Knowledge developed in qualitative evaluation of nurses and patients with type 1 diabetes and poor glycemic control using Guided Self-Determination (GSD).

Background: Though highly recommended, empowerment is difficult to implement in clinical practice. Barriers to empowerment in difficult diabetes care were previously revealed by grounded theories and resulted in the development of a mutual problem solving method, GSD, to overcome the barriers. A randomised controlled trial has confirmed that GSD was effective in group-training for adults with type 1 diabetes and poor glycemic control by improving patients' life skills with diabetes including their glycemic control. A qualitative evaluation has further been conducted to understand how GSD influences communication and reflection, the type of relationships established and the possibility to resolve life-versus-disease conflicts. This evaluation discovered Releasing Knowledge as crucial for the impact of GSD, making reason for further investigation.

Design and settings: Grounded theory was conducted using constant comparative analysis as recommended by Glaser in evaluation of a nurse led one-to-one GSD intervention for patients with type 1 diabetes and poor glycemic control in two university diabetes clinics.

Methods: Multiple data sources were analyzed from 11 dyads between patients with a long history of poor regulation of type 1 diabetes and 6 nurses trained in using GSD material comprising reflection sheets to be filled in by patients before and between conversations with the nurses. Constant comparative analysis was conducted to develop the theory of Releasing Knowledge.

Results: Person-specific knowledge was co-created by patients and professionals and revealed a releasing property which appeared to move through four stages 1) releasing knowledge in the patient's mind, 2) releasing knowledge in a supportive relationship, 3) releasing knowledge in a team and 4) releasing knowledge in daily life. While the basis for releasing knowledge was self-insight gained by patients filling in GSD reflection sheets at home it turned into shared insight involving the nurse and other diabetes team members and significant others such as family, friends, colleagues or study fellows. Releasing knowledge hereby initiated a process of empowerment.

Conclusions and discussion: The study connects the empowering potential of GSD in difficult diabetes care with its ability to provide Releasing Knowledge. By following the co-creation of releasing knowledge, it became clear that it entailed a process of empowerment which involved not only the patient but also health care providers and significant others such as family, friends and colleagues. Findings recommend mutual problem solving methods to be used in difficult diabetes care. Further research must be conducted to understand the importance of using person-specific knowledge as evidence in decision-making and problem solving to accomplish an empowerment consistent care of patients with diabetes or other chronic conditions.

Title: Do people with diabetes understand their clinical marker of long-term glycaemic control (HbA1c) and does this predict diabetes self-care behaviours and HbA1c levels?

Authors: Clark M, Beard E, Hurel S, Cooke D

Institute: UCL Division of Population Health, University College, London UK

Aims/Objectives: Research outside of the UK has demonstrated that people with diabetes have a poor understanding of HbA1c and that this impacts on effective diabetes self-management. The present study sought to replicate and expand on this research in a UK outpatient population by assessing recall and understanding of HbA1c, and whether this predicts diabetes self-care behaviours and HbA1c. Self-efficacy in relation to performing different diabetes self-care behaviours was also measured to establish whether this was associated with understanding of HbA1c.

Methods: 83 participants (women n=46; type 2 diabetes n=41) completed questionnaires assessing their understanding of HbA1c, diabetes self-care behaviours (diet, exercise, self-monitoring of blood glucose and foot-care) and self-efficacy in relation to carrying out these behaviours. HbA1c results were obtained from clinical notes.

Results: Twenty seven percent of participants (n=22) were classified as having a good understanding of HbA1c. Those with poor understanding were significantly more likely to be older (p=.001), have type 2 diabetes (p=.004), a higher HbA1c (p=.001), report lower levels of dietary self-care (p=.029) and self-efficacy relating to exercise (p=.009) and blood glucose testing behaviours (p=.026). Understanding of HbA1c significantly predicted HbA1c levels although the model explained only 12% of the variance.

Conclusions and discussion: The majority of participants had a poor understanding of HbA1c and this significantly predicted HbA1c levels. In light of recent calls for people with diabetes to be aware of their personal diabetes targets, the results from this study support the development of interventions aimed at increasing individuals' understanding of their clinical markers.

Title: Why does self-monitoring of blood glucose not work for some people?

Authors: Barnard K, Royle P, Clar C, Waugh NR

Institute: University of Southampton, UK

Aim: To identify reasons why self-monitoring of blood glucose (SMBG) does not improve glycaemic control in people with type 2 diabetes treated with diet/exercise alone or oral agents.

Methods: Review of previous systematic reviews, and systematic review/meta-analysis of randomised controlled trials (RCTs). Review of observational and qualitative studies.

Results: The updating systematic review and meta-analyses showed little benefit of SMBG in people with type 2 not treated with insulin. Improvements in HbA1c in meta-analyses of RCTs were often of the order of 0.2%, which can be statistically significant but not clinically important. Half of the trials reported a reduction in HbA1c, and all that did find favorable results, included an educational component and/or feedback. SMBG can cause adverse psychological effects including depression, increased anxiety and self-chastisement.

There were 36 relevant observational studies. These are more prone to bias, from confounding factors, and association does not necessarily mean cause. 18 showed no difference in HbA1c, 12 showed a reduction (but often very small), 6 only in certain subgroups, and some showed an increase in HbA1c.

Likely reasons for lack of effectiveness of SMBG include:

a lack of education in how to interpret and use the data from SMBG

a lack of interest in the results from health care professionals

Failure to act on the results

Conclusions and discussion: Several factors may contribute to the lack of effectiveness of SMBG in type 2 diabetes not treated with insulin, with a recurring theme being that the data were not used to alter treatment.

Title: Translating the Diabetes Prevention Program's lifestyle intervention in Chicago communities

Authors: Ruggiero L Moadsiri A, Zhao W, on behalf of the entire Making the Connection Project Team

Institute: School Of Public Health, Illinois Prevention Research Center / Institute for Health Research and Policy, University of Illinois at Chicago, USA

Aims: The overall goal of the research program was to conduct a translation study of a community-tailored version of the Diabetes Prevention Program's (DPP) successful clinic-based lifestyle intervention delivered in community settings by community residents. The primary aims were to: (1) tailor and enhance the DPP's lifestyle intervention for diverse residents in a Chicago, Illinois community; (2) identify, recruit, and train community members to deliver the intervention in the community; and (3) examine the feasibility, acceptability, and impact of the final community tailored intervention.

Methods: *Measures, intervention, and Procedure:* The first phase of the project involved the tailoring and formative evaluation of the community based version of the DPP lifestyle intervention delivered by community members in community settings. Consistent with the DPP intervention, the lifestyle program promoted healthy eating and physical activity to reduce overweight/obesity and risk of developing type 2 diabetes. Data collection included qualitative measures (e.g., focus groups), process measures (e.g., attendance logs, brief qualitative surveys), standardized questionnaires (Fat Related Diet Habits Questionnaire-DHQ, International Physical Activity Questionnaire-IPAQ), and anthropometric measures (e.g., weight, waist circumference). Two one-year Vanguard groups (African American and Latino) were conducted to examine, feasibility, acceptability and preliminary outcome of the community tailored intervention. The second phase of the project involved a translation study examining the final intervention program using a three-occasion (Baseline, 6-month Follow-up, 12-month Follow-up) completely within-subjects repeated measures design. *Participants:* A total of 21 individuals were recruited into the Vanguard groups with 12 in the Latino group and 9 in the African American group. Participant characteristics included: African American or Latino, at least 18 years old, overweight or obese, and absence of a diagnosis of diabetes. For the translation study, a total of 69 participants were included based on the following eligibility criteria: age 18 years and older, Latino, overweight or obese, and not diagnosed with diabetes. Their characteristics included: average age of 38 years; 100% Hispanic; 93% female; 72.5% married; 25% employed, 35% unemployed, and 36% homemakers.

Results: The Vanguard group quantitative and qualitative results suggested that the community program was feasible and acceptable. Detailed Vanguard group results will be presented. For the translation study, Wilcoxon Signed Rank Test results indicated significant improvements ($p < .05$) across time in anthropometric variables (i.e., weight, waist circumference, body fat) and some eating habit and physical activity variables. Detailed translation study results will be presented.

Conclusions and discussion: The formative phase of this project supported the feasibility and acceptability of the community tailored and delivered lifestyle intervention. The translation study demonstrated that the final community-tailored version of the DPP's lifestyle intervention delivered in community settings by community residents holds promise in helping people make healthy lifestyle changes to reduce weight and lower the risk of diabetes. Discussion will be focused on identifying models of sustainability of community based programs.

Title: Psychological well-being and diabetes-related distress across stages of type 2 diabetes in the multi-national Diabetes Attitudes, Wishes and Needs (DAWN) Study

Authors: Peyrot M

Institute: Department of Sociology, Loyola College, Baltimore, West Virginia University, USA

Objective: This study examined the levels of well-being and diabetes-related distress across several criteria for staging type 2 diabetes among adults.

Research design and methods: Participants were 3432 adults with type 2 diabetes from the multi-national DAWN study. Random samples were obtained from each of 11 countries/regions in Asia, Australia, Europe, and North America. All measures were self-reported data obtained during structured interviews. Distress was assessed by a set of items developed for the DAWN study and well-being was assessed by the WHO-5. Diabetes staging criteria included time since diagnosis of diabetes, the timing and nature of anti-hyperglycemic medication regimens, and the timing and number of complications.

Results: Using ANCOVA to control for confounding factors, diabetes-related distress and psychological well-being were significantly ($p < 0.05$) worse for patients with more complications and more intensive medication regimens. Longer duration of insulin use was significantly associated with more diabetes-related distress. Worse distress and well-being were significantly associated with the accumulation of complications over time, but were more strongly associated with recently diagnosed complications than with more distally diagnosed complications. Duration of diabetes closely corresponded to a set of conventional stages based on the staging criteria.

Conclusions and discussion: Although this study did not track outcomes longitudinally over the changing duration of diabetes, well-being and distress varied over stages as defined by the nature and timing of medications and complications. However, the observed patterns were more complex than a linear model of disease staging would suggest.

Title: The Westminster Diabetes Service: A consultant-led, community-based service for patients with type 2 diabetes

Authors: Hepburn S

Institute: Westminster Diabetes Service, London, UK

I began my first job in diabetes two months ago as Clinical Psychologist for the Westminster Diabetes Service. In this presentation, I would like to talk about a major service development being initiated in Westminster. The Westminster Diabetes Service is a consultant-led, community-based service for patients with type 2 diabetes. Opened in November 2005, in 2009 the service saw about 500 patients living in central and northwest London.

However, some groups of people with diabetes living in Westminster systematically fail to make use of the service, and may receive no specialist diabetes input at all. Some cannot physically access the service, because they are house-bound or live in nursing or rehab beds in residential care homes. Others have less visible access difficulties, such as homelessness or severe mental health problems. We are developing an outreach programme to serve these groups. Our principal role will be to provide diabetes education and support for staff working with these individuals, who may know little or nothing about diabetes. In mental health and possibly in homeless services, our role will be to encourage staff to support patients to access the centre in the conventional way. In some areas, our role will be more hands-on, with MDT ward rounds planned for mental health inpatient units and home visits with community nurses.

I will discuss some of the challenges we have so far uncovered in working in outreach. The initiatives will no doubt provide some useful opportunities for research. As a newcomer to the field of diabetes psychology, I would also like to ask for the audience's input to help me direct my focus towards some valuable, interesting and testable research questions.

Title: Measuring the determinants of physical activity behaviour for people diagnosed with type 2 diabetes: Developing a measurement tool in Ticino, Switzerland

Authors: Suggs LS [1], Gross C [1], Bardus M [1], Rossman C [2]

Institute: [1] Institute of Communication and Health, Faculty of Communication Sciences, Università della Svizzera italiana, Switzerland
[2] Institut für Kommunikationswissenschaft und Medienforschung, Ludwig-Maximilians-Universität München, Germany

Aims: The primary purpose of this study is to test the Theory of Planned Behavior (TPB) in predicting physical activity among Type 2 Diabetes Mellitus (T2DM) participants in Ticino, Switzerland. The TPB is used in this study because of its utility in predicting health behaviors, especially physical activity behavior and has been used in several studies around the globe to predict physical activity. However, this will be the first test of TPB in a Type 2 Diabetes population in Switzerland and in the Italian language. TPB surveys include measures of attitudes, subjective norms, perceived behavioral control, intention and behavior. Six indicators for each construct are recommended, measuring both indirect and direct measures of each construct, which results in a survey that can have high respondent burden. Therefore, the secondary purpose is to condense the full survey, based on the data from a cross-sectional study, and test it again in another cross sectional study. This is done in an effort to see if a condensed version of the full TPB can be developed and maintain its power.

Design and methods: This study is following a mix of qualitative and quantitative methods and it has 3 phases. The full version of the TPB questionnaire will be developed in the phase 1 according to a standardized qualitative method. Phase 2 and phase 3 will follow cross sectional designs. The study began in January 2009 and should be completed in April 2010. It is estimated to have from 12,000 to 14,000 people with diabetes in Ticino, between 4% and 5% of the population and 90% have type 2 diabetes. For TPB studies using multiple regression analyses it is reasonable to assume at least a moderate effect size. Generally, a sample size of 80 would be acceptable. Assuming that 20% of patients do not accept participating in the study, 200 patients will be recruited. Approximately 25 patients with T2DM will be enrolled in Phase 1; the qualitative survey development phase. A total of 100 participants will be enrolled in each of Phase 2 and 3, with some, if not many, participants participating in both phases. T2DM patients attending the outpatient clinic named Lugano Diabetes Foundation, those subscribed to the Ticino Association for diabetics, and those seeing participating physicians will be invited to participate in the study.

Planned analysis: Two researchers independently will analyse the content of the responses by labelling the themes and listing them in order of frequency for each of the following: behavioral beliefs, sources of social pressure, and control belief strengths. Multiple regressions, correlations and reliability analyses will be used to test the validity of the questionnaire as appropriate (together with other validation procedures).

Expected outcomes: The TPB questionnaires will allow investigations into specific aspects regarding physical activity for type 2 diabetes. It is hoped that these questionnaires enable a broader understanding of physical activity behavior among people living with T2DM and are useful tools for research with this specific population. It is known that although more effective diabetes therapy have been developed in the past years, the predominance of patients with diabetes do not achieve satisfactory diabetes control. Thus, it is important to understand in greater depth the individual psychological responses in relation to self management, in this study, with physical activity behavior. This study also aims to test whether a condensed version of the TPB survey can maintain its predictive power. We expect that we lose very little power as the condensed version is based on cross section data obtained from the full sample. This will result in a TPB measurement tool that can be used in intervention studies and tested with a similar population across the border in Italy, and adapted to French and German speaking Swiss participants diagnosed with T2DM.

Problems, questions for group discussion:

1. Keeping in mind that the TPB requires a rather lengthy questionnaire to measure it fully, we still wish to assess psychological determinants and barriers (referred to as "background factors" in the TPB) that may influence attitudes, subjective norms, perceived behavioral control, intention and behavior.
   What questionnaires could be used to access psychological determinants or barriers (personality, depression, anxiety, and emotional distress) to be physically activity and can be used in short forms?

2. We hope to extend this work into the French and German speaking parts of Switzerland, however we are concerned that it would not be possible to develop one TPB survey for all three groups.
   What suggestions might you have for dealing with the desire to use the TPB to predict physical activity behavior in a national sample, where 4 official languages are spoken, the cultures are notably different from one another, and about 10% of the population speak languages other than the 3 primary languages?

Title: Lifeskills in adolecents with type 1 diabetes. A study that evaluates the method Guided Self-detemination – developed and implemented for use in pediatric out patient clinics for adolecents and their parents

Authors: Husted G

Institute: Pediatric Ward and Research Department, Hillerød Hospital, Denmark

Background: Type 1 diabetes in adolescents is a demanding desease. Difficulties in the transition of responsibility sharing between parents and adolescents can result in poor adherence, conflict and disease complications. However it is necessary to intervene during early adolescence to get a better glycemic control and reduce risk of late diabetic complications. It is a challenge for parents and involved health professionals to take up an autonomy supportive role versus a controlled one. Much of the research to date use intervention methods that are separate from routine clinical care. Such research provides an important foundation. However there is a need for developing new interventions in pediatric out patient clinics which focuses on autonomous motivation and which is suitable to be implemented in routine clinical pediatric practice. A method to overcome barriers to collaborative care, with an autonomy supportive approach is Guided Self-Determination (GSD). GSD was developed in adult diabetes care and is based on empowerment philosophy, grounded theories, dynamic judgement-building, theories about change and lifeskills theory. The method is practiced by qualifying healthprofessionals communicative competences in combination with having patients to fill in reflection sheets for use at the dialoqes in the hospital. Research has shown that using GSD gives better glycemic control and better quality of life.

Aims: The overall aim of this study is to develop a Guided Self-determination-young intervention which can be integrated into routine out patient pediatric diabetes clinics and which will facilitate appropiate family responsibility sharing, minimize conflict and improve problem solving by autonomative motivation and not control. The purpose is that health professionals and parents are able to support adolescents to develop lifeskills with type 1 diabetes contemporary with better glycemic control.

Design and methods: Adolescent-parent-focused lifeskills intervention in a concurrent mixed methods design in two parts:

Part 1: A multi-diciplinary participant based part where Guided Self-detemination is developed into a Guided Self-detemination-young version and implemented in pediatric diabetes out patient clinics.

Part 2: An interventions study with a concurrent mixed method design(10). The use of quantitative and qualitative approaches in combination provides a specific understanding of how Guided Self-determination-young can support adolescents to develop lifeskills and achieve a better glycemic control.

Participants part 1: 22 adolescents at age 13-18 years with poorly regulated Type 1 Diabetes, their parents, 2 pediatricians, 5 staffnurses and 2 dieticians from two Danish Hospitals (Glostrup and Hillerød).

Participants part 2: 68 new adolecents age 13-18 years with poorly regulated Type 1 Diabetes and their parents are randomized to an intervention group (n=34) or a control group (n=34), and the same healthprofessionals from part 1.

Intervention: Participants from both groups are seen 8 times a year. The participants in the interventions group have appointments for one hour at each visit and their parents are offered two visits alone besides the common ones. The participants in the control group are seen between 30 to 45 minutes at each visit, like they are used to, and parents participate as they are used to do before participating the project. The difference is that participants in the intervention group use reflection sheets before, between and at the appointments.

The following measurements are used as outcome measures in the project regarding the quantitative approach:

- HbA1c
- Perception of Parents Scale (POPS, 42 items, a reduced version)
- Health Care Climate Questionnaire (HCCQ, 5 items)
- Problem Areas In Diabetes (PAID, 20 items)
- Perception of Competence in Diabetes (PCD, 5 items)
- Treatment Self Regulation Questionnaire (TSRQ, 21 items)
- WHO-5 well-being index(5 items)

The outcomes are measurered at baseline, after 6 and 12 months. HbA1c is measured every third month during the study. SMBG per week and cancellations or faillure to show up are registered.

Statistical analyses of the data are planned to be done using SPSS 18.0

Regarding the qualitative evaluation 10 to 12 adolescents and their parents from the intervention group are being followed through the process. Consultations at out patient clinics are being taped and at the end of the study adolescents, parents and professionals are interviewed separately. Constant comparative analysis as recommended by Glaser is used (17, 18).

Results are available december 2011.

Questions for discussion:

1) How important is my qualitative results from research among adolescents with type 1 Diabetes and their parents opposite other qualitative designs– what are the strengths or the weaknesses?
2) What is the challenge for me when I select participants for the qualitative evaluation - how many are needed when I use a mixed method design – what are your experiences and recommendations?

Title: Prediction of diabetes type 1 self-care by the interaction of illness representations and self-efficacy: Should we consider self-efficacy as a mediator and a moderator?

Authors: Recchia S [1,2], Spitz E [2], Steffgen G [1]

Institute: [1] University of Luxembourg, Luxembourg
[2] University Paul Verlaine of Metz, France

Aims: The pilot project MONDIAB (from French "My Diabetes") aimed at exploring psychosocial factors in self-care of diabetes Type I. Theories have shown that health behaviors are influenced by illness representations and by perceived self-efficacy. Numerous studies have investigated the impact of theses beliefs in diabetes self-management. The present study focused on the interaction of illness representations and self-efficacy as predictors of diabetes self-care. Self-efficacy was tested as a mediator and a moderator variable for hypothesized relations between illness representations and self-care behaviors.

Design and methods: MONDIAB's study design is longitudinal with two time measures and two different samples. The first sample has been recruited in patients' associations and clinics of the Lorraine (east of France) by a paper-and-pencil procedure. The second sample participated through an Internet survey. The data presented here are based on the first measurement time. The sample comprised 373 patients with Type I diabetes with a mean age of 31.85 years (SD = 17.291) and 56.8% of females. Participants, completed the Brief Illness Perceptions Questionnaire, the Diabetes Self-Efficacy Scale and the Summary of Diabetes Self-Care Activities Revised Scale. Self-reported health information included duration of diabetes, number of hospitalization and glycosylated hemoglobin (HbA1c) levels.

Preliminary results: Results showed that diabetes self-care behaviors (dietary regime, gylcemic control, exercising) and metabolic control (HbA1c) are weakly to moderately associated to the illness representations (r ranging from -.11 to .35), whereas links to self-efficacy are moderate to strong (r ranging from -.29 to .44). Furthermore, stepwise regression analyses elucidated self-efficacy to be the most powerful predictor of self-care behaviors, as illness representations became non-significant when introducing self-efficacy. In order to understand the mechanism underlying the interaction of illness beliefs and self beliefs in the prediction of diabetes' self-care, we tested the role of self-efficacy as potential mediator and moderator. Regression analyses revealed support for self-efficacy as a mediator variable for the relation between illness representations of response efficacy (i.e. treatment control) and self-care behaviors (dietary regime, gylcemic control, exercising, HbA1c). In accordance with Leventhal's Self-Regulatory Model, self-efficacy is associated to response efficacy and has a direct effect on illness behaviors. Nonetheless, self-efficacy was also tested as a moderator by examining Bandura's assumptions that response efficacy (treatment control) exert effect on behavior when patients perceived themselves as efficacious. Results indicated that self-efficacy moderated the impact of treatment control on self-care behaviors. Thus, patients who believe in their treatment effectiveness and feel self-efficacious will have better scores on diabetes self-care behaviors (dietary regime, gylcemic control, exercising) and have a better metabolic control (lower levels of HbA1c).

Preliminary conclusions: Findings showed evidence for the prediction of diabetes self-care behaviors by the interaction of illness representations and self-efficacy. Regression analyses suggested that self-efficacy played simultaneously the role of a mediator and a moderator in the interaction with treatment control predicting diabetes self-care behaviors. The relation between treatment control and patients' self care behaviors was found to be explained by perceived self-efficacy. Moreover, findings illustrate that patients' adherence could be predicted by the interaction of self-efficacy and treatment control belief. For clinical implications it is essential to elucidate the role played by self-efficacy.

Questions for discussion: Question 1: How can we explain self-efficacy as being both a mediator and a moderator in the relation of treatment control and self-care behaviors ? Question 2: (a) How can we handle different results regarding self-monitoring of blood glucose, diet, exercising and metabolic control levels (HbA1c) and (b) should we use a global score rather than specific sub domains of self-care behaviors?

Title: Development, piloting and validation of a questionnaire to assess diabetes-specific self-care behaviours

Authors: Clark M, Cooke D, Heller S on behalf of the DAFNE UK programme

Institute: UCL Division of Population Health, University College, London, UK

Aims: To develop, pilot and validate a questionnaire assessment tool of diabetes-specific self-care behaviours using a mixed methodological approach. This will incorporate up-to-date recommendations about diabetes self-management that form part of structured education for people with type 1 diabetes but will also have potential for wider application to type 2 diabetes. It will be a generic tool that can be used across different structured education programmes delivered in primary and secondary care.

Design and methods: Questionnaire development will involve an iterative process drawing upon qualitative and quantitative techniques: 1. Identify existing type 1 structured education programmes in UK that fulfill NICE criteria 2. Compare curricula of these courses to identify core components/teachings [Consensus techniques with diabetes professionals who developed and deliver the courses and the Type 1 Diabetes Education Network] 3. Generate patient-completed, questionnaire items and circulate for comment in consensus meeting(s) 4. Pilot questionnaire with users [2-3 focus groups with people who have undergone structured education] 5. Establish validity and reliability [Questionnaire administration to 400 graduates of structured education programmes at 2 time points. Factor analysis]

Planned analysis: Factor analysis; Establish validity and reliability

Expected outcomes: The importance of assessing and evaluating structured education programmes in diabetes has been highlighted in the Department of Health/Diabetes UK Improvement Toolkit for Commissioners and Local Diabetes Communities and the NICE guidance for patient education models. Development of a new patient-completed measure of diabetes self-care behaviours would add to this toolkit and give clinicians and people with diabetes, opportunities to identify and explore aspects of diabetes self-management that may require additional input or support from the diabetes team to help initiate or maintain changes in behaviour. Such a tool could also be developed subsequently for insulin-treated individuals with Type 2 diabetes.

Questions for discussion:

1) Making this generic to structured education programmes for type 1 diabetes (not DAFNE-specific)
2) Broader applicability to type 2 diabetes requiring insulin

Title: Validation of the Polish version of Problem Areas in Diabetes - 5 (PAID-5) questionnaire. Preliminary study

Authors: Kokoszka A

Institute: II Department of Psychiatry, Medical University of Warsaw, Warsaw, Poland

Aims: Comprehensive validation of the Polish translation of the PAID-5.

Design and methods: Problem Areas in Diabetes – 5 PAID-5 (McGuire, et al., 2010), is a new shortened version of 20 items' Problem Areas in Diabetes – PAID questionnaire (Polonsky et al., 1995) that has good psychometric proprieties, however, relations of its scores with variety of clinical characteristics of patients with diabetes has not been studied yet.

The preliminary assessment of psychometric proprieties of PAID-5 and its relations with the domain of the original PAID was conducted. Items belonging to PAID-5 were separated from the PAID items from the database of the ongoing study on the validation of the Polish version of PAID.

Reliability of PAID-5 (N=118) Alpha Cronbach =0,83, whereas reliability of PAID (N=98) Alpha Cronbach = 0.93. Correlation between PAID-5 and PAID is very high (r= 0.94). Also PAID-1, i.e., response to one question "worrying about the future and the possibility of serious complications" has moderate, but relatively high correlation with PAID (r= 0.65).

Results: PAID-5 has moderate, but relatively high correlation with measures used for the assessment of the four subscales of PAID (negative emotions, social support, problems with treatment, problems with eating), i.e, with: depression in HADS (r = 0.44), anxiety in HADS (r = 0.31), depression (r = 0.55) and anxiety (r = 0.61) in Brief Self-Rating Scale of Anxiety and Depression; social support in Oslo-3 (r =- 0.42), problems related with eating in Eating Attitudes Test - EAT (r = 0.23), adherence to treatment (r = -0.21) and in with HbA1C (r= 0.2). The correlations of PAID-5 with the subscales of PAID were very high: with negative emotions - r = 0.95; problems with treatment – r = 0.60; problems with eating - r = 0.63; lack of social support – r = 0.47

Planned Analysis: the assessment of the reliability and validity of PAID-5

Expected outcomes: Assessment of the psychometric proprieties of the Polish translation of PAID-5.

Questions for discussion: The choice of measures for the assessment of the validity of PAID-5.

Title: The working memory of offspring of parents with type 1 diabetes

Authors: Hardiman M [1], Temple R [1], Martinez-Cengotitbengoa MT [2], Alloway TP [3]

Institute: [1] Norfolk & Norwich University Hospital NHS Trust
[2] Norfolk Learning Difficulties Service, NHS Norfolk
[3] Centre for Memory and Learning in the Lifespan, University of Stirling

Background: In the UK in 2002, 1 in 250 pregnancies were affected by diabetes, totalling 3808 live births. Diabetic pregnancy is medically considered to be high risk. Offspring experience a 5x increased risk of stillbirth and 3x increased risk of perinatal mortality. Longer term changes resulting from diabetic pregnancy are known to include anthropometric, metabolic and neurological elements.

Previous studies have extended our understanding of the impact of maternal diabetes during pregnancy on the cognitive development of offspring. Local anecdotal evidence suggested a high frequency of additional educational support being provided to offspring born to mothers with diabetes. Our own previous study points to a specific deficit in working memory amongst a cohort of these children.

Aims: The aim of this study is to explore the working memory of a cohort of offspring born to mothers with type 1 diabetes in more detail by using a dedicated working memory assessment tool. A further aim of the study will be to attempt to correlate any findings with data held regarding the pregnancy and diabetic history of the mother as well as to comparison groups of children born at 36 to 38 weeks to mothers without diabetes and to fathers with diabetes.

Methods: The study consists of four arms. These are (1) offspring born to mothers with type 1 diabetes (ODM) (2) offspring born at 36 to 38 weeks gestational age to mothers without diabetes (EB) (3) offspring born to fathers with type 1 diabetes (ODF) and (4) a control group of children assessed during test kit standardisation, age and gender matched to group (1).

All children are aged between 6 and 14 years old and have been delivered at the Norfolk & Norwich University hospital (NNUH), with the exception of those in group 4. Potential participants are identified via NNUH records and receive a written invitation pack. Follow up telephone calls are made and assessments are conducted in a dedicated clinical research and trials unit on the campus of the University of East Anglia. Sample size calculations indicate 55 participants are required in each arm.

The chosen test kit is the Automated Working Memory Assessment (AWMA). The AWMA is a computer based assessment based on the Baddeley & Hitch model of working memory. It consists of twelve subtests which build to provide four scales (Phonological

Loop, Visuospatial Sketchpad and Central Executive measured both verbally and visually). Assessment takes between 45 and 60 minutes per child.

Data held regarding the pregnancy and diabetic history of the mother consists of maternal age, age at onset of diabetes, gestational age at delivery, whether prepregnancy care was received, whether any severe hypoglycaemic episodes took place during the pregnancy, maternal Hba1c at booking, 12, 24 and 34 weeks gestational age, whether the child was macrosomic and infant birth weight ratio. This data will be available for each participant in the ODM group. Infant birth weight and gestational age at delivery will also be available for participants in the ODF and EB groups.

Planned analysis: Analysis will be conducted within the research team, with additional statistical support from a NNUH statistician. Main effects will be analysed using Manova. Secondary effects will be analysed using Pearson's r and t-tests.

Expected outcomes: As at 27th January 2010 a total of 33 controls, 42 ODM and 39 EB children have been assessed. Recruitment is now commencing for the ODF group. Initial analysis indicates a deficit in phonological loop performance for both ODM and EB groups. Further, a better than anticipated performance has been observed for visuo spatially assessed central executive functions in both these groups.

Phonological loop deficits may correlate with early pregnancy Hba1c. The receipt of maternal pre pregnancy care may be a predictor of offspring phonological loop performance. No correlations appear to be present with the higher than expected performance on visuospatially assessed central executive functions in any group.

Questions for discussion:

1) The deficit in phonological loop performance for the EB group suggests that gestational age at delivery may be a predictor of offspring memory performance. How should this finding be taken forward?
2) Higher than expected participant performance on tasks assessing visuospatial central executive functions do not appear to correlate with any other measures of pregnancy or glycaemic control. Do these results represent a false positive, possibly related to a very high quality assessment environment for visuospatial tasks being used in this research?
3) How could the knowledge gained from this research be used to boost take up rates of pre pregnancy care planning among women with diabetes, without causing undue concern amongst these women about the possible impact of their diabetes on future offspring?

Title: Web-based cognitive behavioural therapy is effective in the treatment of depression symptoms and diabetes-specific emotional distress in type 1 and type 2 diabetes patients

Authors: van Bastelaar K, Pouwer F, Cuijpers P, Riper H, Snoek F

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

Background: Depression is a common co-morbid health problem, affecting millions of diabetes patients worldwide. Besides negatively impacting quality of life, depression is associated with poor diabetes outcomes. A diabetes-specific depression treatment is needed to optimize depression treatment in diabetes patients. Internet is a new and attractive conduit for delivering such an intervention on large scale at relatively low costs.

Aims: To evaluate the effectiveness of a web-based, diabetes-specific depression treatment in adults with type 1 and type 2 diabetes.

Methods: In a randomized controlled trial, conducted in 2008-2009, with open recruitment, 255 adult diabetes patients with elevated depression symptoms, were randomly assigned to the web-based, diabetes-specific depression intervention (n = 125) or a wait-list control group (n = 130). The intervention consisted of an eight-lesson, web-based, diabetes-specific depression treatment, based upon the principles of Cognitive Behavioral Therapy, minimally guided by psychologists. Primary outcome was depression symptoms (Centre for Epidemiological Studies Depression scale) and diabetes-specific emotional distress (Problem Areas in Diabetes Scale), both assessed at baseline, directly after completing the intervention / after an 8-week waiting period, and at 1 month follow-up. Secondary outcome was glycemic control, for which glycosylated hemoglobin levels were inquired at patients treating physician, at baseline and 1 month follow-up.

Results: The web-based intervention is effective in reducing depression symptoms and diabetes-specific emotional distress (with respectively intention to treat analyses: $P = 0.03$, $d = 0.29$; and $P = 0.04$, with $d = 0.02$, and per protocol analyses both $P < 0.001$, $d = 0.71$ and $d = 0.21$). Patients in the intervention group showed significantly higher clinical improvement that the control group (36% vs 19% in intention to treat and 51% vs 19% in the per protocol analyses, both $P < 0.001$). Since glycosylated hemoglobin levels were not poor at baseline, we were unable to show beneficial effect of the intervention on glycemic control ($P > 0.05$).

Conclusions and discussion: Web-based, diabetes-specific depression treatment is effective in reducing depression symptoms, and diabetes-specific emotional distress, yet we do not know the direct benefits of the intervention on diabetes outcomes, in adult type 1 and type 2 diabetes patients.