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- Abstract booklet -

Title: Beyond good intentions: Evaluation of a proactive self-management intervention for screen-detected patients with type 2 diabetes

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Institute: Department of Health Psychology, Utrecht University, Netherlands

Aims: The study Beyond Good intentions evaluates the effectiveness of a behavioral intervention for patients newly diagnosed with type-2 diabetes during a population screening, investigating if a self-management course based on psychological theory is effective on top of and apart from intensive medical treatment in helping newly diagnosed patients to improve their self-management. The intervention takes the form of a brief course, based on the theory of proactive coping and incorporating the elements of anticipation, timing and planning of adequate behavior, to improve diabetes self-care. In a proactive 5-step plan, participants are taught to formulate concrete self-management goals, assess conditions and barriers to goal attainment, plan strategies, and practice and evaluate these strategies via mental simulation.

Methods and patients: 229 diabetes patients were recruited from the Dutch ADDITION study, a screening trial which investigates the effectiveness of early detection and intensive medical treatment in type-2 diabetes, comparing 5-year cardiovascular outcomes of 490 patients randomly allocated to an intensive or usual-care condition. In Beyond good intentions, a factorial (2x2) design was chosen to evaluate the behavioural intervention (experimental versus control) nested within the medical intervention (intensive vs care-as-usual). 81 (of the 123) patients in the experimental group ultimately received the course Beyond good intentions. The 106 control patients received no additional care. Patients completed questionnaires immediately before (t0) and after the course (t1) and at 12 months (t2). The effectiveness of the course was analyzed based on general and domain specific measures of proactive coping, self-efficacy, self-care and weight, using repeated measures of variance analysis to compare groups.

Results: Immediately after the course, at T1, patients in the experimental group reported significantly more proactive coping, higher self-efficacy, a better self-care, (particularly in the domain of physical activity), and significant weight loss (2 kg). The control group reported no changes in proactive coping, self-efficacy or self-care behaviors and actually gained some weight. Preliminary analysis of T2 data suggest that improvements and differences between groups were (marginally) sustained at 12 months, but there was no further improvements in any outcomes, while proactive coping in the experimental group declined to T0 levels. With regard to treatment intensity, there were no differences at T1 or T2.

Conclusions/discussion: A theory driven intervention based on the proactive 5-step plan is effective in helping patients to improve and maintain their self-care, but the lack of further improvements after the course suggests that patients find it difficult to continue using the 5-step plan under changing circumstances and need continual support in managing their disease. Nevertheless, this study shows that brief behavioral interventions do have a surplus on top of and apart from intensive medical treatment in helping recently diagnosed and screen-detected patients to manage their illness.

Title: Efficacy of a new developed education programme (HyPOS) to treat hypoglycaemia unawareness

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Aims: This randomised, prospective multi-centre study was designed to evaluate the efficacy of an education program (HyPOS) for patients with hypoglycaemia problems. It consists of 5 lessons, which focus on the following topics: causes and improvement of hypoglycaemia unawareness, modification of dysfunctional glycemic targets and health beliefs.

Methods and patients: Patients with hypoglycaemia problems were eligible. 164 patients were randomised either to a control group (CG), receiving a standardised training aiming at intensive insulin therapy (n=80), or to HyPOS (n=84). Hypoglycaemia awareness was measured by the hypoglycaemia awareness questionnaire (HAQ) and by a visual analogue scale (VAS). Mild hypoglycaemic episodes (HE) were assessed by data provided by blood glucose memory meters (% of blood glucose < 70 mg/dl).

Results: There were no significant baseline differences between HyPOS and CG (age: 46.2 ±11.6 vs. 45.9 ±13.3 yr.; diabetes duration: 20.3 ±10.7 vs. 22.1 ±10.9 yr.; A1c: 7.1 ±0.9 vs. 7.4 ±1.1%; HAQ: 4.8 ±1.6 vs. 5.0 ±1.7; VAS: 4.3 ±2.4 vs. 4.3 ±2.3; HE: 17.6 ±9.8 vs. 16.0 ±9.2%; severe hypoglycaemic episodes (SHE) treated with glucose or glucagon injection: 0.93 ±2.2 vs. 1.07 ±2.1 events per patient and year). Drop out rate was 10.3%. After a 6 months follow-up hypoglycaemia awareness improved significantly in HyPOS compared to the CG (VAS-□: +1.8 ±2.1 vs. +1.3 ±2.1, p<.05; HAQ-□: 2.7 ±1.9 vs. -2.4 ±2.1 p=.01). The number of HE was reduced significantly (p=.015) by 3.3 ±7.4% in HyPOS compared to 0.3 ±6.4% in the CG. Also the number of SHE dropped to 0.28 ±1.0 in HyPOS compared to 0.45 ±1.3 events per patient and year in the CG (p=.12).

Conclusions/discussion: HyPOS reduced significantly the occurrence of HE, which play an important role in the pathogenesis of hypoglycaemia associated autonomic failure. Also hypoglycaemia awareness improved. Given the rather short follow up period the reduction of SHE in HyPOS is also remarkable. In summary HyPOS seems to be an effective tool for the treatment of hypoglycaemia unawareness.

Title: A systematic review and meta-analysis of randomized controlled trials of psychological interventions to improve glycaemic control in patients with type 1 diabetes

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Aims: Sub-optimal glycaemic control in type 1 diabetes is common and associated with increased psychological distress, morbidity and mortality. We conducted a systematic review and meta-analysis of psychological therapies to assess their effectiveness in improving glycaemic control in type 1 diabetes.

Methods: Medline, Psycinfo, Embase and Cochrane Central Register of Controlled Trials were searched to September 2004. Studies were selected if they were a randomised controlled trial involving participants with type 1 diabetes, children (including adolescents) or adults, and evaluating a psychological therapy (counselling, cognitive behaviour therapy and psychodynamic therapy) to improve diabetes control. Data were extracted on sample size, age and duration of diabetes, type of psychological therapy, its mode of delivery and type of intervention in control group. The main outcome was glycaemic control measured by percentage of glycated hemoglobin. Psychological distress was also measured. Pooled standardised effect sizes were calculated.

Results: 29 trials were eligible for the systematic review and 21 trials for the meta-analysis. In the 10 children and adolescent studies, the mean percentage of glycated hemoglobin was significantly reduced in those who had received a psychological intervention compared to those in the control group (pooled standardised mean difference -0.35 (95% CI -0.66 to -0.04) equivalent to 0.48% (95% CI 0.05 to 0.91) absolute reduction in glycated hemoglobin. In the 11 adult studies the pooled standardised mean difference was -0.17 (95% CI -0.45 to 0.10) equivalent to 0.22 % (95% CI -0.13 to 0.56) absolute reduction in glycated hemoglobin. Psychological distress was significantly lower in the intervention groups in children and adolescents (pooled standardised effect size -0.46, 95% CI -0.83 to -0.10) but not in adults (pooled standardised effect size -0.25, 95% CI -0.51 to 0.01).

Conclusions/discussion: In this review psychological treatments could improve long-term glycaemic control in children and adolescents but the evidence for adults is weak.

Title: A multi-centre randomised controlled trial (RCT) delivering motivational interviewing (MI) to adolescents with type 1 diabetes

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Introduction: Adolescents with Type 1 diabetes experience problems with self care and there are few effective behavioural interventions. Motivational Interviewing is a counselling approach that promotes behaviour change and a considerable amount of research has suggested that MI may be a valuable approach in a variety of health care settings. A pilot study of motivational interviewing and teenagers with Type 1 diabetes indicated a positive effect of MI on metabolic control.

Aims: The aim of the multi-centre randomised controlled trial was to investigate the effects of motivational interviewing on glycosylated haemoglobin and psychological functioning compared to support counselling in adolescents with Type 1 diabetes. The rationale for the RCT was to replicate and extend the findings of the pilot study employing a more rigorous study design.

Methods and patients: A two arm multi centre randomised controlled trial analysed by intention to treat. Sixty-six adolescents with Type 1 diabetes were randomly assigned to intervention and control groups (n=38 intervention and n=28 control) over 5 centres in South Wales, UK. Adolescents received a one year intervention within their homes or a location of their choice. The number of visits were decided by the participant. Measures of mean glycosylated haemoglobin (HbA1c) and a range of psychological questionnaires were taken at baseline, 6 months, 12 months and at one year follow up. The interventionist in the MI group received training and supervision in MI during the intervention which comprised experiential learning methods, quality monitoring of interviews and structured feedback.

Results: At the end of the intervention (12 months) the mean HbA1c in the intervention group was significantly lower than the control group (p=0.04), after adjusting for baseline values. There were significant differences in quality of life, well being and personal models of diabetes. The intervention group scores indicated more positive well-being, improved quality of life and differences in their personal models of illness (all p<0.01). At 24 months, a year after the end of the intervention, the mean HbA1c in the intervention group was significantly lower than in the control group (p=0.039) with significant differences in quality of life with regard to life worry (p=0.001) and anxiety (p<0.001).

Conclusions/discussion: Motivational Interviewing can have a significant beneficial effect on some aspects of psychosocial functioning and glycaemic control in teenagers with type 1 diabetes. A strength of this study is the attention to internal validity through training, quality monitoring and supervision.

Title: Increased risk for depression in patients with type 2 diabetes, but also in women with impaired glucose metabolism: the Hoorn Study

Authors: Pouwer F., Nijpels G., Beekman A.T., Dekker J.M., Heine R.J., Snoek F.J.

Institute: EMGO Institute, VU University Medical Center, Netherlands

Aims: There is accumulating evidence that depression is common in people with type 2 diabetes compared to the general population. However, few studies have investigated the prevalence of depression in people with impaired glucose metabolism. Besides, most prevalence-studies are uncontrolled and may also suffer from selection-bias, as they are conducted in specialized treatment settings. We studied the prevalence and risk factors of co-morbid depression in a community-based sample of older adults, comparing three groups: 1) type II diabetes patients 2) subjects with impaired glucose metabolism 3) normal glucose metabolism.

Methods and patients: We used cross-sectional data from the population-based Hoorn Study, which included 1366 Dutch men and women aged 50-74 years. An OGTT was performed and depression was measured using the CES-D, a validated depression questionnaire. Pervasive depression was defined as a CES-D score > 15.

Results: The prevalence of pervasive depression was significantly increased in people with type 2 diabetes (15-24%) and women with impaired glucose metabolism (23%) compared with participants with normal glucose metabolism (8%). The prevalence of depression was not increased in men with impaired glucose metabolism (7%).

Conclusions/discussion: Results suggest that the prevalence of depression is not only increased in patients with type 2 diabetes, but also in women with impaired glucose metabolism. Potential mechanisms will be discussed.

Title: A comparison of diabetes-related cognitive and social perceptions of type 2 diabetes patients and their non-diabetic spouses in a Canadian and UK sample

Authors: Nouwen A.¹, Lafontaine M.-F.², Belanger C.³

Institute: ¹ University of Birmingham, ² University of Ottawa, ³ University of Quebec at Montreal

Aims: For many patients the demands of their regimen and the presence of diabetic complications are likely to interfere with daily activities and impact upon their quality of life. It is therefore not surprising that diabetes, its management as well as the presence of complications may induce considerable stress in the lives of those concerned. Given that most self-care activities are carried out in the familial environment it is astonishing that only a few studies have examined the relationship between marital interactions and diabetes self-care. The aims of the proposed study are twofold: (1) to investigate perceptions of self-efficacy to follow dietary self-care recommendations and self-efficacy to provide support of both the person with diabetes and their spouses; and (2) to test the validity of the proposed theoretical underpinnings.

Methods and patients: Ninety-six adult-patients with type 2 diabetes (52 men) (50 from the UK and 46 from Quebec, Canada) and their non-diabetic spouses participated in the study. Mean age was 63.0 years (SD 8.2). Selection criteria for each couple include: (a) one of the spouses diagnosed with type 2 diabetes, (b) diabetes for at least 3 years, c) no major changes in diabetes-related medication for the past 3 months, and (d) the couple have been cohabiting for at least 6 months. Both spouses filled out questionnaires on (a) general and demographic information, (b) SDSCA and dietary habits, and (c) dietary self-efficacy, (d) support efficacy, (e) MDQ, (f) diabetes knowledge, and (g) the Dyadic Adjustment Scale.

Results: Patient's responses and those of their non-diabetic spouses are moderately correlated with the exception of perceptions of support. UK patients report more misguided reinforcement behaviours (nagging) from their spouses but also more positive effects from following self-care recommendations. There were no significant country by spouse interactions. Using Bayesian posterior probabilities, MDQ responses from patients were assigned to one of three patient psychosocial profiles. Spouses of patients in the low support – low involvement profile reported giving less support than those in the adaptive copier profile and also had less confidence in their diabetes partners' ability to follow their dietary recommendations than spouses in the adaptive copier or spousal over-involvement profile. There were no significant country by profile interactions. The relationships between dietary self-efficacy beliefs of both spouses and misguided reinforcement behaviours were also examined. As expected, there was a significant negative correlation ($r = -.40$) between 'nagging' and spouses confidence in the ability of their diabetic spouses to self-manage their diabetes. In other words, spouses who doubt the ability of their diabetic spouses to follow their dietary recommendations on a regular basis nag more.

Conclusions/discussion: This study provides further support for the validity of the Psychosocial Taxonomy for diabetes. There appears to be close agreement between perceptions of individuals with diabetes and those of their non-diabetic spouses. The implications for the development of self-care programmes involving spouses of individuals with diabetes will be discussed.

Title: Memory functioning in type 2 diabetes

Authors: Miclea S.

Institute: Clinical Centre of Diabetes, Nutrition and Metabolic diseases, Cluj-Napoca, Romania

Aims: To investigate the nature and extent of memory deficit in people with type 2 diabetes and to assess the effects of other risk factors on memory performance.

Methods and patients: This study compared 123 persons having type 2 DM with 52 healthy controls. Explicit short and long term memory and implicit memory tests were administered, as well as depression and anxiety inventories. Information about other factors related to cognitive functioning, including demographic characteristics, laboratory data and co morbid conditions were obtained from medical records.

Results: The performance of people with type 2 DM is significantly impaired for all memory systems. Persons with type 2 DM also have higher anxiety and depression levels than healthy subjects. Using the multiple hierarchical analysis we found the demographic characteristics account for 16% of the variance and the level of triglycerides explain other 15% ($\beta=-0.393$, $p=0.0001$) of the variance of short-term memory performance. The main predictors of implicit memory performance are also the demographic characteristics (explaining 23.7% of score variance) and the depression severity (r^2 change = 0.061, $\beta = -0.231$, $p=0.02$). The implicit memory performance is also related to high levels of blood pressure but not with the diagnosis of hypertension.

Conclusions/discussion: The memory functioning is significantly impaired in people with type 2 DM. The memory deficit is increased when high levels of triglycerides, blood pressure and depression are present. Measuring the values of BP has a greater clinical relevance than the diagnosis of hypertension. In order to prevent or improve the cognitive deterioration, these modifiable risk factors for impaired memory function in type 2 DM request a more structured and focused practical approach.

Title: Susceptibility to type 2 diabetes: perceptions and family communication regarding inheritance and primary prevention

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Introduction: Besides known risk factors for type 2 diabetes, e.g. older age, obesity, and lack of physical activity, evidence has been found for genetic factors in the pathogenesis of type 2 diabetes. People are more at risk if there is a history of diabetes in close family members, and there is strong evidence for an ethnic susceptibility to type 2 diabetes. In the fight against the diabetes epidemic, providing information to high-risk populations is important. In our opinion, the issue of awareness raising among family members of type 2 diabetes patients deserves more attention. Patients as well as diabetes professionals might play an important role in this process.

Aims: In this project, we will investigate perceptions of type 2 diabetes patients and their relatives on the familial character of diabetes and their knowledge of primary prevention. We wonder to what extent diabetes is an issue in 'diabetes' families. We also are interested in ideas and intentions of diabetes professionals (physicians, family practitioners, nurses, and dieticians) notifying type 2 diabetes patients on inheritance and eventually coaching them in the process of family communication. Four research questions are formulated:

1. Do type 2 diabetes patients worry about their relatives' health regarding diabetes, and if yes, do they communicate their worries?
2. Is inheritance an issue in families of type 2 diabetes patients? If yes, how do family members cope with the consequences of their increased susceptibility?
3. Do type 2 diabetes patients need information on diabetes and inheritance and/or coaching by diabetes professionals in the family communication process?
4. Do diabetes professionals inform type 2 diabetes patients on diabetes, inheritance and the possibilities of primary prevention, and what do they think of coaching patients in the process of family communication?

Design & methods: Type 2 diabetes patients, as well as first degree family members, will receive questionnaires by mail. Questions will be asked about perceptions and knowledge of inheritan-

ce of type 2 diabetes and primary prevention. In order to assess detailed information on family communication, we will discuss the familial character of diabetes with patients in focus group sessions and interrogate family members with in-depth interviews. Diabetes professionals will receive short questionnaires by email asking about inheritance as a potential subject in standard type 2 diabetes care. We also will invite diabetes professionals to join in focus group sessions in order to discuss practical implications of informing patients on diabetes and inheritance and eventual adjustment of standard diabetes care protocols.

Planned analysis: Questionnaires will be analysed using statistical methods using univariate analysis as well as multivariate logistic regression analyses. Data from focus group sessions and interviews will be analysed in a qualitative content analyses using Nvivo, a statistical package for qualitative research.

Expected outcomes: We know communication about genetic risk within a family is influenced both by pre-existing familial, social and cultural factors and by individuals' responses to risk information. If we understand better how these factors operate in families with high risk on type 2 diabetes, we will be able to identify effective strategies which can be implemented in diabetes care and diabetes prevention programs. Including diabetes professionals in this study provides insight in their attitude regarding informing and coaching type 2 diabetes patients in the family communication process and the practical consequences this will induce.

Problems/questions:

1. What would be the best methodology to investigate patients' interactions with family members (in our research the family system includes first- and second degree relatives)? Are there specific measures recommended in the study of family interactions regarding genetic topics and/or preventive information?
2. How to promote ('agenda setting') genetics of type 2 diabetes and family communication as an issue for diabetes professionals (taking into account perceived importance and practical consequences)?

Title: Diabetes prevention: Reaching diverse populations where they live

Authors: Ruggiero L.

Institute: University of Illinois at Chicago, Illinois Prevention Research Center, USA

Aims: The aims of the research program are to collaborate with a diverse Chicago, Illinois community to: (1) tailor and enhance the successful DPP lifestyle intervention for diverse community residents; (2) identify, recruit, and train community members to serve as Lay Health Advisors (LHA) to deliver and sustain the intervention in the community; (3) recruit community based organizations (e.g., schools, Faith Based Organizations, parks) to serve as intervention settings/sites; and (4) conduct an implementation study that examines the final community-tailored and enhanced lifestyle intervention program delivered by community based LHAs.

Design/methods: The first phase of this project is to develop and pilot test a community tailored version of the DPP lifestyle intervention delivered in group format by community members in community settings. The Chicago community includes 41% Latino/Hispanic, 36% African American, and 21% white non-Hispanic residents. Almost 20% of community residents speak primarily Spanish, 43% are bilingual; with over 80% of these speaking Spanish and English. Approximately 14% of community families have annual incomes below the poverty level. Eligibility criteria for the study include age 18 years and older, African American or Latino, overweight or obese, and not diagnosed with diabetes. The second phase of the project is an implementation study examining the final intervention program with a three-occasion (Baseline, 6-month Follow-up, 12-month Follow-up) completely within-subjects repeated measures design. The planned sample size is 200 community residents.

Planned Analysis: The three primary outcomes, healthy eating, physical activity, and BMI, will be examined using a multivariate repeated measures analysis of variance(MANOVA) that includes a within-subjects main effect for Occasion, as well as a between-subjects factor for site (e.g., school).

Expected outcomes: Development of a successful community tailored and enhanced version of the DPP Lifestyle intervention.

Problems/questions:

1. How do we translate the successful DPP lifestyle intervention from the clinic to the community to reach a broader population at risk?
2. What barriers to participation or retention should be anticipated and how can they be overcome?
3. What additional approaches or enhancements (e.g., support, policy changes, environmental changes) are needed to maximize success of a community based lifestyle program?

Title: Quality of life – can we make it person-centred and flexible?

Authors: Skinner T.C., Barnard K.D., Murphy H.

Institute: University of Southampton, United Kingdom

Introduction: Quality of life is being increasingly recognised as an important outcome in health care. However, measures are currently driven by the need to meet psychometrics criteria, without dealing with conceptual issue first. The validity and reliability of such measures must be questioned because validity is defined by the tool developers and reliability is a self-fulfilling prophecy. If we are calling for patient centred care then we should we also develop patient centred measures. Furthermore, tools that just produce a score will have little clinical utility, and as a result will not engage health care professionals. The SEIQOL is widely acknowledged as an exemplar tool to assess the subjective experience of quality of life from the individual's perspective. Unfortunately, it requires a highly skilled interviewer to administer, it is lengthy to complete and it is uncertain whether it provides clinically useful feedback. The Patient Generated Index (PGI) is a measure of quality of life that hopes to combine the benefits of the SEIQOL but address these issues.

Methods: As part of an RCT of Continuous Glucose Monitoring System (CGMS) in pregnancy, an opportunity was taken to conduct a pilot of the PGI, with participants (n = 23) asked to complete it once in each trimester and post pregnancy. This pilot work, along with personal clinical use identified a number of issues:

- People find it hard to complete the first time, but subsequent completions are not a problem
- Interesting, the order in which issues are thought of as impacting on participants quality of life were not related to the importance of the issue
- The issues/areas of concern raised by participants change over time
- Discussion of the PGI has clear clinical utility
- The measure does generate a meaningful and interpretable score

Problems/questions:

1. Can we prompt/help completion of the form without creating/influencing issues?
2. How do you evaluate psychometrics of a measure that takes a different format to traditional measures?
3. How do you assess the clinical utility of a measure and what represents meaningful change – score lower, score less important, an issue no longer a problem?

Title: The role of psycho-social factors in metabolic syndrome: A cross-sectional survey

Authors: Bogatean M., Miclea S., Hancu N.

Institute: Clinical Center of Diabetes, Nutrition and Metabolic Diseases, Cluj-Napoca, Romania

Aims: This cross-sectional survey was aimed to study the relationship between different components of the metabolic syndrome in people with diabetes and certain psycho-social aspects.

Materials and method: So far, 100 people with type 1 and 2 diabetes were assessed using a comprehensive, self-administered survey, comprising: demographic, ethnic, cultural and religious characteristics, income, the structure and the functioning of the social network, work-related factors, presence of emotional disorders and stress, lifestyle factors, adherence to medical recommendations. Laboratory and anthropometric data are also collected.

Planned analysis: Comparisons on psycho-social parameters between people with/without metabolic syndrome, analysis of variance of different aspects of the metabolic syndrome, according to variances in psycho-social parameters.

Expected outcomes: According to the current literature and as the results show so far, we expect to find that people with metabolic syndrome have a higher level of education, higher income status, experience more stress, have less healthy food-choices and are less physically active than people without metabolic syndrome.

Problems/questions:

Is diabetes making a difference?

Title: Study design of the Diabetes and Depression Study (DAD Study). Cognitive behavioural therapy vs. sertraline in patients with depression and poorly controlled diabetes mellitus: A randomized controlled trial

Authors: Petrak F., Hermanns N., Kulzer B., Meinert R., Müller M.J., Schmidt L.G., Herpertz S.

Institute: Department Psychosomatic Medicine and Psychotherapy, Westfaelische Clinic Dortmund/Ruhr-University of Bochum, Dortmund, Germany

Aims: To compare the efficacy of diabetes-specific cognitive behavioural therapy vs. antidepressive medication, specifically the selective serotonin reuptake inhibitor (SSRI) sertraline, regarding improvement of glycaemic control in patients with poorly controlled diabetes and depression.

Design & methods: Subjects: Patients with insulin-treated type 1 or type 2 diabetes mellitus with depression and HbA1c-value > 8%. Design: Multicentre randomised controlled trial (RCT) comparing sertraline vs. CBT. After 12 weeks of open-label therapy, only the treatment-responders (50% improvement of depression) of both groups will be included in the one-year long-term phase of the study. In the long-term phase, diabetological treatment as usual will be given to both groups. CBT-responders will receive no further treatment, while SSRI-responders will be given a sustained sertraline regimen as relapse prevention. The primary outcome variable is a 1% improvement of the HbA1c at the one-year follow-up; the most important secondary outcome variable is remission of depression.

Planned Analysis: The primary analysis population is the intention to treat population which consists of those patients who enter the 12-month follow-up phase. However, if in the short-term phase dropout rates in the two treatment groups differ by more than 10%, then the primary analysis will employ all randomized patients. The reason for this procedure is that the comparison of long-term treatment effects on glycaemic control in patients who have an initial short-term improvement of depressive disorder (HAMD reduction $\geq 50\%$) is valid only if the dropout rates in the short-term phase are similar. The primary analysis is based on the numbers and proportions of patients who demonstrate improvement of glycaemic control. Differences between treatment groups will be tested using Fisher's exact test. The following exploratory secondary analyses are planned (among others): first, to investigate whether improvement in depression shows a stronger association with better HbA1c in the CBT group than in the ongoing medication group; and second, if this is the case, to test if the degree of diabetes self-care will increase more in the CBT group than in the ongoing medication group.

Expected outcomes: We expect that (a) CBT is superior to SSRI regarding improvement of glycaemic control at the one-year follow-up; and (b) both interventions are effective in terms of remission of depression after 12 weeks as well as at the one-year follow-up.

Title: Identifying successful interventions for enhancement of self-efficacy

Authors: Zinken K., Skinner T.C.

Institute: University of Southampton, UK

Aims: Self-efficacy is the most often utilized construct in behaviour-change interventions, having predictive strength regarding future behaviours. Remarkably, an evaluation framework, which would enable assessment of treatment fidelity (i.e. the extent to which the facilitators acted in line with self-efficacy theory), is missing. Thus, the study aims to develop and utilize a self-efficacy coding framework in order to evaluate delivered interventions and identify successful strategies for enhancement of self-efficacy in diabetes care.

Methods: The coding framework: Analysis System for Self-Efficacy Training (ASSET), was derived from self-efficacy theory. Successful self-efficacy enhancing interventions were collected from intervention studies, training protocols and self-management programmes for people with diabetes based on self-efficacy theory to further develop the theoretical coding framework. Videos of 12 three-hour-sessions and a one-day seven-hour session, run by five facilitators, were analysed using ASSET.

Current & Planned Analysis: Currently, facilitating behaviours of health professionals delivering self-management interventions are being evaluated in terms of self-efficacy implementation. Inter-rater agreement of four coders (two psychologists, research nurse and practise nurse) is being assessed to establish mutually exclusive categories and improve the reliability of ASSET. In the next step, a study to determine validity of the coding framework will be conducted.

Expected outcomes: A structured evaluation of educational programmes help to understand the components which contribute to behaviour change and processes of efficient intervention delivery, and to identify successful strategies in diabetes care.

Problems and questions:

Regarding reliability of the coding frame:

1. How to establish mutually exclusive categories?

Regarding construct validity of the coding frame:

2. Does the coding frame enable to assess the self-efficacy oriented interventions?

Regarding predictive validity of the coding frame:

3. How to evaluate the predictive strength of self-efficacy oriented interventions delivered within a group?

Title: The personal experience of diabetes and self-care

Authors: Stothard K.

Institute: Open University, United Kingdom

Aims: This study looks at the connection between illness representations, self-efficacy, self-care and HbA1c level using Leventhal's Common Sense Model of Illness Representations as a theoretical framework. The suitability of Leventhal's model will be explored, and the differences between the experiences of people with type 1 and type 2 diabetes will be investigated. This study also aims to explore the possibility that any differences in experience lead to diverse illness representations and self-efficacy beliefs being produced which may impact on levels of self-care behaviour.

Methods and patients: A two stage study, using a mixed-methods approach was designed. In stage one, 101 participants completed a series of questionnaires. The participants were aged between 30 and 55, were Caucasian and had been diagnosed with either Type 1 (n=44) or type 2 (n=57) diabetes for at least one year. The questionnaires consisted of demographic information, the Diabetes Illness Perception Questionnaire – Revised (Moss-Morris et al., 2002), the Summary of Diabetes Self-Care Activities Measure (Toobert et al., 2000), an adapted version of the Self-Efficacy Scales (Grossman et al., 1987) and a diabetes complications checklist. In stage two, semi-structured interviews were conducted with 12 of the participants who took part in stage one. These were selected on the basis of type of diabetes, sex and self-reported level of self-care behaviour.

Conclusions/discussion: Preliminary results of the statistical analysis of stage one and initial themes emerging from an interpretative phenomenological analysis of stage two will be presented.

Title: Does glycated hemoglobin vary according to young diabetics' life styles or attitudes towards diabetes?

Authors: Bregani P.

Institute: Centro di Endocrinologia dell'Infanzia e dell'Adolescenza. Università Vita-Salute S. Raffaele, Milano Italy

Aims: To identify young diabetics' habits and attitudes that might present correlations with the values of their glycated hemoglobin. This report refers to the first part of a research that will be over at the end of 2006. Patients: 41 subjects, aged 15-19 years, 21 females and 20 males.

Methods and patients: When attending the out-patients' department for the routine check-ups the subjects are asked to fill in a questionnaire investigating the habits referring to socialization and emancipation processes, levels or awareness of assets and problems regarding diabetes, prevalent reactions when facing the thought of the complications of diabetes. For each subject the value of glycated hemoglobin is recorded.

Results: Analysing the data of the questionnaire combined with the scores of glycated hemoglobin, the sample was divided into 2 groups, one with 30 subjects with glycated hemoglobin 8,4 or lower, the other with 11 subjects with glycated hemoglobin 8,5 or higher. The first group was found more advanced with regard the style of life favouring the emancipation processes (they got higher scores answering the items "My parents allow me to do experiences away from family"); the second group, when confronted with various reactions to the thought of complication ("To try not to indulge in the thought, thinking or doing something else", "To try harder to get a good glycemic control", "To feel depressed seeing the task too difficult", "To ask help or advice to parents, doctors or to other young diabetics"), was found to choose with greater frequency the first option.

Conclusions/discussion: The findings drawn from this first part of the investigation give us some hints: experiences away from family, important for all adolescents, seem to have positive influence on the treatment of diabetes; for the subjects with the worst glycated hemoglobin who resort more frequently to the defence mechanism of denial a psychological support is advisable to help them to face their problems with a constructive approach.

Title: Qualitative study into quality of life benefits associated with insulin pump use

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Aims: There is a current lack of published qualitative studies available to inform the quality of life issue of insulin pump use. This study aimed to elicit the experiences of current insulin pump users in a qualitative manner in order to discover the benefits, down sides and effects on their quality of life actually living with an insulin pump provides.

Methods and patients: Current insulin pump users were recruited as they contacted a Roche customer service helpline. Participants were briefly interviewed by telephone about their experiences of living with an insulin pump. Four questions were asked, covering benefits of insulin pump use, any effects on quality of life, whether participants had experienced any down sides to using their insulin pump and any other issues participants wished to raise.

Results: 80 insulin pump users participated in the study. All 80 participants reported both experiencing benefits to using an insulin pump and that insulin pump use had positively affected their quality of life. Key positive themes emerging from the data included greater control (45), greater flexibility (33), increased freedom (28), convenience (7) and independence (5). Interestingly, 58.75% of participants reported down sides to insulin use, with key themes including the size of the pump and difficulties with its concealment (25), technical issues and when things go wrong (17), cost (3) as well as marks on skin, allergies and pain (5).

Conclusions/discussion: Participants overwhelmingly reported experiencing benefits and improvements in their quality of life associated with insulin pump use. For this population, i.e. current insulin pump users, the down sides clearly do not outweigh the benefits as they remain on pump therapy, however, the results of this study may go some way in explaining why some people only stay on pump therapy for a short period of time.

Title: Beliefs about medicines and personal models of diabetes in relation to adherence to medication in patients with type 2 diabetes

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Aims: To explore the relationship between beliefs about medication, personal models of diabetes and adherence to medication in patients with type 2 diabetes.

Methods and patients: 133 participants with type 2 diabetes, aged 35-70 and treated exclusively with OHA prescriptions for more than 1 year, completed questionnaires assessing beliefs about medicines, personal models of diabetes, satisfaction with treatment, self-efficacy for and barriers to medication taking, knowledge about prescriptions and a subjective measure of adherence.

Results: Most (90%) participants believed that specific medicines prescribed for their diabetes were effective and necessary. However, 60% were worried about the potential long term effects of this medication and 25% felt that medicines were overused by doctors. Personal models of diabetes were related to more general beliefs that medicines are harmful addictive substances, to forgetting to take medication ($p = .004$), altering the dose to suit personal needs ($p = .016$), a perception of being able to cope without medication ($p = .003$) and self-efficacy for medication taking ($p = .001$). Lower self-efficacy was related to higher HbA1c ($p = .008$) and BMI ($p = .004$).

Discussion: These results will be discussed in terms of the complex beliefs that people hold about their medication and diabetes which may have a significant impact on self-management and influence adherence to treatment.