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**- Abstract booklet -**

**Title:** Depression and insulin sensitivity and insulin secretion in the risk cohort study

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**Aims:** Depression is related to an increased risk of incident diabetes and this might be mediated by reduced insulin sensitivity. In several population-based studies, associations between depressive symptoms and reduced insulin sensitivity have been found, yet contradictory findings have been reported. In addition, less is known about the association of depression and insulin secretion. Therefore, the aim of the current study is to explore the association between 1) depressive symptoms and insulin sensitivity, and 2) depressive symptoms and parameters of insulin secretion in a European cohort of men and women aged 30-64 years.

**Methods and patients:** The study population was derived from the 3-year follow-up measurement of the Relationship between Insulin Sensitivity and Cardiovascular risk (RISC) study. Patients with diabetes were excluded. Depressive symptoms were defined as a Center for Epidemiologic Studies Depression Scale (CES-D) score  $\geq 16$ . Standard oral glucose tolerance tests (OGTT) were performed. Insulin sensitivity was estimated with the oral glucose insulin sensitivity (OGIS), and the updated Homeostasis Model Assessment for insulin sensitivity (HOMA-2S). Insulin secretion was assessed with the insulinogenic index (Insulin 30 min – Insulin 0 min)/(Glucose 30 min – Glucose 0 min), HOMA for  $\beta$ -cell functioning (HOMA-2B), and three model-based parameters of insulin secretion ( $\beta$ -cell glucose sensitivity, potentiation factor,  $\beta$ -cell rate sensitivity). We adjusted for age, sex, smoking, alcohol, waist circumference and physical activity in multivariable linear regression models. For insulin secretion, we additionally adjusted for prevailing insulin sensitivity.

**Results:** A total of 159 out of 1013 participants (16%) had depressive symptoms. Depressive symptoms were not related to the insulin sensitivity surrogates OGIS (standardized beta ( $\beta$ ) 0.012, p 0.621) or HOMA-2S ( $\beta$  -0.020, p 0.472). Depressive symptoms were related to a lower insulinogenic index ( $\beta$  -0.079, p 0.019), a decreased  $\beta$ -cell rate sensitivity (odds ratio of the highest quartile vs. lowest quartile of  $\beta$ -cell rate sensitivity 0.517, p 0.017), and a borderline statistical significant decrease of the potentiation factor ( $\beta$  -0.066, p 0.051). Depressive symptoms were not associated with HOMA-2B ( $\beta$  0.048, p 0.122) or  $\beta$ -cell glucose sensitivity ( $\beta$  -0.030, p 0.375).

**Conclusions/discussion:** In contrast to several other studies, depressive symptoms were not related to reduced insulin sensitivity in this cross-sectional European cohort of non-diabetic persons. Depressive symptoms appeared to be weakly associated with some parameters of insulin secretion. More prospective studies are needed to study temporal associations between depression and insulin sensitivity and secretion.

**Title:** Determinants of intention to inform family members about family diabetes risk  
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**Background:** One relatively new idea in type 2 diabetes (T2D) prevention is to intervene in high-risk families, which is thought to represent a practical, cost-effective strategy. Indeed, the chance of developing T2D is two to fourfold higher for people with a positive family history. Recent research reveals that T2D patients recognise the need and seem willing to give advice about preventive behaviour to their offspring.

**Aims:** The main objective in our study was to explore which determinants are associated with patients' willingness to play a messenger's role in the family. To get more insight in facilitating and inhibiting factors, we evaluated the potential role of patients' cognitions (including causal illness beliefs) and emotions with regard to their disease.

**Methods and patients:** In a cross-sectional, observational study T2D patients (N=546, response rate 42%) filled in a questionnaire assessing socio-demographic and diabetes-related characteristics, (causal) illness perceptions (IPQ-r), beliefs and concerns about familial diabetes risk, primary prevention and diabetes related family communication. Data are analysed using descriptive statistics and multivariate logistic regression analyses.

**Results:** Participants' mean age was 64 (+11.7) years, 50% was male, 64% had a low educational status (primary school or lower vocational/trade education), and 58% was from Dutch origin (29% Surinamese South-Asian, 13% other (non-) Western countries). In most families talking about T2D seemed not a taboo (58% of the patients indicated T2D is 'sometimes' or 'often' discussed with first- and/or second degree relatives). The majority of patients (63%) reported they intended to inform relatives about possible increased T2D risk and possibilities of primary prevention.

Results from logistic regression analyses indicated that higher educational status, worry about relatives' health, the presence of diabetes-related family communication, and knowing what to tell and which relatives to inform are the most important factors associated with patients' intention to educate family members. Interestingly, positive beliefs about relatives' possibilities to delay or prevent T2D onset did not make a significant contribution in multivariate analyses.

Further exploration learned that worry about the diabetes-related health of relatives is associated with non-Dutch descent, high familial risk perception, and concern about the patient's own diabetes-related health. Perceiving high 'emotional impact' of the disease, and causal attributions concerning 'inheritance', 'chance/bad luck', and 'fate' also contributed to increased feelings of concern.

**Conclusions/discussion:** Results in our study suggest that promoting family risk communication might be a suitable strategy in diabetes prevention. Patients are willing to play a 'messengers role' in the family and they indicated to know what to tell and who to inform. Concord with findings in literature, worry about relatives' health appeared to be an important determinant. The role of control beliefs regarding primary prevention was not obvious in our study.

Possible implications for utilising a family approach in T2D prevention will be discussed.

**Title:** Diabetesspecific cognitive behavioral therapy vs. sertraline in patients with depression and poorly controlled diabetes: first results of the German 'Diabetes and Depression' Study (DAD-Study)

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**Aims:** To analyse the efficacy of a diabetesspecific cognitive behavioral therapy compared the antidepressant sertraline in patients with depression and poorly controlled diabetes (type 1 and type 2 diabetes).

**Methods and patients:** We compared the efficacy of 10 sessions (20 hrs.) of diabetes-specific cognitive behavioral group therapy (CBT) to sertraline (SER) in 251 adult patients with depression and poorly controlled diabetes who were treated with insulin. The diabetes treatment was not part of the study protocol ("treatment as usual"). After 12 weeks of open-label therapy, only the treatment-responders (50% reduction of depression, Hamilton Depression Rating Scale, HAMD) were included in the 1-year phase of the study. CBT-responders received no further treatment, while SER-responders obtained a sustained SER regimen as relapse prevention. Group differences in HbA1c (primary outcome) and HAMD between 1-year follow-up and baseline were analyzed by ANCOVA controlling for baseline values. Subgroup analyses were conducted for type of diabetes.

**Results:** After 12 weeks 115 (45.8%) patients responded to the treatments (CBT 53, SER 62). In the 1-year follow-up the HbA1c changed from 9.3±1.6 to 9.2±1.7 after CBT and from 9.2±1.4 to 9.4±1.4 under SER with no significant treatment difference (p= 0.129). HAMD scores improved after CBT from 18.0±4.6 to 7.8±6.5 and from 18.9±5.1 to 5.5±5.7 under SER; the difference was significant (p=0.020). Subgroup analyses revealed significant differences only within the CBT group and only regarding HbA1c (difference 0.73) favoring type 2 diabetes (HbA1c reduction: -0.40 vs. +0.324 for type1, p=0.0036).

**Conclusions/discussion:** Both treatment groups showed sustained reduction of depression with a small but significant advantage of SER vs. CBT. But, no substantial improvement could be obtained for glycemic control independently of the type of treatment. Even though patients with type 2 diabetes achieved better glycemic control after CBT the results still remained largely above the recommended limits. The results point towards the tailoring of new specific treatment modules to the individual patient rather than recommending 'established' general strategies.

**Title:** Type D ('distressed') personality in primary care patients with type 2 diabetes: Validation of the Type D Scale 14 (DS 14)

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**Aims:** Individuals with a Type D or “distressed” personality tend to experience a broad range of negative emotions across time and situations (trait Negative Affectivity), but are inclined to inhibit the expression of emotions and behaviors in social interaction (trait Social Inhibition). In cardiovascular research, Type D personality has been associated with a more than 3-fold increased risk of adverse health outcomes, including poor psychological functioning, non-fatal myocardial infarction, revascularization and (cardiac) mortality. The Type D Scale-14 (DS14) is a brief self-report measure of Type D personality that has been shown to possess adequate psychometric properties in cardiac patients, but has not been validated in patients with diabetes. Therefore, the aim of the present study was to examine both the validity and reliability of the DS14 in a large sample of type 2 diabetes patients treated in primary care.

**Methods and patients:** A total of 1553 primary care patients with type 2 diabetes (48% male, mean age  $69 \pm 10$  years) completed the DS14, the Edinburgh Depression Scale and measures of loneliness, social support and stressful life events in 2007. A subgroup ( $n = 1012$ ) completed the questionnaire a second time one year later. Using a cross-validation design, the structural validity, reliability, temporal stability and construct validity of the DS14 were determined in male and female patients separately.

**Results:** The two-factor structure of the DS14 was confirmed in both exploratory and confirmatory factor analyses; results were stable across gender. The Negative Affectivity (NA) and Social Inhibition (SI) subscales had adequate reliability in both men and women, as measured by Cronbach's alpha (NA=0.87, SI=0.83), lambda2 (NA=0.87/0.88, SI=0.84), corrected item-total correlations (ranging from 0.47-0.77 for NA, 0.34-0.72 for SI) and mean inter-item correlations (NA=0.50/0.51, SI=0.42). One year test-retest reliability of the DS14 subscales was  $r=0.64/0.63$  for NA and  $r=0.73/0.65$  for SI in men and women, respectively. Paired samples t-tests showed that neither mean total NA ( $p=0.77$  for men,  $p=0.16$  for women) nor mean total SI scale scores ( $p=0.97$ ,  $p=0.80$ ) changed significantly over the one year follow-up period. The construct validity of the Negative Affectivity scale was supported by moderate correlations with other measures of negative affect ( $r$  ranging from 0.55-0.67), while the Social Inhibition scale was not meaningfully related to any of the other psychological constructs.

**Conclusions/discussion:** This study confirms that the DS14 is a valid and reliable instrument to assess Type D personality in both male and female primary care patients with type 2 diabetes. As accumulating evidence endorses the negative impact of Type D personality on disease prognosis and psychological functioning in cardiovascular populations, studies are now warranted to examine whether Type D personality is associated with adverse health outcomes in patients with diabetes as well.

**Title:** Intentional weight loss in overweight and obese patients with severe mental illness: 10-year experience of a behavioural treatment programme

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**Aims:** Obesity is 2-3 fold commoner among people with severe mental illness and has adverse effects on physical and psychological health. We report the experience from the first 10-years of a self-referring weight management clinic.

**Patients and methods:** 52 men and 68 women with severe mental illness aged 42.3±1.2 years (range 18-71 years) enrolled themselves in this clinic. 93 patients had schizophrenia, 26 an affective disorder and 1 had suffered a brain injury. The patients were seen in weekly group sessions lasting 1 hour that involved weight measurement, discussion and education. Patients were allowed to attend as many sessions as they chose. 18 patients dropped out from the programme and re-joined the clinic more than 3 months after leaving the programme. Six patients enrolled three times and one person enrolled four times giving a total of 153 patient episodes. The number of sessions attended per episode ranged from 1 to 402 (mean 67.4 ± 7.0, median 45).

**Results:** Mean baseline weight was 90.5±1.6 kg (BMI 32.1±0.5 kg/m<sup>2</sup>). 6 patients dropped out of the programme within 4 weeks and a further 25 withdrew between 4 and 8 weeks. Thus dropouts within the first 8 weeks were 20%. 108 (71%) and 88 (58%) were still attending the clinic after 12 weeks and 6 months respectively. Data are available for 73 and 57 patients who have completed 1 year and 18 months of the programme respectively. 3 people had attended the clinic continuously for 10 years.

There was a progressive statistically significant reduction in mean weight and BMI throughout the duration of the study with no suggestion of a plateau. The final weight was reduced in all but 11 patients. After 1 year, 58% of patients had lost ≥7% of their body weight. The mean final weight loss was 7.6 ± 0.6 kg (range -43.7 - +17.0 kg).

Men and women lost weight equally. There was no significant difference in weight loss between people with schizophrenia and those with affective disorders or between those taking second generation antipsychotics compared with first generation antipsychotics. There was no significant difference in percentage weight loss between patients who were new to the programme or re-joining the programme after a break of ≥3 months.

There was no correlation between percentage weight loss and baseline weight or BMI. In the first 3 months, younger people lost more weight but there was no significant difference after 6 months. Weight loss was correlated with the number of sessions attended ( $r=0.44$ ,  $p<0.0001$ ). On average, patients lost 0.43 ± 0.08 kg per session.

**Conclusions/discussion:** Long-term weight management of obese and overweight patients with severe mental illness was possible through the provision of simple lifestyle advice within the group setting.

**Title:** Exploring psychological needs of parents of teenagers with type 1: Findings from a web-based survey and focus group interviews

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**Aims:** Parents of teenagers with type 1 diabetes are faced with unique challenges daily, while receiving little or no professional support. In the present study we aim to develop a web-based parent support intervention to help them cope with the parenting stress. In preparation, we conducted a questionnaire survey and focus group discussions on parents' needs and preferences.

**Methods and patients:** Parents of teens (12-19 years) were recruited via the Dutch Diabetes Patient Association and completed questionnaires on the internet about Family functioning (Diabetes Family Responsibility and Conflict Scale, Diabetes Family Behavior Checklist, Parenting Scale), Parental well-being (WHO-5 well-being index, parental disease-related stress (Pediatric Inventory for Parents)) and demographic and diabetes related characteristics (age, gender, education, family status, diabetes onset, duration and HbA1c).

Next, we conducted 6 focus group interviews to elaborate on the impact of diabetes on the parent and their family and explore preferences concerning the content and design of a support website.

**Results:** 255 parents (80% mothers) completed the questionnaires. Their mean age was 46.3±4.6 years and 88.6% were married. Mean age of their teenagers was 15.0±2.1 years, with 52% boys. Mean diabetes duration was 5.4±3.6 years and latest HbA1c as reported by the parent was 8.1±1.4.

Family functioning: More conflicts and non-supportive behavior were related to lower education ( $r=-.29$  and  $-.19$ ;  $p<.001$ ), more parental responsibility ( $r=.37$  and  $.38$ ;  $p<.001$ ), a more over-reactive parenting style ( $r=.26$  and  $.27$ ;  $p<.001$ ), poorer parental well-being ( $r=-.22$ ,  $p<.001$  and  $r=-.12$ ,  $p=.03$ ) and more parental stress ( $r=.47$  and  $.36$ ;  $p<.001$ ).

Parental well-being: On the WHO-5, 71% reported satisfactory well-being, 20% moderate well-being and 9% had an indication of likely major depression. Better well-being was associated with male gender ( $p=.03$ ), being married ( $p=.02$ ), higher education ( $p=.003$ ), fewer conflicts ( $r=-.25$ ,  $p<.001$ ), less parental responsibility ( $r=-.26$ ,  $p<.001$ ), less parental stress ( $r=-.55$ ,  $p<.001$ ), less over-reactive ( $r=-.33$ ,  $p<.001$ ) and less lax ( $r=-.18$ ,  $p=.003$ ) parenting styles.

In the second step, 28 parents participated in 6 focus group discussions. Findings confirmed the psychological pressure diabetes exerts on parental daily functioning - both practical and emotional. Having to cope with the child's diabetes impacts on the partner-relationship, parent-child interaction and siblings. Furthermore, participants indicated that school is a major stressor. Parents generally do not feel supported in the afore mentioned areas. Participants expressed clear preferences about the content and use of a support website. It should offer concrete information on both practical and psychological topics, specified for younger and older teenagers. Most frequently stated is a need for recognition and acknowledgement of their feelings and experiences. Parents expressed a strong wish for peer-to-peer support, e.g. by a forum.

**Conclusions/discussion:** Results indicate a clear need for easy accessible parenting support and advice for parents of teenagers with type 1 diabetes. We are currently in the process of developing such a web-based intervention. Addressing at least diabetes responsibilities, parenting styles and parental stress in the internet course could not only improve family functioning and parental well-being, but also diabetes outcomes of teens.

**Title:** Relationship of glycaemic control and depression. Preliminary results from the German DIAMOS-Study

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**Background:** Diabetic patients with depressed mood use to show an impaired glycaemic control. The causal relationship between affective disorders and glycaemic control has not been fully understood yet. A preliminary analysis from the German DIAMOS-Study, supported by the Competence Network for Diabetes mellitus, investigated the relevance of diabetes distress and self-care behaviour for this relationship.

**Patients and methods:** 208 diabetic patients (Age=43±14 Y., 57% female, duration of diabetes 14±11 Y., 65% Type 1, BMI=29±7 kg/m<sup>2</sup>, HbA1c=9±2%) completed the Center for Epidemiologic Studies Depression Scale (CES-D), the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire and the Diabetes Distress Scale (DDS 17). A blockwise multiple regression analysis was used to determine the relative impact of depressive mood, self-care behaviour and diabetes distress on the dependent variable HbA1c.

**Results:** The first step of the analysis showed a significant impact of the depression scoring (CES-D) on the HbA1c (standardized  $\beta$ =.16,  $p$ =.02;  $R^2$ =.03). This association persisted when in a second step the self-care activity (SDSCA) was included into the model (standardized  $\beta$ =.16,  $p$ =.02;  $R^2$ =.03). Self-care activity itself did not make a significant contribution to the prediction of HbA1c. When in a third step the diabetes distress scoring (DDS) was added to the model, the association between depression and HbA1c became insignificant (standardized  $\beta$ =.10,  $p$ =.17). However now the amount of diabetes distress was a significant predictor of glycaemic control (standardized  $\beta$ =.18,  $p$ =.02;  $R^2$ =.06). A mediator analysis indicated that diabetes distress was a significant mediator in the association between depression and glycaemic control ( $Z$ =2.05,  $p$ =.04).

**Conclusion/discussion:** The multivariate Analysis shows the expected association between depressive mood and poor glycaemic control. Surprisingly the self-care behaviour did not make a significant contribution to the association. Thus it can be assumed that behavioural factors alone may not be the decisive link between depression and poor glycaemic control. This suggests that non-behavioural mechanisms such as immunologic processes should be investigated. The disappearance of the association between depression and glycaemic control in the final model and the mediator analysis showed that diabetes distress was a major mediator in the association. This result is consistent with the findings of van Bastelaar et al. (2010). It may suggest the treatment of diabetes distress to become an essential element of psychological interventions of depression in diabetes. However it has to be recognized that the resulting models explain only small amounts of variance suggesting further research on non-behavioural factors.

This work was supported by the Kompetenznetz Diabetes mellitus (Competence Network for Diabetes mellitus), funded by the Federal Ministry of Education and Research (FKZ 01GI0809).

**Title:** Facilitating factors and barriers in the implementation of web-based depression treatment in routine diabetes care

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**Aims:** A diabetes-specific, 8 weeks web-based cognitive behavioral self-help program (Diabetergestemd.nl, DbG) was developed and tested in a randomized controlled trial. The program was shown to be attractive, feasible and effective in both Type 1 and Type 2 diabetes patients as regards improving mood and reducing diabetes-related emotional distress. These results justify implementation of this e-health tool in routine diabetes care. While efficacy and attractiveness are a prerequisite, they are by no means a guarantee that the program is adopted and maintained in daily clinical practice. In order to achieve optimal social impact, translational research is required, identifying success and fail factors from which effective implementation strategies for DbG can be developed. This study is funded by the National Action Programme Diabetes (NAD).

**Design and methods:** To secure optimal acceptance and use of DbG, relevant stakeholders will first be consulted before finalizing the implementation protocol. We plan to do small focus groups (4-5) with representatives of all the respective organizations. Prior to the interviews we will provide the professionals with background information and the implementation plan, along with key questions. In case group interviews are not feasible, due to time restraints or logistics, we offer to do the interviews individually. Key topics are: characteristics of the target group (for whom, when), feasibility, practical barriers/facilitating factors and additional wishes from professionals with respect to implementing DbG in diabetes care, e.g. training, materials, individual reimbursement etc.

**Planned analysis:** The qualitative data of the focus group and / or interviews will be analyzed using qualitative techniques (ATLAS.ti) (transcription, coding, and retrieval).

**Expected outcomes:** From the data, barriers and facilitating factors for to implementation of DbG will be extracted. We aim to write a report and scientific publication on the results. The report will include an indication protocol with practical guidelines for effective use of DbG and a proposal for coverage of costs/reimbursement. Based on the contents of the report, we aim to provide teams with a protocol for optimal implementation of DbG and referral to this program.

After consultation, a national pilot implementation will be performed, in concert with the diabetes patient organization (DVN) and all relevant diabetes professionals in the Netherlands.

**Problems/questions:**

- How can we achieve maximum participation of diabetes and mental health professionals?
- Which barriers would deserve special attention, and may be specific to a specific group of professionals?

**Title:** Disease management of co-morbid depression and anxiety in primary care patients with diabetes: Design of the DIMACODEA Study

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**Aims:** Depression and anxiety are common in patients with diabetes mellitus, but the treatment of both co-morbid conditions is often not optimal. Besides, depression and anxiety were found to be related to inadequate compliance with medical treatment, poor quality of life, incident diabetes complications and greater mortality. The aim of the DiMaCoDeA study is to test the effectiveness of a disease management approach for depression and anxiety in primary care patients with diabetes mellitus.

**Design and methods:** The current study is a randomised control trial, with an intervention of one year and an additional one year follow up. Randomisation will be at patient level. All eligible primary care patients with diabetes will be invited for participation. They will receive a set of questionnaires assessing depression (PHQ-9) and anxiety (GAD-7). Those who score above a cut-off point on the depression (PHQ-9 > 10) or anxiety scale (GAD-7 > 8) and signed informed consent, will be included in the study. Exclusion criteria are current psychological treatment for depression and/or anxiety, major psychiatric problems (schizophrenia, suicidality), substance abuse, not being able to read or speak Dutch sufficiently. The intervention under investigation is a disease management approach for depression and anxiety, consisting of active screening, stepwise treatment, and monitoring of outcomes. Stepwise treatment consists of: 1) psycho education, 2) coping with depression / anxiety course, and 3) extension of the course with an option for additional drug treatment. The intervention will be compared to care as usual. A total of 160 patients will be randomised into either the intervention group or the care as usual group. The current study will be conducted in collaboration with general practitioners allied to PoZoB (Praktijkondersteuning Zuidoost Brabant), a large managed care organization in the province of Brabant, located in the south of the Netherlands. Our primary outcomes are depression symptoms (PHQ-9) and anxiety symptoms (GAD-7). Our secondary outcomes are quality of life, disease specific distress, health care costs and self-care and life-style behaviours.

**Planned analysis:** To compare the intervention group and the care as usual group, the main analysis used will be the independent- sample T-test.

**Expected outcomes:** We expect that the intervention compared to the care as usual will result in: (i) Reduced anxiety and depressive symptoms, (ii) Improved quality of life, (iii) Reduced disease specific distress, (iiii) Higher health care costs in short term, but lower health care costs in long term, (iiiii) Improved self-care and life-style behaviours

**Problems / Questions:** Can we expect selection bias when patients are asked to return the screener by mail? (maybe patients who are anxious or have depressive symptoms are less inclined to return the screener?)

**Title:** Prevalence of depression in type 2 diabetic patients - clinic and metabolic profile. A multicenter study in Argentina

**Author:** Alvarez A, Bayon C, Finkelsztein C, Job A, Faccioli J, Litwak L, Argibay P, Cajal R, Primerano A y Guinzbourg M

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**Background:** Different authors mentioned the prevalence of Major Depression Disorder (between 15 and 30%) among Type 2 diabetic patients, in comparison with the general population (between 2 and 9%). The relation with depression increases at least 2 or 3 times the risk of morbidity and mortality, while minor or subclinical depression increases the risk in 1,7 time.

Diabetic patients with depression are underdiagnosed (only 50% of them are diagnosed as such) and only 1/3 of those who have both diagnoses are under treatment. Depression is also an independent risk that increases coronary diseases. From the endocrine metabolic point of view, depression influences negatively hypoglycemia, cortisol, insulin resistance and increases PCR and inflammatory cytokines (TNF alpha and IL6).

During the past few years, scientists observed that the serotonin system participates in the glucose homeostasis and eating habits and influences mood and affective emotions as well. According to this knowledge, it is important to measure the risk in relation to certain genetic variables (genetic polymorphism).

Taking all this into account, we are going to study 5 HTTLPR polymorphism, where the SLC6A4 codifies the serotonin transportation.

This polymorphism presents two isoforms (L and S). The S allelomorph seems to be associated to the risk for diabetes 2, obesity and depression.

We are going to study the prevalence of depression among Type 2 diabetic patients in different diabetic centers.

**Our aims are:**

- 1) To establish the metabolic profile of this population and compare them with diabetic patients without depression.
- 2) In case depression is diagnosed, to analyze the evolution of the illness (time of evolution)
- 3) To evaluate if correlations exist between depression and clinical complications of the illness
- 4) To analyze the link between depression and different types of treatment (dieting, oral hyperglycemia insulin and combined hyperglycemia and insulin, etc.)
- 5) To evaluate if depressed diabetic patients are under psychiatric/psychological treatments or not
- 6) To analyze if patients with comorbid disorders are adequately treated
- 7) To evaluate illness consciousness among depressive diabetic patients (according to Beck and Hamilton scales)
- 8) To investigate the stressors associated with the beginning of the clinical illness
- 9) To measure the alexithymia traits
- 10) To investigate 5 HTTLPR polymorphism in patients with depression and diabetes.

**Methods and sample:** We are going to study the first 120 patients who spontaneously accepted to take part in the study and authorized the procedures. Ages range from 40 to 65 years old. We will include the first 120 patients who have been treated for the last 12 months in the ambulatory centers of the whole country.

**Procedures:**

- To obtain individual data of medical follow up.
- To obtain the IMC.
- To measure the abdominal perimeter.
- To measure arterial pressure.
- To obtain samples of blood to check glycemia and A 1 c.
- To take samples of frozen blood for future studies.
- To make mouth swab for the typification of the SLC6A4 gene.
- Patients will be interviewed by a psychiatrist and diagnosed according to DSM IV criteria.
- To standardize depression intensity according to Hamilton scales.
- To evaluate patients' self-consciousness as regards their depression traits or states. (Using Beck's Depression Inventory).
- To evaluate the alexithymic traits with TAS 20.
- Patients' privacy will be protected and no information will be used with other. purposes than those of this study. Patients will have access to information about the study results and their own diagnosis.
- We are going to inform about the results in process.
  
- The sample will be described and the results will be correlated according to statistical usual procedures. This information will be discussed in the next Cambridge meeting.

**Title:** Depression and diabetes: possible mechanisms, treatment implications and investigational strategies

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**Institute:** 1 University of Virginia Medical School, Charlottesville, Va, USA,  
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**Aims:** Compared to the general population, depression is more common among individuals with both type 1 and type 2 diabetes mellitus, and both depression and diabetes are independently related to occurrence of cardiovascular disease. Two recent U.S. studies investigating adults with Type 2 diabetes and one German report investigating adults with Type 1 diabetes demonstrated that more rapid pre-post prandial blood glucose (BG) elevations are associated with more depressive symptoms. We are replicating and extending these findings.

**Methods:** 25 adults with type 1 diabetes used a memory meter for one month before and after being assigned to routine care or an experimental intervention where they were given daily feedback of their BG variability with instructions to reduce this variability.

**Preliminary analyses:** Pre-treatment BG variability and depression correlated +.58, and subjects with an elevated pre-treatment depression demonstrated a reduction ( $p < .05$ ) in depression following treatment

**Expected outcomes:** Regression analyses and causal modelling will be pursued.

**Questions:**

- 1) What are biological and psycho-behavioral mechanisms for the depression-BG variability relationship?
- 2) How does reduction in BG variability lead to reduction in depression?
- 3) What is an optimal research strategy to further explore this phenomena and treatment implications?

**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

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**Aims:** Sufficient exercise is important for people with Type 2 Diabetes Mellitus, as it can prevent or delay 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 / methods:** This study is a non-randomised controlled clinical trial with 376 (2x188) intervention participants and 568 (2x284) 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 36 weeks, after 1 year and after 1 year and 36 weeks for both intervention- and control group. The intervention group has additional assessments after 12 and 24 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 and AN(C)OVA. Major analysis for study aim 2 will be logistic regression. Major analysis for study aim 3 will be a (M)AN(C)OVA. Secondly, multi-level analyses will be done as participants are clustered in seven regions/physiotherapists.

**Expected primary outcomes:**

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

Successful change of the level 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.

Effect on health status: It is hypothesized that health status (both the physical and mental component) will improve significantly more in the intervention group.

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

**Problems / questions:**

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. Is that a serious limitation?

**Title:** Development and pilot study of DiAlert: a lifestyle education programme in Dutch and Turkish Dutch 1st degree relatives of patients with type 2 diabetes. A pragmatic randomised controlled trial

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**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 people from Turkish origin are known to be at increased risk for type 2 diabetes and cardiovascular disease, but so far received little attention. The DiAlert programme is a group educational programme designed to promote body weight loss in overweight first degree relatives of patients with type 2 diabetes.

**Aims:** The main objective of this study is to test and compare the effectiveness of the DiAlert programme in Dutch and Dutch-Turkish 1st degree relatives of type 2 diabetes patients with overweight. The aim of the pilot study was to evaluate the DiAlert programme in terms of feasibility, appreciation, timing and structure.

**Methods:** The DiAlert programme was developed informed by a theoretical framework, examination of diabetes self-management courses, a literature research on existing interventions, consultations with experts and a pilot study. A culturally appropriate Turkish version of the program will be made available.

**Results:** Important topics related to prevention of type 2 diabetes were identified from a diabetes self-management programme. DiAlert consists of two sessions of 150 minutes over two consecutive weeks and is group-based (size is approximately ten participants). The intervention modules were designed to 1. target risk perceptions, 2. educate about the development of T2DM and potentials for prevention, 3. increase self-efficacy and outcome expectancies for physical activity and diet, and 4. making a personal action plan to change lifestyle.

For the pilot, participants were recruited via flyers and a newspaper advertisement. 22 participants (female n=18) were recruited of which 20 participants had a 1st degree relative with T2DM. Participants participated in two different groups (n=10 and n=12). Mean age was  $48 \pm 9.5$  years, mean body weight was  $81.6 \pm 6.1$  kg, and mean BMI was  $28.9 \pm 6.1$  kg/m<sup>2</sup>. Prevention of T2DM and learning about the personal risk of diabetes due to a family history were most frequently reported as reason for signing up. After one week of follow-up participants thought positively about the group sessions, and gave overall mark of  $8.1 \pm 1.0$  on a 1 to 10 scale. After one week of follow-up 95.3% stated being more aware of their risk, 61.9% people said to eat healthier due to DiAlert, and 38.1% people improved their physical activity. All group sessions were delivered by a trained educator within the structured timeframe.

**Conclusion:** The pilot study demonstrates feasibility and appreciation of the group sessions, and the intervention was delivered as intended.

**Planned RCT:** In the RCT participants will be allocated to either the intervention or control group. Recruitment occurs via general practitioners in Haarlem, The Netherlands. Eligible are overweight persons from Dutch or Turkish origin with a first degree relative with type 2 diabetes, aged between 25 and 64 years.

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/questions:** I would like to discuss the transcultural validation and implications of the DiAlert intervention.

**Title:** Design and implementation of a couples-focused lifestyle intervention for adults with type 2 diabetes: The Diabetes Support Project

**Author:** Trief PM, Sandberg J, Fisher L, Dimmock JA, Scales K, Hessler DM, Weinstock RS

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**Aims:** Type 2 diabetes (T2DM) studies report that higher levels of marital and family support relate to better glycemic control, adherence and quality-of-life. Yet, interventions target individuals, with no published reports of couples-focused interventions. The aim of this study is to test the efficacy of a couples-focused intervention by comparing outcomes to an individual-focused intervention and one that provides diabetes self-management education (DSME) plus usual care. The couples intervention is based on Family Systems and Interdependence Theories, which posit that partners must cope communally, by agreeing that collaboration is helpful, by effectively communicating what they each can do, and by talking about problems. The DSP intervention is novel, it includes DSME for both partners, teaches communication skills, and promotes a collaborative, problem-solving relationship, to improve self-management. All contact is by telephone to extend "reach". In this presentation we will describe the design and implementation of this innovative, theoretically-based, couples-focused lifestyle intervention that is currently being assessed in a 5-year clinical trial funded by the National Institutes of Health of the USA.

**Design and methods:** The study is a two site, 3-arm, randomized, controlled trial. We compare outcomes of three groups over time. One group ("Couples") receives DSME (2 calls), and additional (10 calls) couples contact focused on behavior change, psychosocial issues and couples communication. A second group ("Individual") also receives DSME, and additional (10 calls) individual contact that parallels the couples group, focused on behavior change and psychosocial issues. The control group ("Enhanced Usual Care") receives DSME (2 calls) and subsequent usual care with assessment only. This will allow us to explore the additive effect of the interventions to DSME. Patients who have T2DM whose HbA1c is  $\geq 7.5\%$ , and their partners, are recruited. Other inclusion criteria are:  $> 21$  years of age, diagnosed with T2DM for  $> 1$  year, in a committed relationship for at least 1 year, no current medical or psychiatric problems that limit function in ways that will interfere with their ability to engage, able to speak, hear and read English, and access to a telephone. Medical assessments include: HbA1c, height, weight, waist circumference, and resting/sitting blood pressure. Psychosocial questionnaires, all well-validated and reliable measures, assess regimen adherence, dietary behavior, physical activity behavior, quality of life and relationship quality. Potential moderators (e.g. age, gender) and mediators (e.g. self-efficacy) and cost-effectiveness measures are included. Assessments occur at baseline, 4 months (i.e., post-intervention), 8 and 12 months. Educators are trained CDE/dietitians who follow a specific protocol for each contact. Interventions include: education, goal-setting and monitoring of diet and

activity behaviors, blood glucose testing “experiments” to seek patterns and test behavioral changes, and homework to practice and reinforce change. In the Couples arm, contact and homework actively involve the partner to examine how they can support each other. In addition, they learn and practice the “Speaker-Listener Technique”, a way to improve communication skills, and reflect on positive and negative ways they communicate.

**Planned analysis:** We plan a mixed-model statistical design, comparing the longitudinal effects of the two interventions (Individual, Couples) and control condition (Enhanced Usual Care), at four time points (pre, 4 months, 8 months, and 12 months). We will analyze our longitudinal data using mixed-model, MLM techniques. Specifically, we propose a two-level MLM, with repeated observations of our primary outcomes at level 1 (within-subject variables), and our grouping factor (treatment) at level 2. Other non-time-varying subject characteristics (e.g. age, gender) will also be modeled as level 2 predictors. A secondary aim is to determine whether marital quality variables (e.g. marital satisfaction, stress) mediate the effects of the intervention on outcomes. This aim will be assessed using Structural Equation Modeling techniques to assess whether changes in marital quality translate to improvements in health-related outcomes.

**Expected outcomes:** If our hypotheses are supported, the couples intervention will yield greater, and more lasting, improvements than the individual intervention, and both will yield better outcomes than enhanced usual care. In the future, this might lead to a tailoring of interventions to include partners and to promote couples collaboration. Partners do have an effect on patients, sometimes good, sometimes bad. It is time to try to enhance the positive benefits of that effect. Finally, since the intervention we are testing is telephone delivered, is time-limited, and can be delivered by CDEs, we will have developed an intervention that is efficacious, has a high likelihood of adoption and should be easily translatable and disseminable to clinical practitioners.

**Problems/questions:**

1. If efficacious, we might expand to other support persons, e.g. adult offspring, sibling. How would we have to change the intervention?
2. The role of activity- We are aiming for increased activity, but some of the patients are functionally limited. How important is this and how to address it.
3. Thoughts about how to encourage partner support and collaboration without encouraging partner to be like the “diabetes police.”

**Title:** Evaluation of a treatment and education programme for type 1 diabetic patients (PRIMAS)

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

**Aims:** Type 1 diabetes requires a lot of involvement of patients in order to prevent long-term complications as well as acute complications such as hypoglycaemia. Glycaemic control is a full-time job and involves many sorts of self-care behaviour e.g. checking blood glucose levels or insulin injections. In addition patients must adapt these behaviours to each and every situation. Treatment and education programmes can provide the kind of knowledge which is necessary for this adaptation. Modern programmes do not only focus on this mere transfer of knowledge, but rather focus on practising skills to use this knowledge in real life via exercises, homework and group discussions (self-management). Therefore allowing an exchange of experiences between its participants. Instead of a “gluco-centric”-approach, modern programmes highlight patients and their needs (e.g. goal setting, action planning and problem solving). According to recent work modern treatment and education programmes following the selfmanagement-approach should be chosen over traditional “gluco-centric” programmes. Up to now, there is only one treatment and education programme for type 1 diabetic patients available in Germany, which is accepted by health insurance funds. Since this programme was developed in the late 1970s and is a “gluco-centric” one, a new programme was developed to meet the criteria of modern “self-management” and “empowerment”- approaches. Therefore this study compares the established treatment and education programme for type 1 diabetic patients (ZI programme) with the newly developed treatment and education programme for type 1 diabetic patients (PRIMAS) in order to evaluate the PRIMAS programme.

**Design and methods:** This study is a randomized controlled prospective trial with 6 month follow up. Primary outcome variable is glycaemic control as measured by the A1c. Secondary outcome variables are: diabetes knowledge, diabetes related distress, depressive symptoms, self-care behaviour, metabolic risk factors, quality of life and attitudes towards diabetes and insulin treatment as measured by different questionnaires. Baseline data of these variables are collected prior (< 2 weeks) to the execution of the two programmes (V0). Directly after termination of the two programmes, there is another data collection (V1) and 6 month after the termination the follow up data are collected (V2). The two programmes themselves are executed by trained staff of 30 diabetes specialized medical practices throughout Germany. A total sample size of 160 diabetic patients is required for the purpose of this study. The study was approved by the ethics committee.

**Planned analysis:** A non-inferiority hypothesis is tested, meaning that the newly developed PRIMAS programme should produce an impact on A1c and the other outcome variables which is no worse than that of the ZI programme. As a second step superiority, if noninferiority can be confirmed, will be tested.

**Expected outcome:** A substantial decrease in A1c is expected in both groups, whereas the decrease should be greater for the PRIMAS group than for the ZI group. Diabetes knowledge, self-care behaviour, quality of life should be enhanced with greater enhancement within the PRIMAS group. Diabetes related distress, depressive symptoms and metabolic risk factors should be reduced, again with greater reduction within the PRIMAS group. Attitudes towards diabetes and insulin treatment should change in a positive way resulting in an acceptance of diabetes and the necessity of insulin treatment. Again this effect should be greater for the PRIMAS programme.

**Problems/questions which I like to discuss:**

1. Possible problems with a non-inferiority hypothesis
2. Intention-to-treat vs. per-protocol analysis
3. Guaranteeing assay sensitivity

**Title:** The treatment of co-morbid emotional problems in people with diabetes: Evaluation of a mindfulness-based psychological intervention

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**Background:** A considerable proportion of the patients with diabetes experience elevated levels of emotional distress, varying from disease-specific distress to general symptoms of anxiety and depression. The patient's emotional well-being is related to other unfavorable outcomes, like reduced quality of life, sub-optimal self-care, impaired glycemic control, higher risk of complications, and increased mortality rates. 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 effectiveness of a new diabetes-specific, mindfulness-based psychological intervention aimed at increasing the emotional well-being and quality of life of patients with diabetes; second, to investigate the effect of the intervention on self-care, glycemic control, blood pressure, and heart rate variability; third, to explore effect modification (e.g. by number of complications or personality type).

**Design and methods:** The study is a randomized controlled trial. Patients with diabetes with low levels of emotional well-being will be recruited from outpatient diabetes clinics. Eligible patients will be randomized to an intervention group or a wait-list control group. The intervention group will receive the mindfulness program immediately, while the control group will receive the program six months later. The mindfulness program 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. The primary outcome is emotional distress (anxiety, stress, depressive symptoms), for which data will be collected at baseline, four weeks, post intervention, and after six months follow-up. In addition, data will be collected on personality, self-care, mindfulness, quality of life, complications, glycemic control, blood pressure and heart rate variability. The study is supported by grants from the Dutch Diabetes Research Foundation and Tilburg University and has been approved by a medical ethical committee. Trial registration: Dutch Trial Register NTR2145.

**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 co-variates. 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 emotional well-being, quality of life, self-care, and blood pressure of patients with diabetes in the mindfulness group will improve significantly more than those in the control group. Results of this study can contribute to a better care for patients with diabetes with lowered levels of emotional well-being. It is expected that the first results will become available in 2012-2013.

**Problems/questions:** (i) 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? (ii) We have some difficulties with the recruitment of patients. Does anyone have suggestions about how to make this intervention more attractive?

**Title:** First administration of hypoglycaemia fear survey and problem areas in diabetes questionnaire in Slovenian type 1 and type 2 diabetic subjects: a pilot study

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**Background and aims:** 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. 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.

**Patients and 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  $\alpha$  coefficients. Factorial validity was examined using factor analysis.

**Results:** Cronbach's coefficients indicated high reliability ( $\alpha = 0.92$ ) for the whole HFS scale, with  $\alpha = 0.82$  and  $\alpha = 0.93$  for the Behavior and Worry Subscale respectively. Factor analysis indicated that two-factor structure is reasonable. Internal consistency of the PAID was high ( $\alpha = 0.95$ ). 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/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:** Development of the psychological treatment program for young patients with diabetes type 1 and comorbid eating disorder

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**Institute:** Department of Paediatric Endocrinology, Diabetes and Metabolism, 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 method:** 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:** Clinical insights about the feasibility and value of routine monitoring of diabetes related distress (using the PAID) in a regional Australian diabetes clinic

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**Background and aims:** Up to 60% of people with diabetes experience some level of diabetes-related distress, and diabetes reportedly doubles the risk of developing depression. International guidelines recommend routine monitoring of psychological well-being but this seldom occurs in clinical settings. In 2008, a diabetes nurse educator (DNE) in regional Australia commenced routine assessment of diabetes-related distress using the Problem Areas In Diabetes (PAID) scale, for the purposes of monitoring and consequently reducing distress and facilitating access to psychological services as required. As the reliability and validity of the PAID has not been established in an Australian sample, preliminary validation was a secondary aim.

**Methods and participants:** From April 2008 to December 2010, the PAID was completed by 153 people (55% women) with diabetes (type 1: n=106; type 2: n=47) pre-consultation along with standard clinic forms administered by the receptionist. Those with type 2 diabetes were older (mean age 67±12years, range 35-90) than those with type 1 (mean age 45±17years, range 16-82; p<0.01). Twenty-one people (14%; all type 2) did not complete the PAID (reasons included refusal, cognitive or language difficulties, severe mental illness). Relevant demographic and clinical data were extracted from medical notes; all data were de-identified.

**Results:** The PAID demonstrated good internal consistency reliability (type 1: alpha=0.91; type 2: alpha=0.94). Discriminant validity was supported, with those with type 1 diabetes reporting higher levels of diabetes-related distress (mean=31.97) than those with type 2 (mean=25.38; p<0.05). Severe diabetes-related distress (PAID score≥40) was reported by 20% of patients. Patients with insulin-treated type 2 diabetes (n=24; 23%) had significantly higher diabetes-related distress (mean=31.98) than those treated with tablets/lifestyle (mean=23.45; p<0.05). Those with type 2 diabetes aged ≥70years (n=45; 43%) had lower PAID scores than those aged <70years (22.61 vs 27.42 respectively; ns). No sex differences were evident.

Anecdotally, routine use of the PAID has facilitated a more patient-centred approach. Increased awareness of diabetes-related distress has prompted the DNE to seek input from mental health colleagues to improve her skills in addressing minor distress and enable appropriate referrals when needed. Item 20 on the PAID ('feeling burned out by the constant effort needed to manage diabetes') was identified by the DNE as having particular utility as a screening item. Many patients have reported relief after being afforded the opportunity to discuss their distress and greater satisfaction with care received.

**Conclusions:** This study is limited by the absence of a control group (due to naturalistic data collection), other psychological variables against which to validate the PAID, and a relatively small sample size (however routine use is ongoing). Routine monitoring of diabetes-related distress is feasible, acceptable (to practitioner and patients) and valuable in a regional clinic setting, enabling the DNE to develop a 'psychologically-sensitive' practice. These findings also provide preliminary evidence for the reliability and discriminant validity of the PAID in an Australian, unselected, regional clinic sample. Further validation of the PAID, as well as investigation of the utility of item 20 as a single item measure, is warranted.

**Title:** Assessment of the psychometric qualities of the Dutch version of the WHO 5 in adult patients with type 1 and type 2 diabetes

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**Aims:** to evaluate the psychometric characteristics of the WHO-5, particularly internal consistency, factor structure, convergent and divergent validity in a large population of Dutch type 1 and type 2 diabetes outpatients.

**Patients and methods:** In this cross-sectional analysis, Dutch type 1 and type 2 diabetes outpatients from three hospitals, located in Amsterdam, the Hague and Nijmegen were included. Participants were sent two sequential questionnaire booklets to fill out at home and return in pre-stamped envelopes. The first questionnaire contained demographic data as well as the Problem Areas In Diabetes scale (PAID) and the WHO-5 wellbeing index (WHO-5) (n=933, who subsequently received a second questionnaire, which contained the Center for Epidemiological Studies Depression scale (CES-D) and the Patient Health Questionnaire 9 (PHQ-9). This questionnaire was returned by 772 patients. Confirmatory factor analysis was conducted to test the factor structure of the WHO-5 and internal consistency was assessed by calculating Cronbach's alpha. To assess convergent and discriminant validity of the WHO-5, Spearman correlations with the CES-D and PHQ-9 were calculated. Analyses were stratified for type 1 and type 2 diabetes patients.

**Results:** Type 1 patients had a mean age of 43±14 years, a mean diabetes duration of 17±12 years, 45% was male and 19% was lower educated. Mean HbA1c was 62±14 mmol/mol, 34% had experienced at least one severe hypoglycaemic episode during the past year and 49% reported ≥1 complication. The WHO-5 had a single-factor structure (eigenvalue 3.7, factor loadings of 0.89, 0.89, 0.88, 0.82 and 0.81), with only marginal (≤0.04) differences between men and women, except for the eigenvalue (3.56 versus 3.79) and the factor loading of the final item (0.77 versus 0.84). Cronbach's alpha of the WHO-5 was 0.91 (0.90 for men and 0.92 for women) and item-total correlations for each item were >0.70. Correlations with the CES-D, PHQ-9 and PAID were -0.68, -0.69 and -0.62 respectively (p<0.001 for all).

Type 2 patients had a mean age of 61±12 years, a mean diabetes duration of 13±9 years, 52% was male and 40% was lower educated. Mean HbA1c was 61±15mmol/mol, 19% had experienced at least one severe hypoglycaemic episode during the past year and 33% was 67% reported ≥1 complication. The WHO-5 had a single-factor structure (eigenvalue 3.9, factor loadings of 0.91, 0.89, 0.89, 0.84, and 0.88) with only marginal (<0.04) differences between men and women. Cronbach's alpha of the WHO-5 was 0.93, with no gender differences and item-total correlations for each item were >0.70. Correlations with the CES-D, PHQ-9 and PAID were -0.67, -0.68 and -0.55 respectively (p<0.001 for all).

**Conclusions/discussion:** A single-item factor structure of the WHO-5 was confirmed, as well as a high internal consistency for both type 1 and type 2 diabetes patients. Concurrent validity of the WHO-5 was confirmed by moderate to high correlations with the CES-D, PHQ-9 and PAID. The WHO-5 appears to be a suitable instrument to monitor emotional problems in both type 1 and type 2 diabetes outpatients.

**Title:** Brief assessment of diabetes-related distress: PAID short forms not confirmed in an unselected type 2 diabetes sample in regional Australia

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**Aims:** The burden of self-management, the threat of developing complications, and the potential negative impact on quality of life can all contribute to psychological distress in people with diabetes. The 20-item Problem Areas In Diabetes (PAID) scale is perhaps the most widely used diabetes-specific distress screening tool. Recently, two short-form versions, the PAID-5 (items 3,6,12,16,19) and the PAID-1 (item 12), have been proposed. None of the PAID scales have been validated with an Australian sample. Thus, our aim was to replicate the findings that led to the development of the short forms with an unselected population of adults with type 2 diabetes attending a regional Australian clinic.

**Methods and participants:** From April 2008 to December 2010, the PAID was completed by 106 adults with type 2 diabetes (52% women; mean age 67±12years, range 35-90) while in the waiting room prior to a clinic consultation. Twenty-one people (14%) did not complete the PAID (reasons included refusal, cognitive or language difficulties, and severe mental illness). Relevant demographic and clinical data were extracted from medical notes by the diabetes nurse educator (DNE); all data were de-identified. The PAID scores were adjusted to give a total out of 100 (according to scoring guidelines).

**Results:** The mean PAID score for this sample was 25.38±14.67, with 15% of the sample experiencing severe diabetes-related distress (score ≥40). The PAID-20 demonstrated good internal consistency reliability (alpha=0.94). Principal component analysis could not replicate published findings that led to the identification of the PAID-5. A forced one factor solution found that all items except item 1 and item 15 had factor loadings ≥0.5; these two items were thus excluded. A further seven items (2,4,5,9,14,17,18) were excluded based on mean responses <1 (less than 'a minor problem'). The remaining 11 items were subject to internal consistency reliability analysis, with items 3,7,8,10-13, and 16 excluded due to item-total correlations <0.7, leaving items 6,12,19 and 20 forming a reliable four-item scale (alpha=0.83). The total score from these four items correlated highly and significantly with the PAID-20 (rs=0.89, p<0.01). Similarly, we could not replicate the findings that led to the identification of the PAID-1. Item 20 had the highest item-total correlation, and correlated highly and significantly with the PAID-20 (rs=0.68, p<0.01), making it a good candidate for a single item screening measure.

**Conclusions/discussion:** This study is limited by the relatively small sample size (however routine use is ongoing), and the absence of other psychological variables against which to validate the PAID. The findings provide preliminary evidence for the PAID-20 being a reliable tool for use with an Australian sample, but findings that led to the identification of the published short forms could not be replicated. We have identified possible new short forms, the PAID-4 and an alternate PAID-1, but confirmation with a larger Australian sample is required before widespread use can be recommended. These findings suggest that the existing short forms of the PAID may not be optimal and that further investigation is needed.

**Title:** Problems with implementation of the treatment with insulin analogues among patients with type 2 diabetes: results of the baseline study and project follow up

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**Aims:** Assessment of the frequency of problems with adherence to the treatment of diabetes type 2 with analogues of insulin among patients treated with human insulin.  
Assessment of relations between problems with adherence to the implementation of analogues of insulin among patients treated with human insulin and psychosocial factors.

**Methods and patients:** 3618 consecutive patients with diabetes type 2 (1949 [53,9%] women and 1627 [45,0%] men) of age 32-93 years (M =63,94; SD=9,55) filled: (1) Problems Related with Change of Treatment from Human Insulin to Analogues of Insulin Questionnaire (PRCTHIAIQ). That includes 5 questions in a 5 points Likert's scale form (alpha Cronbach = 0,83); (2) WHO-5; (3) Demographic Data Questionnaire; (4) Two items from the Brief Method Of Evaluating Coping With Disease; (5) Assessment of the Perception of Self-Influence on the Disease Course

**Results:** Meaningful percentage of patients reported some problems related with change of treatment from human insulin to analogues of insulin including:

- Lack of necessity to wait 30 minutes for the beginning of meal after injections of biphasic analogue of insulin - 37.6% (moderate or more - 11.4%)
- Refraining from snacks between main meals – 59.2% (moderate or more - 25.8%)
- Remembering about the necessity of additional, modified dosage of biphasic analogue of insulin in case of additional meal/snack – 61.8% (moderate or more – 30.7%)
- Problems with recognitions of hypoglycemia symptoms, after implementation of biphasic analogue of insulin – 32.5% (moderate or more – 9.1%)
- Problems with adherence after change from biphasic human insulin into analogues of insulin – 42.7% (moderate or more - 13.8%)

Results of PRCTHIAIQ correlated (Sperman rho) with: the Perception of Self-Influence on the Disease Course (-0.295\*\*); WHO-5 (- 0.291\*\*); age (0.112\*\*) HbA1c (0.145\*\*).

Mean rank of intensity of problems was the highest among persons with emotion oriented coping style and the lowest among those with problem oriented and the best solutions oriented coping style ( $\chi^2 = 165,423$ ;  $p=0,0001$ ). It was the highest among patients living in villages, and the lowest among those living in big cities ( $\chi^2 = 40,49$ ;  $p=0,0001$ ). It was the highest among people with lowest (elementary) education and lowest among ones with the highest level of education (university) ( $\chi^2 = 86,68$ ;  $p=0,0001$ ); It was also higher among patients with complications than without them (U Mann-Whitney = 1155057,5;  $p=0,0001$ ) and among less intensively (biphasic analogue) treated than more intensively (biphasic analogue + short acting one) (U Mann Whitney = 444996,5;  $p=0,0001$ ).

**Conclusions:** Implementation of treatment with analogues of insulin makes some problems for meaning full group of patients (especially: older, not well educated, living in villages and with complications). The intensity of those problems is higher among patients with maladaptive coping styles than adaptive ones.

**Discussion:** Planned Analyses in follow-up studies: (i) after how long time?, (ii) how to overcome limitations of the baseline study, related with frequent violations of the protocol? (iii) possibility of inclusions of a therapeutic interventions.

**Title:** How do we investigate if Guided Self-Determination-Young improves life skills in adolescents?

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**Aims:** To present how Guided Self-Determination-Young is used in routine paediatric outpatient clinics in triads of adolescents, parents and health care providers and to discuss possible advantages in using a mixed method approach especially (i) if the study shows an effect? (ii) if the study does not show an effect?

**Background:** Adolescents with type 1 diabetes face demanding challenges due to conflicting priorities between psychosocial needs and diabetes management. This often results in poor glycaemic control and conflicts between adolescents and parents. Adolescent-parent conflicts are a barrier to overcome for health care providers (HCP) in their attempt to involve both adolescents and parents in improvement of glycaemic control. Evidence-based interventions involving all three parts and integrated into routine outpatient clinics are lacking. The method Guided Self-Determination proven effective in adult care, has been adjusted to adolescents and parents (Guided Self-determination-Young: GSD-Y) for use in paediatric diabetes outpatient clinics by the adolescent's usual HCPs.

The objective is to evaluate whether GSD-Y used in routine paediatric outpatient clinics will improve life skills and reduce HbA1c concentrations as compared with a control group.

**Design and methods:** The study is a life skills intervention in a mixed methods design comprising a randomised controlled trial and a nested qualitative evaluation recruiting 68 adolescents aged 13 – 18 years with type 1 diabetes (HbA1c > 8,0%) and their parents from two Danish hospitals and randomised for GSD-Y or control. During 8-12 months the GSD-Y group completes 8 outpatient GSD-Y visits and the control group completes an equal number of standard visits. GSD-Y visits involves that adolescents and parents before each visit fill in reflection sheets with their own words and drawings, which may help them to systematically explore and express their individual and common difficulties and experiences with diabetes in daily life. Prepared to appointments in the outpatient clinics adolescents and their parents are guided to communicate openly and reflect mutually by sharing and respecting each others' observations thoughts and feelings as a starting point for a constructive collaboration.

The first adolescent was included September 2009 and the last adolescent will finish the study April 2012.

*Measurements:* Primary outcome is HbA1c. Secondary outcomes are number of self-monitored blood glucose values, levels of autonomous motivation (TRSQ), involvement and autonomy support from parents (POPS), autonomy support from HCP (HCCQ), perceived competence in managing diabetes (PCD), well-being (WHO5), and diabetes-related problems (PAID). Furthermore numbers of cancellations or failure to show up will be calculated.

**Planned analysis:** Primary and secondary outcomes will be evaluated within and between groups by comparing data from baseline, after completion of the visits, and again after 6-month follow-up using PAWS Statistics<sup>18</sup>. The statistical analyses include frequency, mean value, standard deviation and confidence intervals. Appropriate parametric tests will be used for variables fulfilling the normal distribution criteria or appropriate non-parametric tests for variables not fulfilling the normal distribution criteria.

Regarding the qualitative evaluation 10 -12 adolescents and their parents from the intervention group and their HCPs will be followed during the intervention period. The adolescents will be selected on the basis of high PAID scores and a low WHO5 scores at baseline indicating difficulties in life skills. Data will be collected by recording two or three outpatient appointments between 1) adolescent, parent and HCP, 2) between adolescent and HCP, 3) between parent and HCP. Individual interviews will be carried out and recorded with the above-mentioned triads after endpoint measures at 6-month follow-up period using a semi-structured interview guide. To facilitate the analysis NVivo 8 software will be used and at least two researchers will participate in the analysis.

**Expected outcome:** We expect that our study can provide evidence of effectiveness on HbA1c and life skills and feasibility of GSD-Y intervention for three parts and integrated into routine outpatient clinics.

Improvement of life skills will be defined as increases in: HCCQ-scores, TSRQ-scores on autonomy or in relative autonomy index, PCD, POPS, WHO5 and frequency of SMBG per week, and decreases in: TSRQ-scores on amotivation, PAID scores and HbA1c.

Improvement of life skills will be reached if the adolescents have begun to integrate the disease into their lives, e.g. if they have developed autonomously based motivation for blood glucose measurement, registration and regulation, because they think it is important and not because it is imposed by parents or HCPs, or driven by an "I should do" feeling.

**Title:** Psychological, behavioural and social aspects of living with diabetes  
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**Background:** Diabetes is the fastest growing chronic condition in Australia, affecting 1.7 million Australians and increasing at epidemic proportions. Diabetes is progressive, places a significant burden of self-management on the individual, and is known to impair quantity and quality of life. Better understanding of the motivators and behaviours of Australians with diabetes will inform improvement of services and facilities for supporting optimal self-management.

**Aims and research questions:** The Diabetes MILES (Management and Impact for Long-term Empowerment and Success) study is a national survey of English-speaking adults living with diabetes (type 1 or 2) in Australia. It is the largest of its kind ever undertaken in Australia. The survey (to be conducted June 2011) is exploratory in nature, aiming to gather data that will provide insights into the psychological, behavioural, and social aspects of living with diabetes. The research questions relate to the correlates of self-management, adherence, psychological health and wellbeing, self-reported health status and quality of life. We also intend to explore the role of health literacy, health beliefs, access to structured education and psychological support, as well as demographic factors such as economic hardship. We aim to characterise those who have been living successfully with diabetes (i.e. for a long time, reporting optimal psychological and physical outcomes) and to identify factors related to diabetes-related distress and poor physical outcomes. Our data will highlight areas for further research and intervention. The study will also involve the psychometric validation of selected measures in an Australian sample to enable recommendations to be made to clinicians for future use of psychological measures to inform patient-centred care or to evaluate service provision.

**Design and methods:** A multidisciplinary reference group (24 expert advisors) was established to oversee the development of the survey content, and will also oversee the analysis and reporting of the MILES project. The final survey instrument will be piloted with a small sample (N=32) of adults living with diabetes in Victoria. This pilot study will involve cognitive debriefing, whereby participants are encouraged to 'think aloud' about the suitability, understandability and relevance of the items and response options. Following this, approximately 11,000 adults with diabetes (50% type 1, 50% type 2) will be selected randomly from the National Diabetes Services Scheme (NDSS) register. Surveys will be mailed (with reply-paid envelopes) and online completion will be offered as an option. The online survey will also be advertised nationally to enable completion by the wider population of adults with diabetes. The survey consists of numerous validated measures and additional individual items developed/collated by the research team.

**Planned analyses:** Psychometric analyses will be used to investigate the reliability and validity of standardised measures in an Australian sample. Relationships between variables will be explored using correlational, regression, and modelling techniques.

**Expected outcomes:** We expect a minimum response rate of 30%, resulting in a sample size of approximately 3,300 adults. We acknowledge that NDSS registrants may not provide a representative sample of people with diabetes (e.g. up to 50% of people with diagnosed type 2 diabetes are not registered) but this survey represents the first opportunity of its kind to assess the psychological health, behaviour, beliefs, and unmet needs of a large heterogeneous sample of adults with type 1 or type 2 diabetes of various ages and socioeconomic groups. It is anticipated that this study will lead to a series of publications, raising awareness in Australia of the impact of diabetes on psychological and social outcomes, and the role of beliefs and behaviours in achieving optimal outcomes for adult Australians with diabetes. Such data will be used to inform future health policy and service provision.

**Future directions, problems, and questions:** Subject to future funding, this survey is the first phase of a longitudinal program of research dedicated to improving the quality of life and addressing the psychological needs of Australians with diabetes. Future work may include tailoring the survey for specific subgroups, such as older adults, adolescents, parents of children with diabetes, or those from a culturally and linguistically diverse background. Participants of the initial Diabetes MILES survey will be invited to engage in a longitudinal cohort study (with first follow-up planned around 2015). This study presents an opportunity to confirm international findings in an Australian population and also to shape a new generation of psychological research in diabetes. Feedback from the PSAD community regarding high priority issues and research questions, both for the current and future surveys, will be appreciated. Developing a longitudinal national survey is inherently challenging, not least in terms of consolidating diverse multidisciplinary opinions, and balancing psychometric rigour, innovation, and detail with issues such as brevity and respondent burden. Critical discussion around these competing priorities will be beneficial for the development of longitudinal survey in the future.

**Title:** Diabetes self care in low income priority populations attending primary care clinics in the United States

**Author:** Ruggiero L, Choi YK, Zhao W, Hernandez R, Castillo A on behalf of the entire UIC Diabetes Self-Care Study Team

**Institute:** University of Illinois at Chicago, School of Public Health, Institute for Health Research and Policy

**Aims:** The primary aim is to examine an innovative intervention for providing diabetes information and support to impact self-care in underserved priority groups attending primary care clinics serving low-income individuals in the US. This study compares a Medical Assistant self-management coach (MAC) intervention with “treatment as usual” (TAU). The target populations include African Americans and Hispanics. The primary aims of this study are to evaluate the impact of the MAC intervention compared with TAU on glycemic control (i.e., A1C), psychosocial and behavioral mediators, and other biomedical outcomes (e.g., service utilization, lipids).

#### **Design and Methods:**

**Design:** The study uses a prospective randomized two-group split-plot repeated measures design, including a 2 (treatment group: TAU vs. MAC intervention) X 4 (time: baseline, 6-month, 12-month, 18-month) repeated measures design.

**Participants:** Participants were enrolled in this study based on the following inclusion criteria: Hispanic or African American; age equal or greater than 18 years; fluent in English or Spanish; Two previous A1C values > 6.5%; able to provide informed consent; diagnosis of type 2 diabetes; and receiving medication therapy for diabetes. The total baseline sample includes 255 individuals with the following characteristics: mean age of 53.4 years; 69% female; 54% African American and 46% Hispanic; 38% married and 24% never married; 62% with income under \$25,000 USD; 38% without health insurance; and 59.6% with less than high school or equivalent education.

**Procedure:** Eligible patients were enrolled and randomized to receive either self-care coaching provided by a trained medical assistant or “treatment as usual”. The MAC intervention is delivered monthly over a one-year period, including face-to-face contacts during routine primary care visits and regular telephone coaching contacts between clinic visits. The data collection is ongoing.

#### **Measures:**

**Behavioral and psychosocial measures:** The Patient Health Questionnaire-9 is used to measure depression. A multi-item index of self-efficacy is used to assess targeted diabetes care behaviors. Stages of change questions are used to assess motivation (i.e., readiness for change) and achievement of goals (i.e., action/maintenance stages). The Diabetes Distress Scale is used to assess distress among patients with diabetes. The revised Summary of Diabetes Self-Care Activities Questionnaire is used to measure self-reported frequency of completing diabetes regimen activities over the past 7 days. Adherence with routine diabetes care medical and specialty appointments is obtained from the medical records and patient self-report.

**Biomedical Outcome Measures:** A1C is conducted at each assessment point. Body Mass Index, lipid profiles, blood pressure is obtained from medical records. Information is also obtained from medical records on number of physician visits, hospitalizations, and diabetes educator visits.

**Planned Primary Analyses:** The primary hypothesis to be tested is that the A1C levels among patients in the MAC Intervention condition will be lower than the levels among patients in the TAU condition. The primary analysis will be conducted using Generalized mixed effects model (GLMM), which includes a variance structure for repeated data over time (Fitzmaurice *et al*, 2004). This is implemented in the PROC MIXED procedure in SAS 9.2. The psychosocial/behavioral mediators will be analyzed using Baron and Kenny (1986). Behavioral/psychosocial and biomedical outcomes are continuous or counts of events occurring within a fixed time interval. For continuous outcomes, the GLMM mentioned above will be used. Counts are considered to follow the Poisson distribution and will be analyzed using the GLMM with a log link function. Other secondary and follow up analyses will also be conducted.

**Expected Outcomes:** The primary hypotheses are that the MAC Intervention will result in greater improvement in glycemic control, psychosocial mediators, behavioral outcomes, and biomedical outcomes compared to TAU.

**Conclusions:** If effective in improving glycemic control and/or diabetes self-care, the MAC intervention has the potential to be easily implemented in other primary care. Examination of patterns and predictors of self-care and glycemic control will support the field in identifying interventions for these underserved groups.

**Discussion / Questions:**

1. What important questions should we consider beyond our planned primary analyses?
2. We are planning to examine the longitudinal data on depression and self-care as a secondary research area. What suggestions does the group have for these or other potential longitudinal research questions/analyses?
3. Are there available international datasets that would allow us to make cross-cultural comparisons on variables available in our study, such as self-care and depression? Is there any interest in collaboration?

**Title:** The screening profile of young adults joining a flexible rehabilitation program using Guided Self-Determination

**Author:** Zoffmann Vibeke

**Institute:** Steno Diabetes Center, Gentofte, Denmark

**Aims:** The need to improve diabetes care by better enabling patients to utilise their individual and local resources to self-manage the condition is widely recognized, yet there is a lack of access to evidence-based and efficient patient-centred healthcare interventions. As a major initiative to identify patients with special need for psychosocial support, the screening method, Monitoring Individual Needs with Diabetes (MIND) has proved applicable by health professionals in ten countries. The next step is to provide suitable interventions to follow. Especially young adults are difficult to recruit for interventions as they are busy educating and establishing career and family. The primary objectives are: (i) to test if Guided Self-Determination (GSD) adjusted to young adults improves their metabolic control, motivation, self-management of the condition, psychosocial problems and self-esteem. (ii) to determine if MIND-results can predict which patients will take part in and benefit from a GSD intervention.

**Design and methods:** 200 young adults (18-35 yrs) with poorly managed type 1 diabetes at Steno Diabetes Center in Gentofte, Rigshospitalet in Copenhagen, and Haukeland Sykehus in Bergen, are invited to take part in a rehabilitation program using the method Guided Self-Determination in groups or individually, supported by GSD-trained nurses. By filling in GSD-reflection sheets before and between appointments with professionals, patients meet well prepared with enhanced self-insight and ability to talk about unique difficulties in life with diabetes. This facilitates shared decision-making and problem solving between patients and providers and paves the way for patients developing autonomous motivation for glucose control and changes they wish for in their life. Knowledge about the robustness of GSD material across different settings will be part of the outcome.

**Planned analysis:** Patients will answer electronic questionnaires with the scales mentioned below and afterwards be randomised into two groups: 1) GSD intervention in 2010/2011 or 2) delayed intervention when results of 18 months follow-up are made up. The following outcome measures are used: A1C; Health Care Climate Questionnaire (HCCQ); Treatment Self Regulation Questionnaire (TSRQ); Problem Areas In Diabetes (PAID); Perceived Competence with diabetes (PCD); WHO-5; Rosenberg's self-esteem scale (RSES); Self-monitored blood-glucoses (SMBG) per week; Cancellations or failures to show-up.

**Expected outcomes:** Knowledge about the appropriateness of combining MIND and GSD will be part of the results. Knowledge of the profile of those who accept GSD intervention can be important for HCPs who are in search for interventions acceptable by young adults and applicable by diabetes HCPs in practice.

**Problems/questions:** By presenting their PAID and WHO-5 baseline scores I will profile the participants having accepted the invitation to participate in a flexible rehabilitation program using GSD together with GSD trained nurses. Such knowledge will probably be of interest for HCPs in innovation of diabetes services incorporating both material to screen and empower patients.

**Question:** Are PAID and WHO-5 scores comparable regardless the way they have been scored, through the MIND procedure or questionnaires?