23rd Spring Scientific Meeting

Verona, Italy

3rd-5th May 2018

www.psad-easd.eu
Organizers:

PSAD Scientific Spring Meeting, Verona, 3rd-5th May 2018

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Italy
From the Chair

Dear Members,

Welcome to the 23rd PSAD Scientific Spring meeting and welcome to the beautiful and romantic city of Verona.

In an attempt to further promote discussion and exchange of ideas at the meeting, we have made a number of changes to this year’s programme. As you can see from the programme overview, all work will be presented in themed sessions, which will include a mixture of completed work and work in progress. The presentations will be short (10min for completed work and 5min for work in progress) and discussions will take place only after the presentations with the aim to place the work in the larger perspective of the underlying theme. The session Chairs, therefore, will play a much more active role than in previous years.

As per tradition, the scientific programme will start with the Anita Carlson lecture. We are very pleased that Dr Dimitrios Pournaras, Gastrointestinal & Bariatric Surgery Consultant at North Bristol NHS Trust has accepted our invitation. He will talk about his work on bariatric surgery, how the treatment compares to other treatments (lifestyle, very low calorie diets, etc.) and what the psychological implications are. After the lecture and discussion, there will be dinner at the hotel.

Friday will start with the PSAD Science Award followed by the first session on depression. After the coffee break, there will be two sessions, one on person-centred diabetes care and the other on resilience and quality of life in type 1 diabetes.

After lunch, we will resume with a session on technology in diabetes. This will be followed by a parallel session for those interested in the new working group “Diabetes in Children, Adolescents and Emerging Adults” or the European Depression in Diabetes research consortium (EDID) working group.

The social programme will start at 17.30; dinner is at 19.00 at the Ugo’s Osteria restaurant.

On Saturday, we will have an early start (8.30am) with a round table discussion on How to stimulate dissemination of effective psychosocial interventions and assessment methods in diabetes care within the EASD? While we are comfortably discussing psychosocial issues within the PSAD, our measure of success should be whether other disciplines take notice.

The scientific sessions will start at 9.00am with a session on patient reported outcomes (PROs) followed by a session on hypoglycaemia in diabetes. As usual we will conclude the meeting with the business meeting.

On behalf of the Executive Committee, and the local organiser, Dr. Liliana Indelicato, I wish you a fruitful and rewarding meeting and a pleasant stay in Verona.

Prof. Arie Nouwen

Chair of the PSAD
Verona historical city centre

Verona is a city characterised by more than two thousand years of history. During the Roman Empire it was an instrumental political and commercial centre, whose magnificent traces can still be seen: the Roman Arco dei Gavi, the Arena, the Roman Theatre, Porta Borsari, the archeological area near Porta Leoni and the Scavi Scaligeri. This area, situated in the middle of the city, only some meters away from Piazza Erbe, became in the Middle Age centre of political and economic power. Here the marks of different historical periods are harmoniously moulded together: from Roman ruins to magnificent palaces of the 18th –19th century situated between medieval buildings, that flourished under the reign of the Signori Scaligeri, and Renaissance style buildings.

Nowadays Verona attracts people from everywhere thanks to the Arena, the myth of Romeo and Juliet and its precious beauty. Shakespeare had already set here his Romeo and Juliet drama, the most famous and cherished love story of all times. The star-crossed lovers’ places “Juliet’s House” with the famous balcony, Juliet’s tomb and Romeo’s House are among the must-see destinations today.

Osteria da Ugo

Ugo’s Osteria is a restaurant located in the centre of Verona just a few step from Juliet’s house and Porta Leoni. The Osteria serve dishes carefully prepared following the traditional cuisine of the Veneto Region. The menu varies periodically according to the seasonal products and the chef’s creativity. All the recipes are made by the Kitchen Team following step by step the instructions of their Chef Daniele Galletti.

Looking forward to see you in Verona!
Scientific Programme Thursday, 3 May

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<tr>
<td>17.00-18.00</td>
<td>Registration (€150) and welcome reception at the hotel</td>
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<tr>
<td>18.00-18.15</td>
<td>Welcome – Opening remarks PSAD Chair: Arie Nouwen</td>
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<td>18.15-19.15</td>
<td>Anita Carlson Lecture: Professor Dimitri Pournaras, United Kingdom.</td>
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Scientific Programme Friday, 4 May

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<tr>
<td>9.00-9.30</td>
<td>Science Award</td>
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<td>9.30-10.30</td>
<td>Session I Depression</td>
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<td>9.30-9.40</td>
<td>Evaluation of a stepped care approach to manage depression and diabetes distress in people with diabetes: results from the randomised controlled ‘ECCE HOMO’ trial A. Schmitt</td>
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<td>9.40-9.50</td>
<td>Markers of macrovascular dysfunction are associated with depressive symptoms: The MAASTRICHT study M. Schram</td>
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<td>9.50-9.55</td>
<td>The TRIANGLE study: Towards a better understanding of diseases distress, depression, and poor glycaemic control leading to personalised interventions for people with diabetes D. Ehrmann</td>
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<td>9.55-10.30</td>
<td>Discussions, questions and answers Facilitator: Arie Nouwen</td>
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<td>10.30-10.45</td>
<td>Coffee Break</td>
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<td>10.45-11.45</td>
<td>Session II Person-Centered Diabetes Care</td>
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<td>10.45-10.55</td>
<td>Person-centered methods in group-based diabetes education V. Stenov</td>
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<td>10.55-11.05</td>
<td>Living with type 2 diabetes: interactions between women, healthcare professionals and the need for pre-pregnancy care R. Forde</td>
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<td>11.05-11.10</td>
<td>Implementing a team-based person-centered self-management support intervention among people with T2DM diabetes in general practice M. Graue</td>
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<td>11.10-11.15</td>
<td>Improving outcomes in young adults with Type One Diabetes: the D1 Now intervention optimisation process D. Walsh</td>
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<td>11.15-11.45</td>
<td>Discussions, questions and answers Facilitator: Andreas Schmitt</td>
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<td>11.45-12.45</td>
<td>Session III Resilience and QoL in Type 1 Diabetes</td>
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<td>11.45-11.55</td>
<td>Health-related quality of life of adolescents with type 1 diabetes in the context of resilience A. Lukacs</td>
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<td>11.55-12.05</td>
<td>Evaluation of psychosocial factors in adolescents with type 1 diabetes attending summer camps M.I. Colombini</td>
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<td>12.05-12.15</td>
<td>Psychosocial resilience contributes to better glycaemic control in people living with type 1 diabetes J. Huber</td>
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<td>12.15-12.20</td>
<td>Piloting the use of an acceptance commitment therapy intervention to improve quality of life for adolescents with type 1 diabetes T. Bufacchi</td>
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<td>12.20-12.45</td>
<td>Discussions, questions and answers Facilitator: Ingrid Willaing</td>
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<td>12.45 – 13.45</td>
<td>Lunch</td>
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### Scientific Programme Friday, 4 May

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<th>14.00-15.00</th>
<th>Session IV Technology in Diabetes</th>
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<td>Gamification in diabetes management apps – a systematic review</td>
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<td>14.10-14.20</td>
<td>The effect of telemedicine follow up care on patient reported outcome measures: A Cluster Randomized Controlled Trial</td>
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<td>14.25-14.30</td>
<td>Effectiveness of Continuous glucose monitoring versus Stepped TEPPED care with hypoaware, a web-based PsychoEducational intervention, and adding CGM as needed, in adult Type 1 diabetes with impaired hypoglycaemia awareness: ECSPECT-HYPO trial</td>
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<td>14.30-15.00</td>
<td>Discussions, questions and answers</td>
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**15.00-16.00 Parallel Sessions**

**EDID**

**Chairs:** Arie Nouwen, Dominic Ehrmann

**Diabetes in children, adolescents and emerging adults**

**Chairs:** Ingrid Willaing, Dan Grabowski

### Scientific Programme Saturday, 5 May

**8.30-9.00 Round Table Discussion**

**Chair:** Arie Nouwen

**How do we stimulate dissemination of effective psychosocial interventions and assessment methods in diabetes care within the EASD?**

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<th>Session V PRO in Diabetes</th>
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<td>9.00-9.10</td>
<td>Developing a core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi Consensus study</td>
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<td>9.10-9.15</td>
<td>How can we Use Patient – Reported Outcomes to promote patient centred care and psychosocial support in type 1 diabetes routine consultations (UPRO)? - A feasibility study</td>
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<td>9.15-9.25</td>
<td>Outcomes of national project to identify patient-important PRO domains for use in value based-diabetes care in Denmark</td>
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<td>9.25-9.35</td>
<td>Selecting process measures to demonstrate how structured type 1 diabetes education improves glycaemic control: the DAFNEplus logic model on behalf of the NIHR DAFNEplus Study Group</td>
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<tr>
<td>9.35-10.00</td>
<td>Discussions, questions and answers</td>
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**10.00-10.10 Coffee Break**

### 10.10-11.10 Session VI Hypoglycemia in Diabetes

| 10.10-10.15 | Sustaining couples’ relationship to support type 1 diabetes self-care: Co-designing an intervention | J. Sturt, R. Messina |
| 10.15-10.20 | Navigating between Scylla and Charybdis with your eyes closed: Psychological predictors and consequences of nocturnal hypoglycemia in type 1 diabetes | G. Nefs |
| 10.20-10.25 | HypoRESOLVE (Hypoglycaemia - REdefining SOLutions for better lIVEs): a new, multinational study that is also focused on the psychological impact of hypoglycaemia, with funding from the Horizon 2020 programme | F. Pouwer |
| 10.25-11.10 | Discussions, questions and answers | Facilitator: Jane Speight |

**11.10-11.50 PSAD Business Meeting**

**Chair:** Arie Nouwen

**11.50-12.00 Final Remarks**
Session I  Depression

Title: EVALUATION OF A STEPPED CARE APPROACH TO MANAGE DEPRESSION AND DIABETES DISTRESS IN PEOPLE WITH DIABETES: RESULTS FROM THE RANDOMISED CONTROLLED 'ECCE HOMO' TRIAL

Authors: A Schmitt1,2, A Reimer1,2, B Kulzer1,2,3, D Ehrmann1,2,3, T Haak1, N Hermanns1,2,3

Institute: 1 Research Institute of the Diabetes Academy Mergentheim (FIDAM), Diabetes Center Mergentheim (DCM), Bad Mergentheim, Germany  
2 German Center for Diabetes Research (DZD), Munich, Germany  
3 Otto-Friedrich-University of Bamberg, Department for Psychology, Bamberg, Germany

Depression and diabetes distress are common affective conditions in people with diabetes (PWD) and associated with suboptimal treatment outcomes. This prospective randomised controlled trial analysed the effects of a stepped care approach for people with diabetes and comorbid depression and/or diabetes distress.

METHODS and PARTICIPANTS
PWD (T1DM/T2DM) and depression (CES-D score ≥16) and/or diabetes distress (PAID score ≥40) were randomly assigned to either the stepped care approach or a usual care control condition. Stepped care included: (1) diabetes-specific CBT group treatment for depressive symptoms and distress; (2) personal generic CBT depression treatment via telephone (weekly); (3) referral to psychotherapy and/or psychiatric treatment (step 1 delivered in inpatient setting). The control group received inpatient diabetes care and education. Measurement time points were baseline, post-treatment and 12-month follow-up. The primary outcome was a clinically significant reduction of the HAMD depression score (below the cut-off score of 9 or by ≥50%). Secondary outcomes were changes in depressive symptoms (HAMD, CES-D), diabetes distress (PAID), emotional well-being (WHO-5), hrQOL (EQ-5D), diabetes acceptance (AADQ), self-care behaviour (SDSCA), glycaemic control (HbA1c) and markers of inflammation (CRP, IL-6, IL-1Ra, IL-18, MCP-1, adiponectin). Data were analysed using repeated measures ANOVA.

RESULTS
2523 PWD were screened; 1295 were screened positively; 641 met the inclusion criteria; 260 consented and were enrolled into the study (sample characteristics: age 45±14 years; 55% female; 64% T1DM; HbA1c: 8.8±1.5%; mean baseline CES-D and PAID scores: 23.8±9.6 and 39.9±18.5, respectively). 131 persons were randomised to stepped care, 129 to the control condition. 40 persons (15%) dropped out before completing the study. A meaningful reduction of the HAMD depression score (below 9 or by ≥50%) at post-test and follow-up was reported by 96.1% versus 68.0% and 87.0% versus 48.2%, respectively, of those in the treatment group versus control group (p<0.01). Persons in the treatment group reported significantly greater reductions of depressive symptoms in the HAMD interview at both post-test (d=1.71 vs. 1.15, p<0.01) and follow-up (d=1.53 vs. 0.65, p<0.01). However, CES-D depression scores did not indicate significantly greater reductions of depressive symptoms in the treatment group (post-test: d=1.44 vs. 1.15, p=0.07; follow-up: d=0.97 vs. 0.66, p=0.07). Diabetes distress levels reduced in both the stepped care (post-test: d=0.92; follow-up: d=0.66) and control group (post-test: d=0.70; follow-up: d=0.46) with a significant difference between groups at post-test only (p=0.01; follow-up: p=0.13). Emotional well-being was significantly more strongly improved in the treatment group at both post-test (p<0.01) and follow-up (p=0.01). There was also a significantly greater improvement in diabetes acceptance levels in the treatment group at follow-up (p=0.04). Both groups improved in hrQOL, self-care and HbA1c without significant differences between groups (p≥0.09). There were no between-groups differences in changes of inflammation markers (p≥0.31).

CONCLUSIONS/DISCUSSION
The stepped care approach was effective in reducing depressive symptoms, but diabetes distress was reduced on short-term only. Treated persons also reported greater improvements in well-being and diabetes acceptance. However, effects on self-care, glycaemic control and hrQOL were not larger than those in the diabetes care and education group.
Session I Depression

Title: MARKERS OF MICROVASCULAR DYSFUNCTION ARE ASSOCIATED WITH DEPRESSIVE SYMPTOMS: THE MAASTRICHT STUDY

Authors:
Miranda T Schram, a,b,e Marnix JM van Agtmaal, a,b Coen DA Stehouwer, a,b Ben M Sörensen, a,b Tos TJM Berendschot, c Jan SAG Schouten, c Sebastian Köhler, d Nicolaas C Schaper, a,b Ronald MA Henry, a,b,e Carla van der Kallen, a,b Annemarie Koster, f,g Simone JPM Eussen, b,h Alfons JHM Houben a,b

Institute:
a Department of Internal Medicine, b School for Cardiovascular Disease (CARIM), c Department of Ophthalmology, d Department of Psychiatry and Neuropsychology, e Heart and Vascular Center, f Department of Social Medicine, g Care and Public Health Research Institute (CAPHRI), h Department of Epidemiology; Maastricht University Medical Center (MUMC+), Maastricht, the Netherlands

AIMS
The etiologic factors of late-life depression are still poorly understood. The vascular depression hypothesis suggests that microvascular dysfunction is involved in the etiology of depression. However, direct evidence of this association is scarce. Therefore, we investigated whether markers of microvascular dysfunction are associated with late-life depression in a population-based cohort study.

METHODS AND PARTICIPANTS
We used cross-sectional data from The Maastricht Study (n=2029; 83 with clinically relevant depressive symptoms, mean age 59.5 ± 8.2 years, and 49.6% were women). Depressive symptoms and major depressive disorder were assessed by use of the 9-item Patient Health Questionnaire (PHQ-9) and Mini-International Neuropsychiatric Interview, respectively. Clinically relevant depressive symptoms were defined as PHQ-9≥10. We measured microvascular function by use of flicker light-induced retinal vessel dilation response (Dynamic Vessel Analyzer), heat-induced skin hyperemic response (laser-Doppler flowmetry), and plasma markers of microvascular endothelial function (sICAM-1, sVCAM-1, sE-selectin, and vWF). In addition, we calculated a pooled estimate of microvascular function. We used logistic and negative binominal regression analyses to investigate the association between markers of microvascular function and depression, and adjusted for age, sex, diabetes, and cardiovascular risk factors.

RESULTS
After full adjustment, markers of microvascular dysfunction in retina and skin, and the pooled estimate were significantly associated with clinically relevant depressive symptoms (odds ratio pooled estimate 1.31 per SD {1.13; 1.51}). In addition, markers of microvascular dysfunction in retina, plasma, and the pooled estimate were significantly associated with depressive symptoms as a continuous measure (risk ratio pooled estimate 1.05 per SD {1.02; 1.08}). No significant associations were found between markers of microvascular function and major depressive disorder.

CONCLUSIONS/DISCUSSION
Markers of microvascular dysfunction in retina, skin, and plasma are independently associated with depressive symptoms. These findings support the concept that microvascular dysfunction is associated with depression and might provide a potential target for the prevention and treatment of depression.
Session I Depression

Title: THE TRIANGLE STUDY: TOWARDS A BETTER UNDERSTANDING OF DIABETES-DISTRESS, DEPRESSION, AND POOR GLYCAEMIC CONTROL LEADING TO PERSONALISED INTERVENTIONS FOR PEOPLE WITH DIABETES

Authors: Dominic Ehrmann, Andreas Schmitt, Bernhard Kulzer, Norbert Hermanns

Institute: FIDAM – Research Institute Diabetes Academy Mergentheim

AIMS
This study will analyse the association of behavioural (self-management, physical activity), physiological (glycaemic control, sleep patterns, inflammation, neuroendocrine response, heart rate), and psychological (daily hassles, distress, depression) factors within a longitudinal design. The primary research question will focus on how depressive symptoms and diabetes distress are associated with glycaemic control and how daily hassles mediate these associations. This way, possible underlying mechanisms of the associations between depression/distress and glycaemic control can be identified.

Insights from the allostatic stress model are used to help identifying possible mechanisms such as the accumulation of stress and daily hassles that translate to depression and poor glycaemic control. Furthermore, new diabetes technologies such as Flash Glucose Monitoring broadens our understanding of glycaemic control and offers a more detailed analysis of the association between depression, diabetes-distress and different markers of glycaemic control (e.g. mean blood glucose, time in hypo-, hyper- and euglycaemic ranges, glucose variability). New ambulatory wearables in combination with Smartphones are especially suited to measure physical activity, sleep patterns, and heart rate in patients’ daily life. Therefore, enabling tracking of behavioural and physiological factors potentially affecting both mental health and glycaemic control.

DESIGN/METHODS
The study consists of a t0 phase which lasts for 4 weeks and a single follow-up measurement point (t1) 3 months after the end of the t0 phase. At the beginning of the t0 phase, patients will complete questionnaires (depression/distress) and inflammatory markers as well as HbA1c are assessed. Event sampling via ecological momentary assessment (via Smartphones and wearable devices) will be used in the t0 phase to assess self-care behaviour, possible “daily hassles” (e.g. mood, stressful events) and physiological parameters (e.g. sleep pattern and quality, heart rate). Additionally, cortisol levels (saliva) are assessed 8 times during this 4-week t0 phase. At the end of the t0 phase and at the t1 follow-up, patients will again complete questionnaires. During the whole study period, patients will use Flash Glucose Monitoring to continuously assess glycaemic control.

A total number of 200 patients will be recruited, stratified by depression and diabetes-distress status. Four groups à 50 patients are planned: (1) no diabetes distress + no depression (2) elevated diabetes distress + no depression (3) no diabetes distress + elevated depression and (4) elevated diabetes distress + elevated depression.
PLANNED ANALYSIS
Dependent variable of interest is glycaemic control (at the end of the t0 phase and the t1 follow-up). Independent variables of interest are depressive symptoms and diabetes distress (from all measurement points). Mediating factors are daily hassles and physiological variables assessed during the t0 phase. Structural equation models as well as mixed regression analysis are planned to address the research questions in order to account for the longitudinal design.

Additionally, the following confounding variables will be assessed at the beginning of the t0 phase: Childhood adversity, socioeconomic status, social support, work stress, diabetes acceptance, coping with stress, psychiatric disorders, diabetes treatment, late complications. All analyses will be adjusted for these possible confounders.

EXPECTED OUTCOMES
We expect to identify how daily hassles accumulate into distress/depression and what kind of daily hassles have the strongest impact. This in turn is used to identify how glycaemic control is affected by these psychological factors. We also expect to gain a better understanding of how daily hassles and distress/depression are associated with physiological parameters and how these associations affect glycaemic control.

The identification of mediating mechanisms between glycaemic control and depression, diabetes distress as well as neuroendocrine parameters, biomarkers of inflammation, experiences of stress, mood fluctuation, sleep quality and physical activity is important to develop individualized and personalized intervention in people with diabetes and comorbid mental health problems.

Furthermore, this longitudinal, ecological design can lead to a better understanding of the mechanisms that translate depression into higher morbidity and mortality in people with diabetes.

PROBLEMS/QUESTIONS

1. High data quality is challenging in this design since participants are asked to wear the devices and complete the daily event sampling. What is the best strategy to maintain a high adherence to our ecological momentary assessment?

2. We will collect lots of data over a long period of time. What statistical method/analysis strategy is best suited for this time-series design?

3. Any other pitfalls we might have overlooked?
Title: PERSON-CENTERED METHODS IN GROUP-BASED DIABETES EDUCATION

Authors: Stenov V., Wind G., Reventlow S., Hempler N.F.
Institute: Diabetes Management Research, Steno Diabetes Center Copenhagen

BACKGROUND
Diabetes education is widely offered and is a critical component for people living with type 2 diabetes (T2DM). A person-centered approach is pivotal to enhancing the ability of individuals with T2DM to perform self-management. Nevertheless, the concept remains challenging to implement in practice because programs often have a fixed curriculum dominated by biomedical issues and one-way communication. Most person-centered methods are developed targeting individual consultations, although group-based diabetes education is a widespread and efficient method of support. Person-centeredness in group-based diabetes education requires a change in practice towards addressing biopsychosocial issues and facilitating group processes. There is an important gap in the evidence pertaining to developing the best strategies for training healthcare professionals (HCPs) to implement person-centered approaches in group-based diabetes education.

AIM
The aim of the study was to investigate, develop, and implement approaches supporting HCPs in facilitating group-based, person-centered diabetes education among adults with T2DM.

METHODS AND PARTICIPANTS
The study was guided by action research and divided into three research studies: investigating, development, and pilot. In the first study, observations across five settings were conducted. 13 HCPs and 49 group participants took part; the focus was to investigate approaches that supported or hindered person-centeredness in groups. Observations were supplemented by interviews (n=12) and two focus groups (n=16) with group participants, as well as interviews (n=5) with HCPs. In the second study, two workshops were conducted with HCPs (n=14). The aim was to develop approaches to support the facilitation of person-centeredness in groups. In the third study, field observations were conducted investigating how HCPs implemented the approaches. The final workshop evaluated the pilot test and developed new actions to further improve practice. Systematic text condensation and hermeneutic analysis were used to analyze data.

RESULTS
Study I: hindering approaches included a focus on delivering disease-specific information. Communication was dialog-based, but HCPs primarily asked questions with a single correct answer. Supporting approaches included letting participants set the agenda using open-ended questions. Study II: a self-assessment tool was developed to identify HCPs’ strengths and areas in need of professional development. The self-assessment tool was a starting point for a flexible and stepwise customization of professional development to match HCPs’ perceived needs, existing skills, and local circumstances. Study III: three categories described the implementation of new approaches: 1) some HCPs agreed with the concept, but implementation was challenging due to existing organizational structures and practices relying on the biomedical model; 2) other HCPs implemented approaches with a biopsychosocial focus but unable to structure the process; and 3) one setting succeeded with implementation, tailoring content and processes to group participants’ needs, promoting reflection and teachable moments.

CONCLUSION/DISCUSSION
The person-centered concept remains an ideal in many settings. However, the use of action research in professional development created context-sensitive methods and increased HCPs’ readiness to implement. More attention should be paid to systematic training of HCPs. Training should be structured incrementally, incorporating techniques directed towards existing skills and including ample time and resources to train and reiterate new ones.
Title: LIVING WITH TYPE 2 DIABETES: INTERACTIONS BETWEEN WOMEN, HEALTHCARE PROFESSIONALS AND THE NEED FOR PRE-PREGNANCY CARE

Authors: Rita Forde, Jacqueline Collin, Angus Forbes
Institute: King’s College London

BACKGROUND
There is an increasing prevalence of pregnancies among women with type 2 diabetes (T2DM). This group account for almost a half of all pregnancies among women with pre-gestational diabetes in the UK. Such pregnancies are associated with adverse maternal and fetal outcomes which may be improved with appropriate care prior to and during early pregnancy. However, while pre-pregnancy care (PPC) for women with diabetes is associated with improved outcomes, the uptake among women with T2DM is poor, and many women with T2DM are not receiving any PPC.

AIM AND METHODS
To gain a better understanding of why this may be, we purposively sampled and individually interviewed 30 women with T2DM from diverse socioeconomic and cultural backgrounds and 22 healthcare professionals (HCPs). Both groups of participants were from primary and secondary care in an urban area in the UK, and had varied experiences of PPC. Data were analysed thematically using Framework Analysis.

RESULTS
How women viewed them self as a person living with T2DM during their reproductive years influenced their interactions with others, including HCPs, and their self-care behaviours. Such a diagnosis evoked a range of reactions among the women which were generally negatively orientated and depicted a sense of stigma. Women expressed discomfort about their diagnosis at such a young age and conveyed reticence about disclosing their diagnosis, as it resulted in unwelcome attention to their diet or weight. While some suggested that living with T2DM was ‘nothing major’ and saw no reason to divulge it, others indicated that their apparent indifference was a means of minimising their diagnosis. In general, the women’s perception of the severity of T2DM was influenced by the mode of treatment, with some regarding the addition of insulin as defining the importance of their condition and legitimising it to the outside world. Overall women’s interpretation of living with T2DM did not extend to include the need for specific elements of care, such as PPC.

Healthcare professionals disclosed that their inherent views and beliefs about this population were negatively orientated general assumptions about T2DM. They revealed that these views influenced their interactions with women with T2DM and they did not routinely attend to the reproductive healthcare needs of this population. Consequently, HCPs attributed the poor uptake of PPC to women’s ambivalence toward their own care and pregnancy planning (rather than the women’s lack of awareness about PPC) and did not consider that their actions or inaction contributed to this.

CONCLUSION
The way women positioned T2DM within their life may influence how they learn to live with it, develop self-management behaviours and interpret the need for specific care, such as PPC. HCPs need to be sensitised to better understand these influences and to also challenge their own biases, so that the reproductive healthcare needs of this population are incorporated into clinical interactions.
Session II Person-Centered Diabetes Care

Title: IMPLEMENTING A TEAM-BASED PERSON-CENTERED SELF-MANAGEMENT SUPPORT INTERVENTION AMONG PEOPLE WITH T2DM DIABETES IN GENERAL PRACTICE

Authors: Graue M, Kolltveit BCH

Institute: Faculty of Health and Social Sciences. Institute of Nursing, Western Norway University of Applied Sciences

Objectives. To evaluate the effects of a team-based person-centered self-management support intervention among people with T2DM diabetes, competence, autonomy and HbA1c.

Hypotheses. The intervention will 1) increase diabetes self-management, perceived competences and quality of life, 2) increase patient-provider communication and satisfaction with diabetes care and counselling, and 3) decrease emotional distress by using person-centered self-management.

Methods. We have developed a team-based person-centered self-management support intervention for people diagnosed with T2DM. We have conducted one modelling study and two feasibility studies to adapt the intervention from an originally seven session program for people with T1DM diabetes, into a four consultations program for use among people with T2DM. The intervention consists of in-person consultation using a fixed number of diabetes reflection sheets. Each person sets own specific goals and criteria for goal attainment. Primary outcome: Overall goal attainment for lifestyle changes and self-management. Secondary outcomes: Problem Areas In Diabetes (PAID) scale, patient competencies (PCDS), diabetes self-care activities (SDSCA), self-reported health (WHO-5), quality of life (The RAND-12 Health Status Inventory), HbA1c, referrals to specialist care and hospitalization, patient-provider communication, satisfaction with diabetes care and counselling, GPs’ annual use of the electronic diabetes form. In addition, we collect qualitative data on nurses and GPs’ experiences. We will use regression models to measure change in primary and secondary outcomes, and multivariate regression models to correct for possible confounding effects. Differences in changes from before to after the intervention will be analysed by mixed models and generalized estimating equation (GEE). We will use content analysis to analyse the interview data.

Possible impact. Through new knowledge on including the patients’ perspective on living with diabetes in GP consultations we will potentially find more effective strategies to enable people with T2DM to overcome barriers to self-care, improve health outcomes and quality of care.

1) Each person sets his/her own specific goals and criteria for goal attainment. I would like to discuss measures to assess overall goal attainment for lifestyle changes and self-management.

2) Primary care providers are ideally placed to engage patients in a dialogue about their health conditions, circumstances, health needs and personal values and preferences. I would like to discuss strategies to recruit patients in the pilot study.
Session II Person-Centered Diabetes Care

Title: IMPROVING OUTCOMES IN YOUNG ADULTS WITH TYPE ONE DIABETES: THE D1 NOW INTERVENTION OPTIMISATION PROCESS

Authors: D. Walsh¹,², M. Byrne¹, L. Hynes³, MC O’Hara⁴ and S.F. Dinneen²,⁵ on behalf of the D1 Now study team.

Institute:
1. Health Behaviour Change Research Group, School of Psychology, NUI Galway
2. School of Medicine, NUI Galway, Galway, Ireland
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5. Endocrinology and Diabetes Centre, Galway University Hospitals, Galway, Ireland

AIMS
Young adulthood can be a challenging time for Type 1 Diabetes (T1D) self-management as individuals can find it difficult to navigate this time of transition. Unfortunately, this has been associated with poor clinical and psychological outcomes among young adults. There is a need for effective interventions to improve outcomes for young adults. The D1 Now intervention aims to improve self-management and diabetes-related health outcomes among young adults with T1DM.

In previous research, the D1 Now study team have identified three areas as important for self-management among this population: (a) the young adult’s introduction to the adult diabetes services, (b) attendance at clinic appointments and informal contact between appointments and (c) building relationships between young adults and service providers.

The aim of this phase of the D1 Now study is to finalise the components and detail of the D1 Now intervention. Following this phase, we plan to test the usability, acceptability and feasibility of intervention.

Three components of the D1 Now intervention have been identified: (a) a key worker to introduce the young adult to the diabetes service and flexibly address the needs of young adults within the clinic; (b) an online Young Adult Service Portal to facilitate relationship building between staff and young adults and (c) an agenda setting tool to facilitate joint decision making and goal-setting within clinic appointments.

During the intervention optimisation phase, the operationalisation of these components will be developed based on iterative cycles of feedback from young adults and healthcare professionals.

DESIGN/METHODS
This study is a qualitative study exploring the feasibility and acceptability of 3 potential D1 Now intervention components. To test and refine these three identified components, 4 rounds of testing and refining will take place in one diabetes hospital clinic [University Hospital Galway]. Participants will be young adults with T1DM aged between 18-25 years attending an adults’ diabetes service and not currently participating in any other research study. Approximately 20-24 patients will take part in focus groups (n=5-6 per round). Focus groups from each round of testing and refining will follow a semi-structured interview guide and will be audio-taped and transcribed. Recruitment will continue until an adequate level of data saturation had been reached and no new significant insights emerge from interviews.

PLANNED ANALYSIS
Focus groups will be transcribed verbatim and analysed using inductive thematic analysis. NVivo will be used to manage data.
EXPECTED OUTCOMES
The findings will inform the optimisation of the D1 Now intervention, prior to the feasibility testing phase and future randomised pilot.

PROBLEMS/QUESTIONS (maximum of three) that you would like to be addressed in the group discussions

1. How can/should we maximise the involvement of our young adult panel within the focus group testing and refining development phase?

2. Suggestions for the best way to explore and define the key worker role within focus groups? We already have core requirements of what the key worker needs to achieve identified from previous developmental work, however, we have several stakeholders with potentially differing views of how this role can work within a young adult diabetes services. How can this feedback be best integrated to finalise the key worker role prior to the feasibility study phase?

3. Future directions question: number of sites in the randomised pilot and how these sites can then be used in a future RCT (i.e., excluded; assigned previous status from pilot etc.)?
Session III Resilience and QoL in Type 1 Diabetes

Title: HEALTH-RELATED QUALITY OF LIFE OF ADOLESCENTS WITH TYPE 1 DIABETES IN THE CONTEXT OF RESILIENCE

Authors: Andrea Lukács PhD, Mayer Kristina PhD, László Barkai MD, PhD, DSc
Institute: Faculty of Health Care, University of Miskolc, Hungary

AIMS:
The purpose of the study was to assess the health-related quality of life of adolescents with type 1 diabetes from multidimensional approach. The influence of gender, age, diabetes duration, glycemic control (measured by HbA1c), insulin regime, physical activity, resilience, and socioeconomic background (family structure and financial background) on health-related quality of life was investigated.

METHODS and PARTICIPANTS:
In this multicentre quantitative study, 229 adolescents (118 males, 111 females) with mean age of 15.35 ±2.29 were evaluated from 3 pediatric diabetes centres in Hungary. The participants’ mean diabetes duration was 7.47 ±3.87 years, the mean HbA1c was 8.13 ±1.38%. Health-related quality of life was measured using the Pediatric Quality of Life Inventory™ Diabetes Module; resilience was assessed using the Resilience Scale-15, physical activity was evaluated on the basis of self-report.

RESULTS:
There were significant correlations between health-related quality of life and resilience (r=.395; p<.001) as well as health-related quality of life and glycemic control (r=-.149; p<.05) Physical activity positively correlated with resilience (F=16.831; p<.001) and health-related quality of life (F=3.103; p<.05), whereas the use of insulin pump positively correlated with health-related quality of life (F=14.502; p<.001). Treatment with insulin pump therapy (t=-3.514; p<.001), male gender (t=-2.482; p<.01), and higher degree of resilience (t=6.381; p<.001) were determining factors of better health-related quality of life (R=.476, R²=.226). Stronger resilience was significantly predicted by physical activity (t=-3.500; p<.01) and better health-related quality of life (t=6.262; p<.001) (R=.455, R²=.200). Youths with type 1 diabetes living in intact family (8.01 ±1.40) had significantly better glycemic control than those living in incomplete family (8.64 ±1.23).

CONCLUSIONS:
The main goals of diabetes management are to achieve as favourable glycemic control and quality of life as possible. Some factors cannot be controlled such as age, gender and socioeconomic background; however, improving and developing resilience and treatment with insulin pump therapy and encouragement of patients to be physically active seem effective ways to achieve the aims.
Session III Resilience and QoL in Type 1 Diabetes

Title: EVALUATION OF PSYCHOSOCIAL FACTORS IN ADOLESCENTS WITH TYPE 1 DIABETES ATTENDING SUMMER CAMPS

Authors: Colombini M.I., Trezzi C., Pozzi C., Rimoldi C., Rigamonti A., Frontino G., Bonura C., Bonfanti R.
Institute: Department of Pediatrics, Endocrine Unit-Scientific Institute San Raffaele –Milan Italy

BACKGROUND:
Insulin-dependent diabetes mellitus (T1DM) is one of the most common chronic diseases among children and adolescents. The lifelong metabolic disorder requires strict adherence to treatment and to daily care tasks which can greatly affect the patients’ life. The relationship with parents and peers can be altered by the adolescent’s daily coping with diabetes care. From the onset of the diabetes an adolescent is a new individual, forced to redefine a new self-image in relationship with both the intrapsychic and the interpersonal-self.

AIMS:
Aim of our study was to analyze the impact of diabetes on the adolescent's burden and, in particular, to investigate mood, anxiety levels, eating habits, peers and family relationships, self-esteem and quality of life compared to healthy controls.

PARTICIPANTS:
266 paediatric patients with T1DM (148 boys/117 girls) aged from 11 to 17 years attending Summer Camps and 152 healthy controls (69 boys/74 girls) matched for age and sex were enrolled in the study.

METHODS:
All subjects were assessed using: Questionnaire about social difficulty for adolescence, Culture-Free Self-Esteem Inventory For Children-Form AD, Revised Children's Manifest Anxiety Scale (RCMAS-2), Five-items World Health Organization Well-being Index (WHO-5) and Paediatric Quality of Life Inventory (PedsQL). Adolescents with diabetes were assessed using additional questionnaires: Problem Areas in Diabetes (PAID) e Diabetes Eating Problem Survey-Revised (DEPS-R), respectively aimed at the measurement of emotional distress and the behavioral eating problems among adolescents with diabetes.

RESULTS:
Psychosocial difficulties among subjects with T1DM compared to healthy controls were mildly highlighted (21.08±9.07 vs 19.07 ± 8.23 p <.055). In experimential population sample adolescents’ self-esteem resulted lower than in controls (5.86 ± 2.58 vs 7.19 ± 2.39 p < .001). Our findings suggest a relation between the diabetes duration and some psychological factors: mood gets worse when disease lasts more than 1.5 years (7.57 ± 1.25 vs 6.60 ± 2.28 p <.004), higher eating problems (17.68 ± 9.15 vs 12.77 ± 7.78 p <.028) and social anxiety were found in subjects with the diabetes onset after 11 years old (51.00 ± 11.37 vs 46.09 ± 8.55 p <.028).

CONCLUSION/DISCUSSION:
These findings contribute significant information on the effects of T1DM on both emotional and social functioning from the perspectives of children. The study revealed only slightly higher impairment in psychosocial health functioning of children and adolescents with diabetes compared to their healthy peers. Moreover there are some differences in their psychological adjustment related to the timing of the onset. The study was focused on a population sample of adolescents attending summer camps. Our results suggest it might be interesting to increase our work extending it to a cohort of adolescents with T1DM followed as outpatients of the Paediatric Department.
Session III Resilience and QoL in Type 1 Diabetes

Title: PSYCHOSOCIAL RESILIENCE CONTRIBUTES TO BETTER GLYCAEMIC CONTROL IN PEOPLE LIVING WITH TYPE 1 DIABETES

Authors:
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BACKGROUND
Previous research in young adults living with type 1 diabetes has shown that psychosocial resilience is associated with lower HbA1c, but it is possible that for type 1 patients this advantage is confounded by higher residual insulin levels in some patients, helping to make glycaemic control easier for this group of patients.

METHODS
As part of a prospective study (StartRight; n=480), the CD-RISC 10-item resilience questionnaire scale was completed by 141 participants with type 1 diabetes with 2-12 months diabetes duration (mean duration=7.0 (SD 3.3) months; age 36.8 (13.6) years; males 57%). Regression analysis was carried out on those with c-peptide≥200pmol/l, a reliable indicator of a patient’s residual insulin release.

RESULTS
Resilience levels were high in this cohort (M=29.8; SD=7.0); the scale ranges from 0 to 40 (very low to very high resilience). In our regression model which adjusted for c-peptide and age as co-variates, stronger resilience was associated with lower HbA1c values (b=-0.53, p=0.02). The association of c-peptide with lower HbA1c values did not reach significance (b=-0.005, p=0.08), nor did age (b=0.12, p=0.10).

CONCLUSIONS
Stronger psychosocial resilience which tends to increase weakly with age is associated with better glycaemic control in adults with recently diagnosed type 1 diabetes and c-peptide levels above 200pmol/l. This finding is important in that resilience is linked to glucose control, independently of residual insulin levels, as demonstrated by our adjusted model. Follow-up data will provide further insight into the role of resilience, in relation to progressively reducing c-peptide levels, indicating reducing insulin release.
Adolescents with T1D can be vulnerable to a range of emotional problems from dealing with anxiety through to depression. In the absence of treatment, psychological distress during the transition from childhood to adulthood may persist throughout life, thereby substantially increasing the longer-term personal and social burden of the disease. Psychological interventions to date have shown that by focusing on teaching adolescents positive coping strategies the quality of life of adolescents with T1D can be improved. The psychological intervention being trialled in this project is based on Acceptance Commitment Therapy (ACT) and is designed to improve the quality of life and self-care of adolescents with T1D. ACT helps participants to step apart from their thoughts and develop what is called “psychological flexibility”. Psychological flexibility has been shown to be effective in decreasing anxiety and can be developed through the teaching of mindfulness strategies. ACT interventions are particularly well suited to adolescents as methods focus on personal responsibility, choice, and values.

This project will compare a face-to-face ACT intervention with an online mindfulness intervention designed for adolescents with T1D. The proposed project will be conducted as a pilot randomized controlled trial (RCT). As a pilot project, it will not be fully powered but will inform the development of a future multi-site RCT through the collection of quantitative and qualitative data. The co-primary outcomes for the pilot RCT are diabetes quality of life and self-care. Secondary outcomes are glycaemic control, coping styles and psychological flexibility. The aims of the project are as follows:

AIMS
1. Assess the acceptability and feasibility of a pilot multi-modal Acceptance Commitment Therapy intervention designed to enhance the psychosocial and health outcomes in adolescents with type 1 diabetes and compare multi-modal and online modes of intervention presentation.
2. Generate data to inform the development of a fully powered multi-site Randomised Controlled Trial.
3. Determine and compare preliminary effects of the ACT and mindfulness interventions on the psychosocial and health outcomes in adolescents with T1D.

METHODS
The planned intervention will be conducted over six weeks. Three groups will be involved with approximately 10 adolescents with T1D in each group. Group 1 will take part in six weekly face-to-face sessions during which they will be taught ACT strategies. The second group will attend one face-to-face session and then will be taught mindfulness strategies using an app for the rest of the six weeks. The third group will have care as usual.
PLANNED ANALYSIS
Means and standard deviations of outcome measures will be generated for baseline, post-intervention, and three-month follow-up. Estimates of effect sizes will be used to inform power and sample size calculations for a future multi-site RCT. The effect of the ACT on post-intervention and three-month follow-up outcomes for each measure will be explored using linear mixed models including random effects for individuals and adjusting for baseline. Further exploratory analyses will be conducted to examine possible mediators and moderators of the effect of the intervention on outcomes. Qualitative data collected from the focus groups will be analysed using NVivo software to identify themes related to key questions of acceptability and feasibility of the intervention.

EXPECTED OUTCOMES
1. Data to develop a multi-site ACT intervention that has the potential to improve psychosocial and health outcomes in adolescents with T1D and contribute to a smoother transition for adolescents as they become young adults. The processes adopted in this project will ensure that the intervention and delivery is appropriate to adolescents. Positive mental health through the adolescent years can limit health complications in later years.

2. Contribution to the emerging field of Acceptance Commitment Therapy (ACT) and Mindfulness research in relation to chronic disease, T1D and adolescents. Although ACT interventions have been trialled with people with various medical conditions, to date only one has been reported with people with T1D.

3. Empowering of adolescents with T1D in the study by presenting them with the opportunity to express their opinions through the focus groups and contribute to the shaping of a future intervention specifically for adolescents with T1D. This process will contribute to the development of an intervention that may be easily translated.

Questions
1) Is ACT an effective option for Teenagers with diabetes?
2) Can ACT be offered in a workshop style with stand-alone sessions to facilitate increased attendance?
3) Should the same intervention be offered also to parents?
Session IV Technologies in Diabetes

Title: GAMIFICATION IN DIABETES MANAGEMENT APPS – A SYSTEMATIC REVIEW

Authors: Lilli-Sophie Priesterroth, Jennifer Grammes & Thomas Kubiak

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AIMS
Recent years have seen tremendous progress in technical innovations to support the self-management of people with diabetes. This, including smartphone applications (“apps”) tailored to the needs of people with diabetes. Initial evidence shows that these diabetes management apps may have positive effects on daily diabetes self-management. It remains unclear, however, which app features are particularly effective and encourage patient’s engagement in sustained app usage. Gamification, that is the use of game-design elements in non-game contexts, is a promising way to improve app user acceptance, well established in software and app design. The aim of this systematic review was to provide an overview of gamification features in currently diabetes management apps.

METHODS
Google’s Play Store was searched for relevant applications using a broad search strategy (keyword: “diabetes”). We limited our research to freely available apps and examined the identified top 50 matches. Matching apps were reviewed in terms of the features they offer to support self-management. We used a taxonomy comprising 18 gamification techniques derived from the literature to evaluate the applications. Two independent raters tested and evaluated each app.

RESULTS
Accordance between the two raters was high (Cronbach’s alpha = .91). Descriptive analyses revealed an average of 1.82 gamification techniques (SD = 1.79) per app. Three techniques made up 65.93 % of the gamification elements identified in total. The gamification technique most often identified was “feedback” and accounted for 41.75 % of the gamification elements. Six of 18 techniques were not used at all (e.g., use of avatars). 14 % of the apps do not use gamification. One app stood out by implementing nine gamification techniques.

CONCLUSION
The potential of gamification in diabetes management apps has not been fully exploited yet. If gamification was implemented, app designers used a very restricted set of options. Given that gamification has the potential to facilitate diabetes self-management, the efficacy of single gamification techniques warrants for more in-depth systematic research.
Session IV Technologies in Diabetes

Title: THE EFFECT OF TELEMEDICINE FOLLOW UP CARE ON PATIENT REPORTED OUTCOME MEASURES: A CLUSTER RANDOMIZED CONTROLLED TRIAL

Authors:
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AIMS
To evaluate patient reported outcomes (PROMs) for patients with diabetes-related foot ulcers (DFUs) receiving telemedicine (TM) follow-up in primary health care in collaboration with specialist health care compared to patients receiving standard outpatient care.

DESIGN/METHODS
Patients with DFUs were recruited from three clinical sites in western Norway (2012–2016). Inclusion criteria were that patients have type 1 or type 2 diabetes and be aged 20 years or older, presenting with a new DFU to the clinical site. We excluded patients with a diagnosis of mental disorder or cognitive impairment, inability to complete questionnaires in Norwegian or life expectancy less than 1 year. The cluster randomized controlled non-inferiority trial included 182 adults (94/88 in the TM/control group) in 42 municipalities/districts. The intervention group received TM follow-up care in the community; the control group received standard outpatient care. Patient reported outcomes (EQ5D, HADS, WHO5, PAID, Neuro-QOL) were secondary end-points and evaluated for superiority.

PLANNED ANALYSES
Data were analyzed according to the initial group allocation (intention to treat). To account for clustering in treatment groups, we used linear mixed effects regression to investigate differences in mean sum scores for EQ5D, HADS (A/D), WHO-5, PAID and Neuro-QoL (subscales) at end of follow-up. Results are reported as regression coefficients with 95% CIs. Additional analyses: To test whether distance to the outpatient clinic affected the mean scores between the TM and control groups, we conducted a subgroup analysis with a linear mixed model, including only patients who lived 25 km from the outpatient clinic. We also performed additional analyses using a linear mixed model to test whether there was an association between severity of ulcer (grade and stage) and PROM scores and whether there was a difference in the sum scores between the three hospitals within the TM group. All analyses were also repeated excluding 13 patients originally assigned to the TM group who did not receive TM follow-up (per protocol analyses). A greater percentage of participants in the intervention group with ulcers on the toes than in the control group suggested possible differential selection. We therefore repeated the linear mixed-effects regression analyses adjusted for localization of ulcer. Statistical significance was defined as P < 0.05.

EXPECTED OUTCOMES
We hypothesized that the intervention improved PROMs (secondary outcomes) for the TM group. Preliminary analyses show no improvement in the general PROMS (EQ5D, HADS, WHO-5) and little improvement in psychological aspects of diabetes/foot ulcer specific quality of life measured by PAID and NeuroQoL.

PROBLEMS/QUESTIONS THAT YOU WOULD LIKE TO ADDRESS IN THE GROUP DISCUSSION
I would like to discuss the PROMS results from a clinical point of view.
Title: FEASIBILITY AND USABILITY OF A MOBILE PHONE SELF-HELP APPLICATION TO STRENGTHEN MENTAL WELLBEING IN ADULTS WITH DIABETES: A PILOT STUDY

Authors:
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AIMS
Living with and managing diabetes is demanding. In order to reach satisfactory medical and psychological outcomes, persons with diabetes (PwD) and their families are challenged to integrate self-care behaviours within daily life. These constant strains may have adverse effects on emotional wellbeing, self-care behaviours and glycaemic control. Psychological complaints, such as depressive mood, fatigue and impaired social functioning are indeed common in PwD. While there are ample mobile apps that target diabetes self-management, few if any have been developed to support PwD cope with diabetes from a psychosocial perspective. Therefore, we are developing a self-help app using efficacious e-mental health interventions based on cognitive behavioural therapy. The interventions individually aim to improve mental wellbeing i.e. mood, energy, positive social interactions and glycaemic stability. We use the eHealth platform of Minddistrict to build and distribute the app. Our objective is to test the first prototype of the app in a pilot study in order to examine feasibility and usability of the app, and explore changes in psychosocial outcomes of interest.

METHODS
The first prototype of the app will be tested in a non-randomized pilot study with pre- and post-measurements, using online questionnaires. A total of 30 participants will be recruited from the VU University Medical Centre, Academic Medical Centre and primary diabetes care. Participants will have access to the app over a period of three months, during which they determine for themselves the intensity of use and specific modules of the app. Additionally, log-data will be collected and analysed, and semi-structured interviews will be conducted. Feasibility is operationalised in terms of process (recruitment and selection, retention and use of app), used sources (comprehensibility and length of the questionnaires and interviews), and management (method, security and intensity of data collection). This will be measured with retention numbers, log-data of app use, and post-intervention semi-structured interviews. Usability is operationalized in terms of acceptability, comprehensibility, learnability, operability and attractiveness. Effects of app use are documented with regard to mental resilience, confidence in diabetes self-care, diabetes related distress, perceived social support, psychological well-being, fatigue severity, diabetes acceptancy and social functioning, which are respectively measured with the 10-item ‘Resilience Evaluation Scale’ (RES), 6-item ‘Confidence in Diabetes Self-Care Scale’ (CIDS), 5-item ‘Problem Areas in Diabetes 5’ (PAID-5) (31), 2-items of the social support subscale of the PAID-20 (32), 5-item ‘World Health Organization WellBeing Index’ (WHO-5) (33), 8-item fatigue severity subscale of the ‘Checklist Individual Strength’ (CIS) (34), 4-item Diabetes Acceptance Scale (DAS) (35) and 2-item social functioning subscale of the ‘SF-36’ (36).
PLANNED ANALYSIS
We will calculate the frequency and percentages of the feasibility and usability scores and summarize the themes of our qualitative data. Baseline measures will be summarized using mean and standard deviation and, in case of categorical data, frequencies and percentages. The differences between baseline and post access period to the app are analysed using paired sample $t$-tests. $P < 0.05$ will be considered statistically significant. SPSS version 22 will be used for all analyses.

EXPECTED OUTCOMES
We expect that the self-help app will be feasible and valued as useful in terms of strengthening psychological wellbeing and confidence in diabetes self-care by its users. Further improvements and dissemination of the app to a broader audience will then be sought.

Problems/questions: that you would like to be addressed in the group discussions

1. You can measure feasibility and usability in various ways: objectively by using for example log data and subjectively by asking the participants about their experience.
   a. We want to use log data to measure use of app. What is essential to measure and how to interpret the collected data?
   b. Which questions are crucial to ask to the participants in terms of usability of the app?

2. The app is for a diverse group of people with diabetes and aims to prevent psychological complaints. This means we do not expect much change in psychosocial factors. So, when can we consider the app in the pilot successful?
Title: **EFFECTIVENESS OF CONTINUOUS GLUCOSE MONITORING VERSUS STEPPED CARE WITH HYPOAWARE, A WEB-BASED PSYCHOEDUCATIONAL INTERVENTION, AND ADDING CGM AS NEEDED, IN ADULT TYPE 1 DIABETES WITH IMPAIRED HYPOGLYCAEMIA AWARENESS: ECSPECT-HYPO TRIAL**

Authors:
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AIMS
Events of severe hypoglycaemia (i.e. requiring third party assistance) adversely affect quality of life, and lead to significant morbidity and high societal costs in people with type 1 diabetes mellitus (T1D). Both the HypoAware approach, a blended group and online psycho-educational intervention based on the evidence-based Blood Glucose Awareness Training (BGAT), and continuous glucose monitoring (CGM) help patients get their blood glucose into the target range for more of the day and prevent hypoglycaemic event rates in up to 50% of people with impaired awareness of hypoglycaemia (IAH). We aim to evaluate the effectiveness and cost-effectiveness of a stepped-care approach starting with HypoAware, and adding CGM as needed, compared with CGM alone in T1D patients with IAH. We will assess differences in frequency of severe hypoglycaemia’s, as well as hypoglycaemia awareness and psychological well-being.

METHODS
A two-arm, multicenter cluster randomized controlled trial will be performed. We will recruit a total of 115 adult T1D patients with impaired awareness of hypoglycemia, as defined by Gold criteria (i.e., with a Gold score ≥4) and one or more severe hypoglycemic events in the past two years. Participating centers will be randomised into the CGM intervention group or the Stepped-care approach group, the latter starting with structured diabetes education (step 1, HypoAware) and progressing to CGM (step 2) if after 6 months hypoglycemia awareness has not improved or a severe hypoglycemic event has occurred. The primary endpoint will be the frequency of (self-reported) severe hypoglycemia events. As secondary outcomes we will investigate: quality adjusted life years (QALYs) and societal costs consisting of costs of healthcare consumption, informal care and lost productivity; hypoglycemia awareness (Gold score); frequency of mild hypoglycemia; glycosylated hemoglobin (HbA1c); psychological well-being: emotional well-being (WHO-5), fear of hypoglycemia (Hypoglycemia Fear Survey, HFS-II), diabetes-related distress (PAID), health status (EQ5D); and results from the diagnostic glucose sensor: time spent in the euglycemic range (interstitial glucose >3.9–<10.0 mmol/L), sensor-derived hypoglycaemic events, nocturnal hypoglycemia, area under curve (AUC) ≤3.9 mmol/L and glucose variability.

PLANNED ANALYSIS
Primary and secondary outcome data will be analyzed based on the intention-to-treat principle. Because of the repeated measurements, statistical analysis will be performed using generalized estimation equations (GEEs) with SPSS. We will use a linear model for continuous outcomes, a logistic model for dichotomous outcomes, and a Poisson or negative binomial model for count outcomes. In case of skewed continuous data, linear GEE analysis will be performed after log transformation. Besides the crude analysis (only adjusted for the baseline value of the particular outcome), two adjusted analyses will be performed; one adjusted for demographics (sex, age, and education level) and one adjusted for diabetes-related characteristics (episodes of severe hypoglycemia in the previous 2 years, diabetes...
duration, diabetes treatment method, and HbA1c level). A P value of < 0.05 will be considered to be statistically significant.

Differences between participants in the Stepped Care group and CGM group will be compared for all primary and secondary outcomes using Student t tests, Mann-Whitney U test, and Chi-squared test, or using non-parametric testing if not normally distributed. These parameters will also be analyzed within subjects, where measurements from baseline will be compared with 6 and 12 months. For these comparisons the paired T-test, Wilcoxon signed rank test and the McNemar test will be applied, or non-parametric testing if not normally distributed.

Additionally, both cost-effectiveness and cost-utility analyses will be performed.

EXPECTED OUTCOMES
A stepped-care algorithm will guide the health care professional in choosing the appropriate psychoeducational (HypoAware) and/or technological intervention (CGM) when faced with a person with impaired hypoglycemia awareness. Additionally, we expect that the stepped-care approach will decrease the need to escalate to continuous glucose monitoring with ~30% (Diabetes Care 2015; 38: 1592–609). HypoAware will lead to additional costs of €500,- once, whereas CGM costs an additional ~€4500 per year.

Problems/questions: that you would like to be addressed in the group discussions

1. Randomising participating centres, as opposed to randomising participants, might lead to selection bias, as the applied CGM or Stepped-care approach differ greatly in type of intervention. What can we expect in terms of selection bias, and how can this be dealt with most appropriately?

2. The HypoAware programme has a duration of 4 weeks, after which no booster training will be given to the participants. What can we expect the effect of a 4-week psychoeducational programme to be on long-term psychological and behavioural effects in humans? Also, is 12 months follow-up long enough to predict long-term efficacy?
Session V PRO in Diabetes

Title: DEVELOPING A CORE OUTCOMES SET FOR CLINICAL TRIALS OF INTERVENTIONS FOR YOUNG ADULTS WITH TYPE 1 DIABETES: AN INTERNATIONAL, MULTI-PERSPECTIVE DELPHI CONSENSUS STUDY

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AIMS
Young adults with Type 1 diabetes (T1DM) frequently struggle to manage their condition and report suboptimal clinical outcomes. Evidence synthesis on effectiveness of interventions to improve outcomes among this population is hampered by inconsistent choice of outcome measures. We report on an international, e-Delphi consensus study to identify a core outcome set (COS) that key stakeholders (young adults with T1DM, diabetes health professionals, diabetes researchers and diabetes policy makers) consider essential outcomes to measure in future intervention research.

METHODS/PARTICIPANTS
We conducted an international, multi-perspective Delphi consensus study, which involved three phases: (1) Generation of a list of all possible relevant outcomes; (2) an electronic Delphi survey, which contained two rounds and (3) a consensus meeting to agree a final COS. A total of 87 outcomes were generated from a previous systematic review. These outcomes were included in the two electronic surveys which were administered to a sample of international stakeholders. Participants in survey 1 (n=127) and survey 2 (n=81) rated the importance of the outcomes on a scale of 1-9 (1: not at all important; 9: extremely important). Survey 2 participants received information on total mean rating for each outcome for all respondents and a reminder of their personal outcome ratings from Survey 1. Consensus meeting participants (n=12: 3 young adults with T1DM, 4 diabetes health professionals, 4 diabetes researchers and 1 diabetes policy maker) discussed, rerated and voted on outcomes. Final core outcomes were included provided that 70% of consensus meeting participants voted for their inclusion.

RESULTS
Eight core outcomes were agreed for inclusion in the COS at the consensus meeting. These were: measures of diabetes-related stress; diabetes-related quality of life; number of severe hypoglycaemic events; self-management behaviour; number of instances of diabetic ketoacidosis (DKA); objectively-measured glycated haemoglobin (HbA\(_{1c}\)); level of clinic engagement and perceived level of control over diabetes.
CONCLUSIONS/DISCUSSION
This study provides an important first attempt to identify a Core Outcome Set for intervention research for young adults with T1DM. It provides guidance about what outcomes are important to young adults with T1DM and other key stakeholders. Future intervention research with this population should include these core outcomes, encouraging a more coordinated approach to intervention research in the future and facilitating more meaningful synthesis of research findings.
Our COS covers a broad range of aspects of diabetes, including stress, quality of life, medical or biological disease markers, self-management behaviour, level of engagement with health services and perceptions about control over diabetes. The fact that psychosocial outcomes, such as stress and quality of life, were strongly endorsed as important outcomes emphasises the need to broaden the types of outcomes which are traditionally prioritised beyond physiological measures of metabolic control.

Future research is needed to replicate the findings from this COS study, in particular testing its international generalizability, and to determine and provide guidance on the best outcome measurement instruments to select.
Session V PRO in Diabetes

Title: HOW CAN WE USE PATIENT-REPORTED OUTCOMES TO PROMOTE PATIENT CENTRED CARE AND PSYCHOLOGICAL SUPPORT IN TYPE 1 DIABETES ROUTINE CONSULTATIONS (UPRO)? - A FEASIBILITY STUDY

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BACKGROUND AND AIMS

It is well known that many people with type 1 diabetes experience psychosocial challenges, and that there is a significant association between mental health status and glycaemic control. People with diabetes who experience diabetes distress often prefer to talk about this with their diabetes healthcare provider. Thus it seems relevant that dealing with mental health issues is part of routine diabetes care such as diabetes consultations with a diabetologist.

Previous studies have shown that the use of patient-reported outcomes (PRO) prior to consultations, and inclusion of brief summaries and discussions of the PRO assessments in consultations can prime patients to be active. It also facilitates and improves dialogue between diabetologist and patient. Furthermore, studies have shown that using psychosocial PRO can help to direct focus to psychological health, improve psychological well-being and decrease diabetes distress.

In 2017, a dialogue tool was developed as a first step in the UPRO study. Different PRO and dialogue questions were tested in 15 diabetes consultations with five diabetologists at SDCC and Rigshospitalet with iterative evaluations and adjustments. Furthermore a questionnaire for patient evaluation was developed. The next step is to feasibility test the dialogue tool and the evaluation design.

The aim of the feasibility test is to explore:

- How and to what extent were PRO used?
- To what extent was patient-centric care and psychosocial support achieved?
- What are the facilitators and barriers in promoting psychosocial dialogue in routine consultations?
- What are the needs, barriers and facilitators related to implementing the use of PRO in routine consultation?

DESIGN/METHODS

The dialogue tool consists of the validated scales Problem Areas In Diabetes (PAID-5) and the generic well-being scale WHO-5. Furthermore, three dialogue questions “what are your successes?”, “what bothers you most about your diabetes?” and “what is important to discuss with the diabetologist?” were included. The dialogue tool is filled out online by the patient 3 days before their routine consultation. Indicators of low well-being and high distress are available for the diabetologist along with patient answers. Diabetologist and patient discuss patient answers in the consultation.

For the feasibility test we aim to include approximately 30 patients and 2-5 diabetologists to test the use of the dialogue tool in their diabetes consultations (Steno Diabetes Center Copenhagen and Rigshospitalet). Methods for assessing the feasibility of the dialogue tool and research methods will include: 1) audio recording of the consultation to explore how and to what extend PRO were used and observations of approx. 1/3 of the consultations, 2) structured interviews with people with type 1 diabetes and diabetologists after consultations to explore the impact and usefulness of use of the dialogue tool, 3) questionnaires regarding patient and diabetologist perception of the consultation 3) field notes of experiences and log of the recruitment and evaluation procedure. The questionnaires used in the evaluation consist of questions specifically developed for this project (experiences with use of the dialogue tool) and internationally validated scales (The Consultation and Relational Empathy (CARE) Measure and modified versions of the Patient Experience Questionnaire and Positive and Negative Affect Schedule (PANAS-SF)).
PLANNED ANALYSES
The recorded observations will be transcribed and talk time estimated in order to analyse e.g.: talk ratios (talk about psychosocial themes vs. talk about other themes, diabetologist talk vs patient talk) and consultation themes (thematic qualitative data analyses). Interviews with participants and diabetologists will be transcribed and thematically coded with focus on a) how and to what extent the PRO was used and discussed in the consultations b) facilitators and inhibitors in promoting psychosocial dialogue c) needs, barriers and facilitators related to implementing the use of PROs in routine consultation. Questionnaire data from people with diabetes will primarily be analysed descriptively and explored in connection to the data from observations and interviews – e.g. what characterised the consultations of participants scoring positive on the PEQ and CARE?

Findings from the questionnaires, interviews, observations and audio recordings of the consultations will be used to identify necessary adjustments of the dialogue tool, the procedure (use of tool) and the evaluation of the tool as well as potential facilitators and barriers to an effective implementation of the dialogue tool in practice. Findings in phase 2 will also include time consumption for use of the dialogue tool and recruitment and evaluations procedures.

EXPECTED OUTCOME
The study will result in 1) a feasible PRO intervention grounded in existing and validated PRO /tools, patient preferences and diabetologists’ needs and practices 2) a feasible research study (design and evaluation methods) to prepare an up scaled intervention study/effect study.

Problem/Questions:

- What will be the biggest challenge with regards to: 1) implementing the dialogue tool in consultations and 2) carrying out the study in practice?

- What further information do we need in preparation for the following effect study/RCT?
Title: SUSTAINING COUPLES' RELATIONSHIPS TO SUPPORT TYPE 1 DIABETES SELF-CARE: CO-DESIGNING AN INTERVENTION

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AIMS
There is a small but, growing literature around the impact of T1D on spouses/partners, in terms of fear of hypoglycemia, diabetes distress and uncertainty about how best to support their partner. Less is known about how type 1 diabetes specifically affects the relationship and the impacts of including the partner/spouse in diabetes self-care? No intervention studies have been identified. The present study will explore the challenges faced by couples living with type 1 diabetes, the effect that T1D has on partners’ physical health and well-being and the impact on, and of, relationship quality. The aim of the study is to develop an intervention to sustain couples’ relationship to support type 1 diabetes self-care.

DESIGN
This is a three stage study design following the MRC framework for complex interventions.

METHODS
Participant recruitment: Adults with experience of co-habiting as a couple with type 1 diabetes will be recruited through our charity partner Tavistock Relationships, through Diabetes UK membership and social media.

Stage 1: A narrative synthesis of the literature is underway to explore the existing literature on couples living with type 1 diabetes. Gaps in the literature identified by the review will be then addressed by the empirical interview stage. We will recruit persons with type 1 diabetes (PWD, n. 5-10) and partners of people with type 1 diabetes (T1D partners, n. 5-10) individually alongside couples (n. 5-10). We propose semi-structured interviews to capture the spectrum of potentially challenging experiences of living with type 1 and how they can be overcome. We expect it to cover the following topics: involvement of partners in the diabetes management of the PWD, relationship impacts, the burden of the emotionally supportive role, issues relating to diabetes complications, physical support in care provision, diabetes impact on intimacy and sexual relationship

Stage 2: Areas of interest emerging from the interviews will be investigated quantitatively to assess prevalence in a survey. We will use standardised questionnaires in a larger population to detect the magnitude of the issue. Standardized questionnaires will explore diabetes distress, depressive mood; relationship satisfaction and psychological well-being for people with diabetes and partners. We will investigate correlations between years from diagnosis, length of relationship, psycho-social outcomes and other clinical and demographic characteristics of interest. We aim to recruit n. 368 participants in total. Demographic (T1D partners-PWD) and self-report clinical data (PWD) will be collected. The questionnaires are as follows: Diabetes Distress Scale for PWD and T1D partners; The relationship satisfaction scale; the General Life Stress scale; the Core Outcomes in Routine Evaluation.

Stage 3: We propose Evidence-Based Co-Design¹ (EBCD) methods to develop interventions. EBCD will bring together PWD, T1D partners and healthcare professionals at every stage of the intervention design in order to facilitate its development. In this stage we aim to recruit 24-30 participants in total. Three workshops will be held: one with the attendance of the couples, T1D partners and PWD (Workshop 1), another with the contribution of the healthcare professionals (Workshop 2) and a third with the participation of both of these groups (Joint workshop). Co-design working groups will follow the workshops (5 meetings) and a final celebration event will be organized to report results from the EBCD process.
PLANNED ANALYSIS
Stage 1: The interviews will be analysed using a pragmatic thematic approach to identify key themes. Quotes from the interviews will be then interpreted by actors in a film and used as discussion starting point during workshops of stage 3.

Stage 2: Descriptive statistics will examine participants’ characteristics and will also explore trends in the data from the survey. Correlation analysis will be performed between social, demographic and clinical data.

Stage 3: All documentation produced during co-design workshops will be collected for thematic analysis. Issues raised and solutions implemented will be referred in a final report.

EXPECTED OUTCOMES
Our study will result in one or more interventions, recognising that relationship quality in type 1 couples will range from strong to poor and corresponding interventions will be needed ranging from relationship sustainability to relationship repair. These interventions will be underpinned by a published narrative review and an intervention development paper based on stages 2 & 3 findings.

Problems/Questions:
1) Ethical approval has been complex because the committee was concerned that our recruitment methods would limit the diversity of participants and result in potentially inappropriate interventions for a diverse population.

2) Where might couples living with diabetes, health professionals, provider organisations and the voluntary sector expect interventions for sustaining relationships to be delivered and by whom (relationship voluntary sector, diabetes voluntary sector, statutory health providers)?

3) Are the questions we pose of interest and concern to non-UK couples living with diabetes and consequently what is the potential for international study on this topic?

Reference
Session VI Hypoglycaemia in Diabetes

Title: NAVIGATING BETWEEN SCYLLA AND CHARYBDIS WITH YOUR EYES CLOSED: PSYCHOLOGICAL PREDICTORS AND CONSEQUENCES OF NOCTURNAL HYPOGLYCEMIA IN TYPE 1 DIABETES

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AIMS
Hypoglycemia during sleep is common in people with type 1 diabetes, often remains unnoticed, and has been associated with potentially dangerous consequences. Prevention largely relies on behavior of the person with diabetes such as adjusting insulin dose, but the health beliefs that shape these preventive actions have not been studied. In addition, the few existing studies about the impact of nocturnal hypoglycemia on sleep and next day functioning were conducted in laboratory settings rather than real life, focused on noticed nocturnal events only, or did not include partners. It is also unclear whether nocturnal hyperglycemia is a good flag for worries about hypoglycemia and counterproductive prevention behaviors. In terms of treatment, existing programs to reduce (worries about) hypoglycemia have shown some success, but are often not tailored to individual needs.

Given these gaps in the literature, we will examine the following research questions:
- Which elements of the Health Belief Model predict preventive behavior and nocturnal hypoglycemia?
- Is nocturnal hypoglycemia associated with suboptimal sleep, mood, fatigue and cognition in people with diabetes and partners?
- Is nocturnal hyperglycemia associated with worries about nocturnal hypoglycemia and counterproductive prevention behaviors?
- In case of identified problems, what are the merits of tailored treatment based on the Health Belief Model?

DESIGN/METHODS
101 people with type 1 diabetes and their partners will be recruited from three Dutch diabetes clinics. Inclusion criteria are type 1 diabetes, age ≥16 years, diabetes duration ≥1 year. Exclusion criteria are inability to read/speak Dutch, advanced complications, psychiatric conditions, pregnancy, breast feeding, menopause, recent shift work or time zone travel. One-third of the sample will consist of people reporting nocturnal events in the previous month. Of the remaining participants, half are expected to have undetected events.

During a study visit, people with diabetes and their partners will be interviewed about nocturnal hypoglycemia and related themes using a semi-structured format and self-report questionnaires. Ambulatory recording will then take place for seven consecutive days. Measurements will include continuous glucose monitoring, experience sampling using a touch screen mobile device, a wrist accelerometer, and a self-care diary. Additional demographic and clinical data will be extracted from the medical record. Participants will subsequently receive a summary of the most important findings. In case of (a) frequent occurrence of nocturnal hypoglycemia, (b) high worries about these events, (c)
counter-productive preventive behaviors, tailored suggestions for intervention will also be provided. The Health Belief Model can assist in matching perceptions to elements from existing programs or regular care procedures. Participants will be given the option to share findings and suggestions with the diabetes team. If suggestions are applied, treatment effects will be evaluated in an uncontrolled within-subjects A-B design, repeating the abovementioned one-week ambulatory assessment.

PLANNED ANALYSIS
The audiotapes of the interviews will be reviewed using content analysis. For the main analyses, longitudinal techniques will be used (multilevel -mixed effect- regression), controlling or stratifying for demographics and clinical factors.

EXPECTED OUTCOMES
With the proposed study we will test the following hypotheses:

- Less (effective) nocturnal hypoglycemia preventive behaviors are predicted by: (a) lower perceived seriousness of nocturnal hypoglycemia; (b) lower perceived susceptibility to these events; (c) lower perceived benefit of preventive behaviors; (d) more perceived barriers to prevention; (e) lower prevention self-efficacy; (f) less cues to action.

- The likelihood of (effective) preventive behaviors predicts the occurrence of nocturnal hypoglycemia.

- Nocturnal hypoglycemia is associated with worse sleep quality, mood and memory consolidation, more fatigue, and higher self-reported concentration problems in people with diabetes and partners.

- Longer time spent in nocturnal hyperglycemia is associated with higher worries about nocturnal hypoglycemia in the person with diabetes and the partner and with counter-productive prevention behaviors.

- In case of identified problems, the Health Belief Model can guide tailoring of treatment, thereby reducing nocturnal hypoglycemia and worries, and improving sleep, mood, fatigue and cognition in people with diabetes and their partners.

Problems/questions
#1: This multi-method study can be quite intensive for participants. How can we stimulate people to participate and keep them motivated throughout the study?

#2: Given the importance of empowerment, study findings and suggestions are directed to participants. What is the best format to present this information, and how can participants be stimulated to share and discuss it with the diabetes team?
Session VI Hypoglycaemia in Diabetes

**Title:** HYPORESOLVE (HYPOGLYCAEMIA - REDEFINING SOLUTIONS FOR BETTER LIVES): A NEW, MULTINATIONAL STUDY THAT IS ALSO FOCUSED ON THE PSYCHOLOGICAL IMPACT OF HYPOGLYCAEMIA, WITH FUNDING FROM THE HORIZON 2020 PROGRAMME

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**AIMS**
Normalising elevated glucose levels decreases symptoms, prevents microvascular complications, improves cardiovascular health and saves lives, but creates a significant risk for hypoglycaemia when insulin treatment is required. Hypoglycaemia is a serious event associated with cognitive decline, reduced quality of life (QoL), cardiovascular events and mortality. Hypoglycaemia remains the principal barrier to achieve glucose levels necessary to prevent diabetic complications of chronic hyperglycaemia. The main aim of Work Package 6 of the HypoRESOLVE study is to determine the impact of hypos on QoL (also of family members), cognitive functioning and academic performance in people with diabetes.

**DESIGN/METHODS/PLANNED ANALYSES**
We will employ four PhD students and one post doc researcher. We will conduct: 1) a series of systematic reviews (e.g. focused on the impact of hypos on QoL in people with diabetes and family members, impact on cognitive functioning and academic performance, unmet needs regarding hypos) 2) a series of secondary analyses of 100-150 pooled trials to determine the impact of hypos on QoL 3) conduct new qualitative research and a multi-national survey in 10 countries to generate evidence related to unmet care needs and research gaps, in close collaboration with IDF/JDRF. Semi-structured interviews will be conducted by telephone or Skype, recorded, transcribed and analysed thematically. 4) In collaboration with Work Package 7 we aim to determine the impact of hypoglycaemia on work performance in adults (economic impact). Furthermore, current PRO instruments for assessing the burden of hypoglycaemia will be identified and critiqued in a systematic literature review, to which there are two phases. Phase 1 (undertaken in WP6 systematic literature reviews, where further details are provided) will identify all existing PRO instruments that assess the burden of hypoglycaemia. Phase 2 will formally assess the measurement properties of the instruments, identified in Phase 1, using the recommendations of the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative. In collaboration with Work Package 5, a clinical study will be conducted to evaluate the relevance and the impact of asymptomatic and symptomatic CGM detected low values on future hypoglycaemia risk as well as patient reported and health economic outcomes.

**EXPECTED OUTCOMES**
Many, including a more careful assessment of the impact of hypoglycaemia on people with diabetes and their family members. We will also have a more accurate assessment of the impact of undetected hypos by using ecological momentary assessments of mood and energy levels together with the use of continuous glucose measurements.

**Problems/questions** that you would like to be addressed in the group discussions:

1. Any suggestions for improvements?
2. Will 10 countries be enough for the needs assessment study?
3. How to select the countries?
## Participants at PSAD Spring Meeting, Verona, Italy 2018

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