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PsychoSocial Aspects of Diabetes

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- Abstract booklet -

Title: Diabetes associated diet changes responses to food pictures in motivational and emotional brain regions: an fMRI study

Authors: Arie Nouwen[1], Magdalena Chechlacz[1], Pia Rotshtein[1], Silke Klamer[2], Hubert Preissl[2], Niels Birbaumer[2]

Institute: [1] University of Birmingham, UK, [2] Eberhard Karls University of Tübingen, Germany

Aims: Dietary self-care is the cornerstone of the treatment of type 2 diabetes. Whereas temporary food deprivation and restricted diet result in an increase in the reinforcing value of food in healthy people, the effect on emotional and motivational responses to food stimuli of life-long dietary restrictions such as those of type 2 diabetes remains poorly understood. We hypothesized that type 2 diabetes associated diet alters responses to food in emotional and motivational brain regions and that responses to food stimuli within these regions can be predictors of the ability of individuals with type 2 diabetes to adhere to their diet.

Methods: Participants were 11 people with type 2 diabetes and 12 healthy controls matched on age and BMI. Patterns of emotional, external and restrained eating, hunger and BG levels were assessed prior to scanning. Participants with diabetes also filled out the Summary of Diabetes Self-care Activities Scale and a dietary self-efficacy scale. During fMRI scanning participants were presented with 36 pictures of foods, which varied in volume, fat and sugar content, and with 36 non-food control pictures matched for complexity, shape and colour. After scanning participants rated the pictures on valence, arousal (all pictures) and appetite (food pictures only).

Results: Type 2 diabetes increases responses to food stimuli in insula, OFC and basal ganglia. Within these regions we observed increased sensitivity to level of fat in food. Furthermore, increased activation to food within the insula and OFC correlated positively with external eating, dietary adherence and dietary self-efficacy. By contrast, responses within subcortical structures associated with reward learning (amygdala and basal ganglia) were positively correlated with emotional and reward value of food stimuli and negatively correlated with dietary adherence. Finally, the explicit appetite ratings of food stimuli were lower in participants with type 2 diabetes compared to the control group while the overall responses to food versus non-food were found higher within emotional and motivational related brain regions in participants with type 2 diabetes.

Conclusions/Discussion: Living with type 2 diabetes which includes long-term and restrictive diet, changes brain responses to food and the extent of these changes influences adherence to dietary recommendations. Furthermore, we provide evidence that adherence to dietary recommendations and dietary self-efficacy have neurological correlates in motivational/affective brain regions. To understand motivation the dietary self-care and failure to follow dietary recommendations in individuals with type 2 diabetes, a more accurate estimation is needed of the reward value of food and both implicit and objective measures are needed rather then relying solely on subjective self-report questionnaires.

Title: Assessing diabetes support in adolescents: Factor structure of the modified Diabetes Social Support Questionnaire-Friends

Authors: Jamil A. Malik and Hans M. Koot

Institute: Developmental Psychology, Vrije University, Amsterdam

Aims: To determine the factor structure of the modified DSSQ-Friends, confirm it in a second sample, determine the invariance in factor structure across gender, and test the reliability of resulting scales.

Methods: The sample for this study was drawn from 890 children and adolescents in all 28 hospitals in the south-western part of the Netherlands, which have diabetes care for children and adolescents. The study included all 12-18 years old youngsters with Insulin Dependent Diabetes Mellitus (IDDM) in these centers, who are all on daily insulin injection or pump. Out of 545 youngsters who fulfilled the criteria, 456 participated in the present study. The DSSQ-Friends and other questionnaires were completed by the subjects during their regular visit to their local clinics, in the presence of research nurses. Final analyses were conducted on 434 adolescents' including 238 (54.8%) girls. Data was analyzed using SPSS 14.0 and AMOS 7.0.

Results: The DSSQ-Friends is a 54 items questionnaire developed by LaGreca et al., (1995), to measure 6 domains of diabetes specific support by close friends of adolescents. Respondents are asked to rate both the frequency and supportiveness of the behaviors of their friends on a 6 and 5 point Likert scale, respectively. Based on individualized scoring (frequency x supportiveness of the item), items were included only if they emerged supportive for 50% or more adolescents. Four items emerged as non-supportive, and were excluded from the final analyses. Three items rated as non-supportive indicated critical and careless behaviors of adolescents' friends against their diabetes, whereas one item indicated close supervision. Exploratory Factor Analysis (EFA) was conducted on a random subsample of 207 adolescents including 117 (51.2%) girls. Results from the EFA revealed a 5 factor solution explaining approximately 49% of the item variance, with 9 items indicating help during hypos and hypers (labeled Help in Critical Situations; Cronbach's alpha = .92); 13 items indicating behaviors like advising and reminding for self-care (Guidance and Encouragement; α = .90); 13 items indicating help with eating the right food (Nourishment; α = .88); 10 items indicating understating of feelings (Empathy; α = .88); and 5 items indicating companionship in physical activity (Help in Exercise; α = .76). Confirmatory factor analysis was conducted on the remaining subsample of 227 adolescents including 132 (58.1%) girls. All five factors were tested individually and showed good indexes of model fit (average CFI =.98, RMSEA = .05) after deleting 4 items, based on low loadings and content analysis. Factors were also tested across gender and showed good indexes of model fit (average CFI=.96, RMSEA=.06). Finally Cronbach's alpha was calculated, and as indicated above showed good reliability of the 5 factors. Cronbach's alpha also showed good reliabilities ranging from .91 to .79 separately for girls and .93 to .72 for boys.

Conclusions/Discussion: The 46 items "Modified Diabetes Specific Support Questionnaire-Friends" emerged as a valid and reliable scale for Dutch adolescent population with IDDM to measure 5 factors of diabetes specific support from close friends.

Title: Factors predicting adjustment of adolescents with insulin dependent diabetes mellitus

Authors: Jamil A. Malik and Hans M. Koot

Institute: Developmental Psychology, Vrije University, Amsterdam

Aims: To predict adjustment in adolescents with IDDM by testing direct, mediating and moderating effects of diabetes specific and psychosocial factors, using an adapted version of Wallander and Varni's disability-stress-coping model.

Methods: The study sample was drawn from 890 adolescents in all 28 hospitals in the south-western part of the Netherlands, which have diabetes care for children and adolescents. The sample included criteria were 12-18 years old youngsters with IDDM, who were all on daily insulin injection or pump. Out of 545 youngsters who fulfilled the criteria 456 (54.6% girls) participated in the present study. Metabolic control was assessed by measuring HBA1c of all participants. Adolescents filled out questionnaires during their visit in their local clinics, whereas questionnaires were sent to family members and returned by mail. Diabetes parameters were calculated by summing standardized z-scores of level of Hba1c, hospital admissions due to hypoglycemia and hyperglycemia, and mean blood glucose variations per month. Adolescents' adjustment was assessed in four dimensions, (1) Diabetes-related quality of life as assessed by the Modified Diabetes Quality of Life for Youth, (2) General well-being, measured by the Well-Being Questionnaire (WB12), (3) Emotional problems, and (4) Behavioral problems measured by CBCL and YSR. Psychosocial stressors were specified as (1) diabetes related stress, calculated by summing diabetes specific stress, diabetes related fears i.e., fear of self-testing and injecting, and complaints due to hypoglycemia and hyperglycemia, and (2) general stress, calculated by summing scores on a life event scale and general stress faced by adolescents in last two months.

Results: Results from a series of multiple regressions, controlling for gender, showed that three factors i.e., global self-worth, diabetes related stress and social support predicted (1) 45.8% of variance in diabetes quality of life, and (2) 33.5% of variance in general well being, whereas, above mentioned three factors along with general stress predicted 37.0% of variance in emotional problems and factors i.e., diabetes related stress, general stress, and social support, predicted 16.7% of variance in behavioral problems. General stress did not mediate between diabetes parameters and adolescents' adjustment, whereas diabetes related stress fully mediated and explained 21.3% of variance in diabetes quality of life, 15.4% in general well-being, 20.9% in emotional problems and 6.8% in behavioral problems. Three moderating effects were identified. Tangible support obtained from parents and friends moderated the relationship between diabetes stress and quality of life and the relationship between diabetes stress and emotional problems, whereas social support moderated the relation between general stress and emotional problems. Partial mediating effects of diabetes related stress were also identified between socio-ecological and personal factors, and adolescent's adjustment.

Conclusions/Discussion: The adapted Wallander/Varni disability-stress-coping model appeared to work as a satisfactory model to predict adolescent adjustment and explained pathways of adjustment by direct, mediating, and moderating effects of risk and resistance factors. Effects of diabetes parameters on the adjustment of adolescents with IDDM are mediated by diabetes related stress. Effects of diabetes related stress may be moderated by tangible and emotional support from parents and peers.

Title: In-field assessment and feedback of cognitive performance in type 1 diabetes patients – a means for enhancing hypoglycaemia awareness?

Authors: Thomas Kubiak [1,2], Norbert Hermanns [2], Bernd Kulzer [2]

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Objectives: Patients with impaired hypoglycaemia awareness (IHA) lack characteristic autonomic symptoms of hypoglycaemia and often fail to perceive the onset of low blood glucose (BG) levels in time. The role of neuroglycopenic symptoms in the context of IHA is not well understood yet: whereas neuroglycopenic effects often do occur even in IHA patients, they are often not attended to by the patients. The objective of this study was to investigate the possibility of enhancing hypoglycaemia awareness in T1DM patients with and without IHA by giving in-field feedback of attentional performance using hand-held computer (HHC) methodology.

Methods: N = 59 type 1 diabetes patients (M±SD, age 35.3±14.2 years, HbA1C 7.6± 1.5%) were studied, 21 of whom suffered from IHA (35.5%). The participants were equipped with electronic diaries (PSION Series 3a HHCs). Data were acquired using a combined time and event sampling scheme (total monitoring time: 2 weeks). Autonomic and neuroglycopenic symptoms were assessed, and a choice reaction time test was implemented in the HHC. Upon finishing the test, patients were prompted to estimate their performance and feedback of the real reaction time was given. Finally, the participants were prompted to enter their estimated BG level and to perform an actual BG measurement with a memory metre.

Results: 40.2 ± 19.2 trials / patient could be obtained, with an average of 28% of trials being in the hypoglycaemic range. Overall, participants with IHA detected less hypoglycaemic episodes as compared with the other patients (13.0 vs. 34.4%). However, multilevel regression modelling (measurements nested in patients) revealed significant improvements in reaction time estimation accuracy in both groups, which, in turn, were associated with higher levels of neuroglycopenic symptoms during hypoglycaemia and improvements in hypoglycaemia detection.

Conclusions/Discussion: We demonstrated the possibility of enhancing neuroglycopenic symptom perception in T1DM patient, both with and without IHA, using HHC-based in-field performance feedback. However, the sample size is still small, and the processes leading to the observed effect remains still largely unclear, as is the stability of the effects after the end of HHC use.

Title: Unrealistic pessimism about risk of Coronary Heart Disease and stroke in patients with type 2 diabetes.

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Institute: [1] King's College London, [2] University of Wollongong, [3] Northampton General NHS Trust

Aims: This study examined the accuracy of type 2 diabetes (T2D) patients' risk estimates of developing Coronary Heart Disease (CHD)/ having a stroke as a consequence of diabetes and their mood about these risks.

Methods: Patients (N=95) reported their perceived risks of developing CHD/ having a stroke and rated their mood about these risks using a self-report measure. Using the United Kingdom Prospective Diabetes Study (UKPDS) Risk Engine to calculate objective risk of CHD and stroke, we communicated to patients their actual risk of CHD and stroke and we re-assessed their mood.

Results: Patients grossly overestimated their risk of CHD and stroke. A negative relationship between disease risk and mood was seen where higher risk of actual and perceived CHD/stroke was related to worse mood. A positive relationship between mood and extent of perceptual error was further observed; the more inaccurate patients' perceptions of CHD/stroke risk were, the better their mood. Mood improved after patients were given accurate risk information.

Conclusions/Discussion: T2D patients are unrealistically pessimistic about their risk of developing CHD/ stroke. These risks and the extent of perceptual risk error are associated with mood, which improves upon providing patients with accurate risk information about CHD / stroke. These results have implications for the routine communication of risk to T2D patients.

Title: Depressive symptoms increase the risk of all-cause mortality in men with high postload glucose levels - a 30 year follow-up study.

Authors: J. Kruse, N. Schmitz, K.-H. Ladwig, J. Heinrich

Institute: Department of Psychosomatic Medicine and Psychotherapy, University Duesseldorf, Germany

Aims: About 25% of people with diabetes have coexisting depressive symptoms. The aim of the present study was to evaluate the effect of depressive symptoms (exhaustion) on all cause mortality among men with and without postload hyperglycemia (PH) over a period of 30 years.

Methods: In a population based cohort study 1013 men aged 40–59 years at baseline were surveyed and followed for up to 30 years. A 1-hour postload venous blood sample was obtained after an modified oral glucose tolerance test in 1973-75. Depressive symptoms were assessed by an exhaustion scale at baseline. Information on deaths was obtained from the residential registry. Mortality follow up continued until death or September of 2003. We divided the cohort into four groups based on the presence or absence of depressive symptoms and high postload glucose levels at baseline Cox proportional hazards regression models were used to calculate adjusted hazard ratios of death for each group compared with the reference group.

Results: Results: Over 30 years, 477 study participants (47.1%) died. Mortality rates were highest in men with depressive symptoms and coexisting postload hyperglycemia. Hazard ratio for mortality was 0.81 (95% CI 0.64-1.02) for men with depressive symptoms alone, 1.29 (95% CI 0.96-1.73) for men with postload hyperglycemia alone, and 2.02 (95% CI 1.24-3.30) for men with both, postload hyperglycemia and depressive symptoms. After adjustment for demographic, diabetes-related and cardiovascular risk factors, heart diseases, and other chronic conditions results did not change substantially. Baseline depressive symptoms and postload hyperglycemia was independently associated with time to death with an excess mortality of 68% (HR 1.99, 95% CI 1.22 to 3.25). Postload hyperglycemia without depressive symptoms and depressive symptoms with low postload glucose levels have no significant impact (HR 1.28, 95% CI 0.95 to 1.72).

Conclusions/Discussion: The results suggest that the coexistence of depressive symptoms and postload hyperglycemia is associated with an increased risk of mortality in men.

Title: Patient reported outcomes of continuous glucose monitoring (CGM) with real time access to glucose values vs. retrospective analysis: a cross over study.

Authors: Hermanns, N., Kulzer, B., Gulde C., Eberle, H. & Haak T.

Institute: Research Institute of the Diabetes Academy Mergentheim (FIDAM)

Introduction: Results of CGM can be reported to patients either in real time or retrospectively. This randomized cross over trial examines the effect of CGM with real time access to glucose data (RTA) vs. a CGM with a retrospective analysis (RA) of glucose data on satisfaction with CGM and other patient reported outcomes.

Methods: Participants used the CGM device (GlucoDay®, Menarini Diagnostics, Florence, Italy) twice. In one condition patients got real time access to current glucose values and in the other condition glucose values were only reported retrospectively. The order of these two conditions was randomized. At baseline, after the first and the second trial, subjects completed questionnaires about perceived satisfaction with CGM (CGM-SAT, with a total score of satisfaction with CGM, with a perceived benefit scale and a perceived disadvantage scale).They also completed the Problem Areas in Diabetes (PAID), and the state anxiety scale (State Version STAI).

Results: In this study 50 type 1 diabetic patients (age 41.7 ±12.3 yrs., diabetes duration 14.75 ±11.9 yrs., 48 % female, A1c 8.1% ±1.5%, years of education 10.3 ± 2,1 yrs) participated. The correlation between sensor glucose and reference glucose was r=.72 ±.63 during RA and r=.83 ±.56 during RTA. At baseline patients perceived CGM as rather advantageous, after RA and RTA the perceived benefits were reduced (baseline: 47.8 ±10.5; RA: 38.4 ±17.2; RTA: 37.0 ±16.8, $p<.01$), but there was no significant difference between RA and RTA. Interestingly the same was true for perceived disadvantages of CGM (Baseline: 22.9 ±10.6; RA: 18.7 ±10.6; RTA: 19.3 ±12.6 $p<.05$). The total scale of the GCM SAT showed a similar course (Baseline: 101.0 ±16.0; RA: 95.7 ±20.2; RTA: 93.6 ±22.8 $p>.01$). There was also no significant effect on diabetes related distress or state anxiety.

Conclusions/Discussion: After the experience of CGM the possible benefits were perceived as a little bit less positive and potential disadvantages were perceived less negative. Thus experience of CGM corrected expected benefits and disadvantages. But there was no specific significant negative or positive effect of RA vs. RTA on satisfaction with CGM. Furthermore CGM with RA or RTA had no significant effect on the course of diabetes related distress or state anxiety. Exposing type 1 diabetic patients to their current glucose values doesn't seem to have a specific negative impact on the appraisal of CGM or more generic patient reported outcomes.

Title: How to master diabetes in court? – a case study.

Authors: Karin Kanc [1], Vibeke Zoffmann [2]

Institute: [1] jazindiabetes (me&diabetes), Ljubljana, Slovenia; [2] UCSF, København, Danmark

Introduction: begin October 2007, a 32-year old female lawyer IH with type 1 diabetes presented in the diabetologist's office for the second opinion on her glucose regulation. Several attempts to regulate her diabetes by using basal/bolus therapy with glargine and lyspro in the past 3 years have failed and her HbA1c by the time she presented herself in the office was 9.0%. She was quite desperate, as in spring 2007 she has put a lot of effort in learning meticulous carb-counting along with insulin adjustment (functional insulin therapy – FIT), but glycaemic control even deteriorated from 8.5% in April to 9%, end September. She was enrolled as a candidate for insulin pump treatment by then, but did not expect to get a pump earlier than February 2008.

Aims: we decided to explore the possibilities of helping this patient improving her glycaemic control by implementing a decision-making and problem-solving method.

Methods: guided self-determination method (GSD).

Results: IH first explored the relation between important life events and HbA1c: at diagnosis in August 2001, HbA1c was 16%, a year after her glycaemic control improved to HbA1c between 6.6 and 7.1%. In 2003/04, she became a lawyer in a law firm and started to work regularly in court, defending her clients. In 2004, she only just prevented a severe hypoglycaemia in court. Soon after, her glycaemic control started to deteriorate to the level described in the introduction. By means of reflection sheets, several other aspects of IH's life have been explored (goals and intentions, current problem-solving, dynamic problem-solving, room for diabetes in her life, etc.). Moreover, she has set ideal goals for daily blood glucoses and compared them to glucoses known from her experience. Her main problem proved to be that she could "not afford" to experience a hypo while in court, as her reputation as a competent defender of the client would be jeopardized. During GSD consultations and homework, she developed a strategy to cope with court session situations, depending on whether it was a long, medium or short session, and depending on how demanding they were. Mid November, ie 1.5 mo. after she presented herself, the HbA1c has dropped from 9.0% to 7.9% and her overall well-being was much better.

Conclusions/Discussion: GSD proved to be a useful tool in improving glycaemic control in a patient with type 1 diabetes, where other medical attempts have failed to yield positive results.

Title: Overcoming barriers to effective diabetes management in Greece: A report on the development of the DAWN assessment form model of psychosocial care.

Authors: Soren Skovlund [1], Sue Shea [2]

Institute: [1] Novo Nordisk A/S; [2] On behalf of the Hellenic DAWN Study Group

Aims: The aim of the present study, was to develop an effective model of identifying and addressing psychosocial issues as part of routine diabetes care in Greece. The model involved the development of a one-page assessment form consisting of the WHO-5, and a further 9 questions in relation to diabetes specific psychosocial distress (DSPD). In addition to the form, proposals were initiated for a series of practical supporting tools, linked to the items on the form, and designed to enhance HCP and patient interaction with regard to confronting and overcoming barriers to effective diabetes care. The supporting tools include: confidence appraisal; goal setting; problem solving; patient and clinician question prompt lists; complications awareness; and an HCP and patient collaborative action plan. Each is designed for optional use, as and when considered appropriate.

Methods: The form was initially piloted among 400 Greek people attending diabetes services in rural and urban locations in Greece. The study population included men (41%), and women (59%), within an age range of 17-88 years, diagnosed with either Type 1 (16.5%), Type 2 (81.5%), or gestational (2%) diabetes. Following the piloting of the form, a Hellenic DAWN Study Group was formulated, whose role included providing feedback on the use of the form, and advising and commenting on the proposed practical supporting tools.

Results: The form demonstrated good reliability for both the WHO-5 ($\alpha = 0.86$), and DSPD ($\alpha = 0.79$) sections of the form. WHO-5 and DSPD significantly correlated with diabetes treatment type ($r = -.16$, $r = -.30$, $p = 0.01$) and HbA1c ($r = -.17$, $r = -.31$, $p = 0.01$). WHO-5 was further related to BMI ($r = -.30$, $p = 0.01$). The form was able to discriminate between different patient groups based on HbA1c ($p = <.020$, $p = <.001$), sex ($p = <0.001$, $p = <0.001$), and treatment type ($p = <0.030$, $p = <0.001$). Multiple regression indicated the WHO-5 section as a predictor of BMI ($p = <0.001$), and DSPD as a predictor of HbA1c ($p = <0.001$). HCPs welcomed the introduction of both the form, and the supporting tools. To further assist the effectiveness of the model in clinical practice, guidance documents were also produced, including a 'brief reference guide', which can be easily referred to during the consultation.

Conclusions/Discussion: The form is psychometrically reliable and valid. The optional supporting tools allow for interaction enhancement between the HCP and the patient and are considered an essential means of addressing individual needs. The model is of particular assistance to HCPs with limited resources, is welcomed in both rural and urban areas of Greece, and is considered culturally relevant. Work is now underway with a view to long term evaluation of the model, together with its wider scale implementation. Development of a child and adolescent version is also intended.

Title: Diabetes-related symptom distress among groups of different glucose tolerance status: cross-sectional findings of the HOORN-Study.

Authors: Marcel C. Adriaanse, Ph.D. [1], Frans Pouwer, Ph.D. [2,3], Jacqueline M. Dekker, Ph.D. [2], Giel Nijpels, MD, Ph.D. [2], Robert J. Heine, MD, Ph.D. [2,4], Frank J. Snoek, Ph.D. [2,3]

Institute: [1] Institute of Health Sciences, Faculty of Earth and Life Sciences, VU University Amsterdam, the Netherlands. [2] EMOG Institute, VU University Medical Centre, Amsterdam, the Netherlands. [3] Department of Medical Psychology, VU University Medical Centre, Amsterdam, the Netherlands. [4] Department of Endocrinology, VU University Medical Centre, Amsterdam, the Netherlands.

Objective: To determine the level and differences of diabetes related symptoms distress among groups of different glucose tolerance status.

Methods: The cross-sectional study sample consisted of 569 subjects of whom 281 had normal glucose metabolism (NGM), 181 with impaired glucose metabolism (IGM) and 107 with type 2 diabetes mellitus (DM2) of the Hoorn study. Glucose tolerance status was based on fasting and post-load glucose levels. We use the Type 2 Diabetes Symptom Checklist (DSC-R) to assess diabetes-related symptom distress.

Results: The total symptom distress score (range 0-4) was relatively low for NGM (median 0.15), IGM (median 0.18) and DM2 (median 0.24) subjects, though significantly (P = 0.046) different. DM2 subjects reported significantly greater burden of neuropathic pain (P = 0.033), sensibility symptoms (P = 0.004), and total symptom distress (P = 0.005) compared to NGM subjects, but not compared to IGM subjects. The total symptom distress score was significantly associated with fasting glucose (rho = 0.09, P = 0.029) and not with post load glucose levels (rho = 0.06, p = 0.187).

Conclusions/Discussion: Glucose tolerance status is associated with diabetes-related symptom distress.

Title: Preventing type 2 diabetes after gestational diabetes: a qualitative study with postnatal women to inform intervention development.

Authors: K Stothard [1], C May [1], N Lewis-Barned [2], Y Doherty [2], M White [1], R Bell [1]

Institute: [1] Institute of Health and Society, Newcastle University, UK. [2] Northumbria Healthcare NHS Foundation Trust, UK.

Background: Gestational diabetes (GDM) complicates 2-5% of pregnancies. For most women the condition resolves following delivery but they have a 35-50% risk of developing GDM in a subsequent pregnancy and approximately half of all women who have had gestational diabetes will develop Type 2 diabetes (T2DM) within 10 years. Previous research has demonstrated that healthy lifestyle choices – such as controlling weight, diet and increasing physical activity can reduce the risk of developing T2DM for those in high risk groups. It has also been shown that for women who have had GDM their chances of developing it in a subsequent pregnancy are linked to weight gain and lower levels of physical activity. This suggests that an intervention designed to promote healthy lifestyle choices may reduce the risk of T2DM and the reoccurrence of GDM in future pregnancies. However, previous research about interventions to prevent obesity suggests that it is difficult for people to make positive lifestyle changes and hard for them to maintain these changes. Lifestyle interventions designed to support women lose weight after pregnancy have reported low participation rates and high rates of drop out and non-completion. There is limited literature regarding behaviour change in post-natal women which suggests that women may be motivated to make positive lifestyle changes and that self-efficacy is a mediator. However, due to the lifestyle changes resulting from the birth of a baby there may also be barriers such as financial and time constraints and competing priorities. Therefore it is important to explore what type of intervention may be feasible and effective for this population.

Aims: The aim of the study is to explore the views of women who have experienced GDM concerning the appropriateness and feasibility of lifestyle change to prevent T2DM. The findings will contribute to the development of new approaches to diabetes prevention designed for, and with, women in the postnatal period.

Design/methods: This is a qualitative study using a two stage design. The first stage involves semi-structured interviews with up to 40 women. The interviews will be focussed on the experiences of GDM, perception of risk for developing T2DM, and barriers and facilitators for positive behaviour change for diabetes prevention. The topic guide will be based on a range of theoretical concepts reccommended by the National Institute for Health and Clinical Excellence (UK) as the basis for structuring behaviour change interventions. These include outcome expectancies,

self-efficacy and subjective norms and are derived from a number of psychological theories for health behaviour and behaviour change such as Social Cognitive Theory, Theory of Planned Behaviour and Locus of Control.

The interviews will be followed by 8 task groups with 4-6 women participating in each. Participants will be sent written material prior to the task group including a summary of the interview themes. The task groups will involve discussion of the interview themes and tasks designed to elicit preferences for interventions – content of interventions based on psychological theory and practical issues such as organisation and structure. Tasks may include ranking, pyramid and case study exercises.

Women will be eligible to participate if they are aged 16 or more, have had a successful outcome of a pregnancy complicated by GDM within the last 18 months, and received their antenatal care at either North Tyneside General Hospital or Wansbeck General Hospital. Potential participants will be approached prospectively and retrospectively. Sampling will be purposive, based on parity and deprivation score derived from postcode.

Planned analysis: Thematic analysis will be used for both stages of the study. The analysis for the interview stage will inform the development of the topic guide and tasks for the task groups.

Expected outcomes: There are several expected outcomes: Which theoretical concepts are most applicable to this group in terms of their experiences, their requirements and preferences for intervention. Recommendations for practical aspects of intervention eg. individual vs. group, face-to-face vs. phone or postal contact. Different preferences for intervention or needs for different groups of women, for example by parity.

Open Questions:

(A) Are there any psychological theories or central concepts for health behaviour that you think should be included in this study?

(B) What psychosocial mediators of behaviour change do you think may be important for this group of women?

Title: Diabetes Attitudes Wishes and Needs (DAWN) Youth Study.

Authors: Mark Peyrot, on behalf of the DAWN Youth Advisory Group

Institute: Loyola College, USA

Aims: To present methodology and preliminary results of DAWN Youth Study.

Design/methods: A multi-national internet survey of young adults with diabetes, parents of youth with diabetes, and pediatric diabetes care providers. ifferent respondent groups were often asked parallel questions. Topics include self-care, quality of life and psychological well-being, diabetes care, family life, peer support, school environment/support.

Planned analysis: Descriptive analyses comparing responses by different survey groups to create epidemiological profile of problems and resources in different countries. Correlation/regression analyses to assess associations among study indicators, e.g., what relationship does support from different domains have with patient and parent self-care, quality of life, psychological well-being.

Expected outcomes: To increase support for policy and program initiatives to improve quality of care and quality of life for young people with diabetes can their families.

Problems, questions for group discussion:

(A) What topics are most important to drive action initiatives?

(B) What publication strategies will be most effective in disseminating study findings?

Title: Depression and cognitive functions among diabetic patients.

Authors: Simona Primožič [1], Maja Ravnik-Oblak, MD, PhD [2], Rok Tavčar, MD, PhD [1], Mojca Zvezdana Dernovšek, MD, PhD [1]

Institute: [1] University Psychiatric Hospital Ljubljana, Slovenia [2] Department of Endocrinology, Diabetes and Metabolic Diseases, University Medical Center Ljubljana, Slovenia

Aims:

- To estimate the prevalence of depression and other mental disorders among diabetic patients in Slovenia according to the results of the study.
- To find out which of the depressive symptoms are the most common or expressed in studied population.
- To verify particularities of cognitive functions in studied population.
- To estimate relationship between depressive symptoms and cognitive functions among diabetic patients.
- To clarify relationship between glycaemic control, diabetic complications or other features of diabetes and mental disorders, depressive symptoms or cognitive functions.
- To estimate the impact of depressive symptoms, cognitive functions or their interaction on emotional burden of diabetes or effective self-management of diabetes treatment.

Design and methods: About 150 adult Type 1 and Type 2 diabetic patients from outpatients clinic will be included in the study. Data about duration and type of diabetes mellitus, presence of diabetic complications, episodes of hypoglycaemia (number of serious episodes in last six months), glycosylated hemoglobin (HbA1c), diabetes therapy, and BMI will be interceded by physician. Sociodemographic data (gender, age, type of community, education, occupation, other current or passed illnesses or disorders, use of medications for mental disorders or other medications with influence on cognitive functions, alcohol or drug abuse, category of work disability) will be collected. Additionally participants will complete following questionnaires: Problem Areas in Diabetes Survey (PAID), Symptom Checklist-90-Revised (SLC-90-R), Hamilton Depression Inventory (HDI) and The Summary of Diabetes Self-Care Activities (SDSCA).

The next part of survey will be carried out in 14 days from the first day of testing and will exclude participant with history of neurodegenerative damage or disease, unfinished primary school, those who are treated with medications with impact on cognitive functions or those with abuse drugs or alcohol and impaired vision. In the second part of the study the neuropsychological battery will be examined, including Repeatable Battery for the Assessment of Neuropsychological Status (RBANS™), Ruff 2 & 7 Selective Attention Test, Stroop Color and Word Test and Tower of London (TOLDX 2nd Edition).

Planed analysis: Collected data will be analyzed with SPSS 15.0 statistics. T-test, Mann-Whitney u-test, Wilcoxon matched pairs test or analysis of variance will be used besides descriptive statistic parameters. The (multiple) linear regression and Spearman's or Pearson's correlation coefficient will be applied to estimate to relationship between different variables. In case of dichotomy of dependent variable the logistic regression will be used.

Expected outcomes: Results will provide estimation of severity of mental disorders, depression and problems with cognitive abilities among diabetic patients in Slovenia. High prevalence of mental disorders and depression is expected, especially in patients with worse glycaemic control, longer duration of diabetes and with more diabetic complications. Use of depression inventory that offers identification and evaluation of specific symptoms of Major Depression as delineated by DSM-IV will allowed view in clinical picture of depression at diabetic patients.

Additionally it is expected that the collected data will reveal information about relationship between depressive symptoms and cognitive functions (patients with more depressive symptoms will have statistically poorer memory and attention abilities). Patients with worse glycaemic control, longer duration of diabetes, insulin treatment, more episodes of hypoglycaemia, and with more diabetic complications will have significantly higher level of depressive symptoms and poorer cognitive functions.

Nonetheless the influence of interaction of depressive symptoms and cognitive functions on emotional burden of diabetic patients and on effective self-management of diabetes treatment is foreseen. Survey outcomes will enable better understanding of depressive symptoms, cognitive functions, interaction between them, and other related factors which will contribute to better estimation of global health status of diabetic patients in Slovenia and therefore to earlier identification and treatment of their problems.

Problems, questions for group discussion:

(A) What kind of control group(s) (if any) would be appropriate (healthy participants, other outpatients)?

In case, that the answer is yes, how many persons should be included in control group(s)?

(B) Are chosen instruments adequate?

(C) What are recommended statistical analyses?

Title: Cognitive behavioural therapy in elderly type 2 diabetes patients with minor depression (MIND-DIA-Study). Study design of a randomised controlled trial.

Authors: Petrak F [1], Müller M.J. [2], Hautzinger M. [2]

Institute: [1] LWL-Klinik Dortmund, Universitätsklinik der Ruhr-Universität Bochum Abteilung für Psychosomatische Medizin und Psychotherapie, 2 Universität Tübingen, Klinische Psychologie und Psychotherapie

Aims: To evaluate the efficacy of a diabetes-specific cognitive behavioural group therapy (CBT) for elderly patients with type 2 diabetes regarding quality of life and depression symptoms.

Design/methods:

Subjects: Type 2 diabetes patients (N=315), 65 to 85 years of age, with minor depression or mild major depression.

Design: Multicentre randomised controlled trial comparing medical treatment as usual (TAU) vs. weekly sessions of cognitive behavioural group therapy (CBT) or diabetes self-help group (SH). After 12 weeks of open-label therapy, both group interventions will be reduced to one monthly session in the long-term phase of the study. For the cognitive behavioural therapy group the intervention will be changed into a guided self-help group with a focus on cognitive behavioural techniques. The primary outcome variable is a significant improvement of health-related quality of life at the one year follow-up; the most important secondary outcome variables are reduction of depression symptoms, prevention of moderate/severe major depression, reduction of healthcare costs and mortality.

Interventions: CBT is based on a manualised program (12 weekly sessions) designed for older adults with type 2 diabetes, including cognitive and behavioural strategies to overcome depression and to diminish diabetes-related distress, reduce perceived barriers to various aspects of self-management, and enhance coping skills. Elements are: Psychoeducation, support, problem solving, pleasant activities, activity scheduling, thought control techniques, cognitive restructuring, Socratic dialogue, social skills and interpersonal contact training, crisis intervention, emergency planning.

The psychoeducational SH group with a focus on diabetes will be delivered by diabetes educators. Trainers should pay attention, be empathetic and give support to all patients. Beside a friendly atmosphere, it is allowed to educate patients regarding different aspects of living with diabetes.

The participants of the TAU group and their treating physician will receive feed-back regarding the minor or mild depression symptoms but no protocol is established for a specific treatment.

Planned Analysis: The primary response variable is the z-transformed SF-36 score assessed in the one year follow-up. It is planned, to perform a linear regression (analysis of covariance) of z-transformed SF-36 score on type of intervention and baseline score. The hypothesis will be ordered hierarchically (1:CBT vs. TAU, 2: CBT vs. SH) and the 2nd hypothesis will be tested on a

5%-level only if the 1st test was significant on a 5%-level. Analyses will be performed using an intent-to-treat analysis and the last observation carried forward method will be used for the handling of missing data.

Secondary outcomes (depression severity, prophylaxis of moderate/severe major depression, glycaemic control (HbA1c), and mortality) will be primarily analyzed in a descriptive manner. For binary response variables, numbers and proportion of responders will be presented together with 95% confidence intervals for the proportions and continuous variables will be analyzed using summary statistics. If differences between intervention groups are investigated outcomes will be adjusted for baseline values using appropriate models (linear, logistic, or Poisson regression), however, the p-values for such secondary analyses may not be interpreted like confirmatory findings.

Expected outcomes:

Primary hypothesis: CBT is significantly and clinically more effective than TAU in terms of improvement of generic quality of life (QoL) in the one year follow-up.

Secondary hypotheses: (1) CBT offers a specific advantage and is significantly more effective than SH which is shown by a significantly higher increase in QoL compared to SH-groups in the one year follow-up. (2) CBT is significantly more effective than TAU in terms of improvement of depression symptoms and prophylaxis of moderate/severe major depression, improvement of glycaemic control (HbA1c), mortality and cost-effectiveness, in the one year follow-up.

Funding: Approximately 1.000.000 Euro by the German Federal Ministry of Education and Research (BMBF). The MIND-DIA study will be part of the planned Competence Networks Diabetes in Germany.

Problems and questions to be discussed: Currently the best treatment for minor or mild depression in elderly diabetes patients is not identified. Antidepressants are not superior to placebo and psychosocial interventions were not tested in this patients group. Hence, a TAU is the best control group to test the superiority of a new psychsocial treatment. In order to control for the unspecific effect of a group intervention and to demonstrate specific efficacy the SH group is a good comparator because it represents a widely used group treatment in Germany.

(A) What could be the topics of a self-help group that are suitable for a relatively neutral (´non-therapeutic´) group setting without beeing senseless or boring for the patients?

(B) Are there ideas or experiences for a conceptualisation of a ´directed CBT oriented SH group´? Should we train patients to direct the groups or should professional staff always be involved?

(C) More ideas...?

Title: Establishing validity of the analysis system for self-efficacy training.

Authors: Katarzyna Zinken [1], Chas Skinner [2], Rona Moss-Morris [1]

Institute: [1] School of Psychology, University of Southampton, UK; [2] School of Psychology, University of Wollongong, Australia

Aims: The aim of the study is to establish discriminant and predictive validity of a coding tool – Analysis System for Self-Efficacy Training (ASSET). The study aims to answer the following research questions:

Regarding discriminant validity: Is ASSET sensitive to differences between nurses and to changes in behaviour over time in terms of delivery of self-efficacy based techniques?

Regarding predictive validity: Does the application of self-efficacy techniques by nurses identified with ASSET predict patients' diabetes-related outcomes?

Design and methods:

Participants: Five nurses who run an NHS Starting Insulin Programme took part in the study. Thirteen programmes delivered in two (two hour long) sessions, two weeks apart, were video recorded. Fifty six patients (38 males) took part in the programmes (M = 3, SD = 1.5). The patients were people with type 2 diabetes (age M = 62, SD = 11.5) who were referred to the programme due to their increased blood sugar levels and hence increased risk of cardiovascular problems.

Measurements and Procedure:

Observational measure to assess nurses' behaviour: The application of self-efficacy based techniques by nurses was measured using a reliable coding tool, ASSET (Zinken, Cradock, & Skinner, under revision).

Self-report measures to assess patients' outcomes: At baseline and after finishing the programme patients answered the Insulin Treatment Appraisal Scale (ITAS, Snoek, Skovlund, & Pouwer, 2007). Due to patients' negative response at baseline the adapted self-efficacy, intention and behaviour in relation to insulin adjustment scales were administered after finishing the programme only (Peyrot & Rubin, 1988). Three months follow up data are being collected.

Objective measures to assess patients' outcomes: Insulin titration undertaken in the first two weeks after starting insulin and three months after finishing the programme as well as pre and three months post programme HbA1c level (i.e., glycated haemoglobin) are being recorded.

Current and planned analysis:

Discriminant validity: We measured whether significant differences between nurses and programmes in terms of the use of self-efficacy techniques could be observed when coding with ASSET. Nurses' behaviours were analysed by two independent coders. The coding decisions were annotated in ELAN, a coding software. With ELAN elaborate analyses can be performed in terms of length and duration of used techniques. The inter-rater reliability measured using Cohen's Kappa was high, K=.87.

Predictive validity: Predictive validity is being checked by testing whether there is a link between nurses' verbal behaviours assessed with ASSET and patients' related outcomes. The relation between the frequency as well as length of self-efficacy techniques and patients' diabetes-related beliefs, behaviour and health outcomes is being assessed.

Observed and expected outcomes:

Discriminant validity: Significant differences between nurses in terms of the use of specific self-efficacy techniques were identified. The implementation of self-efficacy techniques varied across programmes delivered by one nurse. The differences were observed in the duration and frequency of the implemented self-efficacy techniques and in the overall speech.

Predictive validity: Preliminary analyses are revealing a relation between the use of self-efficacy techniques by nurses and patients' objective outcomes (i.e., titration of insulin and HbA1c change). However, so far the use of self-efficacy techniques seems not to be related to the self-reported outcomes (i.e., ITAS and self-efficacy, intention and behaviour scales).

Problems and questions to be discussed:

1. Regarding analyses to establish predictive validity of ASSET:

a. How plausible is the rationale for administering the self-efficacy scale after the programme and three months later in a follow up but not at baseline?

b. How should we use the HbA1c records and the information on titration in the analyses? Can baseline HbA1c in people with type 2 diabetes predict insulin titration?

2. Regarding disseminating ASSET to a broader public:

a. What are the potential ways of using ASSET (e.g., Self-learning instrument)?

b. How can we make ASSET available to public and how can we protect intellectual property rights?

Title: The Influence of psychosocial variables on adherence, diabetes regulation and quality of life in children and adolescents with diabetes.

Authors: Kristensen LJ [1], Thastum M [1], Mose AH [2], Birkebæk N [2]

Institute: [1] Department of Psychology, University of Aarhus, Denmark; [2] Departments of Paediatrics, Aarhus University Hospital, Skejby, Denmark

Aims: HbA1c has long been the primary benchmark for successful treatment of type 1 diabetes (IDDM). Recent years have brought an increasing awareness of the importance of psychosocial variables affecting not only treatment, but also the patients' quality of life and their ability to adhere to the different aspects of treatment. However the possible path of correlations between HbA1c, adherence, quality of life and psychosocial variables is still an object of debate.

The relation between different aspects of family functioning and the various treatment outcomes (HbA1c, adherence, quality of life) have been the focus of a number of studies. General and diabetes specific conflict, and supportive vs. non-supportive behaviour especially from mothers of children and adolescents with IDDM has previously been linked with HbA1c, adherence and quality of life in the paediatric diabetes population. Until now only a small pilot study conducted by the researchers behind this project has been undertaken to verify whether these results are applicable on Danish children and adolescents with diabetes.

The prevalence of both depression, anxiety and disordered eating behaviours in children and adolescents with IDDM has been another topic of interest for scientific research, but with differing and ambiguous results. Some studies have found an increased prevalence of both depression, anxiety and disturbed eating behaviour especially among adolescent girls with IDDM, whereas others have not.

As for the connection between these psychosocial variables and treatment “outcomes” a negative correlation has been implied. However a larger scale study would be beneficial in confirming these results.

Through the national Danish Registry of Childhood Diabetes (DRCD) we have a unique opportunity to gain access to biological and treatment related data on most of the paediatric diabetes population (more than 95%).

By statistically comparing the information from the DRCD with the answers from our web-based questionnaire measuring a variety of psychosocial variables, the aim of this study is to gain knowledge of the influence of psychosocial variables on adherence, diabetes regulation and quality of life in the Danish paediatric diabetes population. The information obtained in this study will constitute baseline data in a future longitudinal study of psychosocial variables affecting treatment of IDDM.

Design and methods: All Danish children and adolescents with IDDM who have agreed to be part of the DRCD (N=approx. 1700) and their parents are invited to participate. Each family receives a letter with detailed information about the project and individual passwords, enabling both the child/adolescent and one of the parents to log onto separate versions of our web-based questionnaires differentiated according to the age of the child with diabetes. The initial letter also includes a blood sampling kit, and a franked return envelope, in order to obtain a current measure of the patient's HbA1c-level. Those families who do not have access to the internet will be able to get a paper version of the questionnaire. Information about the project will be advertised in relevant media prior to onset, and we hope to secure the participation of staff members at all hospital units treating children and adolescents with diabetes in reminding the patients of the importance of participation. Approximately one month following the initiation of the study a reminder will be sent to the families who have not yet completed the web-based questionnaire.

Planned Analysis: Data will be checked for normality for the purpose of choice of method of analysis. Where national normative data exists (anxiety, depression, generic quality of life, family structure) study population will be compared to these norms. Relations between the different variables will be analysed as coefficient of correlations, and factor and regression analysis will be employed to decide the weighting of the influence of the different variables. Demographic and biological data on non-respondents will be analysed.

Expected outcomes: We expect this study to show the following:

- Generic and diabetes-specific family functioning is associated with adherence, diabetes regulation and quality of life.
- Family functioning can predict diabetes regulation when adjusted for adherence.
- Family structure and parents' level of education is associated with diabetes regulation.
- The incidence of disturbed eating behaviour is higher among Danish youths with diabetes than among same age peers without diabetes, and is associated with adherence, diabetes regulation and quality of life.
- The incidence of depression and anxiety is higher among Danish youths with diabetes than among same age peers without diabetes, and is associated with adherence, diabetes regulation and quality of life.

Increased knowledge on psychosocial variables affecting treatment "outcomes" in the paediatric IDDM population could be a valuable contribution to the development of tools to assist in identification and prevention of undesirable treatment –related problems and psychological disorders, as well as aiding practitioners in choosing and designing interventions.

Problems/questions: Are there any suggestions on initiatives to secure a good response rate?

Title: The effects of psychoeducation on treatment outcomes in mildly to moderately depressed diabetic patients: a pilot study.

Authors: Mirjana Pibernik-Okanovic, Natasa Andrijasevic, Drazen Begic, Dea Ajdukovic, Zeljko Metelko

Institute: Vuk Vrhovac institute, Zagreb, Croatia

Background and aims: Subsyndromal depression is highly prevalent in diabetic patients, implying an increased risk of developing more severe depressive problems. Simple and feasible interventions capable of reaching a substantial proportion of depressed diabetic patients might be useful in preventing severe depression.

This study is aimed at structuring and applying a four-session psychoeducational course in patients with mild to moderate depressive symptoms, and exploring its effects on depression- and diabetes-related outcomes after 6 and 12 months.

Design and methods: Patients with mild to moderate depressive symptoms, determined on the basis of the CES-D scale, will be allocated to either an intervention or a control group in a randomized controlled trial. The intervention group will undergo psychoeducation comprising four interactive group sessions, and a self-help manual/guide on depression management. The control group will continue with regular diabetes treatment, while being informed about the possibilities of treating their depression.

The intervention consists of 3 interactive small group meetings focusing on the following topics: 1. Symptoms of depression; interaction of depression and diabetes 2. Alleviating burden of depression through activities and problem solving and 3. Associations between depression and cognitive processes – thoughts, beliefs and attitudes that induce and maintain depressive symptoms. Practical tasks are planned to be carried out between the group sessions. The fourth session summarizes the course contents and outlines plans for the future.

The employed learning activities attempt to integrate depression-related and diabetes-related issues. Psychological and disease-related variables, including depressive symptoms, diabetes-related distress, diabetes self-care activies, health-related quality of life and glycemic control are assessed at baseline, and re-tested after 6 and 12 months.

Planned analyses: Between-group differences will be analyzed by t-test and analysis of variance for repeated measures. Each group should consist of 165 patients in order to detect clinically reasonable differences in depressive symptoms (α=.05; power 90%).

Expected outcomes: It is hypothesized that the intervention group will demonstrate better psychological and biomedical indicators after a 6- and 12-month follow-up.

Follow-up results of the pilot sample of depressed diabetic patients: Twenty-four patients completed the 6-month follow-up period and 23 were reachable for the re-assessment – 11 from the intervention group and 12 controls. At baseline, the two groups were comparable with respect to age (p=.10), gender (p=.12), diabetes duration (p=.39), diabetes therapy (p=.60), BMI (p=.50), HbA1C values (p=.90), presence of retinopathy and cardiopathy (p=.89 and .55 respectively), previous psychological problems (p=.93) and the CES-D scores (p=.37). The control group had more frequent neuropathy (p=.04), and the intervention group demonstrated higher scores at the PAID scale – both total score (p=.049) and negative emotions subscale (p=.02). After a 6-month follow-up, the intervention group reported a relatively greater decrease in depressive symptoms as measured by the CES-D scale, but the difference between the groups did not reach statistical significance (p=.76). The groups did not differ with respect to glycemic control either (p=.65), although the intervention group significantly lowered the HbA1C variability. A comparable proportion of patients from the intervention and the control group sought and was recommended psychopharmacological support (p=.30).

The qualitative follow-up data indicated that the treated patients reported experienced support to be most important in improving their well-being.

Problems/questions: Issues that I would like to share with the group members:

(1) Is this intervention to simple to produce effects on depression-related and diabetes-related variables? What would represent a reasonable balance between the intervention's complexity and its applicability in everyday clinical praxis?

(2) Would a measure of motivation to participate in preventive actions (measured, for example, by the Nijmegen Motivation List-Prevention; Journal of Clinical Psychology 2004; 60:555-565) ensure treating patients who want be treated? Would randomizing only patients who find preventive actions acceptable for them improve outcomes?

(3) Generally, do interventions which are recommended to patients on the basis of their screening results (and not chosen by patients themselves) represent a good tool to test the effectiveness of psychological interventions?

Title: Nurse-led motivational enhancement therapy for people with type 2 diabetes.

Authors: Winkley K [1,2], Amiel SA [2], Ismail K [1,2]

Institute: [1] Department of Psychological Medicine, King's College London Institute of Psychiatry, London; [2] Department of Diabetes, King's College Hospital, London

Background: Many people with Type 2 diabetes mellitus (T2DM) maintain their HbA1c over target. Poor adherence and fear of insulin are assumed to contribute but this is poorly understood (Donnan, MacDonald et al. 2002; Farmer, Kinmonth et al. 2006). Our systematic review found psycho-social interventions reduce HbA1c in T2DM by ~0.8% (Ismail, Winkley et al. 2004) but these were mainly delivered by psychologists to small select patient groups and have not been translated into practice. Motivational enhancement therapy (MET) (Miller and Rollnick 1991) can improve unhealthy life styles and has been translatable (Project Match Research Group 1997; Knight, McGowan et al. 2006). There are few trials in T2DM (Clark & Hampson, 2001; Smith West, DiLillo et al, 2007) and there is a need for a well powered study in a multicultural UK population using a brief intervention delivered by trained diabetes professionals to establish methodologies to roll out into the NHS.

Aims: To test whether individual MET delivered by diabetes nurses is more effective than usual care in improving glycaemic control in people with T2DM and persistent suboptimal glycaemic control at 18 months. We would also test whether: usual care plus MET is more effective than usual care alone in reducing cardiovascular risk factors and more cost-effective in improving diabetes control; the number of sessions is associated with sustained improvements in diabetes control; and to identify predictors of psychological and biological outcomes.

Design and methods: We propose a 2 arm parallel Randomised Controlled Trial (RCT) design. The setting includes patients registered at two South London hospital diabetes clinics. The case definition would be potentially eligible adults resident in the London boroughs of Lambeth Southwark and Lewisham, aged 18-65 years who have had diabetes for ≥ 5 years and persistent suboptimal glycaemic control defined as HbA1c ≥ 9% on 2 occasions in the past 12 months despite 2 appointments with a diabetes health professional. Exclusion criteria are i. severe mental disorders ii. terminal illnesses and severe endstage diabetes complications; vi. morbid obesity with a BMI >50kg/m2 as there is usually comorbid psychiatric morbidity; no telephone or mobile phone access as telephone contact is part of the intervention. The hospital electronic patient registers will be used to generate a list of all those potentially eligible. A random sample will be selected and invited to participate by his/her lead diabetes consultant. Patients who consent and meet the study criteria will undergo a run-in period for 3 months to optimise their diabetes care and to reduce the Hawthorne effect. Those participants whose HbA1c remains ≥9% after the 3 month run-in period will be randomised. Baseline measures will be collected at the end of the run-in period before randomisation and will include: main sociodemographics; biological factors including glycaemic control and complication status; psychological factors such

as presence of common ICD-10 mental disorders, diabetes specific distress and fears around injecting and self-testing. We will also include an economic assessment.

Description of interventions:

Group 1: Standard care: We will deliver standardised usual care as recommended by the UK National Institute of Clinical Excellence (NICE 2002).

Group 2: Standard care plus MET: Usual care will continue as described above. The main components of the MET intervention will be manualised. MET is a client-centred, directive method of enhancing motivation to change health behaviours based on a recognition or conviction of a health problem and second the degree of self-efficacy which reflects the confidence in one's ability to bring about a particular behaviour change successfully (Miller and Rollnick 1991; Miller and Rollnick 2002). Participants will receive 4 individual face to face (weekly/fortnightly) sessions from trained diabetes specialist nurses. Sessions will include: standardised assessment and feedback of the participant's perceived problem areas in their diabetes care; the level of importance, confidence, and readiness to change in diabetes specific behaviours; creative writing tasks; and a change plan completed collaboratively. Following the 4 sessions we propose a maintenance phase of 10 coaching support sessions.

Expected outcome: The primary endpoint will be change in HbA1c from baseline to 18 months.

Sample size: A 1.0% difference in HbA1c in the intervention group was used as the minimal clinically acceptable reduction at 18 months. At power of 90%, p=0.05 and standard deviation of 1.8, 107 patients in each arm is required. Assuming a maximum 30% dropout the estimated total sample required is n=306.

Planned analysis: The sample characteristics will be described. ANCOVA will be used to estimate the differences between MET and usual care group in HbA1c level at 18 months using baseline HbA1c and other possible confounding variables as covariates. Subsidiary outcomes (e.g. lipids and weight) will be analysed in the same way.

Problems / questions:

(A) Discussion of the content of the MET intervention.
(B) Discussion of the length and duration of the MET intervention.
(C) Which diabetes-specific and psychological measures should we include?

Title: Motivation for diabetes management based on autonomy. A program for young adults with type 1 diabetes in connection with status appointments at Steno Diabetes Centre.

Authors: Vibeke Zoffmann

Institute: UCSF and Steno Diabetes Centre Copenhagen

Aims: To implement and test a short version of the method Guided Self-Determination (GSD-short) in a program designed to help young adults with type 1 diabetes develop motivation for diabetes management based on autonomy. Two groups of young adults are especially expected to benefit from the intervention: those who are living with persistent poor glycemic control and those perceiving many psychosocial problems related to the illness despite good glycemic control. GSD-short is expected to function both as an intervention and a screening of the population to discover those with psycho-social problems.

Design and methods: From November 2007-January 2008 HCP (nurses, physicians and dieticians) have been trained in using GSD reflection sheets and advanced communication. Currently they are practising under supervision.

Young adults (18-35 years) with type 1 diabetes at Steno Diabetes Centre will in 2008 be invited to participate in a RCT investigating if GSD-short will help them develop autonomous motivation forming part of developing life skills with diabetes and achieving self-determined A1c goals.

Taking into account that young adults are busy being in a process of training and establishing career and family the intervention is offered to the patients within usual time frame in connection with a status visit normally taking place every second year. Patients prepare themselves by filling in two packets of reflection sheets before conversation one with a nurse ("your life with diabetes") and one with a physician 3 months later ("your goals for BG and A1c"). These conversations are expected to initiate a process of developing an autonomy based motivation for diabetes management. Three months later at normal visit in outpatients the patient's self-determined goal for A1c and plans for changing behaviour will be written in the electronic patient journal.

If the first conversation reveals many psychosocial problems or if the diabetes is extremely poorly regulated (A1c ≥ 9.5) a full GSD-program and 5 more appointments will be offered to the patient. Similarly control patients with A1c ≥ 9.5 are offered 5 more appointments (without GSD sheets).

Planned analysis: Differences between the intervention and control group will be analysed at baseline, ½ year and 1 year after first appointment.

Expected outcomes: the intervention group is expected to:

1) report higher autonomy index (scores of autonomous motivation subtracted scores of motivation based on control) (TSRQ);
2) report higher amount of self-monitored BG;
3) higher perceived autonomy support from professionals (HCCQ);
4) higher perceived competence with diabetes (PCD);
5) fewer problems related to diabetes (PAID);
6) lower A1c;
7) fewer appointments cancelled or stayed away from.

Problems and questions: As GSD-short is expected to function also as a screening method of the population of young adults we expect it to provide more information about people's psychosocial needs than a rough definition of the subjective quality of life. See suggested sub groups a,b,c,d (figure 1) according to A1c level and PAID score.

We can compare the information from PAID score and the insight gained by GSD-short. Besides the planned scores we might follow how people move between the groups a-d

	PAID score < 30 Indicates high subjective quality of life with diabetes	PAID score ≥ 30 Indicates low subjective quality of life with diabetes
A1c < 9,5 Well regulated diabetes	A. Well regulated diabetes High subjective quality of life with diabetes.	B. Well regulated diabetes Low subjective quality of life with diabetes.
A1c ≥ 9,5 Poorly regulated diabetes	C. Poorly regulated diabetes High subjective quality of life with diabetes.	D. Poorly regulated diabetes Low subjective quality of life with diabetes.

Autonomy support through GSD-short

Title: Community based diabetes screening: An innovative method of reaching underserved populations.

Authors: Laurie Ruggiero[1] and Willa Lang [2]

Institute: [1] University of Illinois at Chicago; [2] National Kidney Foundation of Illinois

Aims: Estimates are that 171 million people worldwide had diabetes in 2000 and this epidemic is expected to increase to 366 million by 20301. In the US, underserved groups, such as low income individuals and undocumented immigrants, may not have medical homes and therefore are unlikely to be screened for diabetes. As a result, there are many people with undiagnosed diabetes and diabetes related complications, such as kidney disease. Innovative methods are needed to reach and screen underserved groups to promote prevention in those at risk and provide medical care for those newly identified with diabetes. Community based screenings, such as health fairs, school events, and church events, offer one approach to reach people who are unlikely to seek diabetes screenings through a health care provider. One promising model for community based diabetes and kidney disease screening is that of the KidneyMobile of the National Kidney Foundation of Illinois. The aim of this presentation is to describe the community based screening and education model of the KidneyMobile.

Design/methods. The Kidney Mobile is a mobile van that is taken to various community sites, such as schools, churches, businesses, and parks. Screening is conducted for diabetes, and kidney disease, among other health conditions. A variety of tests or measurements are conducted during the screening event: random plasma glucose level with follow-up A1C if elevated; microalbuminuria (protein in urine); pyuria (white blood cells in urine); hematuria (red blood cells in urine); blood pressure; body mass index, and waist circumference. In addition to conducting health screenings, the KidneyMobile staff and volunteers provide the following: (a) educational materials on the prevention and treatment of diabetes and kidney disease; (b) on-site educational sessions on the prevention of diabetes and kidney disease, especially including lifestyle changes; (c) on-site individual feedback on the results of the screenings provided by a nurse practitioner (or other volunteer health professional); (d) referral to a local health clinic for individuals without current health care providers and who need further evaluation and/or treatment; and (e) follow-up calls and support for those referred for further evaluation and/or treatment.

Specifically, individuals are invited to participate in educational sessions conducted in a state of the art classroom in the Kidney Mobile. The educational sessions are focused on the prevention of disease through lifestyle change, especially modification of eating habits. Following the completion of all screening tests, individuals meet one-on-one with a nurse practitioner (or volunteer

health professional) to receive personal feedback on the screening results, individualized counselling, and assistance in obtaining a referral to an appropriate community based health provider if they do not currently have one. If an individual's screening results suggest a need for immediate medical attention, then the individual is referred to the emergency room and assistance is provided to ensure follow-through where needed. Kidney Foundation staff conduct periodic follow-up phone calls to individuals who were identified at screening events to have possible diabetes or kidney disease to ensure that they are able to access the needed medical care.

Planned Analysis. Data on test results, anthropometric measurements, and sociodemographic and health information are currently collected at each screening event. Data entry and analysis on the data collected from screenings is currently underway. Data will be summarized and analyzed to describe the screening participants and the rates of likely cases of diabetes and kidney disease identified in the screening events.

Expected outcomes. The expected outcome is that we will be able to describe the characteristics of community individuals who attend community based diabetes and kidney disease screenings. Another outcome is to be able to describe the rates of cases of newly identified diabetes and kidney disease based on the screening results. In addition, we hope to be able to demonstrate that the Kidney Mobile is a feasible and effective method for screening hard to reach individuals for diabetes and kidney disease.

Problems/questions.

Are community based diabetes screenings being conducted in other countries?

If yes, how are screening events conducted?

Are community based screenings an approach that is accepted, promoted, and/or funded by diabetes associations, corporate entities, or government organizations?

Reference:

Wild, S., Roglic, G., Green, A., Sicree, R., King, H. (2004). Global Prevalence Of Diabetes: Estimates For The Year 2000 And Projections For 2030. Diabetes Care, 27, 1047–1053.

Title: Diabetes self-care coaches: using medical assistants to support diabetes care in primary care clinics.

Authors: Laurie Ruggiero and Diana Ingram

Institute: University of Illinois at Chicago

Background: In the US, the burden of diabetes, including prevalence and risk of complications, is greater for low-income individuals and minority groups, especially Latinos and African Americans. Few controlled studies have focused on strategies to enhance diabetes self-management in minority or other underserved populations. One approach to increasing our ability to reach and impact these underserved groups is to train nonprofessionals or paraprofessionals to work with multidisciplinary diabetes care teams in primary care settings to support optimal diabetes self-management with minimal added expense. The purpose of this study is to develop, implement, and evaluate the impact of an innovative intervention that combines diabetes self-management education, training, and support with aspects of case management delivered by Medical Assistant Coaches (MACs), to support optimal diabetes self-management (and secondary and tertiary prevention) in low-income minority populations with type 2 diabetes.

Aims: The primary aims of this study are:

1. To evaluate the impact of the MAC Intervention on A1C compared to TAU;
2. To evaluate the impact of the MAC Intervention on psychosocial mediators (e.g., self-efficacy, diabetes related distress) and behavioral outcomes (e.g., self-care patterns) compared to TAU;
3. To evaluate the impact of the MAC Intervention on short and longer term biomedical outcomes (e.g., service utilization; quality of life indicators) compared to TAU.

Design and methods: This study compares the Medical Assistant self-management coach (MAC) intervention with “treatment as usual’’ (TAU). Recruitment will occur accross several primary care clinics serving low-income individuals in Chicago. The target sample size is at least 900 African Americans and Latinos receiving care at these clinics. The proposed study will use a prospective randomized two-group split-plot repeated measures design. Specifically, it will be a two (treatment groups: TAU, MAC) by four (time: baseline, 6-month, 12-month, 18-month) repeated measures design. The MAC Intervention is individually tailored based on the Transtheoretical Model and culturally tailored (including Spanish translation). The intervention is also supported by an interactive computer program to facilate standardized assessment, coaching, and provision of educational materials. The MACs receive extensive training in diabetes care, behavior change counseling theory and strategies, diabetes education approaches, and cultural sensitivity. The MAC intervention will be delivered monthly over a one-year period, including both face-to-face contacts during routine primary care visits and regular telephone coaching contacts.

Planned analysis: The primary outcome variable will be glycemic control measured by A1C values. Secondary outcomes include: psychosocial mediators (e.g., self-efficacy, depression, diabetes distress), behavioral outcomes (e.g., self-care behaviors, stage of change), and short- and longer term biomedical outcomes. Questionnaire assessments will be conducted using clinic-based interactive computer approaches (including audio and Spanish translation). The data will be entered online to enhance accuracy and centralize and simplify data management across sites. The primary hypothesis to be tested is that at the end of 18 months in the study, 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 the normal linear mixed model analysis. The factors included in the primary analysis are the experimental Group (MAC vs. TAU) and Time (0, 6, 12, 18 months). The primary analysis will be carried out according to the intention-to-treat (ITT) framework, which requires that patients be analyzed with the group to which they were originally randomized.

Expected outcomes: The expected outcomes are that the MAC Intervention will result in greater improvements in short and longer term biomedical outcomes. It is expected that patients receiving the medical assistant coaching intervention will have improved A1C values across time compared with the TAU group In addition, among the MAC Intervention, it is hypothesized that there will be: (a) greater improvements in lipids, BMI, blood pressure, and cholesterol levels; (b) a greater proportion of individuals receiving annual recommended screenings (e.g., eye exam, foot exam); (c) better attendance at routine diabetes care medical visits and increased referral visits to registered dietitians (RDs), diabetes educators, and other specialists; and (d) greater improvements in quality of life indicators (e.g., fewer ER visits, diabetes-related admissions, missed work days).

Problems and questions to be discussed:

1. Are paraprofessional or nonprofessional individuals used to support diabetes care in other countries; and if so, what barriers are being encountered from health care professionals, health systems, and/or payers in using these individuals to support care?
2. If paraprofessional or nonprofessionals are involved in diabetes care, what models or approaches are being used and how effective are these approaches?
3. What level, amount, and type of training do you think is needed for these other groups to support diabetes care?

Title: Level of depression and anxiety in the main stages of type 2 diabetes: the pilot study.

Authors: Kokoszka A [1], Bojarska M [2], Miszczyszyn Z [3], Radzio R [4], Mućko M [5], Pędziwiatr K [1], Skłodowska Z. [6]

Institute: [1] II Department of Psychiatry, Medical University of Warsaw, Poland; [2] Provincial Specialistic Hospital, Lublin, Poland; [3] Private Clinic of Internal Medicine and Diabetology, Przemyśl, Poland; [4] Nowowiejski Hospital, Psychotherapy Center, Poland; [5] Department of Medical Psychology, Medical University of Warsaw, Poland; [6] Diabetic Outpatients Clinic, SZPZLO Warszawa – Ochota, Poland

Aims: There is no research on relation of intensity of depressive and anxiety symptoms with the main stages of the course of diabetes type 2. Clinical experience suggests, that patients with low mood and increased anxiety may be observed after three crucial events in the course of the diabetes and its therapy: diagnosis of diabetes and initiation of its treatment, beginning of insulin therapy and diagnosis of the first complications. This worsening of mood may be understood as a result of the dysfunction of coping mechanisms, that depends on coping skills of the individual and his or her social support. The aim of the present study is the preliminary verification of hypothesis that the level of depressive and anxiety symptoms depends on time passing from one of three crucial events (diagnosis, beginning of insulin therapy, diagnosis of complications) in the course of diabetes type 2.

Planned analysis: correlations of symptoms intensity and length of time from the last crucial event, analysis of variance and analysis of regression.

Design and methods: 100 consecutive adult patients with type 2 diabetes fills: Hospital Anxiety and Depression Scale (Zigmond, Snaith, 1983); Brief Self-Rating Scale of Depression and Anxiety (Kokoszka, 2008); The Oslo 3-items social support scale (Dalgard, 1996); Family Apgar (Smilkstein, Ashworth, Montano, 1982). Demographic data and data about the course of diabetes, including the current HbA1c are collected.

Expected outcomes: It is a currently conducted pilot study. The results of approximately 100 patients will be presented. It is expected that they will confirm the hypothesis that the current mood of patients with diabetes is related with time distance from one of crucial events in the course of this illness, as well as on social support, including family functioning.

Problems and questions to be discussed: (a) replacement of the applied methods with better ones and/or an inclusion of additional methods and (b) additional statistical analyses.

Title: The soul-D study: the role of psychological and social factors on diabetes outcomes in people with newly diagnosed type 2 diabetes in South-London.

Authors: Winkley K [1,2], Amiel SA [2], Ismail K [1,2]

Institute: [1] Department of Psychological Medicine, King's College London Institute of Psychiatry, London; [2] Department of Diabetes, King's College Hospital, London

Background: The National Health Service (NHS) recognises the bio-psychosocial model for chronic disease. The NHS Quality and Outcomes Framework (QOF) dataset now screens for depression. Those at high risk of Type 2 Diabetes (T2DM) may be socially disadvantaged, factors also associated with more mental health disease. Depression is associated with onset of T2DM (Knol, Twisk et al, 2006), and cross-sectional studies suggest associations between depression and HbA1c (Lustman, Anderson et al, 2000) and prospective studies are needed. Quantifying the impact of depression and other psychosocial issues at diagnosis of type 2 diabetes, on diabetes control, cardiovascular risk and complications 2 years later will inform development of interventions designed to improve mental health status and adapt to other factors found to be important predictors of adverse outcome.

Aims: The main hypothesis is to test whether depression at baseline is independently associated with glycaemic control in adults with T2DM at 2 years. Subsidiary aims are to examine whether:

- QOF screening for depression is prospectively associated with improved health
- diabetes-specific psychological, community and individual social factors (such as ethnicity) at baseline are associated with glycaemic control at 2 years
- depression is associated with diabetes related outcomes such as cardiovascular risk factors and lost productivity at work at 2 years.

Design and methods: A prospective cohort will be used to study a range of explanatory factors and outcomes, repeated measures and temporally assess short- and long-term associations at individual and community levels. The setting includes adults (age 18-75 years) with T2DM from GP practices in the London boroughs of Lambeth, Southwark and Lewisham and Bromley (LSLB) serving a multiethnic and socioeconomic diverse population of approximately 1.25 million. The sampling frame will consist of consenting GP practices. We have conservatively estimated that the average incidence rate of T2DM is ~ 22/10,000 patients. The case definition includes clinically defined diabetes recommended by World Health Organization (WHO) and recent diagnosis (≤6 months). The exclusion criteria are i. severe mental disorders; ii. terminal illness; iii temporary residents and those outside the catchment area of LSLB; iv. other types of diabetes; v. severe endstage diabetes.

Main explanatory variables at baseline:

Psychological factors:

1. The main explanatory variable is depression measured by the 2-item QOF depression screen and the 9-item depression subscale of the Patient Health Questionnaire (PHQ). Participants

who screen positive for depression on the PHQ-9 and a random sample of the non-depressed will undergo further clinical test of depression.

2. Other common mental disorders will be measured using the PHQ (anxiety, panic, phobias and eating disorders) and we will measure disordered eating, smoking and alcohol consumption.

3. Diabetes specific distress will be measured by the Problem Areas in Diabetes scale (PAID). The 30-item Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ), will be used to determine fear of injections.

4. We will assess diet and physical activity.

5. Cognitive status, memory, personality and quality of life will be tested using the Telephone Interview for Cognitive status (TICS-M), National Adult Reading Test (NART), NEO five-factor inventory and Medical Outcomes Survey Short-Form 36 (MOS SF-36), respectively.

Social factors: Individual (such as education and occupational status) and community social factors (such as social deprivation). Work productivity and sickness absence will be measured using the WHO Health and Work Performance questionnaire (HPQ).

Biological factors: Will include, glycaemic control (HbA1c); microvascular complication status; blood pressure; lipids; BMI and waist circumference.

Main outcome: This will be HbA1c at 24 months. Interim HbA1c will be collected at 6, 12 and 18 months. Subsidiary outcomes at 24 months: measures of biological status will be repeated.

Sample size: The prevalence ratio between depressed (the exposed group) and non-depressed (control group) is 1:9. The estimated minimum clinically significant difference in the change scores in HbA1c in the depressed group is 0.5% greater than in the non-depressed group. At a power of 90%, p=0.05 and standard deviation of 1.77, the sample size required was estimated at n=1215 people. Assuming a 30% drop out the total sample required is n=1738. This is powered to also examine differences in cardiovascular risk factors, such as blood pressure.

Planned analysis: The baseline characteristics of the cohort, stratified by depression status, will be presented. Univariate and multivariable analyses of the cross-sectional and prospective associations between depression at baseline and other potential explanatory variables, with outcomes, will be conducted. The primary analysis will be an ANCOVA to examine mean HbA1c at 24 months in depressed and non-depressed groups taking into account the baseline HbA1c and other potential confounders. The effect of potential covariates will be analysed using mediational analysis.

Problems and questions to be discussed:

(A) Are we failing to measure some fundamentally important diabetes cognitions? For example, fears about starting insulin or other medication to control diabetes.

(B) Are there any other diabetes-specific (or other) measures we can and should include?

Title: The self-efficacy effect of a group-based diabetes educational programme in an urban population of nigerian adults with type 2 diabetes mellitus.

Authors: Adeyemi-Doro AO [1] and Tade TA [2]

Institute: Lagos University Teaching Hospital, Lagos, Nigeria. [1] Dept of Medicine; [2] Dept of Medical social services

Aims: To evaluate the empowerment and metabolic effects of a group-based diabetes education programme (DEP).

Design and methods:

General information: The DEP will be located in the Victoria Island local Government Area (LGA) of Lagos state, Nigeria, which is an urban, commercial, metropolitan community.

Trial characteristics: Study is case controlled, with a sample size of 200 subjects and 100 controls.

Sampling method: Convenience sampling method will be used by extending invitations to patients to attend the DEP through primary and secondary care providers in the Local Government Area or through community based publicity.

Participants: Subjects will comprise of Nigerian adults with type 2 diabetes, male and female, between the ages of 30 – 60yrs, who speak English fluently, do not have any visual, hearing or physical limitations that would impede group participation, and who attend and complete the DEP. Subjects having previously attended a formal group educational programme will be excluded. Controls will comprise of patients who meet the above criteria but decline to attend or are willing but do not. Controls will also be matched for age, sex and educational level.

Intervention:

Theoretical model: The Empowerment model will form the theoretical basis of the programme; using problem based learning and the five step behavioral change model.

Subjects will undergo a DEP comprising of a single session lasting for about for 4½ -5hrs (including tea and lunch) and a follow-up session of 2-3hrs six months later. Proposed ongoing support is a 2-3hr session annually. Educators will comprise of a diabetes specialist registrar, clinical psychologist, dietician and community nurse. Venue is a community social meeting point. Group sessions will consist of a minimum of six participants and a maximum of twenty.

A written curriculum for the DEP content has been developed, comprising of general education on diabetes disease process and treatment, lifestyle changes, blood glucose monitoring, complications, psychosocial issues, behavioral change, and will be delivered based on needs assessment. Subject will also develop individual self-management plans.

Controls will undergo routine treatment as given by their care providers.

Outcome measurements:

Empowerment outcomes will be assessed at baseline and follow-up, and at subsequent annual ongoing support programmes. Psychosocial distress will be evaluated using the Diabetes Distress Scale (DDS). Empowerment/Self-efficacy assessment will be determined using the Diabetes Empowerment Scale. Quality of Life measure using the ADDQol diabetes specific instrument. Measures of self-management activities will also be conducted.

Metabolic outcomes to be assessed at baseline and follow-up include, HbA1c measurement using the DCA 2000+ Analyzer (Bayer), Fasting blood glucose (Trinder's analytic method), body weight (Seca), and blood pressure (Omron digital Sphygmomanometer).

Planned analysis: Analysis will be by intention-to-treat. Mean outcomes and mean change from baseline after six months follow-up will be compared. Statistical significance will be taken as P values of <0.05.

Expected outcomes: Statistically significant differences in all outcomes between subject and control groups, favouring improved outcomes for subjects.

Problems and questions to be discussed:

(A) Subjects attending the DEP maybe required to pay out-of-pocket for participation. Will this create a sampling bias?

(B) Will using questionnaires developed and validated in different geographical and ethnic populations create significant drawbacks with regards to result validity?

Title: The experiences of pregnancy and childbirth in women with diabetes; development of a research protocol.

Authors: Cathy E. Lloyd, Sarah Earle, Sally Clifford and Philip Dyer

Institute: The Open University, and Birmingham Heartlands Hospital, U.K.

Aims: 1) to identify the key concerns of women with diabetes in their experience of maternity service provision, 2) to incorporate those concerns in the development of a research proposal which includes the views of both lay people and health care personnel, and 3) to develop appropriate ways of collaborating with service users for the purposes of health services research.

Methods: As part of the development of a research proposal to the UK Department of Health to investigate the experiences of women with diabetes during pregnancy and childbirth, three discussion groups were convened. Women with either pre-existing or gestational diabetes who had experienced the full range of maternity service provision whilst having their baby were invited to participate, along with the diabetes specialist nurse/midwife.

Topics discussed included: pre-pregnancy counselling, services during pregnancy, improving services for pregnant women with diabetes, researching the experiences of pregnant women with diabetes, and involving lay people in research on pregnancy and diabetes. Discussions were audio-recorded and later transcribed for analysis.

Results: Of the 30 women who were contacted and invited to participate, only 5 declined. Thirteen women attended one of three sessions, 7 invitees did not attend and 5 were unable to attend for health reasons. Particular concerns identified by participants include high expectations of service provision which were unfulfilled in practice, problematic relationships with health care professionals and experiences of fragmented care. In all three discussion groups women reported feeling that the health care professionals' over-riding concern was with their diabetes, in particular blood glucose levels and insulin treatment, at the expense of a more positive experience of pregnancy and childbirth. Participants in two of three groups were in favour of the development of new/alternative support systems for mothers-to-be. Poor communication during labour was also highlighted. The presence of the DSN during the discussions may have limited the amount of feedback some attendees felt they could provide. None of the attendees had been involved in any research activities, and all indicated that they were interested in collaborating in a range of ways in the development of a research proposal to investigate issues around diabetes and pregnancy.

Conclusions: This research has shown that it is possible to engage with lay people in order to identify the concerns of women with diabetes who have experienced maternity service provision. Informal discussion groups are an acceptable way of gaining insights into the experiences of women with diabetes during pregnancy. The research priorities of lay people and health care professionals may differ and future challenges include the merging of these priorities to promote further research.

Problems and questions to be discussed:

(A) What criteria for exclusion to the study should be considered?

(B) What medical data (if any) should be collected?

(C) How can we best secure the engagement of service users, not just in terms of participating in interviews but also in terms of active partnership with health care professionals?

Title: A European guideline for preventing diabetes: recommendations on achieving behaviour change.

Authors: Greaves CJ [1], Sheppard K [1], Abraham C [2], Roden M [3], IMAGE guideline development group [4]

Institute: [1] Peninsula Medical School, UK; [2] University of Sussex, UK; [3] Karl Landsteiner Institute, Austria; [4] International collaboration group, led form University of Dresden, Germany

Aims: To summarise, with an emphasis on behaviour change methods, the evidence from systematic reviews and evidence-based guidelines on interventions for promoting physical activity and weight loss in populations at risk of type 2 diabetes. The recommendations will form part of a practice-oriented, evidence-based European guideline for the prevention of type 2 diabetes and its co morbidities (www.image-project.eu).

Design and methods: To date, we have systematically searched Medline, Embase and PsycInfo to identify relevant reviews and evidence-based clinical guidelines. We specifically looked for variation in the effectiveness of interventions due to differences in a) theoretical basis, b) behaviour change techniques used c) mode (group vs individual) or delivery mechanism d) intensity (N sessions, contact time, N techniques used) and e) characteristics of the target population (e.g. age, sex, class and ethnicity). An initial review by two authors of study titles and abstracts identified 20 articles, of which so far 10 have been examined in detail.

Planned analysis: A first draft descriptive summary and critical discussion of this evidence, with extraction of key figures, has been compiled and we will present our preliminary findings. We now seek to consult on the scope of the review and the initial findings, to determine in which directions the review might be usefully expanded. We will present a brief protocol for further searching and synthesis of the evidence, including proposed methods for evaluating and rating the scientific quality of systematic reviews and guidelines included in our review.

Expected outcomes: Our initial findings suggest that there is consistent evidence that a) behavioural interventions for weight loss (through diet or physical activity) are moderately effective, b) more intensive interventions which use formal behaviour change, behaviour maintenance techniques and planned follow-up/review, seem to be the most effective. Beyond these preliminary findings, we expect to be able to make recommendations about intervention structure (e.g. group vs. individual, type of person delivering the intervention, setting), and intervention content (e.g. the role of specific techniques aimed at motivation /intention-formation, supporting action and longer-term behaviour maintenance). We also aim to review the evidence for some specific intervention packages and for community-level interventions. We also plan to make practical recommendations about the development and implementation of lifestyle change programmes in different settings.

Problems and questions to be discussed: We hope that through group discussions at PSAD, we will be able to a) receive feedback about the scope of our reviewing activities and recommendations for specific articles to consider for future inclusion (i.e. should we broaden the scope to include other risk behaviours, or narrow down in some way, and what specific intervention techniques or packages should we seek to examine) b) receive formative feedback about our proposed methods for taking this review forward (e.g. are the proposed quality criteria sound, should we grade the evidence, any other suggestions?).