PSAD
PsychoSocial Aspects of Diabetes

The 19th PSAD Scientific Spring Meeting

9 – 11 May, 2014

Santpoort, the Netherlands

# PROGRAMME &

# ABSTRACTS

Dear members,

Welcome to the 19th Scientific Spring Meeting of the PSAD Study Group, welcome to The Netherlands! Ten years ago, in 2004, PSAD members met in Amsterdam, and for this year's meeting Santpoort is the venue. The meeting will take place at a scenic estate, "Landgoed Duin & Kruidberg", located in the National Park "Zuid-Kennemerland", close to Amsterdam and Haarlem. The main building was constructed in 1907 by a tobacco and tea trader named Jacob Theodoor Cremer. At that time, he and his wife Annie Hogan owned the biggest house in The Netherlands. Cremer was also a politician; he was member of the Tweede Kamer (House of Representatives). In wintertime, the Cremer family lived in Amsterdam, during the summer they moved to Duin and Kruidberg.

Please take a look at this year's PSAD scientific programme, which as always looks very interesting.
In line with our tradition, the meeting will start with the Anita Carlson lecture. We are very pleased that our colleague Dr. Deborah Christie, University College London Hospitals NHS Foundation Trust (UCLH), has accepted our invitation to give the 2014 lecture. Deborah is a licensed Consultant Clinical Psychologist and Honorary Reader in paediatric and adolescent psychology. She is currently clinical lead for the department of child and adolescent psychological services which has an international reputation for its application of systemic psychological practices in the care of young people with chronic illness. The title of her presentation is: "Young people living with diabetes: finding ways to understand what they understand". After the lecture, there will be a welcome reception and dinner.
Saturday morning will start with the PSAD/Novo Nordisk Science Award, followed by work in progress presentations. To make sure that members also have enough time to meet each other, we have organized parallel sessions between 10:40 and 11:40. Before lunch, a debate will take place, focusing on the –almost Shakespearian- question: to screen or not to screen for depression?
After lunch, an overview will be given about the recently conducted DAWN2 study. This large international study focused on the psychosocial aspects of diabetes and was conducted in 17 countries, and 4 continents. We will continue with completed work and at

16:15, all members who are interested in research into the associations between depression and diabetes, are invited to attend the EDID meeting (European Depression in Diabetes research consortium). Around 17:30, the social programme will start.
Sunday we will start with two parallel round table discussions: we aim to achieve highly interactive, informative and valuable discussions! This year, the discussions will focus on "How to write a successful grant application" (Prof. Frank Snoek and Dr. Suzanne Pieper) and "Qualitative research methods" (Dr. Cathy Lloyd and Dr. Julie Smith). The meeting will continue then with members presenting more work in progress and the business meeting.

On behalf of the Executive Committee, and the local organiser, Dr. Maartje de Wit (VUmc, Amsterdam), I wish you a rewarding, informative meeting, with interesting contacts and an opportunity to enjoy the beautiful house and estate "Duin & Kruidberg"!

Prof. Frans Pouwer,
Chair of the PSAD

## Programme

**Friday, 9 May** Room: Parijs & Zurich

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| 17.00 – 17.15 | Welcome - Opening remarks | Frans Pouwer |
| 17.15 – 18.00 | **Anita Carlson Lecture**<br>Young people living with diabetes: 'Finding ways to understand what they understand' | Dr. Deborah Christie<br>Clinical Psychologist and Honorary Reader in paediatric and adolescent psychology at University College Hospital in London, UK |
| 18.00 – 18.30 | Discussion | |
| 18.30 | Welcome reception and dinner at the hotel | |

**Saturday, 10 May** Room: Parijs, Zurich & Amsterdam Buitenveldert

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| 8.30 – 9.00 | PSAD/Novo Science AWARD | Chair: Frans Pouwer |
| 9.00 – 10.20 | Work in progress | Chair: Cathy Lloyd |
| 9.00 | Kaleidoscope Model of Care | Katharine Barnard |
| 9.20 | Designing and implementing effective behaviour change interventions to improve outcomes in diabetes: Identifying behavioural research priorities | Molly Byrne |
| 9.40 | Are interventions to reduce diabetes-specific distress effective? | Kathryn Dennick |
| 10.00 | Can multimedia technology be used for the effective delivery of diabetes structured education programmes? | Debbie Cooke |
| 10.20 | Tea/Coffee break | |
| 10.40 – 11.40 | Parallel session: Work in progress | Chair: Christel Hendrieckx |
| 10.40 | Type 1 diabetes in the family: An exploratory study of family challenges and resilience factors and their translation into a research based framework for family interventions | Ulla Møller Hansen |
| 11.00 | Emotional problems in adolescents with type 1 diabetes and their parents/caregivers: the true scope of the problem | Per Winterdijk |
| 11.20 | 'It makes a difference, coming here': a qualitative exploration of barriers and facilitators to clinic attendance among young adults with type 1 diabetes | Lisa Hynes |
| 10.40 – 11.40 | Parallel session: Work in progress | Chair: Arie Nouwen |
| 10.40 | Cultural adaptation of a web-based cognitive behavioural therapy programme for Turkish diabetic patients with depressive symptoms | Emine Kayan |

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| 11.00 | Effects of liraglutide on cognitive functions and mood in patients with type 2 diabetes mellitus | Anna Pogorelova |
| 11.20 | Identification of novel biomarkers linking depression and diabetic foot ulcers: potential targets for the prevention of first foot ulcer | Zola Mannie |
| 11.30-12.30 | Debate | |
| | To screen or not to screen for depression? | Norbert Hermanns & Cathy Lloyd |
| 12.30– 13.30 | Lunch | |

Saturday, 10 May (continued) Room: Parijs & Zurich

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| 13.30-14.15 | DAWN2 overview | Frans Pouwer |
| 14.15-15.15 | Completed work | Chair: Giesje Nefs |
| 14.15 | Diabetes treatment: a psychological impact analysis | Mónica Carreira Soler |
| 14.30 | Motherhood and diabetes: a research program on childbearing in women with type 1 diabetes | Carina Sparud Lundin |
| 14.45 | Flexible guided self-determination intervention for young adults with poorly controlled type 1 diabetes improved glycemic control and psychosocial functioning in women but not in men: a real life randomised controlled trial | Vibeke Zoffmann |
| 15.00 | Binge eating and problems with implementation of the treatment with insulin analogues among patients with type 2 diabetes. Results of initial analyses | Andrzej Kokoszka |
| 15.15-15.25 | Tea/Coffee break | |
| 15.25-16.10 | Completed work | Chair: Maartje de Wit |
| 15.25 | Bolus calculation and carbohydrate estimation – assessment and associations with glycaemic control | Dominic Ehrmann |
| 15.40 | Diabetes non-acceptance is a stronger predictor of reduced self-care and poor glycaemic control than depressive mood or diabetes distress in cross-sectional and prospective | Andreas Schmitt |

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|---|---|---|
| | analyses | |
| 15.55 | Effectiveness of a systematic depression screening of diabetes patients in a tertiary referral center for diabetes | André Reimer |
| 16.15– 17.00 | EDID Meeting | |
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| 17.30 | Social Programme | |

## Tour at the museum Het Dolhuys

**Psychiatry is everywhere**

Psychiatry is a lively topic. One in four Dutch people are affected by a mental problem. This does not mean we are any crazier than the rest of the world. We all know someone affected by depression, burnout or Alzheimer's. Thanks to mental health care taking up a more prominent position in society, people with psychiatric problems have become a more noticeable presence in everyday life. Yet still not enough is known about psychiatry and people with psychiatric problems often face prejudice. You are encouraged to think about the boundary between crazy and normal and question the representations of 'madness'. Experience the world of madness in the Dolhuys. Meet madmen and lunatics, or clients as they are known today, in this interactive museum and find out how the Netherlands has dealt with madness throughout the centuries.

## Diner at the Jopenkerk

Haarlem was once a city with many breweries. Beer brewing was by 1400 the most important commercial activity of the city. By the late Middle Ages, beer from Haarlem was exported all over the world. In 1994, inspired by all this history and the loss of all the historic breweries, a group of enthusiastic Haarlemmers took up the challenge of putting Haarlem back on the world beer map. That year, after centuries of absence, Haarlems Jopenbier was brought back onto the market. Now, the former Jacobs church is a fully operational brewery and restaurant!

**Sunday, 11 May 2014** Room: Parijs, Zurich & Amsterdam Buitenveldert

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|---|---|---|
| 09.00 – 10.00 | Parallel round table discussions | |
| | 1. How to write a successful grant application? | Suzanne Pieper & Frank Snoek |
| | 2. Qualitative research methods | Julie Smith & Cathy Lloyd |
| 10.10 – 11.50 | Work in progress Chair: Frans Pouwer | |
| 10.10 | HypoAware: a combined group and online educational program for diabetes patients with problematic hypoglycaemia. A cost-effectiveness randomized controlled trial | Stefanie Rondags |
| 10.30 | Feasibility pilot study of a web-based self-management program as addition to the PRISMA course | Michael van Vugt |
| 10.50-11.10 | Tea/Coffee break | |
| 11.10 | Positive Attitudes towards Diabetes in the Young and Older Generation (PADYOG): A comparative study of the attitudes of young and elderly people living with diabetes | Robert Priharjo & Julie Smith |
| 11.30 | An exploratory study of the experience of diagnosis and the bio-psychosocial factors that affect and are affected by the process of integration of the disease in adults with newly diagnosed type 1 diabetes | Mette Due-Christensen |
| 11.50 – 12.30 | PSAD business meeting | EC |
| 12.30 - 12.35 | Closing remarks | F. Pouwer |
| 12.35 | Lunch | |
| | END OF PSAD SCIENTIFIC SPRING MEETING | |

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# KALEIDOSCOPE MODEL OF CARE

**Authors:** K. Barnard & C. Lloyd
**Institute:** University of Southampton

**AIMS:** To develop and undertake a feasibility study of a novel complex intervention (Kaleidoscope Model), designed to improve biomedical outcomes, psychological factors and self-management in adults with T2DM in routine primary care.

**DESIGN/METHODS:** Cluster multi-centre feasibility study.
An experience based participatory design method based on the NIHR experience based design approach will be used to develop a brief holistic assessment for people with T2DM and healthcare professionals; addressing internal and external factors affecting self-management using existing validated, reliable measures. The intervention will be evaluated in the context of existing evidence for complex interventions. We will recruit a multidisciplinary panel of people with diabetes, GPs, diabetologists, specialist nurses and social scientists to test the intervention, provide feedback and review revisions, in an iterative process of development and refinement. The broader views of people with T2DM through the Diabetes UK user involvement group and Diabetes Research Network will be sought on intervention usability and acceptability. Phase I will end with an intervention ready for use in the feasibility trial.

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|---|---|
| Design: | A cluster multi-centre feasibility study |
| Setting: | 3 GP clinics |
| Participants: | 150 adults |
| Intervention: | Kaleidoscope Model |
| Comparator: | Usual care (3 matched GP clinics) |
| Outcomes: | Acceptability, usability, psychosocial assessment, HbA1c |
| Duration: | 24 months |

Inclusion Criteria:
- ≥18 years
- Diagnosed with T2DM for at least 6 months
- Any treatment regimen
- Willing and able to complete iPad assessment questionnaires

Exclusion Criteria:
- Type 1 diabetes
- ≤18 years
- Pregnant or planning a pregnancy
- Participation in other simultaneous clinical trial
- Unable to complete English language assessment tools

Phase II: Data collection:
Participants will be recruited face-to-face and via letters. Data collection of psychological outcomes will occur at baseline and 6-months. Demographic and biomedical data will be collected (age, gender, ethnicity, marital status, education, employment, body mass index (BMI), $HbA_{1c}$, lipids, blood pressure, waist circumference, current therapy regimen).Study participants will complete the assessment in clinic immediately prior to the consultation with support from a Research Assistant as necessary, then answer a 2-item questionnaire immediately following the consultation to assess the topics discussed and goals set. PNs will answer the same

questionnaire immediately following the consultation. Participants will be invited for repeat assessment at 6 months.

**PLANNED ANALYSIS:** Main feasibility data analysis will be descriptive: recruitment rates, participant characteristics, acceptability of trial procedures and process variables for future effectiveness trial.
The study will be powered to detect changes in self-care behaviour. Using 5% significance level, 90% power, test-retest correlation of 0.42, effect size 0.3, the required sample size = 117. We will approach 150 people to allow for drop-out. We will conduct a preliminarily examination of the associations between baseline measures and attrition using linear and logistic regression.
Qualitative interviews (*n*=30), as well as those who decline to participate or drop out, and PNs will explore perceptions and experiences of the intervention and how it might be improved to fine-tune it prior to future randomised controlled trial (RCT).

**EXPECTED OUTCOMES:**

- an interactive tailored internet intervention for self-management in people with T2DM
- a parallel enhanced interactive tailored intervention for healthcare professionals in general practice, including identification of specific training needs
- To review and define important outcomes to meet the needs of people with T2DM and healthcare professionals for RCT

**PROBLEMS/QUESTIONS:**

1. What are the most appropriate measures to ensure maximum usefulness with minimum participant burden?
2. What are the pitfalls of using IPad assessment prior to clinic appointment?
3. What outcomes would you suggest for translation across to large-scale multi-centre RCT?

# DESIGNING AND IMPLEMENTING EFFECTIVE BEHAVIOUR CHANGE INTERVENTIONS TO IMPROVE OUTCOMES IN DIABETES: IDENTIFYING BEHAVIOURAL RESEARCH PRIORITIES

**Author:** M. Byrne
**Institute:** School of Psychology, National University of Ireland Galway, Ireland

**BACKGROUND:** There is powerful evidence that changing people's health-related behaviour can impact the leading causes of mortality and morbidity (National Institute for Health and Clinical Excellence, 2007). Behaviour plays a central role in determining people's health (for example, smoking, poor diet, excessive alcohol consumption, lack of exercise, failure to screen for illness and risky sexual practice). Interventions to change behaviour have significant potential to alter current patterns of disease and behaviour is likely to be more amenable to change than other health determinants, such as genetics or social circumstances. Behaviour is also central to managing chronic illnesses, such as diabetes. Behavioural change is central to successful interventions to manage diabetes within health services, targeting patients' behaviour (e.g. self-management of blood sugar levels for people with diabetes) and healthcare providers' behaviour (e.g. implementing clinical guidelines on preventing, monitoring and managing foot ulcers among patients with diabetes).However, many attempts to intervene and alter health behaviour related to diabetes have been unsuccessful, or only partially successful. Often, this has been because they fail to take account of the theories and principles of successful planning, delivery and evaluation. Behavioural interventions to improve outcomes in diabetes are likely to be 'complex', with multiple components and agents. The UK Medical Research Council has proposed that in developing complex behavioural interventions, behavioural theory should be used to allow us to develop interventions which are likely to work and will be replicable (Craig, et al., 2008). Health psychologists are leading the development of the scientific methods for studying behaviour change (Michie, 2008), with the potential to significantly enhance PHHSR through development and application of evidence-based behavioural theory and employing theory-linked, evidence-based behaviour change techniques (Abraham & Michie, 2008).

**AIMS:**The aim of this session will be to discuss an exciting new five year programme of research in Ireland at the Health Behaviour Change Research Group which is focusing on identifying national behavioural research priorities in the areas of health services and public health related to diabetes. Once these behavioural priorities have been identified, the researchers will build a programme of research developing and evaluating interventions to address the behaviours.

**DESIGN/METHODS:**Initial work will involve identification and prioritisation of behaviours relevant to diabetes using consensus methods. We will generate a list of topics by means of a national survey; this will be followed by using nominal group technique to establish the level of consensus around identified priorities. Later work will focus on selecting prioritized behaviours, and developing relevant theory (by systematic reviews of the literature and conducting qualitative research with relevant stakeholders) to explain the behaviour and identify possible mechanisms to target in behaviour change interventions. This will be followed by development, piloting and eventual evaluating by Randomised Controlled Trial of interventions.

**PROBLEMS/QUESTIONS**:

1. What are the views of members of PSAD on behavioural research priorities to impact health outcomes for people within diabetes?
2. What are the most effective ways to develop interventions to target these behaviours? Who needs to be consulted and engaged in this process?
3. With limited resources, should we prioritise public health/population-level behavioural interventions over health services interventions to impact on diabetes related behaviours?

# ARE INTERVENTIONS TO REDUCE DIABETES-SPECIFIC DISTRESS EFFECTIVE?

**Authors:** K. Dennick[a], J. Sturt[a], D. Hessler[b]& L. Fisher[b]
**Institute:** [a]King's College London; [b]University of California, San Francisco

**AIMS:** Diabetes-specific distress (DSD) has been an important indicator of diabetes wellbeing in clinical practice and an outcome measure in research studies for over 25 years. DSD displays cross sectional and time concordant relationships with HbA1c and is associated with depressive symptoms and self-management behaviours in type 1 and type 2 populations. Little is currently known about the potential for, or strength of, interventions to reduce DSD. We undertook a systematic review to identify whether, to what extent and which interventions might reduce DSD.

**DESIGN/METHODS:** We undertook a systematic review, using Cochrane methods, to identify all published experimental studies in which DSD has been assessed both before and after interventions using the two validated DSD assessment scales; Problem Areas in Diabetes (PAID) Scale or the Diabetes Distress Scale (DDS). A comprehensive search strategy was derived to identify studies on diabetes distress, or diabetes 'and' general emotional/psychological health, quality of life or psychological, educational or behavioural/self-management interventions. Screening was duplicated by two independent reviewers. Foreign language papers have been translated, and publications for studies in progress at the time of the initial search, and inadequately reported outcome data for included studies, have been sought from authors. Data have been extracted, and quality assessment and data synthesis are in progress. Short forms/screeners, sub-scales and other non-validated adaptations of the PAID and DDS are excluded from analyses at present, owing to heterogeneous usage and the necessity for homogeneity in outcome assessment. Interventions have been defined as the most 'active' arm and/or that emphasised by authors, and the comparison exposure as the least active arm. To promote homogeneity in intervention type, only 'psycho-social' interventions have been included in analyses at present (e.g. diabetes drug and service delivery interventions have been excluded). A search of Medline, Embase and PsychInfo revealed19,223 citations that included a measure of DSD. 1055 full text papers were included and 1049 have been obtained, 334 of which have been included. These constitute 222 unique studies and 101 unique intervention studies, of which five have been confirmed as still in progress and 79 have been obtained thus far; 53 RCTs, 4 quasi-RCTs and 22 pre-post designs. To date, interventions in 28 RCTs and four quasi-RCTs have sufficient homogeneity and report adequate outcome data for meta-analysis. These study samples include 2417 adult type 1 (n=4), type 2 (n=23) and mixed (n=5)participants, with a combined mean age of 58 yrs (range 36-70).Twelve study samples are community based, and the remainder were derived from specialised diabetes clinics. The mean length of the longest follow up is 10 months (range 2-36). A symmetrical funnel plot indicated publication bias is unlikely.

**PLANNED ANALYSIS:** Meta-analysis (RevMan 5.0) is being undertaken to establish the overall effectiveness of interventions on DSD, and explore pre-defined sources of statistical heterogeneity via sub-group and sensitivity analyses. Effect sizes have been estimated as standardised mean differences and combined in random effects models.

**EXPECTED OUTCOMES:** Findings currently indicate that DSD does not display significant reductions across all types of interventions (psychological, educational, behavioural/self-management and peer) -.03 (-.11 to .05, n=32, $I^2$=42%). Sensitivity analyses indicate no impact of including only RCTs -.03 (-.11 to .05, n=26, $I^2$=39%) and interventions comprising face-to-face delivery (i.e. excluding remote delivery, e.g. internet) -.02 (-.12 to

.07, n=28, $I^2$=45%). However, all meta-analyses suggest notable statistical heterogeneity in intervention effects, affirming the necessity to appropriately explore sources of heterogeneity related to intervention content. Categories of intervention type specified by authors are broadly defined, inconsistently applied and do not create meaningful, homogenous sub-groups; many authors label complex interventions comprising distinct components as broadly 'self-management'. This results in substantial statistical heterogeneity within such sub-categories; psychological interventions -0.04 (-0.25 to 0.17, n=6, $I^2$=30%), educational interventions 0.06 (-0.11 to 0.23, n=8, $I^2$=53%) and self-management interventions -0.03 (-0.11 to 0.05, n=17, $I^2$=46%). Some 'psycho-social' interventions may be effective in reducing DSD, yet this must be teased out via appropriate consideration of intervention content and delivery medium. The picture is additionally complicated by the use of active comparators, non-inferiority hypotheses, low levels of DSD at baseline in many studies (i.e. floor effects/iatrogenic harm), and poor reporting of outcome.

**PROBLEMS/QUESTIONS:** Data have been extracted on specific intervention components and delivery medium, and we are now employing a bottom up process of re-categorising the interventions in order to facilitate appropriate sub-group analysis. These data will be available by May 2014. We are keen to consult expert opinion in terms of a) affirming our re-categorisation of interventions and intervention inclusion decisions and b) informing our interpretation of these findings, and c) in relation to other important process decisions, namely the appropriate selection of intervention and comparison exposures.

# CAN MULTIMEDIA TECHNOLOGY BE USED FOR THE EFFECTIVE DELIVERY OF DIABETES STRUCTURED EDUCATION PROGRAMMES?

**Authors:** R. Herring, M. McCormack, S. Warburton, D. Gash & D. Cooke
**Institute:** University of Surrey

**AIMS:** This study will explore the feasibility of delivering group-based, diabetes structured education, incorporating principles of behaviour change theory, for adults with diabetes remotely using multimedia that combine synchronous ("real-time" e.g. live video conferencing, chat room) and asynchronous ("anytime, anywhere") learning. This is innovative as previous work in this area has tended to rely purely on asynchronous learning online. This would be an alternative to but would not replace traditional face-to-face methods of delivery. Approximately only 6% of newly diagnosed adults with diabetes (type 1 or 2) access structured education and it is envisaged that offering these remote, online methods of delivery would increase uptake rates. The specific aims of the study are to:1) To review the effectiveness of remote delivery of self-management interventions for adults with diabetes, which include live, synchronous, interactive skills-based learning; and to identify the critical ingredients for successful intervention delivery; 2) to explore the feasibility and acceptability, amongst people with diabetes and their health care professionals, of modifying and transferring group-based, diabetes structured education to a virtual learning environment.

**DESIGN/METHODS:** Systematic review and a questionnaire survey of approximately 400 diabetes outpatient clinic attendees, and qualitative, semi-structured interviews with 1) a subsample of potential users (n=5) recruited via the survey and selected on the basis of their responses to the questionnaire; and 2) health care professionals (n=5) who would be responsible for delivering such an intervention.

**PLANNED ANALYSIS:** Firstly, to conduct a systematic review using narrative methods. Secondly to carry out a questionnaire study to specifically examine the acceptability of online delivery of diabetes structured education and follow up support. Thus, the survey responses will be analysed descriptively. The qualitative analysis will be informed by the principles of grounded theory. Themes and hypotheses identified in early interviews will be used to inform later phases of data collection. Members of the qualitative research team will read through and cross-compare different participants' transcripts using the method of constant comparison. Regular meetings will be held during and after data collection to explore patients' underlying reasoning, discuss deviant cases and reach agreement on recurrent themes and findings. A qualitative data−indexing package (NVivo) will be used to facilitate data coding and retrieval.

**EXPECTED OUTCOMES:** It is envisaged that this study will result in two publications: 1) a systematic review paper; 2) a paper outlining the scoping work for the development of a feasibility study evaluating the online delivery of diabetes self-management education in type 1 diabetes. It is intended that this work will feed into the development of a feasibility study for which further funding will be sought.

**PROBLEMS/QUESTIONS:**

1. How do you define interactive online delivery of group-based diabetes structured education? What might the critical ingredients of such an intervention look like?
2. What are the pros and cons of online delivery of group-based, diabetes structured education programmes for adults with diabetes (type 1 or type 2)?

# TYPE 1 DIABETES IN THE FAMILY: AN EXPLORATORY STUDY OF FAMILY CHALLENGES AND RESILIENCE FACTORS AND THEIR TRANSLATION INTO A RESEARCH BASED FRAMEWORK FOR FAMILY INTERVENTIONS

**Author:** Clea Bruun Johansen
**Institute:** Steno Diabetes Center, Health Promotion Center, Patient Education Group, Gentofte Denmark

**AIMS:** Adult diabetes management is a continuous undertaking that is often conducted in a family setting. Family members often play an important role in the everyday management of diabetes providing moral, emotional and practical support. Thus, severe problems such as struggles with self-management and blood sugar control, poor well-being and psychological disorders are not only relevant to the individual adult with diabetes. On the contrary, these problems affect – and are affected by – the entire family. Family can serve as an important protective system, playing a central role in improving well-being and self-management. Family may, however, also serve as a risk factor. Diabetes specific risk factors are, for instance, negative emotional tone and poor problem solving and conflict resolution. It is, furthermore, an often overlooked fact that family members of people with diabetes are profoundly affected by their relative's diabetes. Even though the important role of family is established in the literature, the vast majority of non-pharmacological diabetes interventions only target individuals. The few family interventions existing at the present; rarely target the family as a unit. They tend, rather, to target only the person with diabetes. The effects of psychologically based family interventions are, however, well documented outside the field of diabetes. A review of therapies for adults and the family for instance concludes that these therapies are effective in addressing a range of relationship problems and prevalent health problems among adults, including chronic conditions such as heart disease, cancer and chronic pain. There seems to exist an as yet, unexploited opportunity for combining the existing knowledge on family therapeutic models and the specific dynamics and resilience factors within families affected by type 1 diabetes. A family intervention specifically addressing adults with type 1 diabetes and their closest relatives has the potential of addressing the family as a dynamic unit, and not just a support system for the individual with diabetes. The aims of this PhD.-study are to develop a framework for family interventions in adult type 1 diabetes and to test a 'prototype' family intervention to promote self-management and emotional well-being of the person with type 1 diabetes as well as his/her family members.

**DESIGN/METHODS**: Around 20 families will participate and data will be collected using qualitative interview methods and Design Thinking. Design Thinking is an innovative, user-driven approach which adopts an ethnographic perspective as its starting point. Different cultural probes (images, image maps, quotes, statements, and diaries) will be used to actively engage participants and to explore and develop new solutions. Thus the methods will closely engage families affected by type 1 diabetes in all parts of the study. The project will be carried out in three consecutive steps. The first phase is based on in-depth, qualitative interviews with families affected by type 1 diabetes. Based on results from the previous study phase, ideas will be generated on how to design a diabetes family intervention leading to the formulation of a concrete prototype intervention ready for a feasibility test. At this step we plan to assess the feasibility of the intervention. We will explore the experiences of the person with diabetes, family members and care providers.

**PLANNED ANALYSIS:** Data will be analysed according to the method of systematic text condensation, formulated by Malterud. The procedure consists of four steps: 1) reading all the material to get an overall impression and identify preliminary themes; 2) identifying, classification and sorting of meaning units related

to previously identified themes and labelling of code groups; 3) systematic abstraction of meaning units within the thematic codes; and 4) re-conceptualization of data and development of concepts and descriptions. The concept of 'family resilience' will serve as a psychological theoretical point of reference for the analysis and furthermore as a source of concrete inspiration for the generation of ideas throughout the study. Family resilience models seem well suited for chronic illnesses as they emphasise adaptation processes, competences and solutions for problems as opposed to, for instance, a traditional psychodynamic focus on family pathology and deficits. Important general family resilience factors consist of stress management strategies, emotion regulation skills, collaborative goal setting and problem solving capacity. Contemporary resilience-based family approaches include solution-focused therapy, narrative therapy and the family resilience approach.

**EXPECTED OUTCOMES**: The study will hopefully provide insights into methods for actively involving the family in identifying appropriate areas for intervention and methods for developing interventions with the target group "in the driver´s seat" in order to achieve high relevance and usability. Likewise, we expect that the study will provide specific recommendations for family interventions in diabetes.

**PROBLEMS/QUESTIONS:**

1. How can I facilitate recruitment of participants for this study – that is around 20 families affected by diabetes?
2. Are there any obvious challenges in a qualitative study that aims to develop a framework for family interventions?

# EMOTIONAL PROBLEMS IN ADOLESCENTS WITH TYPE 1 DIABETES AND THEIR PARENTS/CAREGIVERS: THE TRUE SCOPE OF THE PROBLEM

**Authors:** P. Winterdijk, G. Nefs, F. Pouwer & H.J. Aanstoot
**Institutes:** Diabeter, Center for Paediatric and Adolescent Diabetes Care and Research, Rotterdam, the Netherlands; C*o*RPS – Center of Research on Psychology in Somatic diseases, Department of Medical and Clinical Psychology, Tilburg University, Tilburg, The Netherlands

**BACKGROUND:** The number of children and adolescents with type 1 diabetes (T1D) is rapidly increasing, a chronic condition not only affecting the child but the entire family, school, and society. Despite recent advances in diabetes management, glycemic outcome has not improved significantly in this group. Psychosocial problems seriously hinder diabetes self-care and contribute to poor glycemic control. Previous research has suggested that up to 30% of all young people with T1D will be confronted with a mood or anxiety disorder at least once while growing up. However, the true scope of the problem is still unknown, as earlier studies have important limitations: small sample size, only using self-report questionnaires to measure depression and anxiety, focusing on depression only and/or a cross-sectional design. European data are scarce and emotional well-being of parents or caregivers was frequently not included, while being a significant risk factor for psychopathology and suboptimal diabetes management in children with T1D.

**AIMS:** To establish the prevalence and two-year course of mood and anxiety disorders among *adolescents* with T1D.
Describe treatment and follow-up, once the diabetologist has been informed of the presence of a mood or anxiety disorder.
Establish the prevalence and course of elevated symptoms of depression and anxiety among *parents/caregivers* of adolescents with T1D.
Identify demographic, clinical and psychological risk factors associated with the occurrence of emotional problems in a two-year period in adolescents with T1D and the parent/caregiver who is primarily involved in diabetes care.
With the results of this study we aim to improve the detection of emotional problems in adolescents with T1D and their parents/caregivers, thereby opening avenues for prevention and timely treatment. After initiation of this project, we will try to extent this study by recruiting additional funds to establish a T1D cohort also including participants from other paediatric diabetes clinics and with long-term follow-up (>2 years).

**DESIGN/METHODS:** In a two year prospective study, 650 adolescents (12-18 years) from the Diabeter paediatric diabetes clinics in Rotterdam, Deventer and Veldhoven, the Netherlands, will be invited to undergo the World Health Organization Composite International Diagnostic Interview to establish the presence of mood and anxiety disorders. In addition, they will complete the Children's Depression Inventory-2 (depression), Generalized Anxiety Disorder-7 (anxiety), and Problem Areas in Diabetes Scale teen version (diabetes-specific distress). Parents/caregivers will complete the Patient Health Questionnaire 9-item scale (depression), Generalized Anxiety Disorder-7 (anxiety), and Problem Areas in Diabetes Scale revised parent version (diabetes-specific distress). Follow-up assessments will take place after one and two years.

**PLANNED ANALYSIS:**

| Construct | Instrument | Baseline | 1 year | 2 year |
|---|---|---|---|---|
| *Adolescent* | | | | |
| Mood/anxiety disorder | CIDI – Adolescent | x | x | x |
| Lifetime history mood/anxiety disorder | CIDI – Adolescent | x | | |
| 1-year history mood/anxiety disorder | CIDI – Adolescent | | x | x |
| Severity of depressive symptoms | CDI-2 | x | x | x |
| Severity of anxiety symptoms | GAD-7 | x | x | x |
| Diabetes-specific distress | PAID-T | x | x | x |
| Sex, age | Medical record | x | | |
| Highest educational level | Medical record | x | x | x |
| Diabetes duration, age at diagnosis | Medical record | x | | |
| Lifetime $HbA_{1c}$ | Medical record | x | x | x |
| Physical/psychiatric co-morbidities | Medical record | x | | |
| Care provided mood/anxiety disorder | Doctor | x | x | x |
| *Parents/caregivers* | | | | |
| Elevated depressive symptoms | PHQ-9 ≥10 | x | x | x |
| Elevated anxiety symptoms | GAD-7 ≥10 | x | x | x |
| Diabetes-specific distress | PAID-PR | x | x | x |
| Sex, age, education, partner | Medical record | x | | |
| Socio-economic status family | Medical record | x | | |
| Primary diabetes caregiver | Self-report, doctor | x | x | x |
| Relation to child, description family | Medical record | x | | |
| History mood/anxiety disorder | Medical record | x | | |
| Psychiatric problems in family | Medical record | x | x | x |

**PROBLEMS/QUESTIONS:**

1. Suggestions for additional psychological measurements?
2. We are interested in the relationship between high glucose values and depression, therefore we will be tracking glucose and A1c values. Do you have suggestions for additional clinical measurements (cortisol, microbioma, etc.)?

# 'IT MAKES A DIFFERENCE, COMING HERE': A QUALITATIVE EXPLORATION OF BARRIERS AND FACILITATORS TO CLINIC ATTENDANCE AMONG YOUNG ADULTS WITH TYPE 1 DIABETES

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**AIMS:** Clinic attendance during the period sometimes known as 'emerging adulthood' is irregular. Emerging adults (18-25 year olds) experience multiple developmental and lifestyle transitions, creating an environment which can increase the challenges and risks facing young people with diabetes. In addition to the fundamental considerations of diabetes care, the adult diabetes clinic has an important role to play in risk minimization and providing education and support which is developmentally appropriate. The aim of this study is to develop a theory of clinic attendance among young adults with type 1 diabetes based on accounts from young adults and health care staff describing barriers and facilitators to clinic attendance. This grounded theory study is embedded within a mixed methods study. The aim of the overall study is to develop and test a theory of clinic attendance among young adults with type 1 diabetes in Ireland. This theory will form the basis for the development of a complex intervention to improve clinic attendance to be tested in future research.

**DESIGN/METHODS:** Semi-structured interviews have been carried out with 15 young people with type 1 diabetes and 7 members of staff regularly working with young adults in the local young adult diabetes clinic. Data is being gathered and analysed using a Straussian Grounded Theory approach. The process of theoretical sampling is ongoing among the young adult group. This means that, as the study proceeds, data are sought in order to refine the concepts which are emerging from the data. This will continue until data saturation has been reached, meaning categories and the relationships between them are sufficiently well described. Grounded theory is the most appropriate methodology on which to base this research as it is a poorly understood topic which is influenced by multiple factors related to young adults, the nature of diabetes, health care staff and diabetes services.

**PLANNED ANALYSIS:**An exploratory approach was taken in early interviews. Open ended questions were asked in order to explore the attitudes of young adults and staff towards the young adult clinic, and issues which influenced the role of the clinic in the management of diabetes. For example, young adults didn't always feel they needed to attend appointments regularly if they believed they were managing well, but according to staff the care offered by the clinic is always necessary to maintain control. In line with theoretical sampling, the interview guide was modified to sample for the concepts which were emerging from the data. The questions have become more specific as data collection has progressed, e.g. 'People have told me that they feel motivated when they have an appointment coming up, or have just been to an appointment. Would that be the same for you?' The analysis of the data is proceeding in conjunction with data collection. The data were coded in order to organise the raw data into concepts. Phases of coding were followed, called open, axial and selective coding. Analysis through these phases is not linear, instead moving forward and backward. Emerging concepts were gradually organised into conceptual chunks, which were then organised into categories defined by their properties and dimensions. Constant comparison and theoretical comparison techniques were used in order to fully understand the dynamics in the data and to test the explanatory power of emerging concepts and categories. The theory has begun to take shape through refinement and integration

of the categories. The core category, central to the theory of clinic attendance and represented extensively in the data, has been tentatively identified as 'Alliance'.

**EXPECTED OUTCOMES:** A substantive theory will be presented which will provide an understanding of the conditions which contribute to positive experiences in the clinic, factors which appear to directly hinder or promote regular clinic attendance, and the psychosocial and environmental variables which influence clinic attendance through their impact on diabetes self-management among young adults. Recommendations for the design of complex interventions depend on the development of an understanding of the processes which influence outcomes in a particular context. To further behavioural research, interventions must be based on theoretical foundations and be sensitive to the context in which the intervention will take place. The use of grounded theory ensures both conditions are met, increasing the possibility that a feasible and acceptable intervention will be proposed and implemented.

**PROBLEMS/QUESTIONS**: It appears that transition is something that just happens and is not seen as a process, and that young adults don't see themselves as having an attendance pattern.

1. What implications does this have for the design of service improvements, where young adults don't perceive a problem?
2. How should clinic attendance/engagement be measured?
3. What role should the clinic have in the self-management of young adults in between appointments, if any?

# CULTURAL ADAPTATION OF A WEB-BASED COGNITIVE BEHAVIOURAL THERAPY PROGRAMME FOR TURKISH DIABETIC PATIENTS WITH DEPRESSIVE SYMPTOMS

**Authors**: E. Kayan, M. de Wit & F.J. Snoek
**Institute**: VU University Medical Center

**AIM/BACKGROUND:**In this project, a cultural sensitive web-based self-help program will be developed for Turkish diabetes patients with depressive symptoms, based on the web-based self-help program Diabetergestemd.nl. Diabetes and depression frequently co-occur and affect each other adversely. This co-occurrence is associated with a negative impact on glycemic control, lower quality of life and impaired general functioning. Increased health care and social costs are also prevalent. Early treatment of depression in diabetes can result in significant health gains. Unfortunately, depression in diabetes patients is not always diagnosed and this seems even more the case in patients with a non-Western ethnic minority background. 400.000 Turks are living in The Netherlands, the largest group of non-Western migrants. The prevalence of both diabetes as well as depressive symptoms is higher in this group as compared to the native Dutch. As the presentation of depressive symptoms seems to be more somatic, offering depression treatment in a somatic context could be helpful especially for this group of patients. Over the past years, we developed Diabetergestemd.nl (DbG) for diabetes patients with depressive symptoms. The effectiveness was tested in a randomized controlled trial. DbG has been shown to be effective; however no patients with a non-Western ethnic minority background participated in the trial. Adjusting DbG can improve the attractiveness of the program and ensure the reach of a larger group of diabetes patients with a Turkish background.

**DESIGN/METHODS:** We will conduct a pilot study to examine the suitability of this web-based self-help program for Turkish diabetes patients with depressive symptoms. At first we examined the literature and conducted interviews with professionals (1 psychiatrist, 2 general practitioners, 1 diabetes nurse, 2 psychologists, 1 spiritual attendant, 1 internal medicine specialist and 1 researcher on depression in Turkish patients). The information and insights gathered during the first period have been aggregated in the second phase and transformed into functional requirements for a cultural sensitive version of the program for Turkish diabetes patients with depressive symptoms: DbG-TR. The main adjustments of the program are the addition of blended care: we will start and end the course with a group meeting led by a diabetes nurse. In between the two group meetings, patients follow 5 online modules at home. After the 3rd module, the coach will contact the participant by telephone asking how the modules are proceeding and encouraging the participant to keep on following the course. DbG-TR is based on cognitive behavioural therapy. Modules cover topics of 1) cognitions, emotions and behaviour, 2) stress management, 3) anti-ruminating techniques, 4) assertiveness and communication and 5) the future. Each lesson will end with a homework assignment, which is provided with feedback by Turkish coaches. An obvious adjustment is the use of the Turkish language during the meetings and on the online modules. Another modification is the use of characteristic Turkish example patients, more visually oriented design of the website and the reducing of modules from 8 in to 5. During the last phase of this project, DbG-TR will be offered in a pilot setting to approximately 50 Turkish diabetes patients (type 1 and 2) with co-morbid depressive symptoms. Measurements at baseline and 3 months include socio-demographic and clinical features, mental health status and changes in depressive symptoms (PAID-5, K-10, EQ-5D and the Lowlands Acculturation Scale (LAS)). User satisfaction and experiences will be assessed at 3 months by means of a short questionnaire and interviews. Satisfaction and

experiences of the health care professionals will also be evaluated. Log data will be used to assess the actual use of the online intervention (number of modules completed, time spent per module).

**PLANNED ANALYSES:** Pairwise comparisons will be done to examine changes over time from baseline to 3 months. Means of patients and professional use and satisfaction scores will be calculated and interview data will be analysed.

**EXPECTED OUTCOMES:** We expect an improvement in depressive symptoms of participants. Furthermore, we expect that the cultural sensitive DbG-TR is feasible, appreciated and usable for Turkish diabetes patients.

**PROBLEMS/QUESTIONS:**

1. What would be the best strategy for publishing our data? We have data of cultural adjustments based on interviews and literature search, development of DbG-TR, and qualitative and quantitative pilot data?
2. How should I identify the feasibility of DbG-TR? User satisfaction of participants and health care professionals: could this be measured by personal or focus group interviews, or…?
3. What suggestions do you have concerning the implementation of DbG-TR within the care setting?

# EFFECTS OF LIRAGLUTIDE ON COGNITIVE FUNCTIONS AND MOOD IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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**Institutes**: 1. IM Sechenov First Moscow State Medical University, Russia; 2. Middlesex University, UK

**BACKGROUND:** Obesity, poor metabolic control, insulin resistance and dyslipidaemia in type 2 diabetes mellitus (DM) are known to be associated with mood disorders and cognitive deficits. Patients with diabetes are reported to have brain abnormalities in the hippocampus and amygdala, similar to those found in patients with depression. Treatment strategies which can improve cognitive functions and treat mood disorders while simultaneously reducing glycosylated hemoglobin ($HbA_{1c}$) without additional risk of hypoglycemia or weight gain signify an important area of research.
Glucagon-like peptide-1 (GLP-1) is a gastrointestinal hormone having both peripheral and central effects. Liraglutide is a long-acting first analogue of GLP-1, which is capable of crossing the blood-brain barrier. Subcutaneous treatment of liraglutide in mice resulted in prevention of synaptic loss and deterioration of synaptic plasticity in the hippocampus, and reduction of beta-amyloid plaque count, linked to neuronal cell death in Alzheimer's disease. Clinical trials demonstated that liraglutide is well-tolerated by humans, markedly improves glucose control without risk of hypoglycemia and has an additional favorable effect of body weight and plasma lipids. The results of the 3a trial programme (Liraglutide Effect and Action in Diabetes; LEAD) demonstate an improvement in health-related quality of life, as well as mental and emotional health, especially in patients in the liraglutide 1.8 mg group. Authors consider that this positive effect was driven by a combination of greater glycemic control, weight loss and reduced concern about weight gain. The clinical impact of GLP-1 influence on receptors in hippocampus and amygdala and its potential to treat depression and cognitive deficits in patients with type 2 DM is still unclear.

**AIM:**To prospectively evaluate the effects of liraglutide on mood and cognitive functions in depressed patients with type 2 DM.

**DESIGN/METHODS**: Patients with type 2 diabetes, with $HbA_{1c}$> 7.5%, having Patient Health Questionnaire (PHQ-9) score ≥ 12, with no major other conditions such as cerebrovascular accident in a 6-month period prior the study, no known psychopathology, substance abuse or dementia other than depression will be randomly allocated to one of two treatment conditions, namely GLP-1 (liraglutide once-daily 1.8mg) and GLP-1 placebo treatment. The treatment will be double blind. The duration of the treatment will be 12 months. Patients will be recruited from outpatient and hospital department of clinics in Moscow.

**PLANNED ANALYSIS**:Measurements will take place at baseline, post-intervention at 3, 6, 9, 12 months and include:(1) questionnaires (a) The 9-item PHQ-9 and the Beck Depression Inventory (BDI) assessing depressive symptoms (PHQ-9 will be our depression screen while the effect of the intervention will be assessed by the BDI); (b) State-Trait Anxiety Inventory (STAI) for measurement of symptoms of general anxiety; (c) Perceived Stress Scale (PSS) for recent perceived general stressors; (d) International Physical Activity Questionnaire (IPAQ); (e) Pittsburgh Sleep Quality Index (PSQI); (f) Problem Areas in Diabetes Questionnaire (PAID) to assess diabetes distress; (g) The Summary of Diabetes Self-Care Activities Scale (SDSCA), a self-report measure of adherence to diabetes self-care activities (including caloric intake). Validated versions of all measures and scales are available in Russian; (2) neuropsychological tests (CANTAB working memory and executive function, Probabilistic reversal learning task as an indicator of neuroplasticity); (3) blood tests (8-point self-monitored plasma glucose profiles, $HbA_{1c}$, inflammatory markers (hsCRP; IL-6 and TNF-α) and markers of

oxidative stress (plasma F2-isoprostanes (IsoPs): iPF2a-III and iPF2a-VI ); (4) body weight, calculation of body mass index (BMI), BDNF.The results will be analysed using repeated measures ANOVAs with co-variates where appropriate. Geisser-Greenhouse corrections will be applied where assumptions of sphericity are not met.

**EXPECTED OUTCOMES**:The primary clinical endpoints are the change in BDI score and $HbA_{1c}$ levels from baseline to 12 months; secondary outcome variables are CANTAB tasks.

**PROBLEMS/QUESTIONS**:

1. Do we need a placebo group or standard care or standard care plus GLP-1?
2. Should we include people with insulin?
3. GLP-1 action may reduce depression through two different mechanisms, namely: the physiological effects (antiapoptotic, neuroprotective) and its influence on diabetes distress (better and easier control, reduced appetite). How can we disentangle these two mechanisms? For example, should we include a control group receiving working memory training, or insulin treatment, or SSRIs?

# IDENTIFICATION OF NOVEL BIOMARKERS LINKING DEPRESSION AND DIABETICFOOT ULCERS: POTENTIAL TARGETS FOR THE PREVENTION OF FIRST FOOT ULCER

**Authors:** Z. Mannie & A. Nouwen
**Institute:** Middlesex University

**BACKGROUND:** Diabetic foot ulcers are a serious complication of depression that could lead to amputations and even increase mortality rate due to cardiovascular events. Depression predicts the first foot ulcer, and the presence of depression increases the mortality rate exponentially. It is now well established that there is a very strong link between depression and diabetes, in general. However, mechanisms linking depression to diabetic foot ulcers are not well described, but could include endocrine, inflammatory, oxidative and endothelial processes.

**AIMS:** We propose to conduct two related studies:
Study 1: We aim to identify potentially modifiable biomarkers that are hypothesized to mediate the relationship between depression and risk for diabetic foot ulcers e.g. waking cortisol secretion for hypothalamic-pituitaryadrenal axis (HPA) regulation, serum Brain-Derived Neurotrophic Factor (BDNF) - a neurotrophin implicated in maintaining neuronal plasticity/repair and angiogenesis, proinflammatory cytokines, oxidative stress and endothelial function.
Study 2: In this pilot, we aim to examine whether reducing depression using cognitive behavioural therapy (CBT) will, through its effect on these biomarkers, potentially reduce the risk of developing diabetic foot ulcers. If demonstrated, this study may ultimately lead to studies showing that CBT can be used to reduce the prevalence of these foot ulcers in at risk patients. CBT will be compared to standard care for diabetes (control). Ultimately, our aim is to collect data on recruitment/retention rates, and variability/clustering in outcome measures, to confirm the sample size calculation and timeline for the full-scale trial.

Participants: We will have 4 groups of participants.
Group 1 will be participants with depression (PHQ-9 ≥12) who have diabetic neuropathy but no foot ulcers (N=60).
Group 2 participants will have diabetic neuropathy but no foot ulcers, and a PHQ-9 score <5 (N=60).
Group 3 will be a control group of healthy participants without diabetic neuropathy, foot ulcers or depression (N=60).

**DESIGN/METHODS:**
Study1: This will be a cross-sectional between groups design. Participants with diabetes will be recruited from the diabetes foot clinics and diabetes clinics from South Manchester. Friends and family of the participants with diabetes will be approached to act as control for the study.
Study 2: This will be an open-labeled randomized controlled design. Only depressed participants with neuropathy but no foot ulcers will be included (Group 1). Participants will be randomized using a computer generated program and will be matched for age, sex, and BMI.

Assessments:
All assessments will be performed at baseline (all participants) and at 3 and 6 months in patients included in Study 2 only.

Questionnaires: PHQ-9, BDI, STAI,YSQ-S,PSS,IPAQ and EuroQol
Anthropometric: BMI, WHR, BP.
Biochemical Measures:
1. From fasting blood: Serum BDNF, Proinflammatory cytokines (hsCRP; IL-6 and TNF---α), Oxidative stress (plasma F2-isoprostanes (IsoPs): iPF2a-III and iPF2a-VI, HbA1c
2. Waking salivary cortisol: sampled 3 times from waking at 15minute intervals.
3. Endothelial function: Skin perfusion measurement with Laser Doppler for endothelial-dependent and independent vasodilatation (Iontophoresis technique)

**EXPECTED OUTCOMES:**
Study 1:We expect that the depressed high risk group will show cortisol hypersecretion, increased oxidative stress, higher levels of proinflammatory cytokines, serum BDNF deficiency and endothelial dysfunction compared to both the depressed group at low risk and the control group. There will be more impairment in the depressed group at low risk of diabetic foot ulcers compared to the control group.
Study 2:The group receiving CBT will show significant improvements from baseline in the biomarkers compared to the control group.

Power calculations:
Study1: Evidence suggests that the endothelial-dependent vasodilatation effect size between patients with diabetic neuropathy and control participants without diabetes is medium sized, d=0.51. Based on this estimate, to detect with 80% power, two-tailed $\alpha = 0.05$, we would need 60 participants per group (overall N = 180).
Study 2: We expect a moderate effect size of CBT on depression in diabetes. As there are no studies that have examined the effect of CBT on the selected endpoints we will include group 1 participants; half of whom will receive CBT (Intervention group) and the other half will receive standard care (Control group) which will enable us to perform power calculations for a substantive intervention study.

**PROBLEMS/QUESTIONS** regard the design of such a study, especially as it is in two parts.

4. For study 1, what control groups would be most appropriate, i.e. a healthy control group (nodepression, no diabetes) and/or a non-depressed group with diabetes at low risk of diabetic foot ulcers?
5. CBT (3 week or 12 week course) or an antidepressant e.g. Sertraline? Implications for involvement of a psychiatrist.

# DIABETES TREATMENT: A PSYCHOLOGICAL IMPACT ANALYSIS

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**AIMS:** In recent years progress has been made in the treatment of diabetes, which has had positive effects on glycemic control in patients with diabetes. This study aims to analyze the psychological differences presented in patients with diabetes mellitus type 1 (DM1) and type 2 (DM2) depending on the type of diabetes treatment.

**METHODS AND PARTICIPANTS:** 374 patients with diabetes (259 with DM1 and 115 with DM2). The sociodemographics and diabetes treatment were collected through a structured interview.
Depressive symptoms were assessed with the Beck Depression Inventory (BDI-II), anxiety with the State-Trait Anxiety Inventory (STAI), fear of hypoglycemia with the Fear of Hypoglycemia Questionnaire (FH-15), quality of life with the Diabetes Quality of Life (DQOL) and distress with the Diabetic Distress Scale (DDS). Differences in variables depending on the type of treatment were analyzed with ANOVA. We used SPSS version 19.0.

**RESULTS:** With regard to type of therapy, there were no significant differences in depression and quality of life in patients with DM1 based on type of treatment (oral anti-diabetic agents –OAD and insulin, insulin alone, continuous subcutaneous insulin infusion -CSII-, paradigm real time - PRT-). However, in DM2 differences were found between the treatments (diet and exercise, insulin, OAD and OAD and insulin). Patients treated with OAD and insulin (together) had scored higher in depression symptoms ($p=0.001$), in trait anxiety ($p=0.017$), in distress ($p=0.004$) and worse quality of life ($p<0.001$) with respect to the patients treated only with diet and exercise.

**DISCUSSION/CONCLUSION:** With regard to type of treatment in this study no significant differences were found on type of treatment in the DM1 patients. Significant differences were found, however, in anxiety, depression, distress and quality of life in DM2 patients treated with insulin and OAD. This study suggests that receiving insulin with supplemental OAD treatment would increase the self-care burden in the DM2 patient, and therefore, would worsen quality of life and emotional results.

# MOTHERHOOD AND DIABETES: A RESEARCH PROGRAM ON CHILDBEARING IN WOMEN WITH TYPE 1 DIABETES

**Authors:** C. Sparud Lundin & M. Berg
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**AIMS:** MOtherhood and DIABetes (MODIAB) is a research program with a person-centered focus aiming to promote a healthy childbearing, and early parenthood for the mother with diabetes, the fetus/child and the whole family.

**METHODS AND PARTICIPANTS:** The research program includes studies on diabetes and pregnancy, childbirth, early parenthood and web support. In this abstract, the following studies are presented: Two qualitative studies exploring experiences a) during pregnancy and b) after childbirth regarding breastfeeding, glycemic control, support and well-being in 23 women with type 1 diabetes. A comparative study conducted by structured telephone interviews 2 and 6 months after childbirth comparing breastfeeding rates and experiences, diabetes management and well-being in 108 women with type 1 diabetes and 105 women in a reference group. One survey investigated Internet use, needs and expectations of web-based information and communication in 105 childbearing women with type 1 diabetes.

**RESULTS:** During pregnancy, thewomen feel “controlled by the blood glucose levels” for the unborn child´s sake who “makes demands” to be born healthy. This situation is made worse when care providers show lack of competence and when paying more attention towards the unborn child than to the pregnant women themselves. For women with type 1 diabetes, the intensive antenatal, diabetes care during pregnancy is abruptly interrupted after the child is born. They are in a vulnerable situation of own fluctuating and unstable blood glucose as insulin needs decrease, while attempting to establish breastfeeding. The mothers with diabetes are less likely to breastfeed their children at 2 and 6 months than mothers without diabetes. In addition to higher education level, delay of establishing breastfeeding affects the likelihood of long-term breastfeeding. Everyday life is often filled with uncertainty and unpredictability for women with diabetes and they often have to down-prioritize their own needs in favor of the child. A feeling of being disconnected from professional care after childbirth further contributes to experiences of extraordinary exposure. Most of these mothers experience considerably more instable glycaemia, especially the first two months after childbirth, and more hypoglycemic episodes in relation to breastfeeding the first six months. Managing diabetes and breastfeeding is a challenge and compared to mothers without diabetes, they are more affected by disruptions in daily life. They report lower levels of general well-being including general health and vitality the first six months after childbirth. Well-being is negatively influenced if breastfeeding affects diabetes management. A high proportion of women with type 1 diabetes seek diabetes-related information on the Internet, especially before, during, and after pregnancy. They state needs and/or expectations of professional and peer support and information on different diabetes-related issues during the childbearing phase.

**CONCLUSIONS/ DISCUSSION:** The need of extended support is apparent and comprises support from both professionals and relatives, but also peer support from mothers with similar experiences of diabetes and childbearing. In order to support these women during a vulnerable life phase, we have identified a need for developing a person-centered support, especially during the post partum period up to 6 month after childbirth.

# FLEXIBLE GUIDED SELF-DETERMINATION INTERVENTION FOR YOUNG ADULTS WITH POORLY CONTROLLED TYPE 1 DIABETES IMPROVED GLYCEMIC CONTROL AND PSYCHOSOCIAL FUNCTIONING IN WOMEN BUT NOT IN MEN: A REAL LIFE RANDOMISED CONTROLLED TRIAL

**Authors:** V. Zoffmann, D. Vistisen &M. Due-Christensen
**Institute:** Steno Diabetes Center

**AIMS:** To report the results of a randomized controlled trial, testing the effect of a flexible Guided Self-Determination (GSD) intervention on glycemic control and psycho-social functioning among young adults with poorly controlled type1 diabetes (T1D).

**METHODS AND PARTICIPANTS:** January 2010 - February 2012 we randomized 18-35 year old patients with T1D duration ≥1 year and Hemoglobin-A1c ($HbA_{1c}$) ≥64 mmol/mol (8.0%) 2:1 to GSD immediately (intervention) or 18 months delayed (control). Seven group-based or individual GSD-sessions were offered freely drawing on reflection sheets for patients and advanced professional communication. The intervention was provided by nurses GSD-trained 40 hours. Effect was measured after 18 months. Primary outcome was HbA1c measured every three months. Secondary outcomes were changes in psychosocial functioning self-reported in electronic questionnaires at baseline and after 9 and 18 months including Problem Areas in Diabetes (PAID), theWHO-5 well-being index (WHO-5), Rosenberg's self-esteem scale (RSES), Health Care Climate Questionnaire (HCCQ), Treatment Self-Regulation Questionnaire *(*TSRQ) and Perceived Competence in Diabetes Scale (PCD). In addition, the questionnaire entailed questions on treatment regimen (pen or Continuous Subcutaneous Insulin Injection CSII) and number of self-monitored blood glucose measurements (SMBG) the past week. Furthermore demographic data were included and contained information on level of education as well as status of co-habitance and employment. Information on BMI, smoking, and complication status was retrieved from a local electronic database.Analyses included linear regression and repeated measurement following intention to treat.

**RESULTS:** 200 (50% men) were randomized to intervention (n=134) or control-group (n=66), mean age 25.7(5.1), diabetes duration 13.7(6.8) years. A borderline significant decrease in $HbA_{1c}$ in the intervention group compared to the control group (-4.1 vs. -1.2 mmol/mol, p=0.073) was driven by a significantly higher reduction in GSD-women (-5.2 vs. +0.7, p=0.017) whereas significant decreases (p<0.001), yet parallel, were observed in GSD-men and control-men (-3.1 vs. -3.2, p=0.955). Significantly higher improvements in the GSD-group's psychosocial functioning were again driven by improvements in GSD-women relative to the control-women. Improvements in men could not be related to the intervention.

**CONCLUSIONS/DISCUSSION:** The flexible GSD-intervention improved glycemic control and psycho-social functioning among young adult women with poorly controlled T1D. Improvements among men were not related to the intervention. Though young adults are known to be difficult to access they were willing to take part in this flexible intervention. Considering the high prevalence of poor glycemic control and high psychosocial distress it is an advantage that the intervention can be provided by nurses after a limited amount of training. The possibility to integrate GSD into clinical practice increases hereby. In women, a 5.9 mmol/mol lower $HbA_{1c}$ represents a statistically and clinically significant outcome which together with the significant improvements of psychosocial functioning makes reasons to seriously consider implementing GSD

among young adult women with poorly controlled T1D. Despite improvements - with or without intervention - were seen among men, research is still needed in order to increase effectiveness among men.

# BINGE EATING AND PROBLEMS WITH IMPLEMENTATION OF THE TREATMENT WITH INSULIN ANALOGUES AMONG PATIENTS WITH TYPE 2 DIABETES. RESULTS OF INITIAL ANALYSES

**Author**: A. Kokoszka
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**AIMS:**

1. Prevalence of binge eating among persons with diabetes type 2 at stage of implementation of treatment with insulin analogues, previously treated with human insulin.
2. Replication of the previous study on the frequency of problems with adherence to the treatment of diabetes type 2 with analogues of insulin among patients treated with human insulin.
3. The comparison of the frequency of problems with adherence to the treatment of diabetes type 2 with analogues of insulin among patients with and without – binge eating.

**METHODS AND PARTICIPANTS:** 2533 patients with diabetes filled: (1) Problems Related with Change of Treatment from Human Insulin to Analogues of Insulin Questionnaire,that includes 5 questions in a 5 points Likert's scale form (alpha Cronbach = 0,83); (2) WHO-5; (3) Demographic Data Questionnaire; (4) Two items from the Brief Method Of Evaluating Coping With Disease; (5) Assessment of the Perception of Self-Influence on the Disease Course; (6)modified Screening for Binge Eating Questionnaire (Tomalski et al, 2008). Ultimate diagnoses of binge eating were based on DSM-IVR criteria.
Due to protocol violation, mainly time of the examination between 30 and 60 days after the implementation of change from human insulin treatment to analogues of insulin and use other treatment than biphasic human insulin in the previous treatment only, only 1007 persons 495 (49,2) women and 512 men; of age 30-89 were included in the presented analyses.

**RESULTS:**263 (10.6%) of initial group of 2533 patients and 111 (11.0%) of 1007 met DSM-IV criteria of binge eating. 204 (20.3.%) were identified as of risk of binge eating according to screening instrument.
The results confirm earlier findings (Kokoszka, in preparation) indicating that meaningful percentage of patients experience some problems related with change of treatment from human insulin to analogues of insulin including:
Patients with binge eating made more adherence errors than those without binge eating:
Injecting a biphasic analogue much earlier before a meal – rank 539.5 versus 456.8; U Mann-Whitney test – 36894.5; $p < 0,001$
Snacking between main meals – rank 529.3 versus 460.9; U Mann-Whitney test - 38848,5; $p < 0,006$
Forgetting about changing the insulin analogue dose after eating a snack – 527.6 versus 452.1; U Mann-Whitney test - 36993,500; $p < 0,003$
Feeling of hypoglycemia – rank 475.4 versus 469.3; U Mann-Whitney test - 45005,000; $p < 0.795$

**CONCLUSIONS:** Implementation of treatment with analogues of insulin makes some problems for meaningful group of patients.The intensity of those problems is higher among patients with binge eating.

**DISCUSSION:**
1) further data analyses, 2) reconsideration of exclusions due to protocol violations

# BOLUS CALCULATION AND CARBOHYDRATE ESTIMATION – ASSESSMENT AND ASSOCIATIONS WITH GLYCAEMIC CONTROL

**Authors:**D. Ehrmann, N. Hermanns, A. Reimer, T. Haak &B. Kulzer
**Institute:** FIDAM – Research Institute Diabetes Academy Mergentheim

**AIMS**: Intensive insulin therapy requires the ability of correct bolus calculation and carbohydrate estimation. Interestingly, a recent meta-analysis showed that carbohydrate counting had no effect on glycaemic control. The aim of this study was to develop a new questionnaire to separately assess the ability for bolus calculation and carbohydrate estimation. Furthermore, the distinctive associations of bolus calculation and carbohydrate estimation with clinical outcomes especially glycaemic control were investigated.

**METHODS AND PARTICIPANTS:** The "ASsessMent of the Ability of Bolus Calculation and CaRbohydrate EsTimation" questionnaire (SMART) was developed consisting of 10 items for bolus calculation (CALC) and 12 items for carbohydrate estimation (CARB). Inpatients with type 1 or type 2 diabetes on intensive insulin therapy were asked to participate. HbA1c and patients' blood glucose meters were used to determine glycaemic control. 411 patients took part (13% type 2 diabetes) and nearly 56,000 data points from 114 patients' blood glucose meters could be read-out spanning a total of 18,545 days. Mean age was 42.9 ± 15.7 years, 48% were female, mean diabetes duration was 17.9 ± 12.6 years, and patients had a mean HbA1c of 71 ± 19.7 mmol/mol (8.6 ± 1.8%).

**RESULTS**: The CALC-scale achieved a good Cronbach's alpha of 0.78 with a mean item selectivity of $r_{it}$=0.46 and a mean difficulty of 66% correct answers (mean score = 6.6 ± 2.6). The CARB-scale achieved a sufficient Cronbach's alpha of 0.67 with a mean item selectivity of $r_{it}$ = 0.31 and a mean difficulty of 60% correct answers (mean score = 7.2 ± 2.5). Better bolus calculation was associated with a higher level of education (r = 0.24, p<.05), better HbA1c (r = -0.27, p<.05), lower mean blood glucose (r = -0.29, p<.05), and a lower fluctuation of blood glucose values (r = -0.43, p<.05). Better carbohydrate estimation was associated with a lower body mass index (r = -0.2, p<.05), lower mean blood glucose (r = -0.3, p<.05), a lower frequency of hyperglycaemia (r = -0.27, p<.05), and a higher frequency of euglycaemia (r = 0.26, p<.05). Patients with an insulin pump were better in both scales than patients with MDI therapy (CALC: 7.2 ± 2.4 vs. 6.4 ± 2.7, p<.01; CARB: 7.8 ± 2.1 vs. 7.1 ± 2.6, p<.01). Patients with type 1 diabetes were better in both scales than patients with type 2 diabetes (CALC: 6.7 ± 2.7 vs. 5.4 ± 2.8, p<.05; CARB: 7.5 ± 2.3 vs. 5.2 ± 2.7, p<.05). Patients with previous diabetes education were significantly better in both scales (CALC: 6.8 ± 2.5 vs. 5.7 ± 2.8, p<.01; CARB: 7.4 ± 2.4 vs. 6.5 ± 2.6, p<.01).

**CONCLUSIONS/DISCUSSION**: The SMART questionnaire is a reliable and valid tool to assess patients' abilities to calculate their insulin dose and to estimate their carbohydrate content. Furthermore, the study demonstrates that both abilities have substantial associations with glycaemic control. While bolus calculation seems to be more influential for HbA1c and fluctuation of blood glucose, carbohydrate estimation is more important for keeping blood glucose in an euglycaemic range.

# DIABETES NON-ACCEPTANCE IS A STRONGER PREDICTOR OF REDUCED SELF-CARE AND POOR GLYCAEMIC CONTROL THAN DEPRESSIVE MOOD OR DIABETES DISTRESS IN CROSS-SECTIONAL AND PROSPECTIVE ANALYSES

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**AIMS:** Acceptance and integration of diabetes into life is often called a precondition of effective diabetes self-care and good metabolic control. However, evidence of the assumed negative impact of insufficient diabetes acceptance on diabetes outcomes is limited. We conducted this study to analyse the concurrent and prospective associations of diabetes non-acceptance with self-care activities and glycaemic control.

**METHODS AND PARTICIPANTS:**321 inpatients with type 1 or 2 diabetes (age 44 ± 15; 51% female; BMI 29 ± 7; 66% type 1; duration 14 ± 10; 94% with insulin; HbA1c 8.7 ± 1.7%) were assessed for diabetes non-acceptance (AADQ, 6-item version), diabetes distress (PAID), depressive mood (CES-D), self-care activities (SDSCA), and glycaemic control ($HbA_{1c}$). 164 of these patients could be reassessed in a 12-month follow up. The cross-sectional and prospective correlations of diabetes non-acceptance with self-care and glycaemic control were analysed and compared to those of diabetes distress and depressive mood using Steiger's *z*-test of differences between correlations. Additionally, multiple regressions were performed to test these associations for independence from demographic and clinical covariates.

**RESULTS:** In cross-sectional analyses ($N$ = 321), higher diabetes non-acceptance correlated significantly with reduced total self-care ($r$ = -0.27), less adherent general diet ($r$ = -0.25) and blood glucose testing ($r$ = -0.34), and higher $HbA_{1c}$ ($r$ = 0.28). All correlations were significantly higher than those of diabetes distress or depressive mood with these diabetes outcomes (all $P$< 0.05). In prospective analyses ($N$ = 164), higher diabetes non-acceptance at baseline correlated significantly with reduced total self-care ($r$ = -0.32), less adherent general diet ($r$ = -0.33) and blood glucose testing ($r$ = -0.29), and higher $HbA_{1c}$ ($r$ = 0.18) at 12-month follow up. In contrast, neither baseline diabetes distress nor baseline depressive mood correlated significantly with any of these outcomes at 12-month follow-up (all $P$> 0.30). Adjusting for age, sex, BMI, education, diabetes type, diabetes duration, and treatment did not alter the observed associations.

**CONCLUSIONS/DISCUSSION:** According to these results, insufficient diabetes acceptance is a better predictor of poor self-care and glycaemic control than depressive mood or diabetes distress, independent from demographic and diabetes-related variables. Assessing diabetes acceptance may facilitate the detection of patients at high risk of poor diabetes outcomes and improve the adjustment of psychosocial treatments in these patients.

# EFFECTIVENESS OF A SYSTEMATIC DEPRESSION SCREENING OF DIABETES PATIENTS IN A TERTIARY REFERRAL CENTER FOR DIABETES

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**AIMS**: The frequent comorbidity of diabetes and depression is associated with an increased risk of poor health outcomes. However, in diabetes care mostly pre-existing depression diagnoses are considered.T his investigation evaluates the effectiveness of a systematic depression screening as a means to detect previously unknown clinical depression in an inpatient setting.

**METHODS AND PARTICIPANTS:**At a German tertiary referral centre for diabetes, patients were systematically screened using the Center for Epidemiologic Studies Depression Scale (CES-D) and the Problem Areas in Diabetes Scale (PAID) over the course of 9 months. Positive screened patients (CES-D ≥ 16 and/or PAID ≥ 40) were invited to a diagnostic interview in order to clarify a potential depressive disorder according to ICD-10 diagnostic criteria. Data were analysed using descriptive statistics and a one-way analysis of variance for the examination of group differences.

**RESULTS:** 806 diabetes patients (aged 49 ±15 yrs., 45% female, 57% type 1 diabetes, HbA1c 8.7 ±1.6%) participated in the screening. 325 patients (40%) were screened positive, at which120 (37%) of those patients already had been diagnosed with and were being treated for depression. Out of the remaining 205 patients who were invited to the diagnostic interview, 183 (89%) participated therein. 80 of those patients (40% of all depressed patients) were diagnosed with a previously unknown depressive disorder. Comparing patients with clinical depression (n=200) to non-depressed patients (n=481) revealed significantly poorer glycaemic control (HbA1c: 8,9% vs. 8,5%; *p*=0.03). However, no significant difference was found between patients with subclinical depressive symptoms (n=125) and controls (8,7% vs. 8,5%; p=0.34).

**CONCLUSIONS/DISCUSSION:** Without the systematic screening for depression 40% of actual depressive disorders would have been overlooked, preventing adequate treatment of these patients. The significantly worse glycaemic control in depressed patients indicates their elevated health risks and emphasizes the relevance of screening for depression.

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# HYPOAWARE: A COMBINED GROUP AND ONLINE EDUCATIONAL PROGRAM FOR DIABETES PATIENTS WITH PROBLEMATIC HYPOGLYCAEMIA. A COST-EFFECTIVENESS RANDOMIZED CONTROLLED TRIAL

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**AIMS:** The problem of recurrent hypoglycaemia demands special attention, as acknowledged by professionals and patients. About 30% of patients on intensive insulin therapy experience 1 or more episodes of severe hypoglycaemia yearly and its related negative psychosocial impact. Based on epidemiological data, we can estimate the number of adult insulin-treated diabetes patients in the Netherlands to be around 46000 patients. Currently they do not receive structured, evidence-based professional help. For these patients diabetes care could be improved by implementing a structured, evidence-based self-management intervention targeted at reducing hypoglycaemia. Based on research to date and preliminary findings, we can expect our new intervention HypoBewust (HB; HypoAware) to help improve medical outcomes and reduce the psychosocial burden and related costs. With this study we aim to establish the cost-effectiveness of our psycho-educational intervention HB compared to care as usual for diabetes patients with problematic hypoglycaemia.

**DESIGN/METHODS**: We will perform an economic evaluation in a cluster Randomized Controlled Trial with measurements at baseline, 2, 4 and 6 months follow-up for the intervention and control group and an additional 12 months for the intervention group to see if anticipated effects will be maintained over time. The control group will receive HB as an incentive after the 6 months follow-up measurements. We will randomize 9 hospitals across the Netherlands to two groups. We aim to include 128 adult patients with type 1 or insulin-treated type 2 diabetes, who have experienced 1 or more episodes of severe hypoglycaemia in the past 2 years and/or have reduced hypoglycaemia awareness. The intervention group receives HB (a 4 week blended group/online psycho-educational intervention aimed at improving patients' skills in detecting, treating, predicting, preventing and coping with hypoglycaemia) and the control group receives care as usual (according to hospital guidelines: 1-3 appointments with diabetes nurse, endocrinologist, dietician or psychologist and telephone/email contact).
Primary outcomes: We will ask participants about frequency of severe and mild hypoglycaemia and hypoglycaemia awareness. Secondary outcomes: fear of hypoglycaemia (HFS-II), diabetes-related distress (PAID-5), health-related quality of life (EQ-5D), symptoms of depression and anxiety (HADS), and confidence in diabetes self-care behaviours (CIDS). Also we will gather cost-effectiveness outcomes on health care consumption and sick leave. HbA1c and medical information will be retrieved from the participants' medical files.

**PLANNED ANALYSIS:** Data are analysed based on intention-to-treat principle. Analysis of covariance will be applied and mean differences between the experimental and control condition calculated for the primary and secondary outcomes. To compare the difference between intervention and care-as-usual groups from baseline to follow-up, regression analysis will be performed using Generalized Estimating Equations (GEE), taking into account the correlational nature of repeated measures within subjects, and securing minimal loss of patients due to incomplete data. Analyses will be corrected for age, gender, diabetes duration and type of diabetes.

The cost-effectiveness and cost-utility analysis will be done according to the intention-to-treat principle. Missing cost and effect data will be imputed using multiple imputation techniques. Incremental cost-effectiveness ratios (ICERs) will be calculated and 95% confidence intervals will be estimated. Cost-effectiveness acceptability curves will also be estimated. Adjustment for confounders and effect modifiers will be done if necessary.
In the budget impact analysis, the effectiveness of HB will be extrapolated using a simple Markov model over a period of 5 years. Perspectives that will be considered are the societal, government (Budget Kader Zorg) and insurer perspective. Resource utilization is calculated by multiplying the number of eligible patients with the resource utilization rates obtained from the economic evaluation.

**EXPECTED OUTCOMES:** We expect significantly larger improvements in the HB group relative to care as usual at 6 months follow-up: a) In terms of health related outcomes: a reduction in frequency of severe hypoglycaemia and an improvement in quality of life, b) In terms of cost-effectiveness: a significant reduction in societal costs due to a reduction of sick leave and health care consumption. We also expect anticipated improvements in the HB group in health-related outcomes and cost effectiveness to be maintained from 6 months to 12 months follow-up in the intervention group.

**PROBLEMS/QUESTIONS**:

1. How reliable is self-report about mild hypoglycaemia (we ask about number of measurements this past week, number of measurements below 4 mmol/l and number of times feeling low, without confirming with a test)? How can we make this measure more objective, while keeping extra costs at a minimum?
2. After this study HB will hopefully be implemented in Dutch diabetes care. Do you have suggestions on how we can make sure this transition from research into practice will be successful?
3. Could you think of other hypotheses that would be interesting to be tested with these data?

# FEASIBILITY PILOT STUDY OF A WEB-BASED SELF-MANAGEMENT PROGRAM AS ADDITION TO THE PRISMA COURSE

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**BACKGROUND**: Self-management support is a key component of overall diabetes care. Promoting patient's self-management can help improve both medical and psychological outcomes. The PRISMA self-management course, which is based on the DESMOND-program developed in the United Kingdom, supports type 2 diabetes patients with the management of their disease, by means of 2 face-to-face sessions. However the positive effects of the intervention slowly decrease over time. To further sustain the durability of the PRISMA course, an online addition is currently being developed. This online addition will support T2DM patients with their self-management during and after the PRISMA course.

**AIMS**: We are planning on performing a pilot study investigating usability, feasibility and fidelity of an online program for sustaining patient self-management behaviour during and after the completion of the PRISMA course.

**DESIGN/METHODS**: Participants for the online program are people diagnosed with T2DM from primary and secondary diabetes care, who are enrolled in the face-to-face PRISMA course. The online addition for PRISMA will include: diabetes information, activity- and diet-diaries, self-monitoring, goal setting, action planning, action evaluation, forum social support and consultation preparation. The development of the online program was informed by the Health Action Process Approach (HAPA) model for closing the intention-behaviour gap and for supporting the maintenance phase of healthy behaviour.For the pilot study, participants will be followed for 3 months and fill out questionnaires at 2 time points (0 and 3 months ) prior to their scheduled clinic visits. Additionally some participants will be invited for interviews and/or focus groups. Primary endpoints of this study are: feasibility, usability (questionnaires, interviews/focus groups), and fidelity (program logs) of the online self-management program. Secondary endpoints are: risk awareness, outcome expectancy, self-efficacy (intentions of behavioural change), action planning, coping planning (behavioural maintenance) (RACK), illness perception (B-IPQ), diabetes-related emotional distress (PAID-5) and emotional Well-being (WHO-5).

**PLANNED ANALYSIS**: For the qualitative analyses, information from interviews and focus groups will be transcripted, evaluated and interpreted by multiple independent researchers. All quantitative analyses will be conducted by using SPSS software. Longitudinal linear regression will be used, reflecting the relationship between the longitudinal developments of the secondary outcome variables. All analyses will be corrected for baseline values, gender and age.

**EXPECTED OUTCOMES**: We expect that uptake and acceptability of the online program among participants will be high, due to integration of the online program into the existing face-to-face PRISMA course, during and after the course. The online program is specifically tailored for T2DM patients, and uses the same methodology as the face-to-face course, increasing feasibility and fidelity. Fidelity is further targeted by adding patient forums with participants of the PRISMA-course, and automated triggers from the online program to log-in at least once a month. While the face-to-face program improves motivation and intention for behaviour change, the online program targets behaviour maintenance and relapse prevention.

**PROBLEMS/QUESTIONS**:

1. What additional behavioural change techniques could benefit this self-management program?
2. Are there other ways of improving feasibility and fidelity of the online program?
3. Are there other ways for assessing feasibility?

# POSITIVE ATTITUDES TOWARDS DIABETES IN THE YOUNG AND OLDER GENERATION (PADYOG): A COMPARATIVE STUDY OF THE ATTITUDES OF YOUNG AND ELDERLY PEOPLE LIVING WITH DIABETES

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**AIMS:**
Living with diabetes has been found to be challenging particularly in women in which they have experienced a range of stressors, and that there is a complex cyclical relationship between stress and diabetes with the potential for this to become a spiralling one (Smith,2012). In another study (Priharjo, 2014) it was suggested that the difficulties were also observed in young people and the elderly. The later study also showed the association between the patients' positive views with psychosocial outcomes. However it is debatable whether patients who view themselves positively tend to achieve a better outcome. Therefore, the aims of the study are:

- To investigate common elements of 'positivity' (focus on positive) in young and older people with their diabetes. Areas such as self-concept including ego defensive, values on family and social functioning, severity of diabetes/ diabetes care profile and beliefs on support from health care professionals will be examined.
- To investigate factors contributing to positive attitudes of living with diabetes in the two groups. Demographic variables such as age, gender, marital status, types of diabetes as well as clinical
- To compare the level of 'positive attitudes' between the young and older people with diabetes.
- To develop the Diabetes Positive Attitudes Rating Questionnaire (DPARQ) for young or older people with diabetes.

**DESIGN/METHODS:** Youngpatients (age: 15-24 years old) and elderly patients (age: 75 years old upwards) and who are registered to the selected GP surgeries in Cambridgeshire and Essex will be asked to participate in this study. The intention is to recruit 50 patients from the two groups, who are considered to have positive attitudes by their General Practitioners (GPs), Diabetes Specialist Nurses or Practice Nurses. The demographic data will be collected for further analysis. Patients who agree to participate will be interviewed separately or invited to focus groups. The plan is to interview 15 young patients and 15 elderly and then 10 of the young patients and 10 from the elderly group who will be invited to separate focus groups.

**PLANNED ANALYSIS:**
The data obtained from the interviews/ focus group **will** be transcribed verbatim. Thematic analysis will be utilised to investigate the emerging themes from both groups. In addition to this, narrative stories will also be collated. Further analysis will be conducted to combine and compare the results obtained from the two groups so that a comprehensive list of themes can be produced. MAXQDA–Qualitative Data Analysis software will be utilised to create the code system, to organise and sort the established categories. The results will inform the next stage of the study in which Diabetes Positive Attitudes Rating Questionnaire (DPARQ) for young or older people with diabetes will be developed. The purpose of the questionnaire is to measure attitudes of people with diabetes in terms of positivity.

**EXPECTED OUTCOMES:** Results will provide the common elements of 'positivity' (focus on positive) in young and older people with their diabetes. The study is also expected to highlight whether the elements and

factors contributing to positive attitudes in the two age groups could be similar or different. Finally, it is hoped that a questionnaire will be developed and tested in the next study.

**PROBLEMS/QUESTIONS:**

1. Are there any existing tools to measure positive attitudes of patients with diabetes particularly in young and elderly age groups?
2. The proposal is suggesting that a phase in a sequential research design is applicable for developing the questionnaire. The discussion question is whether there are other more appropriate techniques to achieve this.

# AN EXPLORATORY STUDY OF THE EXPERIENCE OF DIAGNOSIS AND THE BIO-PSYCHOSOCIAL FACTORS THAT AFFECT AND ARE AFFECTED BY THE PROCESS OF INTEGRATION OF THE DISEASE IN ADULTS WITH NEWLY DIAGNOSED TYPE 1 DIABETES

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**AIMS:** Being diagnosed and learning to live with type 1 diabetes (T1DM) affects all areas of life. At time of on-set, adults (≥ 18 years of age) are routinely taught therapeutic self-management skills. In spite of the self-management education at onset and a range of new technologies within treatment modalities, many adults with longer duration of type 1 diabetes exhibits poor control and are affected by complications and psychological problems connected to the disease such as depression and/or distress. A potential factor in explaining this variance may be their experience of, and response to diagnosis. The factors that may determine an individual´s response to diagnosis and the person's ability to integrate the disease are wide ranging. It may both be a variety of protective or detrimental biological, social and psychological characteristics as well as factors relating to their experience of diagnosis. The aims of the study are to explore the experience of being diagnosed with type 1 diabetes in adulthood. In addition which and how bio-psychosocial factors affect and are affected by clinical outcomes and the process of integration of the disease in everyday life. The findings will inform the development of a framework for a research based intervention in adults with newly diagnosed type 1 diabetes to promote successful integration of bio-psycho-social factors during the first two years after onset.

**DESIGN/METHODS:** The population will consist of adults (≥18 years of age) who have been diagnosed with type 1 diabetes within the past two years. Participants will be recruited from King's Hospital, London UK and Steno Diabetes Centre, Copenhagen Denmark. The study design is mixed method. The first part is a register based study on approximately 300 adults. Data on variations in weight, HbA1c, c-peptide, amount of insulin used, GAD and TSH during the first two years of diabetes will provide information on the physical trajectory e.g. time span for the honeymoon phase. Moreover data on circumstances of debut (e.g. intercurrent disease) and family history of diabetes, age, gender, socio-economic status, education, employment and civil status will be collected to provide information on the social factors. Also a number of self-reported generic and diabetes specific questionnaires will provide information on the psychological factors in the participants. These will be chosen after a more extensive literature review. In addition one focus group interview (FGI) will be conducted with a group of 6-8 persons to provide a broad understanding of the complexity and variance in the experience during the first two years after onset. The second part of the study willinvolve in-depth interviews with 10 persons within the first two years of on-set strategically chosen from the results of the first part. The same quantitative data as in part one will be collected in these persons. Concurrent with these interviews a prospective study with 8 persons from the time of diagnosis to 12 months after will be initiated. This will involve in-depth interviews, field observations of consultations and personal diaries containing information of their experiences. The observations will provide information on the self-management education offered and the interaction with health care providers. The participants will be asked to record their experiences concerning change in their perception of the illness during the time of entering into and out of the honeymoon phase. This information will be an important adjunct to the in-depth interviews and the quantitative data that will also be collected in this group.

**PLANNED ANALYSIS:** The register based study will provide descriptive information on variations in the physical trajectory of the disease as well as the psychosocial aspects. The qualitative data will be analysed using inductive thematic analysis. Data will be systematically organized into meaningful groups with tentative codes. Further analysis of the tentative codes will be conducted to find patterns and meanings pointing to more specific themes and codes. The data will be compared in order to find differences and similarities according to the specific themes and codes.

**EXPECTED OUTCOMES:** The expected outcome is to understand the complexity and variability in the way adults with newly diagnosed type 1 diabetes subjectively experience the impact of diagnosis and how this effects the integration of the illness in everyday life. The qualitative data will provide understanding of different personal constructs and the quantitative data inform about the magnitude and variance in measureable variables. By combining methods and building on the specific strengths of both, a far-reaching and more comprehensive knowledge will appear. This knowledge is expected to provide a basis for the development of a research based intervention to promote successful integration of bio-psycho-social factors during the first two years after on-set.

**PROBLEMS/QUESTIONS:**

1. Are there any other bio-psychosocial variables that would be important to collect data on?
2. Would other qualitative data collection methods be appropriate?
3. Any experience on cross country studies?