

## **PhD thesis**

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### **Guided Self-Determination-Youth**

1. a life skills intervention for adolescents with poorly controlled type 1 diabetes and their parents

*'It is the guide's job to draw attention to what is valuable to look at, but he leaves it to the traveller to decide if it's valuable to him'* (Grendstad1978 p.15-16).

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# Summaries

## English summary

Caring for type 1 diabetes is demanding for adolescents, parents and health care providers (HCPs). The importance of good glycaemic control for preventing long-term diabetic complications is well-recognised. For adolescents with type 1 diabetes the target HbA1c level is  $< 58$  mmol/mol (7.5%) without frequent hypoglycaemia. Currently, 31% of Danish adolescents achieve this target. Guided Self-Determination (GSD), a life skills approach developed to facilitate empowerment in the patient-provider relationship, has been demonstrated to reduce HbA1c by 3 mmol/mol (0.4%) and to improve life skills in adults with type 1 diabetes. In the current study GSD was adjusted and developed to adolescents and their parents (Guided Self-Determination-Youth (GSD-Y)) and integrated into paediatric diabetes outpatients with the adolescents' usual interdisciplinary HCPs. The hypothesis of the study was that using GSD-Y in routine paediatric outpatient clinics would reduce HbA1c concentrations and improve adolescents' life skills compared with those in a control group.

The primary outcome was HbA1c. The secondary outcome was the development of life skills. This study had a mixed-methods design comprising a randomised clinical trial (RCT) and a nested concurrent and sequential qualitative evaluation.

The study took place at two specialised paediatric diabetes outpatient clinics in the Capital Region of Denmark. Two physicians, five nurses and two dieticians were trained and tested to practice GSD-Y from November 2007 to December 2009. Randomisation began in August 2009 and ended in November 2010. Seventy-one adolescents between 13 and 18 years of age with poorly controlled type 1 diabetes ( $\text{HbA1c} \geq 64$  mmol/mol (8.0%)) and their parents were stratified according to their usual HCPs and enrolled sequentially at their regular outpatient appointments. They were randomised to eight GSD-Y sessions versus a control group with eight usual outpatient clinic visits. HbA1c levels were measured at baseline and every third month during 30 months. The secondary outcomes were measured using questionnaires composed of six scales completed by the adolescents at baseline before the randomisation, at the end of the intervention, and at a six-month follow-up. The scales were the *Perceived Competence in Diabetes Scale* (PCD), the *Health Care Climate Questionnaire* (HCCQ), the *Treatment Self-Regulation Questionnaire* (TSRQ), the *Perception of Parents Scale* (POPS), the *Problem Areas In Diabetes* (PAID) and the *WHO5 scale*. At the same time points, the adolescents reported their weekly self-monitored blood glucose values. A case report form (CRP) was completed by the HCPs to capture hypo- and hyperglycaemic episodes, hospital admissions, non-attendance, parental participation, and the use of the reflection sheets. Qualitatively, the development of life skills was evaluated through analyses of digitally recorded outpatient visits collected during the trial followed by individual interviews after a six-month follow-up period.

This thesis is based on three original papers. Paper I provides a description of GSD-Y, its theoretical framework, the intervention and its outcome variables, including the evaluation methods. The other two papers are based on the results of the RCT (Paper II) and the results of the qualitative evaluation (Paper III) of the GSD-Y intervention.

Paper I: The GSD method is a problem-solving and decision-making method designed on a theoretical and empirical basis to overcome barriers to empowerment in adult patient-provider interactions. GSD has been adjusted for use with adolescents, their parents and their usual interdisciplinary HCPs (GSD-Y) and is composed of 18 reflection sheets for adolescents, five for

parents and six for dieticians' visits. Filling in the reflection sheets before each outpatient visits, adolescents and their parents are guided to systematically explore and share their challenges in managing the disease with HCPs using mirroring, active listening and values-clarifying responses as part of their communication. The aim is to identify the adolescents' potential for change and support them in developing life skills for managing their diabetes in an autonomously motivated way. The paper describes the study protocol.

Paper II: Fifty-seven adolescents (79%) completed the trial and 53 (75%) delivered six-month follow-up data. All analyses were intention-to-treat analyses. No effect of GSD-Y on HbA1c could be detected by mixed-model analysis with adjustment for baseline HbA1c and identity of the HCP ( $p = 0.85$ ). Adjusted for multiple testing GSD-Y reduced amotivation ( $p=0.001$ ) for diabetes self-management, a finding that persisted at follow-up. Compared with the control group, trial completion was prolonged in the GSD-Y group ( $p<0.001$ ) requiring more visits ( $p=0.05$ ) with a higher yearly rate of non-attendance ( $p=0.01$ ). Parents participated less in GSD-Y adolescents' sessions than did the parents of the control group ( $p=0.05$ ).

The conclusion was that GSD-Y does not seem to improve HbA1c but results in a decrease of amotivation for diabetes self-management, which is maintained at follow-up.

Paper III: A nested and purposefully selected sample of adolescents ( $n=13$ ) and their parents participated in a qualitative evaluation of the use of GSD-Y. Data were collected during the intervention – through 37 digital recordings from outpatient visits - and at the end of the six-month follow-up – through 21 individual interviews with the adolescents, their parents and HCPs. Realistic evaluation was used to evaluate what worked for whom in what circumstances and how. As signs of emerging life skills, the adolescents began to develop new relatedness with HCPs and parents, to become decision-makers in their own life with diabetes and to grow personally. The conclusion was that GSD-Y turned outpatient visits into person-specific, meaningful visits with improved cooperation patterns in the triads but that GSD-Y was not capable of meeting parents' needs for individual supervision during adolescence. The combination of reflection sheets and professional communication skills seemed to support adolescents in starting a process of developing life skills.

Thesis: The results of the RCT and the qualitative evaluation are discussed together and related to previous research in the area. The complementary mixed-methods approach was beneficial in nuancing the entire evaluation of GSD-Y. According to the RCT, GSD-Y has no effect on HbA1c but reduces adolescent's amotivation for diabetes self-management which is sustained at follow-up, whereas GSD-Y may be useful in improving cooperation between adolescents, HCPs and parents and life skills development in adolescents according to the qualitative findings. It was concluded that it is not possible to integrate GSD-Y into usual outpatient visits in its extant design. For the time being it is not recommended that GSD-Y be integrated into outpatient visits in its current form. Further adjustments and development of GSD-Y are recommended especially the parental part of GSD-Y, which does not seem to meet parents' needs for supervision during adolescence.



## Dansk resumé

Det er en udfordring at håndtere type 1 diabetes for teenagere, deres forældre og behandlere i ungdomsårene. God blodsukkerkontrol i ungdomsårene er afgørende for at forebygge diabetiske senkomplikationer i voksenlivet. Målet for teenagere er, at HbA1c skal være under 58 mmol/mol (7,5%), uden at de oplever flere tilfælde af hypoglykæmi. I øjeblikket har 31% af danske teenagere med type 1 diabetes et HbA1c niveau under denne værdi. Metoden Guidet Egen-Beslutning (GEB) er udviklet til voksne med type 1 diabetes. Metoden støtter til autonom motivation for diabetesbehandling ved anvendelse af en *empowerment* tilgang mellem patient og sundhedsprofessionel. Målet med metoden er, at patienterne udvikler livsdygtighed med sygdommen. I voksenregi har metoden vist at kunne reducere HbA1c med 3 mmol/mol (0,4%) og at forbedre livsdygtigheden. Metoden er i dette studie blevet tilpasset til teenagere (GEB-Ung), deres forældre og familiens tværfaglige sundhedsprofessionelle kontaktpersoner og integreret i besøgene i diabetesambulatoriet.

Den overordnede hypotese var, at brug af GEB-Ung ved ambulante besøg vil medføre et fald i HbA1c og forbedre unges livsdygtighed sammenlignet med en kontrolgruppe.

Det primære effektmål var HbA1c. Det sekundære effektmål var udvikling af livsdygtighed. Studiets design var mixed methods bestående af et randomiseret klinisk forsøg og en indlejret sideløbende og sekventiel kvalitativ evaluering.

Studiet foregik på to specialiserede pædiatriske diabetesambulatorier i Region Hovedstaden. To læger, fem sygeplejersker og to diætister blev trænet til og testet i at bruge metoden fra november 2007 til august 2009. I august 2009 startede inklusionen, og den sidste patient blev inkluderet i november 2010. 71 teenagere mellem 13-18 år med dårligt reguleret type 1 diabetes HbA1c  $\geq$  64 mmol/mol (8,0%) og deres forældre blev stratificeret i forhold til deres vanlige sundhedsprofessionelle kontaktperson og inkluderet i studiet i den rækkefølge, som de kom til deres planlagte tider i ambulatoriet. De blev randomiseret til enten otte GEB-Ung ambulante sessioner eller til otte normale ambulante besøg. HbA1c blev målt ved start og derefter hver 3. måned i 30 måneder. Til at vurdere, om teenagerne udviklede livsdygtighed anvendtes et spørgeskema med seks validerede skalaer. Spørgeskemaet blev udfyldt af teenagerne før randomiseringen, ved afslutningen af forsøget og efter seks måneders opfølgning. De seks skalaer var: *Perceived Competence in Diabetes Scale* (PCD), *Health Care Climate Questionnaire* (HCCQ), *Treatment Self-Regulation Questionnaire* (TSRQ), *Perception of Parents Scale* (POPS), *Problem Areas In Diabetes* (PAID) og *WHO5*. Derudover oplyste teenagerne antal blodsukkermålinger i den forgangne uge, når de udfyldte spørgeskemaet. Ved hvert ambulante besøg registrerede de sundhedsprofessionelle antal hypo-og hyperglykæmitilfælde, hospitalsindlæggelser, udeblivelser og afbud, deltagelse af forældre og brugen af refleksionsark i en *Case Report Form*. Til den kvalitative evaluering blev lydoptagelser fra ambulante besøg analyseret og individuelle interviews foretaget seks måneders efter afslutningen af interventionen til at vurdere, om teenagerne udviklede livsdygtighed.

Afhandlingen er baseret på tre originale artikler. Artikel I beskriver den teoretiske referenceramme for GEB-Ung, indholdet i interventionen, effektmålene og valg af metoder til at evaluere brugen af GEB-Ung. Artikel II består af resultater fra RCT, og artikel III indeholder resultaterne fra den kvalitative evaluering.

Artikel I: Metoden GEB er en problemløsning og beslutningstagningsmetode, som er empirisk og teoretisk udviklet til at overvinde de barrierer, der hindrer *empowerment* i relationen mellem voksne patienter med type 1 diabetes og de sundhedsprofessionelle. GEB blev justeret til teenagere, deres

forældre og deres sædvanlige sundhedsprofessionelle. Metoden indbefattede brugen af 18 refleksionsark til teenagere, fem til forældre og seks hvis besøg hos en diætist. Arkene udfyldtes inden det ambulante besøg, og de sundhedsprofessionelle guidede ved besøget både teenagere og deres forældre til systematisk at undersøge og dele deres udfordringer i livet med diabetes med hinanden med afsæt i de udfyldte ark. De sundhedsprofessionelle anvendte spejling, aktiv lytning og værdiklargøringsrespons som en del af deres kommunikation. Målet var at identificere teenagernes potentiale for forandring og at støtte denne i at udvikle autonom motivation som en del af livsdygtighed i at håndtere deres diabetes. Derudover beskriver artikel I protokollen bag forsøget.

Artikel II: 56 teenagere (79%) gennemførte studiet, og 53 (75%) indleverede seks måneders opfølgings data. Alle analyser er intention-to-treat analyser. Ved brug af en mixed model, der justerede for HbA1c ved studiets start og sundhedsprofessionel sås ingen effekt på HbA1c ( $p=0.85$ ) ved studiets afslutning. Justeret for multipel testning sås, at brugen af GEB-Ung metoden reducerede amotivation ( $p=0.001$ ) for egen diabetes behandling ved afslutning af forsøget, hvilket var fastholdt ved opfølgningen. Sammenlignet med kontrolgruppen brugte GEB-Ung teenagers længere tid til at gennemføre interventionen ( $p<0.001$ ), havde flere besøg ( $p=0.05$ ) og flere udeblivelser pr år ( $p=0.01$ ). GEB-Ung forældre deltog mindre i deres teenagers ambulante besøg end forældre i kontrolgruppen ( $p=0.05$ ). Det konkluderedes, at GEB-Ung ikke forbedrer HbA1c, men reducerer amotivation for egen diabetes behandling som tegn på udvikling af livsdygtighed.

Artikel III: En udvalgt gruppe af GEB-Ung deltagerne på 13 patienter og deres forældre samt sundhedsprofessionelle deltog i den kvalitative evaluering af GEB-Ung. Data bestod af 37 lydoptagelser fra ambulante besøg indsamlet i løbet af interventionen og 21 individuelle interviews med teenagere, deres forældre og sundhedsprofessionelle foretaget seks måneder efter interventionens afslutning. Realistisk evaluering blev anvendt til at undersøge og illustrere mekanismer, der aktiveres ved brug af GEB-Ung i vanlig ambulant praksis. Det konkluderedes, at GEB-Ung teenagerne begyndte at udvikle livsdygtighed. Tegn herpå var at de begyndte at udvikle en ny samhørighed med både sundhedsprofessionelle og forældre, de begyndte at foretage autonomt motiverede beslutninger i deres liv med diabetes, og de påbegyndte en udvikling præget af personlig vækst.

I afhandlingen diskuteres de samlede resultater og relateres til anden forskning på området og dermed komplementerer og nuancerer de to studier den samlede evaluering af GSD-Y. Kvantitativt viste GEB-Ung ikke effekt på HbA1c, men var i dette studie i stand til at reducere amotivation for unges egen behandling af diabetes også ved follow-up. Kvalitativt så GEB-Ung ud til at kunne forbedre samarbejdet mellem unge, sundhedsprofessionelle og forældre og igangsætte udvikling af livsdygtighed hos unge. Det konkluderes, at det ikke er muligt at integrere GEB-ung i det nuværende design i vanlig ambulante besøg. Det anbefales, at metoden ikke integreres i ambulatoriebesøg i sin nuværende form. Der er brug for at GEB-Ung videreudvikles og tilpasses yderligere, og især ser det ud til, at forældredelen ikke fuldt ud imødekommer forældres behov for supervision i løbet af teenageårene.

## Original papers

This thesis is based on three papers, which are referenced according to their Roman numerals.

### Paper I:

Husted GR, Thorsteinsson B, Esbensen BA, Hommel E, Zoffmann V. Improving glycaemic control and life skills in adolescents with type 1 diabetes: A randomised controlled intervention study using the Guided Self-Determination-Youth method in triads of adolescents, parents and health care providers integrated into routine paediatric outpatient clinics.

BMC, Pediatrics 2011, 11:55.

### Paper II:

Husted GR, Thorsteinsson B, Esbensen BA, Gluud C, Winkel P, Hommel E, Zoffmann V. Effect of guided self-determination youth intervention integrated into outpatient visits versus treatment as usual on glycemic control and life skills: a randomized clinical trial in adolescents with type 1 diabetes. Submitted to Trials 2013-12-10.

### Paper III:

Husted GR, Esbensen BA, Hommel E, Thortsteinsson B, Zoffmann V.

Adolescents developing life skills for managing type 1 diabetes: A qualitative, realistic evaluation of a Guided Self-Determination-Youth Intervention. Re-submitted to Journal of Advanced Nursing 2014-02-03.

## Abbreviations

ADA:	The American Diabetes Association
AR:	Autoregressive
BAE:	Bente Appel Esbensen
BT:	Birger Thorsteinsson
CMO:	Context, Mechanisms, Outcome
CRF:	Case Report Form
CSII:	Continuous subcutaneous insulin infusion
EV:	Eva Hommel
GRH:	Gitte Reventlov Husted
GSD:	Guided Self-Determination
GSD-Y:	Guided Self-Determination-Youth
HbA1c:	Glycated Haemoglobin A1c (a difference of 1% is equivalent to 11 mmol/mol)
HCCQ:	Health Care Climate Questionnaire
HCP:	Health care providers
ISPAD:	The International Society for Pediatric and Adolescent Diabetes
ITT:	Intention-to-treat
MAR:	Missing At Random
MDI:	Multiple Daily Injections
MI:	Motivational Interviewing
PAID:	Problems Area In Diabetes
PAR:	Participatory Action Research
PCD:	Perceived Competence in Diabetes
POPS:	Perception Of Parents Scale
PSAD:	Psychosocial Aspects of Diabetes
RE:	Realistic Evaluation
RMMM:	Repeated measures mixed model
SDT:	Self-determination theory
SMBG:	Self-monitored blood glucose measurements
TSRQ:	Treatment Self-Regulation Questionnaire
VZ:	Vibeke Zoffmann
WHO5:	Emotional Well-Being Scale

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## **Introduction**

Poorly controlled type 1 diabetes during adolescence is a challenge for adolescents, parents and health care providers (HCPs). Despite advances in technology, the haemoglobin A1c (HbA1c) levels are higher than recommended among adolescents. Current support from HCPs and parents does not always seem to have an impact on glycaemic control or to support adolescents in better self-management of diabetes. This thesis expands on the Guided Self-Determination (GSD) method, which was developed and tested in adult diabetes care (1) and further developed and tested for patients with schizophrenia (2) and in neonatal care (3,4). The hypothesis of the study was that using Guided Self-Determination-Youth (GSD-Y) in routine paediatric outpatient clinics would reduce HbA1c concentrations and improve adolescents' life skills compared with those in a control group. The study was a life skills intervention using a mixed-methods design comprised of a randomised clinical trial (RCT) and a nested, concurrent sequential qualitative evaluation (5).

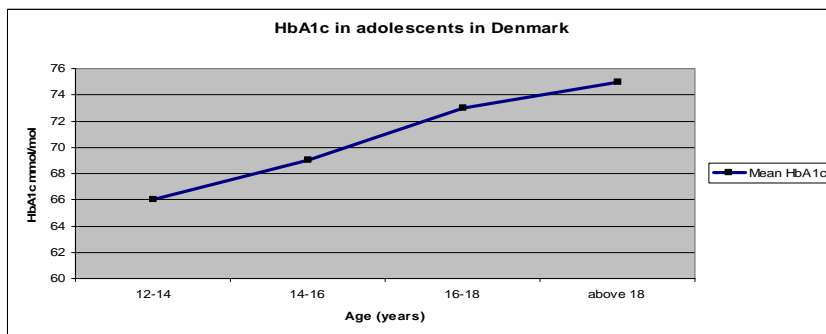
## **Background**

### **Type 1 diabetes in adolescents**

Type 1 diabetes is a genetic disease of the immune system characterised by pancreatic beta cell destruction and a consequent lack of insulin (6). It is often diagnosed during childhood or adolescence and is the third most common chronic disease in children and adolescents in Denmark with approximately 25 new patients per 100.000 persons annually (7). The incidence of type 1 diabetes continues to increase across Europe with an average increase of approximately 3-4% annually (7). Based on the DanDiabKids, a Danish national diabetes register for children, there were 1,367 adolescents 13-18 years of age with type 1 diabetes in 2013, representing an increase of more than 3% annually over the previous 10 years (8). The treatment regimen is complex and demanding, requiring multiple daily insulin injections (MDI) or continuous subcutaneous insulin infusion (CSII), frequent blood glucose monitoring, attention to physical activity, diet and carbohydrate intake monitoring (9). The recommended target for HbA1c levels in adolescents with type 1 diabetes is below 58 mmol/mol (7.5%) without frequent hypoglycaemia (10). Although complications are rarely observed during adolescence there is evidence that they begin to develop soon after diagnosis and accelerates during puberty (11,12). Keeping blood glucose levels as close as possible to normal is known to prevent or postpone diabetic complications (13-15). On average, adolescents do not obtain the required degree of diabetes self-management or achieve the recommended HbA1c levels (16,17). Thus only 31% of Danish adolescents with type 1 diabetes meet the recommended HbA1c target (18). The increase in HbA1c in Danish adolescents aged 12-19 years was 0.12% yearly (CI 0.09–0.14%) from 2004 to 2011 (Jannet Svensson, DanDiabKids, personal communication) (18). Figure 1 illustrates the HbA1c levels during Danish adolescence. Although the survival of childhood-onset type 1 diabetes seems to have improved (19), the prognosis is generally poor (20,21). It has been estimated that the number of life years lost is approximately 17 years for a child who is diagnosed at the age of 10 years (22). It is unknown what triggers the disease and no cure has been developed yet.

### **Challenges faced by adolescents living with diabetes**

Many adolescents are able to handle the demanding tasks of diabetes management perceiving it as a habit. However, most adolescents experience difficulties in integrating the diabetes regimen into



**Figure 1.** Changes of HbA1c levels in Danish adolescents in 2004-2011, based on 9051 measurements

their lives and face huge conflicts between the requirement for diabetes management and psychosocial developmental needs and challenges (9,23). The period is often associated with neglect of self-monitoring (24), dietary recommendations, and insulin administration (25,26), resulting in poor glycaemic control (27,28). Belonging to a peer group and fitting into the group's social norms and behaviour may be perceived as more important to the quality of a teenager's life than diabetes treatment (29). Avoiding care management of the disease often leaves adolescents with feelings of guilt and frustrations (30). At the same time adolescents have the conflicting experiences of being scrutinised, blamed, and controlled by their parents (31), as well as the experience of being vulnerable to the disease and still requiring guidance from their parents to manage the daily treatment (32-34). This increases conflicts and harms adolescent-parent cooperation as well as self-management of the disease (35,36). Feeling different from peers and at the same time striving to develop independence from parents causes feelings of frustration and helplessness and reduces motivation to manage their own care (37). The rates of depression are threefold higher among adolescents with type 1 diabetes than in the general population (38,39) and higher levels of psychiatric morbidity 12 years after the diagnosis are observed (40).

### **Challenges faced by parents in transferring responsibility in diabetes management**

The responsibility for the management of diabetes should gradually be transferred from parents to the adolescents (9,29). Some parents are, however, reluctant to transfer responsibility for diabetes management, doubting the adolescents' diabetes self-management abilities (41). This may lead to conflicts and communication patterns that inhibit the development of autonomy in diabetes self-management (42). Other parents leave all responsibility to their adolescents, attempting to avoid conflicts (43) or expecting them to be competent due to their age and the length of time since their diagnosis (44,45). Both approaches may lead to poor glycaemic control (28,46). Despite negative parental influence there is strong consensus in the official guidelines (6,11) and in studies (47) that parental involvement and shared responsibility during adolescence is important (29,48). A supportive but authoritative, emotional and warm parenting style promotes improved glycaemic control (49,50). Parents are, however, unsure of how to act and communicate (42) to support the development of diabetes self-management during adolescence (51). A mixed-methods study reported that parents want help from HCPs to tailor the demands of chronic disease to the unique demands of the family's situation (52). However, parents often feel disempowered, alienated, and ignored due to providers' expectation that the family passively comply with the given advices (52). A review detailed the burden of being a parent to a child with type 1 diabetes; the frequency of depression increases in mothers when they try to manage day-to-day challenges (53) whereas fathers are more likely to become stressed due to the fear of long-term complications (54). Studies

suggest that poor parental coping has a directly negative impact on both glycaemic control and psychosocial function in adolescents with type 1 diabetes (55,56).

### **Challenges faced by HCPs in their interactions with adolescents and parents**

HCPs view adolescence as a difficult time in which the management of diabetes guidance and their cooperation with adolescents and parents is complex (24,57-60). In line with previous research a study identified (61) that HCPs have difficulties in navigating between adolescents' needs for developing self-management skills (59,62) and involving parents in the management of diabetes during adolescence (48,52,63). HCPs should encourage parental involvement (6,11) that facilitates adolescents' development of self-management and independent decision-making through a gradual transfer of responsibility and management of the disease (64-66). However, usual diabetes education and routine outpatient clinic visits appear to have little effect on conflict resolution, the transfer of responsibility, self-management skills or improved glycaemic control (47,67). Therefore, helping adolescents integrate diabetes self-management into their lives and facilitating the cooperation of both adolescents and parents are continuing challenges for HCPs. To prevent poor self-management and improve glycaemic control in adolescents the emphasis in the approach has shifted from the medical management of diabetes to methods in which adolescents care for themselves in cooperation with parents and HCPs (68). Most HCPs are socialised to the traditional diagnostic methods in nursing and medicine and have an expectation of compliance or adherence by adolescents and parents (69). Such methods are useful in acute care and treatment but inconsistently helpful to individuals with chronic diseases to the develop self-management skills (69). Adolescents and their parents have described the experience of being expected to comply (62,70,71) as being marginalising and disempowering to the them (52,72). The traditional terms compliance and adherence appear to capture neither the complexity of living with diabetes in the family nor the requirement to manage the disease in the context of youth. Accordingly, the terminologies are gradually being replaced by the term 'self-management' in the context of paediatric diabetes (68). Schilling defines self-management in the following way; *'Selfmanagement of diabetes in children and adolescents is an active, daily and flexible process in which youths and their parents share responsibility and decision-making for achieving disease control, health and well-being through a range of illness-related activities'* (68 p.92). This definition states that development of self-management in diabetes is a process and that the responsibility for disease management in daily life is placed on adolescents and their parents. This seems to assign HCPs to adopt the role of being the expert in diabetes treatment and to help adolescents and parents reflect on their situation and their cooperation behaviours. In this way, families may become capable of managing daily life and making informed choices (69).

### **Interventions in adolescents with type 1 diabetes**

Behavioural and psychological interventions with a family-centred approach have been developed as supplements to medical care and treatment to improve self-management and glycaemic control during adolescence (36,73,74). Such studies are often conducted by specially trained psychologists or trained mental HCPs and delivered separately from usual clinic visits. There is, however, a consensus that their overall impact on glycaemic control is at best, modest to moderate (73,75-77). Prior to this thesis two interventions involving adolescents and parents, integrated into usual care and tested in RCT designs (67,78) were identified. Laffel et al. conducted a family-centred teamwork intervention involving 105 adolescents and their parents. The intervention focused on the



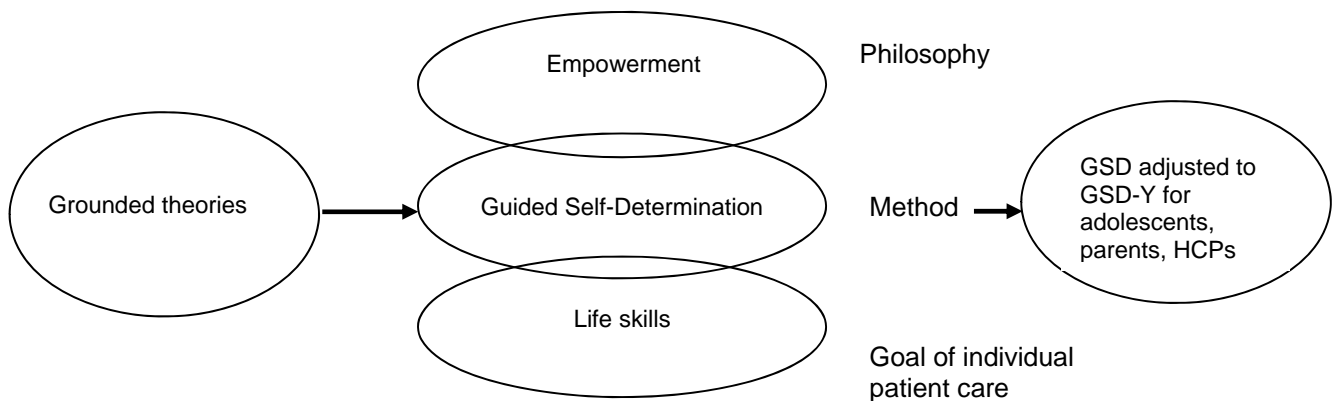
importance of parent-child responsibility-sharing for diabetes and on ways of avoiding conflicts. The intervention was performed by research assistants in cooperation with the families prior to routine diabetes visits. The study showed a significant increase in family involvement and a significant decrease in HbA1c (from 68 mmol/mol to 64 mmol/mol (8.4% to 8.2%)) far above the recommended level of 58 mmol/mol (7.5%) (78). In a pilot study involving 67 adolescents, Murphy et al. combined diabetes skills training with increased parent-adolescent teamwork and demonstrated the potential benefits of parental involvement in a structured six-month family-centred small-group education programme run by the adolescents' usual HCPs. No effect on HbA1c was reported (67). In search of evidence for effective interventions only Grey's coping skill study was identified (79). However, this method was neither integrated into a real-life context nor administered by the patients' usual HCPs or included parents. One review concluded that, so far, there was insufficient evidence to recommend the use of a particular intervention because no interventions had been proven effective in RCTs for adolescents with poor glycaemic control (76). In adults with type 1 diabetes the GSD method demonstrated an effect on glycaemic control and life skills when delivered in groups by the patients' usual nurses (80). The strength of GSD is that it acknowledges that patients are active participants in their care, are experts in their lives with diabetes and are capable of making their own decisions. Therefore, the method, appeared to be consistent with the term 'self-management' in adolescent diabetes care (68) and a worthy candidate for consideration in paediatric diabetes outpatient care.

## **The theoretical framework around GSD-Y**

### **Development of Guided Self-Determination in adults**

Vibeke Zoffmann (VZ) developed GSD in adults with difficult type 1 diabetes through programmatic qualitative research (81) in four stages (1). First, interactions between HCPs and patients with poorly regulated diabetes in 11 dyads at a Danish university hospital were investigated. The study resulted in three grounded theories explaining why barriers to empowerment seldom were overcome: *Life Versus Disease in Difficult Diabetes Care: Conflicting Perspectives Disempower Patients and Professionals in Problem Solving* (82), *Relationships and Their Potential for Change Developed in Difficult Type 1 Diabetes* (83), and *A Person-Centered Communication and Reflection Model* (84) (Summarised, Appendix A). Second, the GSD method was developed through participatory research involving 25 patients with diabetes and 12 diabetes nurses to identify how the barriers in the relationship could be overcome. Third, the method was implemented and evaluated qualitatively in a one-to-one setting involving 11 dyads (1). Finally, a RCT of GSD (n=50) used in groups documented its effect by improvement of glycaemic control (3 mmol/mol (0.4%)) and life skills (80). The GSD method is based on empowerment (85), Self-Determination Theory (86), life skills theory (87), theories of dynamic judgement building (88), the trans-theoretical stages of change theory (89), value clarification theory (90) and humanistic psychology (91). GSD was developed to function as a link between empowerment regarded as a philosophy (85) and life skills as the goal of individual adult care for people with diabetes (92). It is within this theoretical framework that GSD-Y was adjusted, developed and tested (Figure 1).

**Figure 1.** Illustration of the main theoretical framework around Guided Self-Determination-Youth



Inspired by Zoffmann ((1), p.10)

### **Empowerment as a philosophy**

GSD is based on the empowerment philosophy (93) and seen as an alternative to the pathogenetic paradigm (85). When VZ argued (1) that GSD is consistent with empowerment she referred to the conceptualisation of empowerment by Anderson and Funnell (85). Empowerment is defined: *'The process of empowerment is the discovery and development of one's inborn capacity to be responsible for one's own life. People are empowered when they have enough knowledge to make rational decisions, control, resources to implement their decisions and experience to evaluate the effectiveness of their actions'* (85 p.11). Empowerment involves self-directed behaviour change embedded in the patient's daily life and is viewed both as a process and an outcome (85). As a process empowerment has the purpose of increasing one's ability to think critically and act autonomously; as an outcome, empowerment is similar to choosing a direction in one's life (94). Although research has documented that practicing empowerment can be learned by professionals (95) and has a positive effect on diabetes self-management (96) there have been difficulties in implementing this approach in clinical practice (97). The GSD method was therefore developed to practice empowerment in the patient-provider relationship (1).

### **Guided Self-Determination as a method**

GSD is also based on Self-Determination Theory (SDT), an empirically developed theory on the importance of developing internally motivated self-determination through research (86). Self-determination is defined as; *'Self-determination is a quality of human functioning that involves the experience of choice, in other words, an internal perceived locus of causality. Self-determination is the capacity to choose and to have choices being the determinants of one's action'* (86 p.39). Self-determined motivation is based on autonomous reasons to act. This involves that an individual having an experience of choice and using the available information to make decisions according to self-selected goals (86). Contrarily, individuals with controlled reasons to act do not experience a real sense of choice but instead experience initiating choices as pressure to perform and act in accordance with recommendations. Individuals who act based on amotivation feel helpless and are unable to control their behaviour because they act in a half-hearted manner and are buffeted by forces beyond their control. These different forms of motivation are conceptualised as lying along a continuum from non-autonomous to completely autonomous motivation for human action (98). According to SDT, autonomous reasons to act require the fulfilment of three basic needs:

competence, autonomy and relatedness. Competence is perceived as when an individual meets optimal challenges and is able to overcome them effectively. Autonomy occurs when individuals experience a sense of choice and volition to act in accordance with their interests and values. Relatedness refers to the warmth and caring that is received through interactions with others, resulting in a general sense of belonging (98).

To facilitate the development of life skills through autonomous motivation VZ developed different semi-structured reflection sheets for each non-autonomy-supportive interaction that was identified between adults with diabetes and nurses (1) (Appendix A). The development of reflection sheets was inspired by Swedish behavioural health education research in adolescents (99), values theory (90,91), stages of change theory (89), SDT (86), theories in using metaphors (100), communication theories (101), an open health concept (102), and dynamic judgement building (88).

### **Life skills as the goal of individual diabetes care in Guided Self-Determination**

VZ recognised GSD as an approach to developing life skills, defined as *‘those personal, social, cognitive and physical skills that enable people to control and direct their lives and develop the capacity to live with and produce change in their environment’* (103 p.121). A life skills approach encourage the individual to develop a broader repertoire of behaviour and to become a balanced, self-determined person who choose one’s behaviour in accordance with one’s own values (90). This includes solving problems creatively, foreseeing and evaluating one’s actions and seeking help from others when cognitively or emotionally coping with life situations are needed. (87). VZ found that HCPs and the patients persisted in cooperating and solving problems in the same manner over and over again, but still hoping for a different result (1). Therefore, the theoretical perspectives of life skills were considered to be the goal for individual diabetes care to change previous cooperation patterns and problem-solving strategies between patients and HCPs (1).

### **Practicing Guided Self-Determination in adults to develop life skills**

HCPs and patients are guided through a shared decision-making process in six steps of life skills training (87), 1) establishing a mutual relationship with clear I-you-borders, also called I-you-sorted mutuality (83) 2) self-exploration 3) self-understanding, 4) shared decision-making, 5) action and 6) feedback from action. The apparatus in GSD to ensure life skills development is HCPs’ use of communication methods such as mirroring (104), active listening (105) and values-clarifying responses (90) in combination with the use of the different semi-structured reflection sheets filled in by the patients before they meet HCPs. Mirroring is defined as telling another person what one observes followed by a pause - for example repeating the person’s last word to make him feel heard and giving him the opportunity to hear himself. The pause encourages reflection or, perhaps, more elaboration (104). Active listening is defined as telling the other person how you have understood the message in his total communication. The recipient tries to understand the feelings of the sender and the meaning of the message. The recipient formulates her perception of the message without valuing, analysing or giving advice and sends it back to the sender to make the person validate his/hers perception (105). The purpose of values clarification is to start a process to reconsider and clarify one’s own values (106,107). It gives the recipient something to think about concerning the way he acts, as well as his attitudes, interests and assessments. A values-clarifying response is defined as a reply or a question that stimulates reflection and self-insight. It often cannot be answered immediately but has the potential to stimulate a clarifying process (90). An example of a values-clarifying response is *‘What does knowing your blood sugar during the day mean to you?’*

When patients meet HCPs, the completed reflection sheets are the starting point for their conversation. The core principle is to bring concrete difficulties and challenges about living with diabetes into an individual’s awareness and to support him/her in expressing and critically reflecting on alternative solutions. Instead of being told what to do, patients are supported in finding solutions that accord with their own values (92).

## Hypotheses and Objectives

The hypotheses of the study were that using GSD-Y in routine paediatric outpatient clinics would reduce HbA1c concentrations and improve adolescents’ life skills compared with those in a control group.

The objectives of the study were the following;

- 1) To test whether GSD-Y could be integrated into routine paediatric outpatient diabetes clinics in collaboration between adolescents, their parents and the interdisciplinary diabetes HCPs.
- 2) To test whether GSD-Y reduces HbA1c and improves life skills in adolescents with type 1 diabetes.
- 3) To illustrate and explore how GSD-Y influences developing life skills in adolescents supported by their parents and their HCPs.

The study comprised of two studies;

**Study A:** A RCT with a six-month follow-up evaluating the impact of GSD-Y on glycaemic control and the development of life skills in adolescents with type 1 diabetes when integrated into outpatient clinic visits.

**Study B:** A qualitative, realistic evaluation of the use of GSD-Y in a nested sample of the adolescents, their parents and the involved HCPs.

**Figure 3** Timeline of the study

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November 2007	GSD-Y development and adjustment GSD-Y training
August 2009	HCPs passing the final GSD-Y tests Randomisation begins Quantitative data collection begins
December 2009	Qualitative data collection begins
November 2010	Randomisation ends
March 2012	Qualitative data collection ends
August 2012	Completion of trial N=57 ( GSD-Y n=26, Control n=31)
July 2013	Six-month follow-up period completed N=53 (GSD-Y n=23, Control n=30)

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It was anticipated that the adjustment and development of GSD-Y would last 1 year. It was anticipated that the RCT (Study A) would last from 14-18 months including the six-month follow-up period (108). The adjustment and development period lasted 22 months, and the RCT

lasted 24 months but actually reached 35 months after including the six-month follow-up.

The adjustment and development of a GSD-Y version is presented in the thesis. Study A answers objective 2 and its results are given in paper II. Study B answers objective 3 and its results are given in paper III. Objective 1 is answered in the thesis after a discussion of the methods and results.

## Methods

### **Considerations and activities concerning adjustment and development of GSD-Y**

GSD is a complex intervention consisting of several interacting components (109). The adjustment and development of GSD-Y included four key components: a) What in GSD needed to be changed to turn it into a GSD-Y version involving adolescents and parents? b) How did HCPs learn to practice GSD-Y competencies? c) Was GSD-Y acceptable for adolescents, parents and HCPs? d) Was a GSD-Y version feasible in usual outpatient visits? Nine interdisciplinary HCPs (two physicians, five nurses, two dieticians) and 22 adolescents 13-18 years old (10 girls) who had had type 1 diabetes for at least one year from two paediatric outpatient clinics from hospitals in the Capital Region of Denmark, as well as their parents volunteered to participate from November 2007 - August 2009. This period was interrupted by a four-month break due to a strike among nurses.

### **Evidence and considerations for transferring GSD to a paediatric context**

Adolescents are considered different from adults living with a chronic disease when their developmental stage is taken into account (110,111). The conflicts that exist between life and diabetes (110,111) and the difficulties faced when broaching person-specific topics during outpatient visits (59,61,62,71) are, however, similar challenges to those in adult care (1). Because GSD was developed for diabetes care (1) and the aforementioned challenges are similar, GSD was considered suitable for adolescents.

The theoretical framework around GSD was considered suitable for a paediatric context because a) empowerment approaches have been applied in studies of adolescents with chronic conditions and diseases (97,112-114), b) Self-Determination Theory was developed through studies of adolescents and has been further applied in research among adolescents with chronic conditions and diseases (106,115), and c) applying life skills as the goal for individual behavioural change has previously been used in health promotion programmes (116-120) and in somatic care of adolescents (121,122). The main differences faced when applying GSD to a paediatric context are 1) that the participation of the adolescents' parents are an important condition, 2) that both nurses and physicians should practice the method to ensure that continuity between the adolescents and their usual contacts could be maintained during the trial and 3) that dieticians should possess GSD-Y competencies to act in accordance with the method when meeting with adolescents allocated to the GSD-Y intervention. In adult care, the use of GSD requires patients to have cognitive skills such as abstract thinking, reflection and problem-solving to cooperate in a mutuality-expecting approach (92) aimed at supporting the patients' development of life skills (87). In adolescents such cognitive skills further develop from the age of 13 (123). Theoretically the method was considered to support adolescents who were at least 13 years old in developing life skills. In GSD-Y life skills is defined; '*The ability to solve problems, to communicate honestly and directly, to gain and maintain social support, and to control emotions and personal feeling*' (119 p.75). This definition is based on research in problem prevention in adolescents (119) and comprises the processes of psychological and social

skills that adolescents are expected to develop (124); it also captures the interrelationship with parents and HCPs which the GSD-Y version should include.

Concerning parent's participation in GSD-Y it was expected that they would accept to use the method as GSD was developed for adults and because they were interested in new ways to support their adolescents in managing diabetes (48,52).

### **Methodological considerations and practical actions**

The methodological considerations for how to adjust and develop the GSD-Y version were inspired by the part of participatory action research (PAR) that involves participants through on-going dialogue, joint discussions and reflections (125-127). The antecedents of using this part are that new methods are developed according to real-life contexts and are more likely to be integrated into existing contexts (125-127). HCPs were considered to be the experts in paediatric diabetes outpatient care; adolescents and parents were the experts in living with diabetes and in participating in outpatient visits. None of them were considered co-researchers. Gitte R. Husted (GRH) and VZ considered themselves to be the experts in GSD and to be the researchers who conducted the entire research process and determined the final GSD-Y version.

The pedagogical considerations for how to teach HCPs to practice GSD-Y competencies were based on transfer of learning theory (128) in combination with structured reflection methods, 'reflection in' and 'reflection on' action (129). To enhance the transfer between learning from a theoretical learning context to a real-life context, a shift between theoretical teaching courses and practical training sessions took place (130,131). The practical training sessions initially consisted of fictive patient cases constructed by GRH based on examples from the literature and HCPs' experiences of typical challenges in outpatient clinics. GRH filled in the semi-structured reflection sheets beforehand and HCPs acted out the cases using role play. When HCPs felt confident when practicing GSD-Y in fictive cases, they began training with real adolescents and parents in usual outpatient visits. GRH's qualifications for teaching and supervising in GSD were based on her master's degree, where she had worked theoretically with GSD (61). Subsequently GRH observed 'bed side' how VZ practiced GSD in one-to-one settings and thus gained theoretical insight into the background and essentials of GSD.

### **Simultaneous activities in adjustment, development and training of GSD-Y**

Adjustment, development and training occurred simultaneously. VZ and GRH conducted a structured GSD-Y programme over a period of three months (Table 1). Prior to the courses the HCPs were given a compendium containing literature on the theoretical foundation of GSD including the three communication forms: mirroring (104), active listening (105) and values-clarifying responses (90). Course I was led by VZ and consisted of the theoretical framework of GSD and an introduction to all reflection sheets including their empirical background, aim (Appendix A) and start of personal training in using the method. Course II & III were led by VZ and GRH. Course II focused on practical communication training in dyads (HCPs and adolescents) and triads (HCPs, adolescents and parents), and training the use of reflection sheets for autonomously motivated glycaemic control and glucose measurement. Course III focused on using the method in triads and ways for HCPs to avoid entering into alliances with one part. Four repetition courses (IV-VI a+b) were added because of the strike (Table 1). In each course discussions and reflections were shared between researchers and HCPs on how a GSD-Y version could suit adolescents and parents. Reflection sheets that were added or changed during the period

were presented and discussed at regular meetings and individual training was provided under the supervision of GRH. Each HCP should practice all reflection sheets in two adolescents and their parents in usual outpatient clinic.

**Table 1. Programme for HCPs.** Overview of planned GSD-Y courses and the extra courses for HCPs added to achieve GSD-Y competencies. All together 44 hour lessons were provided. The number in the brackets refer to the different reflection sheets (Appendix A)

Planned GSD-Y courses and training Nov 2007-Feb 2008	Extra GSD-Y courses and training provided Sep 2008-June 2009
<b>Course I: Introduction to GSD</b> (eleven hours) 1. Introduction to the theoretical idea of GSD 2. Evidence in adult care 3. Communication theory in GSD and an introduction to mirroring, active listening, values-clarifying responses 4. Introduction to all reflection sheets 5. Introduction to and personal training in dynamic problem solving of self-experienced problems (5a,5b,6a)	<b>Repetition course IV: Communication training</b> (four hours) 6. Repetition of GSD-Y communication & training (1b,1c,1d,2) 7. Repetition of autonomy supportive communication in dyads in fictive cases (3.d,4a,4b,4c)
<b>Course II: Communication in dyads &amp; triads</b> (eleven hours) 8. GSD-Y communication training (1b,1c,1d,2) 9. Training in autonomy supportive reflection sheets in fictive cases in dyads and triads (3.d,4a,4b,4c) 10. Dynamic problem solving HCPs and adolescents (5a,5b,6b)	<b>Repetition course V: GSD-Y in triads</b> (four hours) 11. Repetition of GSD-Y communication in triads in fictive cases (1b, 2, 3a,3b,3c) 12. Personal training in dynamic problem solving of self-experienced problems (5a,5b,6a)
Each HCP is asked to practice the unfinished sentences with one adolescent between course II & III	Each HCP continues supervised practising with two adolescents and their parents using all reflection sheets
<b>Course III: GSD-Y in triads</b> (six hours) 13. GSD-Y communication training in triads using fictive cases (1c, 1d,,2, 3b,3c) 14. Training the use of dynamic problem solving in triads using fictive case (5a,5b,6b) 15. Training how to introduce the autonomy-supportive reflection sheets connected with glycaemic control (1b, 3.d,4a,,4c)	<b>Repetition courses VIa &amp; VIb: GSD-Y (two x four hours)</b> 16. Repetition of GSD-Y communication between dyads and triads in fictive cases (2, 3a,3b,3c, 4b) 17. Repetition of dynamic problem solving training fictive cases in triads (5a,5b,6a) 18. Repetition of the aim of each reflection sheet
Each HCP practice with two adolescents and their parents using all reflection sheets	Each HCP continues supervised practice with two adolescents and their parents using all reflection sheets

### Fidelity assessment in HCPs learning to practice GSD-Y competencies

Methods to assess if HCPs followed the principles in delivering GSD-Y correctly and their competence in doing so are defined as fidelity assessment (132,133). For this purpose digital recordings of the fictive and real training sessions were used. The recordings were transcribed verbatim by GRH, assessed and returned to the HCPs. They were asked to self-assess (129) their GSD-Y competencies with respect to identifying their use of the three communication forms and to identify how their performance corresponded to the three grounded theories (1). Figures of the grounded theories guided HCPs' self-assessments (Appendix B) and were followed by reflection on action with GRH to ensure progress in GSD-Y competencies. Before start of the mixed-methods study, a digital recording of the last outpatient visit and a written test developed by GRH assessed that HCPs adequately explained GSD-Y's three grounded theories, explained GSD-Y communication techniques by providing examples of mirroring, active listening and values-clarifying responses, and in their answers to unfinished sentences reflected an attitude of collaboration consistent with empowerment (85) (Appendix B).

### Supervising and testing HCPs' ability to practice GSD-Y competencies

Outpatient training visits were scheduled for one hour. A subset of visits was first conducted by GRH to act as a role model before HCPs started to practice GSD-Y. GRH participated in HCPs' outpatient training visits and observed how HCPs delivered and practiced GSD-Y and talked with

adolescents and parents subsequently about their experiences using reflection sheets and about the content of the visits. The digital recordings from the fictive cases had showed that HCPs were able to use mirroring, active listening, values-clarifying responses but had difficulties providing autonomy support when using the reflection sheets concerning blood sugar management and dynamic problem solving. Therefore additional individual training and supervision was provided by GRH throughout the period (scheduled for 40 hours per HCP). All HCPs passed the final tests from August 2009 - December 2009.

## **Final adjustment of GSD-Y for its use in triads of adolescents, parents, and HCPs**

### ***Adjustment of reflection sheets***

Based on GRH's registered observations and feedback from HCPs, adolescents and parents, only minor vocabulary adjustments were needed compared to the adult version. For instance in reflection sheet number 2; '*Working together – your life with diabetes*' the first sentence '*Those who know the way I live, think that..*' was changed to: '*Those (classmates, friends, teachers, my mother, my father, sisters, family) who know the way I live, think that*'. (Appendix A – adolescent's part). Five reflection sheets for parents were selected from the adult version and modified by replacing the term 'your diabetes' with 'your child's diabetes' (Appendix A –parents part). These reflection sheets were selected because they included insights into previous management patterns and reflected supported problem solving in the adult version (1).

### ***Development of new reflection sheets***

HCPs found that solely collecting adults' evidence-based data on the trade-off between hypoglycaemia incidences and eye changes was inadequate (134). GRH and VZ developed a new reflection sheet illustrating the amount of hypoglycaemia related to different levels of HbA1c based on data from youths 13–18 years of age from the DanDiabKids Register (Jannet Svensson, unpublished data). This reflection sheet was added to visit 4 (Appendix A, 4.b., '*Advantages and disadvantages of high and low blood sugar*').

GRH observed that no reflection sheets asked how sharing responsibility for diabetes (for instance, getting up in time to measure blood sugar) should be divided between adolescents and their parents. A model of responsibility sharing developed for Swedish adolescents with type 1 diabetes (135) presented in Bergen in 2009 was modified by GRH in agreement with Olinder and added to visit 3. HCPs had difficulties in summarising after each visits which topics to work on until the following visit. GRH developed an agreement sheet for that purpose (Appendix A).

Five new reflection sheets were developed for visits with dieticians. GRH observed that the adjusted reflection sheet for visit 1 helped identify the current challenges but did not support the process in solving them. Two reflection sheets were developed for this purpose: *Experiment 1 (a situation at home)* and *Experiment 2 (a situation away from home)*. After a short training period, GRH determined that the adolescents had difficulties practicing the experiments because they needed knowledge about how to manage carbohydrate counting. Three reflection sheets were developed for this: '*Review of the 500 and 100 rule*' and '*How do I get Rapid and what I eat and drink to match*' (Appendix A, 1.b – 3.b dietician).

## **Ensuring acceptability of GSD-Y among adolescents, parents and HCPs**

The recorded visits verified that the adolescents were able to use abstract thinking to reflect and to use the reflection sheets in cooperation with HCPs and parents. The reflection sheets were not always filled in beforehand because adolescents had forgotten it. HCPs handled this by reading the



semi-structured text aloud and waiting for the adolescents to complete the prompts orally and subsequently asked them to write it down. This ensured that the reflection sheets were used close to the original intention. An alteration of the adult order of reflection sheets was made because the reflection sheets concerning autonomous motivation for blood sugar management were found to be necessary before working with the sheets for dynamic problem-solving (Appendix A, visit 5 & 6). Parents expressed that the five selected reflection sheets for their visits were helpful for gaining insight into reasons for previous choices and reactions and supported shared problem solving. HCPs expressed that the use of GSD-Y was acceptable but constituted a change from usual outpatient visits. A structured order of reflection sheets used at each visit was highly valued. HCPs and adolescents managed fewer reflection sheets than in the adult version per visit. The number of reflection sheets was reduced from 21 to 18 for adolescents when seeing physicians or nurses: five were selected for parents and six for dieticians. A structured programme for the GSD-Y visits was made (Appendix A, the front-page).

### **Ensuring feasibility of GSD-Y in usual outpatient visits**

Duration of outpatient visits was extended to one hour (routine visits 30-45 minutes) to provide time for talking about the reflection sheets and usual regulation topics. Older adolescents (16-18 years) had difficulties attending during the day time. Extra late outpatient appointments were provided twice a month at one of the hospital clinics. At the other hospital late appointments were routinely provided weekly.

It was not possible to determine how often adolescents should attend to ensure continuity in GSD-Y. In adult care group intervention had been conducted over a period of nine weeks and in the individual setting it lasted from eight weeks to eleven months. Based on these experiences it was decided that adolescents should attend eight times over 8-12 months - monthly for the first four visits and every other month for the subsequent four visits, thereby providing time to work on the larger amount of sheets for dynamic problem-solving between the visits (Appendix A, visit 5 & 6). Parents should be offered two parental GSD-Y visits to work with the selected reflection sheets. Based on HCPs experiences, the first visit was appropriately placed after the adolescents' second visit. This should allow the adolescents to gain insight into own values and experiences before relying to parents' versions. The second visit was placed after six months. Thus adolescents and parents could work with a common problem challenge if needed.

### **Unexpected challenges to the activities during the adjustment and development period**

Translating GSD to an adolescent context was expected to elicit a number of challenges such as the number of reflection sheets per visits and understanding the vocabulary by the adolescents. In addition many unexpected challenges occurred that were related to external circumstances. These are described below and offer an insight into why the period was prolonged.

Three nurses at one of the hospitals were replaced with new nurses with minor or no experience in paediatrics or paediatric diabetes care prior to the start of the GSD-Y courses in November 2007. A central diabetes nurse who used to follow all adolescents with type 1 diabetes at the other hospital died in January 2008 just after the first GSD-Y course. This altered the organisation of the diabetes team and two novices in the paediatric diabetes outpatient clinic visits took over. These five HCPs' GSD-Y training with real adolescents and parents was therefore postponed until Fall 2008 when they were confident in paediatric diabetes outpatient visits. The two-month strike among nurses in Denmark during Spring/Summer 2008 interrupted the GSD-Y training for four months. Outpatient

visits were cancelled during the strike and afterwards closed due to summer holidays. GSD-Y training was postponed until September 2008 because HCPs had to manage their usual outpatient visits. Four adolescents and parents who had agreed to participate in HCPs' GSD-Y training did not want to continue. HCPs had to find new participants. Finally GRH went on partial leave for four months (Sep 2008-Jan 2009) due to critical illness and death in her family (Appendix H).

## Summing up

It was anticipated that the adjustment, development, and training period would last for 12 months but it lasted 22 months. All HCPs completed their GSD-Y training and passed the tests ensuring they were able to deliver and practice GSD-Y as intended. The adjustment and development of a GSD-Y version did not alter the original purpose of GSD as it only resulted in minor changes to the original version. The differences between GSD and GSD-Y are shown in Table 2. GSD-Y was deemed acceptable and feasible for the participants based on dialogues, observations and reactions showing that GSD-Y was efficient in the sense that it had the expected theoretical influence (1) on interactions within dyads and triads. Therefore, the study commenced despite the design of GSD-Y version had been interrupted and challenged due to unforeseen circumstances.

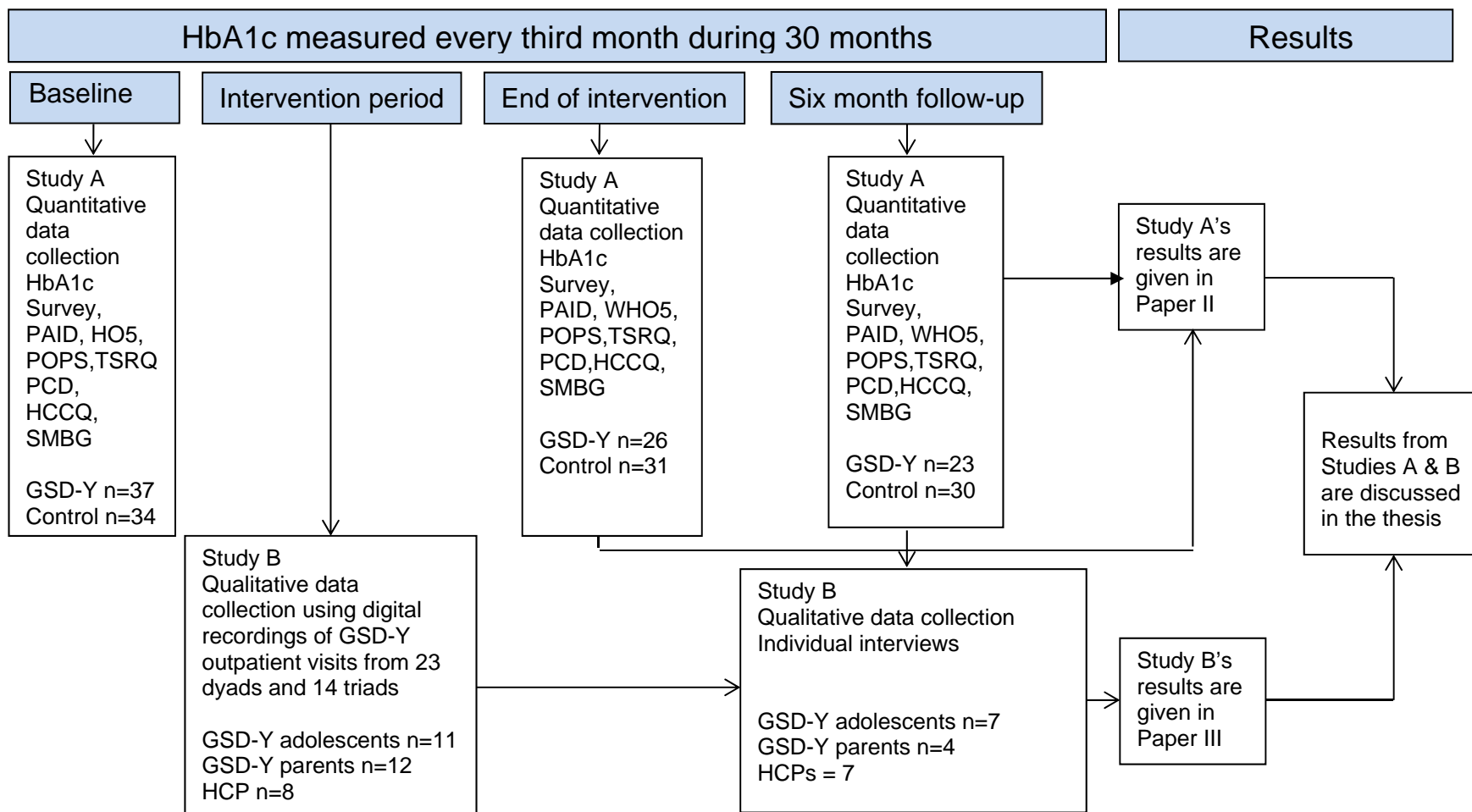
**Table 2.** Summary of the differences between GSD and GSD-Y

GSD Adult version	GSD Youth version
<p><b>When tested in one-on-one settings</b>            Delivered in a day clinic and a 24-hour unit by 6 nurses            Eight one-hour conversations in a course lasting eight weeks - 11 months according to the participants' availabilities            21 reflection sheets            Participants got a start packet consisting of seven reflection sheets to be filled in before the first conversation - afterwards the order of the following reflection sheets were decided by the GSD nurse</p> <p><b>When tested in group settings</b>            Three groups with 10-12 participants in each group            GSD was delivered weekly in 2-hour sessions eight late afternoons (2 nurses and VZ in each group)            Four weeks – one week vacation – four weeks            Predefined order of reflection sheets</p>	<p>Delivered in one to one settings in usual outpatient visits by 5 nurses, 2 physicians            Eight visits in 12 months for adolescents - monthly visits for four months, four visits every two months            Two GSD-Y visits for parents at three &amp; six months            One-hour visits            18 reflection sheets for adolescents, five for parents, six if seeing the dietician            Dietician visits are added to the eight GSD-Y visits            Reflection sheets to support autonomy support in blood glucose management comes before dynamic problem solving            Predefined order of the reflection sheets made by the researchers</p>

## Design of the study

A mixed-methods design was chosen as recommended for evaluating complex interventions (109,136) (Figure 4). The design comprised a RCT and a nested, concurrent and sequential qualitative evaluation (5) of the use of GSD-Y to encompass all of the objectives of the study and to avoid disturbing the RCT. The strategies were combined as follows. The concurrent strategy was used during the trial as both quantitative and qualitative data were used. The quantitative data measured an effect and the qualitative data explored and illustrated GSD-Y's impact on life skills development. At the end of the six-month follow-up, the sequential qualitative evaluation took place by exploring and illustrating how GSD-Y worked from the perspectives of a nested sample of adolescents, parents and HCPs. The data from each study were analysed and reported separately (Paper II & III). In the thesis, the results from the two studies are discussed together (137). By converging the effect and the findings of GSD-Y, contrasting and comparing is possible leading to a nuanced and complementary evaluation (5,138) of the use of GSD-Y.

**Figure 4. A mixed-methods design comprising a Randomised Clinical Trial and a nested, concurrent and sequential qualitative evaluation.**



## **Site and setting**

Two specialised paediatric diabetes outpatient clinics from two hospitals in the Capital Region of Denmark participated. One clinic was a full-time paediatric diabetes outpatient clinic and the other was a part-time clinic. Adolescents up to the age of 18 years are normally seen in such clinics.

## **Participants**

Two hundred and seventy-four adolescents were assessed for eligibility. The inclusion criteria were: 1) age 13-18 years at entry; 2) type 1 diabetes for more than one year and with insulin treatment from the onset of the disease; 3) HbA1c  $\geq$  64 mmol/mol (8.0%) at the final visit prior to entry into the study and an average HbA1c  $>$  58 mmol/mol (7.5%) during the year prior to inclusion; 5) no diagnosed psychiatric disease; 6) not consulting with a psychologist at the time of recruitment; and 7) the ability to speak and understand Danish. Two approaches were used to ensure that all eligible adolescents were identified. Data from the DanDiabKids Register (18) were used to identify adolescents with a mean HbA1c  $>$  58 mmol/mol (7.5%). Subsequently each HCP was asked to provide a list with their current adolescents. GRH investigated these adolescents' records, calculated their HbA1c average and compared the lists with results from DanDiabKids and finally talked with each HCPs to ensure that all criteria for participation were assessed.

Parents, who spoke, read and wrote Danish, did not have severe illness or mental problems and were not in current psychiatric or psychological treatment at time for recruitment, were invited. Two physicians (one from each clinic), five nurses (three from one clinic) and two dieticians (one from each clinic) who had at least one year of experience in diabetes paediatric outpatient clinics prior to the start of trial period and had passed the test in providing GSD-Y participated (Table 3).

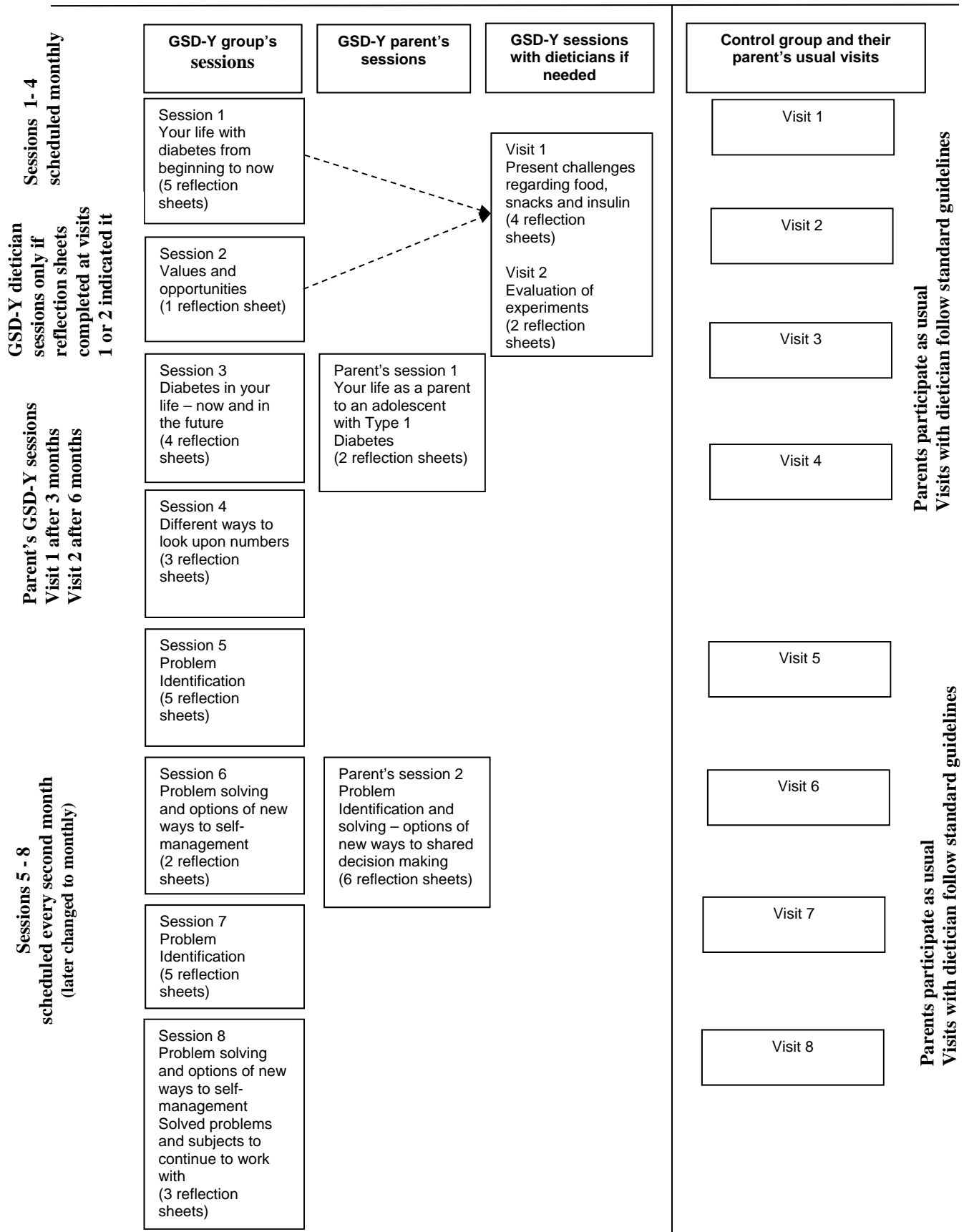
## **GSD-Y intervention**

The GSD-Y group participated in eight GSD-Y outpatient sessions and parents were offered two visits (Figure 5) with a standard duration per visit of one hour. They saw either their usual physician or nurse. Before and between visits, the adolescents and parents were asked to fill in the semi-structured reflection sheets. Adolescents were referred to dieticians if filled in reflection sheets from visit 1 (1.e) or 2 (sentence ten) indicated a need for that (Appendix A). A referral implied a minimum of two visits. Each GSD-Y visit started with talking about the reflection sheets. The participants kept the original reflection sheets and a copy was placed in the adolescents' record.

## **Control group**

Participants in the control group were offered eight outpatient visits with a standard duration per visit of 30-45 minutes. The parents participated as in usual care. If dietician guidance was needed, HCP referred the adolescents according to usual standard procedure.

**Figure 5.** Overview of the scheduled content and number of GSD-Y sessions and control visits.



## Study A – The Randomised Clinical Study

### Outcome measures and data collection

#### The primary outcome

The primary outcome HbA1c was measured every third month for 30 months in both groups and was analysed at the Department of Clinical Biochemistry (Herlev), using Variant Analysis Mode, TOSOH Automated Glycohaemoglobin Analyzer HLC-723 G8 (normal range 23-40 mmol/mol (4.3%-5.8%)). The HbA1c analyses in Denmark were found to be falsely high (discovered in Spring 2013) due to problems with a freeze-dried calibrator (139). All values analysed before 26 January 2013 at Herlev were consequently decreased by 2.7 mmol/mol (0.24%), following the recommended guidelines (139). Analyses conducted at the adult clinics at Steno before 13 December 2012 and at Hillerød before 15 December 2012 were decreased for those (n=11) who had been transferred to adult care after the six-month follow-up.

#### The secondary outcomes

The secondary outcomes were the development of life skills. As there is no universal scale with which to measure life skills in the context of diabetes, the Danish versions of six scales that all have been used in studies in adolescents before, were chosen being consistent with the GSD-Y's intended impact. Their appropriateness for use with adolescents was confirmed by members of Psychosocial Aspects of Diabetes (PSAD), specialists on psycho-social aspects of diabetes, Arie Nouwen, professor in psychology at Middlesex University, London and Mark Peyrot, professor in sociology at Loyola University, Baltimore (personal communication). Four of the scales had been used to measuring the development of life skills in adults (80): the 5-item *Perceived Competence in Diabetes Scale* (PCD), which measures the degree of competence that is perceived by patients in managing diabetes (140); the 5-item *Health Care Climate Questionnaire* (HCCQ), which measures the degree to which patients experience autonomy support from HCPs (141); the 21-item *Treatment Self-Regulation Questionnaire* (TSRQ), which consists of three subscales that measure the patients' motivations for taking their diabetes medication, checking their glucose levels, following their diet and exercising regularly using the three following levels: (I) autonomous, (II) controlled, or (III) a-motivated (142); and the 20-item *Problem Areas In Diabetes* (PAID), which uses a 5-point scale to measure the perception of the current emotional burden of diabetes-related issues (143).

To capture how parents' participation in GSD-Y might have impacted adolescents' perceptions of parental autonomy and involvement, two subscales from the Perception Of Parents Scale (POPS) scale were chosen, consisting of 26 items (13 for mothers and 13 for fathers)(144). POPS is a 7-point Likert scale, based on Self-Determination Theory and consistent with the theoretical framework of GSD. POPS was the only scale which required to be translated into Danish. Two full-parallel back-and-forth translations were provided by professional translators (native English-speaking persons) and by VZ and GRH in accordance with recommended guidelines (145). To assess the adolescents' emotional well-being the 5-item WHO5 scale was added (146).

Development of life skills was defined as a significant increase in the scores on PCD, HCCQ, TSRQ autonomy, TSRQ relative autonomy index (formed by subtracting the TSRQ-scores on control from the TSRQ-scores on autonomy), POPS, and WHO5 and a significant decrease in the scores on the PAID, TSRQ control and TSRQ amotivation.

The reliability and internal consistency of the scales using Cronbachs  $\alpha$  had proved to be good in adolescents: PCD (0.89) (115), HCCQ (0.84) (147) TSRQ (0.95) (115), PAID 0.92 (148), POPS 0.88 (149) and WHO5 0.82 (146). Examples of questions and scoring details are given in Appendix C. The six scales were compiled into one questionnaire (Appendix C). Prior to the RCT eight adolescents, four from each hospital (4 girls – 2 from each hospital) age 13-18 years who had participated in the design of GSD-Y completed the questionnaires to test face validity. No difficulties in understanding or answering the questions were identified and no changes were required. It took between 15- 20 minutes to complete.

Other secondary diabetes outcomes directly related to patient management that might be influenced by GSD-Y included the registration of: (i) insulin delivery (continuous subcutaneous insulin infusion (CSII) or multiple daily injections (MDI); (ii) the number of self-monitored blood glucose (SMBG) values during the prior (last) week; (iii) hypoglycaemic episodes (frequency and severity); and (iv) admissions to the hospital (e.g., episodes of ketoacidosis or hypoglycaemia).

Diabetes outcomes indirectly related to patient management and registration of the integration of the GSD-Y into usual outpatient was (i) attendance during the trial (ii) parental participation in visits.

During the intervention period, a case report form (Appendix D) was used to collect the data that were directly and indirectly related to patient management at each outpatient visit by the adolescents' usual HCPs except for the number of SMBG which were self-reported when the adolescents completed the questionnaires. The questionnaires were completed at baseline, at the end of the intervention and at six-month follow-up. Demographic data were collected at baseline.

### **Randomisation**

The adolescents were stratified according to their usual HCPs to ensure continuity in care and treatment. The generation of the allocation sequence was determined according to when adolescents had their regularly scheduled outpatient appointments. The adolescents were randomised using opaque sealed envelopes containing a twice-folded piece of paper indicating the group assignment and prepared in blocks of four, each comprising two GSD-Y intervention assignments and two usual care assignments. The four envelopes in a block were randomly mixed and then consecutively numbered from one to four by GRH. HCPs carried out the randomisation by following a list with names of the adolescents who fulfilled the inclusion criteria required by GRH. Equal numbers of GSD-Y and control adolescents were allocated to each physician and nurse—approximately 10 to each. A CRF (Appendix D) was completed on the date of randomisation by the HCPs to ensure that the adolescents fulfilled the in- and exclusion criteria. GRH checked all of the completed CRF prior to start of the trial. GRH met with HCPs regularly to update the randomisation list and to identify if any new adolescents might fulfil the HbA1c criteria or if some stopped. Due to the nature of the intervention, neither adolescents nor HCPs could possibly be blinded to the group allocation after randomisation. After informed consent was obtained the adolescents provided a blood sample for HbA1c measurement and completed the questionnaire while in the clinic before randomisation to eight GSD-Y sessions or eight control visits. Adolescents randomised to the control visits were informed that they would be offered GSD-Y after end of their study period.

### **Sample size**

A power calculation based on the primary outcome measure HbA1c with an absolute difference of 1.0% (11mmol/mol) in HbA1c between the GSD-Y group and the control group (power 0.80; two-

sided level of significance 0.05) indicated that 26 patients in each group would be required. This calculation was based on results and a standard deviation of the HbA1c value of 1.3% from a study on coping skills training (79). To allow for an attrition rate of 25%, we aimed to recruit 68 adolescents. The flow diagram depicts the trial profile (Appendix E, Figure 1).

### **Statistical analysis**

The purpose of the analysis was to compare the effects of GSD-Y to the effect of usual treatment on HbA1c and on the six scales and SMBG at the end of the intervention period and after a six-month follow up. Furthermore the occurrence and rate of hypoglycemic attacks during the intervention periods were compared between the two groups.

To describe the baseline characteristics of the two groups, means and standard deviations or median and range were calculated.

Intention-to-treat analyses were conducted using two sided tests at the 0.05 level of significance.

Holm's test was used to control for multiple testing (150).

The HbA1c, scales and SMBG were analysed using a linear mixed-model with repeated measures (RMMM) assuming an unstructured covariance matrix (for tests of the assumptions of such a model see footnotes of Table 4b, Appendix E). The primary result was based on a model that included the indicator of the intervention (I, reference: group 2), an indicator of follow-up (F, 0 for end of experiment and 1 for time of follow-up) and the interaction between the two (I\*F). Two hypotheses were tested: 1) that GSD-Y has an effect on the mean level of HbA1c at the end of the intervention that is sustained until follow-up (main effect of I) and 2) that the intervention changes the level of HbA1c from the end of the experiment until follow-up (interaction between intervention and follow-up). Thus, a significant main effect of the intervention in the presence of an insignificant main effect of follow-up and insignificant interaction between follow-up and intervention would suggest that the intervention had an immediate effect that was neither augmented nor blunted during the follow-up period. Two additional exploratory analyses were conducted: (i) an analysis without adjusting for the stratification variable (HCP), and (ii) an analysis with an additional adjustment of the baseline value of log(HbA1c) to adjust for severity of the disease. Log transformation of HbA1c was necessary to approximate the Gaussian distributions assumed in the analysis.

The rates of hypoglycaemia were compared between the groups for each type of severity (number of attacks divided by the period/days of observation) using a non-parametric test (Mann-Whitney) (neither the Poisson model nor the negative binomial model provided adequate fit between model and data). The occurrences of hypoglycaemia were compared using the Cochran-Mantel-Haenszel test of the relative risk (risk of group 1 over that of group 2). Since the results were clearly insignificant adjusted analyses using logistic regression were not attempted.

Missing values were handled in the mixed-model analysis. Since the number of variables approached the number of patients the material was too sparse to use multiple imputations, which would improve the precision and remove any bias caused by missingness, provided that the latter only depends on the observed data (are missing at random (MAR)). However, the mixed-model with repeated measures utilises all observed values and provides unbiased estimates as long as the MAR condition is fulfilled. Thus, the results of all the analyses using the mixed-model should be unbiased provided, the relatively mild assumption of MAR is fulfilled.

The fact that regular measurements of the HbA1c level are routinely made in the patients allowed a supplementary post hoc analysis of the HbA1c level designed to attain constant periods and frequencies of observation of the HbA1c level. The time series of two groups were compared



including the HbA1c level measurements obtained every third month starting with the measurement obtained 3 months following randomisation and covering a period of 30 months, so that the period of intervention/control was included for all patients. The results were subjected to a repeated-measure mixed-model regression analysis. Akaike's criterion was used to choose between an autoregressive (AR)(1) and a compound symmetric covariance matrix because convergence was not obtained using an unstructured matrix. A main effect of intervention, main effect of time and interaction between the two and adjusted for baseline HbA1c and HCP were tested.

For a withdrawal analysis the baseline data for GSD-Y adolescents who completed the eight sessions were compared with GSD-Y adolescents who did not. Pearson Chi-Square or Fisher's exact test were used for the dichotomous variables. For continuous variables t-tests were used when data were normally distributed and Mann-Whitney U tests when not (details provided in the tables, Appendix E). The data were analysed using SPSS version 17 & 19.

### **Study B – The Qualitative Realistic Evaluation**

Realistic Evaluation (RE) is a theory-driven method originally developed for evaluating social work practice and policy (151,152) but it has expanded from its social science roots to health care contexts for evaluation of transition programmes for youths with diabetes (153), cardiac rehabilitation (154) palliative care (155), mental illness (156) and education (157,158).

Methodologically RE positions itself between positivism and constructivism believing that a given intervention always occurs in an open system in which many factors additional to the intervention itself may affect the effectiveness (152,159). The strength in using RE is that it provides the possibility of identifying 'what works for whom, and how and in what circumstances' in the particular setting of interest (152,157,159) and is therefore recommended as a supplement to a RCT when interventions are complex and transferred to a new context (157).

The focus in RE is on evaluating the relationships between Context, Mechanisms and Outcomes (CMO) (152). *Context* refers to interpersonal and social relationships connected to situations and localities (152 p.58). *Mechanisms* refer to how participants interpret and act upon an intervention and are not directly observable. Mechanisms can be 'constraining', which refers to the failure of an intervention, and/or 'enabling', which refers to the success of an intervention in the particular context they operate in (152 p 70). *Outcome* is the result of the combination of mechanisms and context (152,159).

The initial step in RE is to formulate conjectured CMO configurations based on the underlying theory of the intervention being used followed by data collection, data analysis and presentation of the findings (159). The formulated conjectured CMO configurations are not understood as hypotheses that test or demonstrate the constant conjunction that programme X produces outcome Y but are understood more broadly (152 p.215). In RE, the researcher '*try to understand the conditions required for an interventions' causal potential to be released and whether this has been released in practice*' (152 p.215). By evaluating the proposed CMO configurations, it should be possible to identify the causal potential that enables or constrains the development of life skills in GSD-Y (160).

### **Sample**

Thirteen purposively sampled (161) adolescents and their parents from the GSD-Y group (n=37) from both hospitals with adolescents' variation in age, sex, living situation, duration of diabetes and different HbA1c levels at baseline were selected to ensure that different needs for developing life

skills were captured. To explore and illustrate whether HCPs were able to integrate GSD-Y in outpatient visits, eight HCPs participated in the evaluation (Appendix F).

### **Data collection**

Thirty-seven outpatient visits (45-60 minutes) were digitally recorded from December 2009 until January 2012 followed by 21 individual digitally recorded interviews (60-90 minutes) conducted by GRH after the end of follow-up from November 2011 until March 2012. Interviews with the adolescents and the parents took place separately. Interviews were conducted in their homes except one family, who preferred to come to the hospital. HCPs' interviews were conducted at the hospital. The adolescents and parents did not know GRH prior to the interviews. A copy of their filled in reflection sheets were used in the semi-structured interviews (161 p.339-349), which aided the participants in their reflection upon their experiences (Appendix F). Because the participants were very positive about GSD-Y during the interviews, questions were posed, such as *'You have been telling me many positive things about GSD-Y. You have not told me if there were some things that were difficult or negative about the programme. Please give me an example of the worst thing about participating in this programme?'* To elaborate on their experience of GSD-Y combined with their individual quantitative results, they were asked about their perception of impact on HbA1c. The interviews with the adolescents and their parents were conducted on the same day, whereas the interviews with HCPs were conducted subsequently. Data from the outpatient visits and interviews were transcribed verbatim by a secretary and controlled by GRH. The N'Vivo software (version 8) supported the sorting and analysis of data.

### **Analysis**

It was proposed that the outcome of GSD-Y would be the same as in the adult version, namely that adolescents would start to develop life skills (103). An operationalisation of how life skills development in adolescents could be recognised was made through eight life skills outcomes (108) and subsequently incorporated into eight conjectured CMO configurations (Appendix F) based on evidence in adolescent's type 1 diabetes in paediatric contexts and from mechanisms identified to be activated by GSD in adult care (92).

The analysis was conducted in four steps. 1) The transcribed text from outpatient visits was extracted according to each of the eight conjectured CMO configurations and coded deductively and inductively. Codes were compared within each participant and then compared across sub-group participants of adolescents, parents and HCPs. 2) The transcribed interviews were managed by following the same procedure used in step one. The codes from GSD-Y visits were compared with codes from interviews showing that the interaction pattern between the parties had changed. 3) Text and codes from step one and two were sorted into a table according to each CMO configuration to organise and delineate relationships inspired by Kazi (151) as no specific guidelines for the analysis process is given in the RE literature (152,159). Participants' experiences of the context before and after the intervention revealed changes and constraining and enabling mechanisms. Codes were formulated based on their experiences. For instance, experiences related to the CMO-2 *'adolescents are able to communicate openly and honestly with HCP'* were coded *'from monologue to dialogue'*, *'from isolated thoughts to sharing thoughts'*, *'from resistance to starting to considering different diabetes management solutions'* (Example Appendix F).

All codes were compared, and several observed outcomes were related to GSD-Y sessions expressing what worked in GSD-Y, for whom, in what circumstances, and how. 4) Induced and deduced outcomes and condensed outcomes from each of the eight CMO patterns were compared and discussed by the research team, and finally condensed into three outcomes which were identified to be connected to the eight predefined life skills outcomes (Appendix F).

## **Ethical considerations**

The study was reviewed by the Danish National Committee on Biomedical Research Ethics, registered with the Danish Data Association, the Current Controlled Trials registry (ISRCTN54243636) and performed in accordance with ethical recommendations (The Declaration of Helsinki). Prior to the randomisation, the adolescents and the parents were informed by their usual HCPs both orally and in writing regarding the purpose of the study (Appendix G). Written informed consent was obtained from all adolescents and parents of minors (younger than 15 years of age) prior to enrolment (Appendix G). The purpose of the study was repeated prior to the interviews by GRH. During the interviews GRH was aware that different feelings, both during the interviews and subsequently, might occur and adolescents and parents were encouraged to contact their usual contact HCPs or GRH if needed. The interviews took place as planned.

## **Results**

### **Study A - The Randomised Clinical Trial**

#### **Participants**

Seventy-one adolescents and their parents from the two hospitals were randomised over 16 months to GSD-Y (n=37) or usual care (n=34) (Appendix E Figure 1,2, Table 1 baseline characteristics). The number of enrolled adolescents was higher than planned to ensure that HCPs got equal numbers of GSD-Y and control participants. A total of 138 adolescents did not meet the eligibility criteria distributed on; 119 the HbA1c criterion, 11 language barriers, eight in current psychological or psychiatric treatment or possible psychiatric disorders based on information from records and HCPs. Twenty-seven adolescents were not invited because they were usually treated by HCPs who had not been GSD-Y trained; 26 adolescents declined to participate (no reasons given); six participated in other studies, six lived far away and normally attended the outpatient clinic 3 to 4 times yearly. Three new adolescents fulfilled the age criteria in combination with HbA1c during the enrolment period (are included in the flowchart). None was registered reaching the age limit. The long randomisation period was attributable to a) non-attendance/cancellations, b) adolescents/parents needing extra time to consider participation, c) parents not attending as expected meaning that consent forms could not be signed, d) adolescents forgetting to bring signed consent forms, e) HCPs forgetting to invite/not having the time to invite/being absent due to conferences/furthering their educations.

Fifty-seven adolescents (80%) completed the eight sessions; 26 GSD-Y and 31 control adolescents. Fifty-three (75%) adolescents delivered six months follow-up data, 23 in the GSD-Y group and 30 in the control group. In total, 30% (n=11) in the GSD-Y group did not complete their eight GSD-Y sessions compared to (n=3) in the control group. It was decided to stop these 10 GSD-Y adolescents' participation after two years in the trial. It was deemed unrealistic that they would

fulfil since they had completed between 0-6 (mean 2.8) GSD-Y sessions; number 11 wanted to move to an adult clinic. A withdrawal analysis showed no differences between the GSD-Y adolescents who completed the eight sessions and those who did not except of the age at onset of diabetes which was highest among those who completed ( $p=0.04$ ). (Appendix E, Tables 2a, 2b).

### **Primary outcome – HbA1c**

HbA1c was measured across 30 months to get equal observation time for both groups. Fifty-seven percent of the planned measures were missing. The results of the mixed-model analysis showed that there was no significant difference between the mean HbA1c levels of the two groups of main effect of intervention ( $p=0.86$ ), no significant changes over time in the mean values of the groups neither for an overall of main effect of time ( $p=0.65$ ) nor between time and intervention ( $p=0.55$ ) (Appendix E, Figure 2, Table 3). The baseline HbA1c values were  $80\pm 3$  mmol/mol ( $9.5\pm 0.3\%$ ) in the GSD-Y group and  $73\pm 2$  mmol/mol ( $8.8\pm 0.1\%$ ) in the control group (mean $\pm$ SE). At the end of the intervention, the HbA1c levels were unchanged: in the GSD-Y group they were  $80\pm 3$  mmol/mol ( $9.5\pm 0.3\%$ ) versus  $76\pm 2$  mmol/mol ( $9.1\pm 0.2\%$ ) in the control group. At follow-up, the results were  $82\pm 3$  mmol/mol ( $9.6\pm 0.3\%$ ) in the GSD-Y group versus  $79\pm 3$  mmol/mol ( $9.4\pm 0.3\%$ ) in the control group.

### **Secondary outcomes – life skills**

The GSD-Y group significantly decreased the level of amotivation for diabetes self-management at the end of the intervention period as a sign of life skills development compared with the control group. This effect was maintained at follow-up. No other secondary outcomes related to the scales were significantly influenced by the GSD-Y intervention compared with treatment as usual when multiple testing was conducted (Appendix E Tables 4a, 4b).

### **Secondary outcomes directly related to patient management**

There were no significant differences between the groups in the number of SMBG measurements during the intervention period ( $32\pm 14$  versus  $32\pm 13$  measurements per patient per week,  $p=0.89$ ) or at follow-up ( $31\pm 13$  versus  $31\pm 19$ ,  $p=0.88$ ) or differences according to the occurrence of mild, moderate, and severe hypoglycaemic episodes or risk for hypoglycaemia observed (Appendix E Table 5). Similarly insulin delivery, insulin doses, admissions to the hospital, and occurrences of ketoacidosis did not differ between the groups at the end of the study.

### **Secondary outcomes indirectly related to patient management**

#### **Attendance**

The GSD-Y group had more non-attendance incidents yearly compared with the control group ( $0.9\pm 1.1$  versus  $0.4\pm 0.6$  missed visits,  $p=0.02$ ). The yearly number of cancellations did not differ between the groups ( $1.1\pm 1.1$  versus  $0.8\pm 1.4$  cancellations,  $p=0.07$ ).

#### **Parents participation**

Parents of the GSD-Y group participated in fewer of their adolescents' sessions than parents of the control group (median 3.5 versus control 7 visits;  $p=0.05$ ). Twenty-three (68%) of the GSD-Y parents received parental GSD-Y visit 1 (at a median of 6 months (2-14)) and 11 (30%) received visit 2 (at a median of 13 months (5-20)).

## Other results

### Prolonged study period

The duration of the trial period was longer than designed – expected duration was a maximum of 365 days (108) and the GSD-Y group spent significantly more time than the control group (Appendix E, Table 6). Adolescent in the GSD-Y group needed more than one visit per session to work with the scheduled reflection sheets (Appendix E, Table 7) and spent more visits in total to complete the eight sessions (12 median visits range 8-16) than the control group (8 median visits range 7-12). None of the groups got their first visit as scheduled (Appendix E, Table 8). After the first year of the study, visits were scheduled monthly instead of every second month as planned to initiate faster completion (Figure 5). It was not possible to determine whether this had an effect. The flow of the visits was influenced by HCPs being absent due to further education, conferences, long-term sicknesses, movement of one outpatient clinic, and financial savings resulting in reduced nurses at one clinic leaving more patients to the GSD-Y nurses (Appendix H).

### The use of reflection sheets in the GSD-Y group

All of the reflection sheets were completed by all 26 GSD-Y adolescents except two sheets identifying patterns and motivation for blood sugar management behaviours (Appendix A, 3.d and 4.a.), which were not used by 10 adolescents (39%). The reflection sheets were filled in beforehand between 1-9 times (an average of 5.3 times) or done together with HCPs during visits 1-7 times (an average of 2.4 times). It was especially when working with the reflection sheets for sessions 5 & 6 (dynamic problem solving) that extra visits were needed (Appendix E Table 7). Twenty-three parents (n=23) used the reflection sheets for visit 1, and 11 parents used the sheets for visit 2.

### HCPs completion of adolescents in the GSD-Y and the control group

The numbers of GSD-Y adolescents that the HCPs completed were not equal (range 1-6) (Table 3).

**Table 3.** The characteristics of the HCPs who participated in GSD-Y, and their experiences in outpatient diabetes clinic visits prior to beginning the GSD-Y training and upon commencing the trial. The number of adolescents who were assigned to the GSD-Y or control groups and to each HCPs and the number of adolescents each HCPs completed in trial are indicated.

HCP No.	Profession	Experience in paediatric outpatient diabetes care at the beginning of GSD-Y courses and beginning of the trial: training (years/months)	trial (years.months)	No. of enrolled GSD-Y adolescents	No. of completed GSD-Y adolescents	No. of enrolled control adolescents	No. of completed control adolescents
HCP1	Nurse	7 months	2.2	5	3	5	4
HCP2	Nurse	6 months	2.1	6	6	3	2
HCP3	Nurse	8 months	2.3	4	3	6	6
HCP4	Nurse	8 months	2.3	5	5	5	5
HCP5	Physician	1yr	3	7	3	5	4
HCP6	Physician	1yr	3	5	5	5	5
HCP7	Dietician 1	9 yr	11	4	4	5	5
HCP8	Dietician 2	15 yr	17	9	9	1	1
HCP9	Nurse	5 months	2.7	5	1	5	5

### Dietician visits

Adolescents from the GSD-Y group were more often referred to the dietician (50%), with each having 1 to 6 visits, compared with (11%) the control group, with each having 1 visit.

## **Findings of study B – the Qualitative Realistic Evaluation**

The analysis illustrated that HCPs practiced GSD-Y in usual outpatient visits. The use of reflection sheets in combination with mirroring, active listening, and values-clarifying responses illustrated that communication became focused and reflection became situational. GSD-Y contributed to the development of life skills in adolescents with type 1 diabetes by involving adolescents and subsequently parents in decision-making and problem solving. Three condensed outcomes were identified as signs of development of life skills in adolescents: 1) developing new relatedness with HCPs and parents; 2) becoming decision-makers in their own lives with diabetes; and 3) growing personally (Appendix F). A summary of the findings is given below and is fully given in paper III.

### **Developing new relatedness with HCPs and parents**

The use of GSD-Y turned routine outpatient visits into person-specific and meaningful visits and gave voices to the adolescents. The relationship between adolescents and HCPs changed from being dominated by the HCPs' or parents' perspectives into mutual relationships. The adolescents hereby got an active role in the visits, giving them a feeling of being seen and listened to as the individuals they were and not of being perceived 'as a patient'. Parents saw their prior role during the visits as inhibiting their teens from gaining a position to take on responsibility. The adolescents' engagement and responsibility for their diabetes was also surprising to the HCPs. The HCPs' previous feelings of having to solve the problems or take action in cases of disagreements between the parties changed. Instead, HCPs became aware of how to use their new communication skills in a neutral fashion. The adolescents and the parents hereby obtained insight into previous inappropriate patterns of diabetes management, during which quarrels and disagreements had been a common part of their relationship. They began to share and understand each other's intentions and perspectives and possible ways by which to modify previous patterns of interaction. The circumstances in each family were, however, more or less complex and in some cases the cooperation patterns could not be changed. For others, methods to solve problems were explored and discussed, either between all of the parties or between just the adolescents and HCPs. New understandings of the adolescents' own situation, reactions and intentions, as well as insights into their parents' and HCPs' perspectives, were mechanisms that led to the new relatedness between the parties.

### **Becoming decision-makers in their own lives with diabetes**

The adolescents began a process of becoming decision-makers in their own lives with diabetes. The focused communication and depth of thinking due to the reflection sheets had helped them identify their personal difficulties that were preventing them from managing the disease. HCPs had previously informed the adolescents of how often and when blood sugar tests should be performed. In contrast, the HCPs supported the adolescents in setting their own goals and in making their own decisions about why and when to perform these tasks. Some adolescents began to think ahead by considering how to handle situations such as sports, e.g., remembering the blood sugar device, insulin, food and juice by themselves. Others decided to conduct concrete experiments, e.g., 'doing numbers' when together with peers to become open about their disease. The adolescents discovered that previous reasons for taking care of the disease often had been external, e.g., avoiding being perceived differently, being scolded and getting into quarrels. These reasons had not previously been internally important to them. The benefit of this insight was that adolescents changed their view of managing their disease and saw, e.g., blood sugar measurements as positive tools. This transition resulted in an emerging acceptance and integration of the disease in their everyday lives.

Through the GSD-Y intervention, the HCPs discovered the potential of the adolescents to make self-determined solutions. Both adolescents and parents connected the adolescents' skills in becoming decision-makers with the HCP-adolescent one-to-one visits, which allowed for the adolescents to feel ownership of their disease. Some parents realised that they may have stepped back too much during GSD-Y being unsure how to support without taking too much control again.

### **Growing personally**

The adolescents began a process of personal growth due to changes in their relationship with HCPs and parents and due to their new ability to become decision-makers in their own lives. Using the reflection sheets, the adolescents discovered resources that they could use to manage their diabetes of which they had not previously been aware. They gained a deeper insight into and awareness of how they had attempted to manage life previously, often without success. The developed ability to identify barriers to living with diabetes and to participate in mutual reflection and problem-solving with the HCPs and subsequently with their parents helped them to start to bridge life and diabetes rather than to persist in attempting to separate them. This had an important impact on their self-perception, including those adolescents who had not improved their regulation as much as they had wished. The parents noticed that their adolescents had matured during the GSD-Y. They discovered that their adolescents were able to speak for themselves at outpatient visits. Some were unsure whether it was due to the intervention, the natural developmental process - or a combination of both. From the HCPs point of view the adolescents had grown personally. The HCPs experienced the adolescents as having learned to reflect and speak truly about life with diabetes when compared to the adolescents in the control group.

## **Methodological considerations and discussions**

### **Changes to the original study protocol**

Though the study protocol (Paper I) guided the conduction of the study certain deviations occurred because of the prolonged study period. More visits were required to complete the eight GSD-Y sessions, reflection sheets were not always filled in beforehand and parents did not receive all of their GSD-Y visits. The deviations meant that measurements were not conducted as scheduled and that the analysis plan for Study A was replaced with ITT analyses. In study B, the sample was not selected based on the baseline scores and the final results from study A were not available when the interviews were conducted. Finally, RE was chosen for the qualitative analysis being more appropriate than Grounded Theory (162) when evaluating complex interventions. In the following sections discussions of some of the factors that may or may not have threatened the internal and hence the external validity of the results are presented.

### **Adjustment and development of GSD-Y in collaboration with the participants**

GSD-Y is considered a complex intervention consisting of several interacting components (109). Prior to conducting a RCT, it is recommended to follow guidelines for developing complex interventions and to conduct a pilot study (109,163,164). A pilot study was not chosen because it would have left too few adolescents for the RCT. It is, however, a limitation of the adjustments to GSD-Y not having paid enough attention to possible challenges in the context in which GSD-Y was transferred (109). Noting key uncertainties such as the extent of non-attendances and cancellations during a period of 3-4 months and reasons that reflection sheets were not filled in beforehand, might

have added knowledge to the practicability of a GSD-Y version (109,165). Adjustments based on such registrations in combination with joint discussions with the participants to identify possible solutions could have led to relevant pilot tests of the use of e.g. text messages as reminders for outpatient appointments, the use of telemedicine solutions when attendance was hindered or filling in reflection sheets on the internet. Similarly, a registration whether extra visits were necessary when reflections sheets were not filled in beforehand and if a difference might exist between completing them together with HCPs or alone would be valuable. Such pilot tests might have contributed to an adjustment of a GSD-Y version that was more feasible (109,165). It is considered a strength that attention was paid to input from all participants on how to develop a GSD-Y version that was acceptable, efficient and delivered correctly in accordance with the theoretical framework when developing complex interventions (109,163,166). The conclusion on GSD-Y's potential as a worthy candidate to be evaluated in a mixed-methods design was therefore based only on these key points. For further adjustment and development of GSD-Y it is recommended to follow, for instance, the Medical Research Council's framework (163) to ensure that all key elements are considered as described in Eiser and colleagues' study in young adults with diabetes (167).

### **Mixed-methods design**

The main advantage of the design was the complementary evaluation of GSD-Y despite the two studies was not mixed as intended. The sample for the qualitative study was not selected based on baseline scores on PAID and WHO5 (Paper I) to capture lack of life skills, because not all data were available when this part of the study began. Similarly the results of the RCT were not available when the interviews took place. Evidence to explore and explain the barriers of GSD-Y to improving HbA1c and adolescents' perception and reasons for decreased amotivation were missed. This limited the benefit of the sequential design (137 p.85). However, the use of mixed method is considered a strength. Without the qualitative study, it would not have been possible to explore and illustrate what worked in GSD-Y for whom and how and to what extent; without the RCT the lack of an effect on HbA1c and the decrease in amotivation for diabetes self-management would not have been identified. The possibility of combining the results in the joint discussion (138) is considered a strength of the evaluation of GSD-Y, when transferred to a new context.

### **Validity**

#### **Assessment of treatment fidelity during the intervention**

It was important to assess whether GSD-Y was delivered correctly during the study (fidelity) to make valid conclusions about the analyses (132). Clear criteria for how HCPs should deliver GSD-Y were defined a priori (Paper I) and HCPs completed a CRF at every visit registering what took place and who participated in each visit and regular meetings with took place to discuss possible fidelity issues. Throughout the intervention period, digital recordings of random and of the nested GSD-Y sample took place involving all HCPs. GRH listened to the recordings directly, and correction and repetition of the communication forms and individual re-training of specific reflection sheets occurred throughout the study (Appendix H). These actions sought to strengthen the internal validity of the study. One challenge to keep treatment fidelity during the study was that HCPs had to shift between usual outpatient visits and GSD-Y visits. This might be one of the reasons that repetition was needed to maintain a GSD-Y approach. Another reason and a limitation was that each HCP only was assigned five GSD-Y adolescents. The slow enrolment, the prolonged



study period and frequent non-attendance might also have had an impact on the ability of HCPs to maintain their GSD-Y-competencies. Whether these circumstances explain why some HCPs completed fewer adolescents in the GSD-Y group than did others or whether these findings were due to the individual challenges in each family, as verified in Study B, remains unknown. However, the use of reflection sheets is considered a strength for treatment fidelity, as emphasised in paper III, which suggests that the visits had become person-centred and meaningful.

## **Internal validity in study A**

### **Randomisation**

Randomisation was conducted using numbered and sealed envelopes by the adolescents usual HCPs. This was a limitation, because cheating could have taken place as discussed in paper II. It would have strengthened the procedure if an independent person had performed the randomisation or if computerised randomisation had been used (168,169).

Surprisingly the randomisation period lasted 16 months, despite adolescents' being invited according to their regularly scheduled visits; at minimum every third month. This enrollment method was shown to be inadequate. Unfortunately none of the clinics recorded non-attendances or cancellations routinely. Such records might have enhanced the attention to recruitment difficulties (109). Invitations to open meetings followed by immediate randomisation or a written invitation followed by personal phone calls before scheduled appointments might have contributed to quicker inclusion. It is considered a strength that a CRF was used by HCPs at randomisation to ensure that the adolescents and parents still fulfilled the in- and exclusion criteria.

To prevent selection bias, adolescents were stratified according to their usual HCPs, in an attempt to balance the number of GSD-Y and the usual outpatient visits delivered by each HCP. Having HCPs allocated to both study arms, increased the risk of contamination between the groups. It is unlikely that the HCPs were able to switch off their GSD-Y competencies when seeing the control group. A possible spill-over effect and risk of type II error was present (170) as discussed in paper II.

The two groups of adolescents seemed dissimilar according to the HbA1c levels at baseline. Given the GSD-Y adolescents' randomly higher HbA1c at baseline, it must be questioned whether this group, on the one hand, has had greater likelihood to accomplish a decrease. On the other hand, they might have had less self-management competencies and more parental conflicts as demonstrated in previous studies (9,35,64,171,172). Stratifying for HbA1c, might have resulted in more equal HbA1c levels at baseline but would have reduced the chance for ensuring continuity in adolescents' seeing their usual HCPs. The sample size did not allow for stratification for both (173). Instead, the different baseline HbA1c levels were incorporated in the statistic models.

### **Participants**

The sample did not include adolescents or parents, who did not speak, write, and read Danish, lest the participants not have been able to prepare and work with the reflection sheets between visits. Moreover, the use of an interpreter would require extra time at each visit to translate the communication between the parties, but also that the interpreter achieved GSD-Y competencies to ensure that they delivered the intervention correctly. The exclusion of participants without Danish language skills may be considered a limitation of the study.

## Statistical validity

The power analysis was based on the primary outcome, HbA1c and calculated on the sample size to reduce the risk of type I and type II error (170). The difference of 1% (11mmol/mol) in HbA1c may seem unrealistic because HbA1c normally deteriorates during adolescence (174). However, this level has been used in other RCTs comparable to GSD-Y (79,175). As discussed in paper II it may be considered a limitation that HbA1c was chosen as the primary outcome both at the end of the intervention period and at follow-up because the time of periods differed significantly between the groups. It was a strength that HbA1c *post hoc* could be observed over 30 months in both groups. HbA1c values were missing in both groups which was a limitation (Appendix E, Table 3). This was handled by using the repeated measures mixed model (RMMM) (176). Because the RMMM method is a likelihood-based method using all observed values, the results will not be biased if the data are missing at random. The strength of using the RMMM method was that it covers all situations except the one for which data are not missing at random (176).

A RCT design is considered the gold standard regarding statistical validity, but as shown in this study it may not be optimal in a clinical setting testing a complex intervention. The secondary outcomes follow-up measurements were not delivered within a predefined period of +/- as recommended (170) and differed significantly between the groups. This is a limitation and has an impact on the interpretation of the results and the study's internal validity (170). It cannot be excluded that the significant reduction in amotivation may have been improved by factors other than GSD-Y (170). The fact that amotivation was sustained at follow-up may indicate, that GSD-Y has the potential to reduce amotivation for diabetes self-management.

ITT was used (177). ITT means that every participant randomised to the intervention is included in the analyses, including withdrawal, non-compliance and protocol violators. The use of ITT may be criticised because adolescents who actually did not receive the intervention were included as participants receiving the intervention (177). In total 11 GSD-Y adolescents did not complete the eight GSD-Y sessions and one did not start at all; one is not considered to have an impact on the results. A per protocol analysis was not conducted as this is not recommended when participants do not follow the study protocol (statistical advice from CTU). The use of ITT is considered as a strength of the internal validity but it may represent a conservative estimate of intervention effect. However, the ITT effect estimates reflects how an intervention will work in clinical practice, not under some ideal situation.

To reduce the risk of mass significance and the risk of type I error (170), Holms test was used (150). The observed  $n$   $p$  values were ordered according to size ( $p(i)$  is the  $i$ 'th smallest  $p$  value) and the corresponding null hypotheses were tested in that order using the significance level  $0.05/(n + 1 - i)$ . As soon as a test was insignificant the remaining null hypotheses were accepted without test. Using Holms test, significant findings for TSRQ autonomy, TSRQ index and POPS autonomy mother were not maintained.

The reliability and internal consistency of the selected scales were shown to be good in previous studies in adolescents and four of the scales had been sensitive to capturing changes in life skills development in adults (80). Therefore, face validity of the scales was chosen.

It may be considered a threat to internal validity that POPS is not designed for adolescents with type 1 diabetes (149). POPS was chosen to assess whether adolescents perceived autonomy support and involvement from parents in adolescence being consistent with the theoretical framework round GSD-Y (1) and showed to be able for capturing such changes.

## **External validity**

It is difficult to generalise or apply the results beyond the study context despite the ability of the RCT design to minimise the influence of systematic and personal biases (170). The discrepancies between the study protocol and how the study was completed may be considered threats to its external validity.

## **Validity in study B**

Criteria appropriate within qualitative research to assess validity include credibility (internal validity), dependability, confirmability, and transferability (178).

### **Credibility**

A purposeful sample (161) from both hospitals from the GSD-Y group was followed during the intervention and those who first completed the study were included for interviews. The strength of the selected sample was that it was a varied group concerning sex, age, duration of diabetes, and family constellations (Paper III) which may not have been the case if the selection had followed the study protocol. The fact that the sample for interviews also had different HbA1c levels at follow-up ensured, that their judgement of GSD-Y did not rely solely on the HbA1c outcomes (Appendix F). Two different data sources were collected involving adolescents, parents and HCPs. By combining the data sources it was possible to illustrate and explore processes and outcomes. Particularly the digitally recorded visits can be considered strengths and important in establishing credibility, as they verified what actually happened during the visits. All of the semi-structured interviews were conducted using copies of the completed reflection sheets, which supported the parties in reflecting on how they experienced GSD-Y (179). Adolescents and parents were not acquainted with GRH which may have contributed to them being more open and honest in contrast to the HCPs who had worked with GRH during the study. It may have strengthened the validity of the interviews with HCPs if a researcher not acquainted with them had conducted these interviews. One may argue that interviews with the control group would have strengthened the credibility.

### **Confirmability**

The eight proposed conjectured CMOs ensured that the analysis addressed the intended focus of the evaluation: to explore and illustrate the use of GSD-Y. This is a strength of the RE approach being theory-driven (152). GRH and VZ performed the analyses independently and then jointly followed by discussions with Bente A. Esbensen (BAE) to ensure that the emerging and condensed outcomes covered the proposed CMOs and that data not by chance or systematically had been excluded (179). Pre-conceptions were discussed throughout the analyses to decrease the risk of subjective interests influencing the analysis and interpretation process (179). Finally the condensed outcomes, figures and tables were discussed with all of the authors to ensure confirmability (178). GRH, VZ and BAE are all nurses who brought complementary perspectives and competences to the analysis process. None had experience within the paediatric diabetes context. Birger Thorsteinson and Eva Hommel are physicians and not familiar with qualitative research. They posed clarifying questions that ensured a reflective appraisal of the entire process, which was considered a strength.

### **Dependability**

To ensure dependability the different steps in RE were described from the proposed CMOs, selection of the sample, data collection methods and sources, and analysis process (paper III). By including quotes from outpatient visits and interviews adding transparency to the study findings and

the process of coding the data, identification of CMO's was made explicit. Thereby, it is possible for other researchers to judge whether they could arrive at similar condensed outcomes if they followed the analysis process. The greatest challenge in using RE was distinguishing between context and mechanisms - difficulties that have been discussed in other studies (156,160,180). In addition when doing RE analysis it is recommended to do several circles of evaluation until nothing new emerges (152). This is a limitation of RE when used in a mixed-methods study conducted by one person. However, completing several circles is not always observed in RE studies (154-156). The findings might have been saturated by exploring if the condensed outcomes could be refined by interviewing all of the participants who were followed during the study (152). They may also have had contrasting experiences that could provide evidence in reasons for their prolonged study, or reasons not being able to complete GSD-Y at all, which might expand the study findings. This is a limitation of the study findings (152).

### **Transferability**

The findings from qualitative studies are not considered facts that are transferable to a larger population (178). Due to the thoroughness of RE, the findings may be theoretically transferrable to understanding and intervening in interaction patterns between adolescents, parents and HCPs in other clinical subpopulations with chronic disease. However, whether the findings of this study may be applicable to other settings is best judged by the reader.

## **Discussion of the results of study A and B**

The hypothesis of the study was that using GSD-Y in routine paediatric outpatient clinics would reduce HbA1c concentrations and improve adolescents' life skills compared with those in a control group. The quantitative study (paper II) showed that GSD-Y did not seem to improve HbA1c compared to usual care but significantly decreased amotivation for diabetes self-management which was sustained at follow-up. The qualitative study (paper III) illustrated that adolescents began to develop life skills identified as a new relatedness with HCPs and parents, becoming decision-makers in their lives with diabetes and growing personally. The results of both studies indicate that the use of GSD-Y seems to influence the development of life skills in a limited degree.

### **GSD-Y's impact on HbA1c**

GSD-Y did not reduce HbA1c compared to the control group. The aim of 1.0% (11mmol/mol) decrease in HbA1c may be considered too ambitious. The clinical relevance of reducing with 1.0% (11mmol/mol) has been demonstrated in the DCCT study. Such a fall may lead to an estimated fall of 30% in the risk of micro-vascular complications (134). The importance of reducing the risks of complications in adult life due to poor glycaemic control in adolescence is evident (20,181-183), however, no methods that have been integrated into adolescents' outpatient visits and been provided by their usual HCPs have so far been proven effective (147,184,185), as discussed in paper II. In a retrospectively longitudinal cohort study of 1,449 youths with type 1 diabetes (mean age 11.4 year) quarterly visits were associated with better glycaemic control (186) as also reported in a Danish study (187). However, routine or even frequent visits did not seem to have an impact on HbA1c either in the GSD-Y or the control group. The lack of effect may be explained by a study by Greenings et al. suggesting that autonomy-supportive interventions are not suitable for adolescents because they lack the necessary experience and judgement to benefit from self-reliance (188). This is in contrast to Hill, who showed that autonomy supportive interventions significantly increased

competence in adolescents' diabetes self-management (115). However, a meta-analysis suggests that only multicomponent interventions have an effect on HbA1c in adolescents (189). As GSD-Y is considered to be a multicomponent intervention the lack of effect may be explained by the extended time between GSD-Y visits and an excessively lengthy intervention period, which may have reduced momentum of the intervention's impact on HbA1c. An additional explanation is that the GSD-Y is not effective in reducing HbA1c.

In adult care, a positive impact on HbA1c was found 3-12 months after testing the original version of GSD in groups (80). VZ conducted all GSD group sessions in adults in collaboration with two GSD-qualified nurses (1 p.194). Whether VZ's participation may have had an impact on treatment fidelity remains unverified, but one may argue that possible deficiencies in the nurses' GSD competencies could be corrected immediately. Such correction was not an option in GSD-Y as corrections took place between visits. Another difference from the adult version was that HCPs were not given the opportunity to change the order of the reflection sheets on account of the HCPs' being novices in using the method (190). By this the individual adolescents' readiness to work with specific topics was not considered. Therefore, the theoretical idea behind GSD-Y may have been weakened due to the lack of self-determination or autonomous motivation (98).

Although some group interventions have been found to be associated with improved glycaemic control compared to individual interventions (36,79) the lack of effect on HbA1c may be explained by the individual setting. The qualitative findings indicated that other factors are at play during adolescence. Adolescents' longing to be and behave like others, lack of acceptance and integration of the disease and pre-established resistance to parental interference in their self-management were factors of considerable importance (paper III) consistent with previous research on achieving good glycaemic control (110,111,191). The possibility that competing difficulties shifted attention away from the sheets identifying the adolescents' patterns and motivation for blood sugar management was evident in the quantitative study. Ten GSD-Y adolescents (39%) did not fill in one or two of the sheets on glucose management (paper II). Whether this may also be related to GSD's basic reliance on using 'pen and paper', which is not in accordance with contemporary youth's typical communication media, or competence deficits of HCPs in using those sheets (or a combination) was not explored. However, the qualitative findings illustrated that these reflection sheets were important to adolescents in gaining insight into their own reasons for self-management (paper III). In adult care, these sheets may have been essential for the decrease in HbA1c (92).

Another explanation of the lack of effect on HbA1c may be found in the qualitative study. More than 50% of the interviewed parents experienced that they had reduced their involvement on account of being unsure about how to avoid acting controlling. One may argue that GSD-Y thereby had the opposite impact as intended. The intention to involve and provide them with deeper knowledge about or additional skills in acting autonomy supportive for glucose self-management may not have taken place. One such barrier was observed in the quantitative study; GSD-Y parents participated significantly less in common outpatient visits and 42% did not receive the second parental GSD-Y visit. This may either indicate that the parents did not need two visits or that GSD-Y was not fully adjusted to capture parents' individual needs for guidance (52). Instead visit two may be replaced with a teaching session for groups of parents focussing on how to motivate autonomously because parental involvement is crucial for achieving better blood glucose management (47,49). Perhaps also a combination of more joint visits with greater attention on shared responsibility and cooperation concerning blood glucose regulation would be valuable as suggested in Nansel et al.'s study (192).

### **GSD-Y's impact on development of life skills in adolescents**

GSD-Y significantly decreased amotivation for diabetes management a result that was maintained at follow-up compared with the control group (paper II). This decrease was consistent with qualitative findings that identified personal growth as one of the signs of the development of life skills (87,119). The qualitative study illustrated that adolescents changed from being passive spectators to becoming active participants in their own diabetes care both at outpatient visits and beyond. Amotivation is regarded as a sign of hopelessness and meaninglessness (98) that is connected to feelings like having no intention to, or believing unable to change one's situation (193) and is a predictor of psychological distress and depression (75). Therefore, the decrease in amotivation and the personal growth is regarded as important results towards establishing a constructive approach to diabetes self-management (115). The qualitative study illustrated that they actively began to change previous self-management patterns and started to accept their diabetes as a part of themselves finding it meaningful. The findings support those of Karlsson et al. who showed that the development of growth is influenced by an internal process as well as by the confirmation provided by others (37). The decrease in amotivation and personal growth was found to be activated by adolescents having visits alone in combination with the use of reflection sheets giving them a voice. Communication hereby became personal, focused and reflection became situated. Thus, both parents and HCPs discovered and acknowledged the adolescents' resources, competences and decreasing amotivation for diabetes self-management (paper III). Discrepant perceptions of adolescents' competence in diabetes management have been described between parents and adolescents and between adolescents and HCPs (61,194). Such discrepant perceptions are known to contribute to poorer well-being, to have negative impacts on glycaemic control and to reduce motivation for developing self-management skills (195). According to the results of the qualitative study, the triad's participation in GSD-Y seemed to reduce these discrepancies. Surprisingly, the WHO5 scale did not capture any changes in adolescents' well-being in the quantitative study. Decreased amotivation was not accompanied by a significant increase in parental autonomy support or involvement (POPS) despite such a pattern was illustrated in the qualitative study. The adolescents' new relatedness with their parents was activated by insight into each other's previously inappropriate interaction patterns. This was emphasised by both adolescents and parents as paving the way for constructive cooperation characterised by mutual respect and understanding (paper III). Adolescents experienced their parents refraining from behaviours characterised by control, which are known to trigger resistance (172). According to Wong, parental autonomy support includes the extent to which parents value and use techniques that facilitate independent problem-solving, choice and self-determination in their adolescents (196). This support requires the use of non-judgmental language and behaviour (144). Although a significant result in the POPS scale was not identified, qualitative evidence showed that adolescents began to involve their parents and experienced them as supportive and cooperative partners (paper III), as described by Wong (196). Whether this change was facilitated especially by the use of Olinder's adjusted figure of shared responsibility (135) or by the use of all of the reflection sheets were impossible to determine. According to the qualitative study all of the reflection sheets seem to be needed to support the complexity of diabetes management as it manifests in adolescence, despite the quantitative study suggested that the number of reflection sheets used was difficult to manage during the scheduled sessions (paper II). In contrast to the results in adults (80), significantly higher autonomy support from HCPs (HCCQ) in the GSD-Y group was not documented. However, insignificant increases were observed in both groups (paper II). This finding was surprising because qualitative evidence showed that adolescents

perceived that the visits had become person-specific in accordance with the intended theory-driven intervention (92) identified as a new relatedness with HCPs (paper III). The lack of effect in the quantitative study may be explained by a spill-over effect and the possibility of a type II error as discussed in paper II. According to the qualitative study, especially the use of reflection sheets facilitated a change from compliance-expecting problem-solving approaches towards mutuality-expecting approaches, in line with the empowerment philosophy for GSD-Y (69,93). The reflection sheets seemed to be autonomy supportive within themselves and preventing HCPs from expressing controlled motivation attitudes or entering into alliances with one of the parties as illustrated in paper III.

The findings of the qualitative study revealed that motivation for diabetes management had previously been others-determined as defined by Mullen (87). The adolescents began to behave in more autonomous and self-determined ways becoming decision-makers in their own lives with diabetes (paper III). Some adolescents began exhibiting planfulness when going out, being engaged in the responsibility of diabetes self-management. However, this qualitative evidence was inconsistent with results of the two TSRQ subscales; autonomous motivation and autonomy index, after controlling for multiplicity (150). The qualitative evidence showed that adolescents began to identify their own reasons for and interests in diabetes management as signs of the development of life skills (87,103,119) (paper III). This is an important result because autonomous motivation for treatment has proven to be predictive of changes in the behaviour of adolescents (115), treatment outcomes for glycaemic control (141) and insulin adherence in adults (142). As discussed in paper III there are diverging opinions on the age at which adolescents can be considered as competent in decision-making (197,198). In a review of adolescents' competence in decision-making in health care Mårtenson and Fägerskiöld concluded that the decision-making process depends on parents' and HCPs' attitudes rather than the capacity of the adolescents (199). Their findings were supported by Coyne and Gallagher's study (200). Our findings are consistent with findings from both studies. In GSD-Y it was illustrated that adolescents aged 13-18 years increased their ability to make autonomously motivated decisions after developing new relatedness with HCPs and parents. Autonomy and volition, not independence, are the important antecedents of effective change (201). The results from the quantitative study showed that GSD-Y adolescents spent different numbers of visits and different time to complete the eight sessions. This is in line with the use of GSD in adults in one-to-one settings (Table 2) (1). These findings suggest that GSD-Y cannot be standardised but must be tailored to match the individual's needs considering the adolescents' actual situations. It is also worth noting that 30% did not complete GSD-Y, which on the other hand may indicate that GSD-Y was too demanding or challenging to manage for some adolescents. This was, however, impossible to elaborate on in the qualitative study. Whether the use of electronic versions of reflection sheets or telemedicine consultations as an alternative to GSD-Y visits could have fulfilled the individuals' needs remains to be tested. However, the effectiveness of internet interventions has yet not shown effect on HbA1c in adolescents with type 1 diabetes (202) but does not seem to hinder a good relationship between HCPs and adolescents (203).

The results from the two studies were shown to have clinical relevance, defined as making a difference in the adolescents' everyday life. The clinical relevance of reducing amotivation was found in younger adults - an increase of four units in amotivation corresponded to a 5-6 mmol/mol (0.5%) higher HbA1c value on average (204). A planned five-year follow-up may provide evidence for GSD-Y's long term impact on amotivation, influence on HbA1c, or any of the other outcomes.

## **The possibility of integrating GSD-Y into routine outpatient diabetes clinics**

The test of whether GSD-Y could be integrated into routine outpatient clinics showed through the quantitative results that it was not possible the way it was designed. This was verified through the prolonged intervention period, lack of filled in reflection sheets beforehand, adolescents not attending/cancellations/completing and parents not receiving their planned GSD-Y visits. Contrarily the qualitative findings illustrated that HCPs integrated GSD-Y into routine visits thereby changing the content of the visits and the relationships between the parties. No clear answers can therefore be given to objective 1. This is the first time a complete GSD version was transferred to a paediatric context involving adolescents, parents and interdisciplinary HCPs. GSD is a complex and a novel method whose effectiveness has been tested only on one sample (n=50) (1); its effectiveness remains to be tested in larger populations. Integration challenges or genuine ineffectiveness may not yet have been identified. The difficulties in integrating complex interventions into existing systems are well-known (147,175,184,205). GSD-Y was doubtless time-consuming to learn and required on-going supervision to practice and become integrated, which is not unusual (206). HCPs being absent due pursuit of continued education, long-term sickness, the relocation of one of the outpatient clinics and financial savings (resulting in reduced staff) - such challenges must be expected doing research in a real-life context. It is, however, worth considering whether GSD-Y is a suitable method in adolescents. The method motivational interviewing (MI) has been transferred to paediatric contexts. The main difference between MI and GSD-Y is the use of reflection sheets. Therefore, GSD-Y should theoretically be suitable and possible to use in adolescents. However, MI has only shown effect on HbA1c when the principles have not been woven into routine visits and conducted by the patients' usual HCPs (207,208). Based on the results from Studies A & B it is not possible to confirm or disconfirm the suitability of GSD-Y. Whether the design of GSD-Y or the weaving of GSD-Y into routine visits explains the integration barriers and lack of effect, like verified in MI studies, remains to be tested. Results from a Swedish study will suggest if GSD-Y is suitable for treating groups of adolescents with type 1 diabetes when starting CII treatment, involving parents and separated from usual care (209).

## **Conclusions and future research**

The use of the mixed-methods approach added nuance and complemented the evaluation of GSD-Y. GSD-Y did not seem to reduce HbA1c but improved life skills in adolescents by decreasing amotivation for diabetes self-management compared to a control group. This effect was sustained at follow-up. The qualitative realistic evaluation study illustrates that the method was integrated into usual outpatient clinic and influenced the development of life skills in adolescents by changing the relatedness between adolescents and HCPs and subsequently between adolescents and parents. Adolescents became decision-makers in their own lives with diabetes and started growing personally. Based on the results of the studies it is not possible to confirm or disconfirm if GSD-Y is suitable in adolescents but it was demonstrated to be impossible to integrate this GSD-Y version into routine visits. Important knowledge regarding the acceptability, applicability, efficacy, and feasibility for integrating GSD-Y into routine visits was produced by this study that offers benefits to future research. Retrospectively one may conceptualise this study as a type of pilot investigation. I cannot recommend the integration of GSD-Y into usual outpatient visits in its current version. Further adjustments and developments are needed and should address the following issues:



- Testing GSD-Y over a shorter course period, in one-to-one setting separate from the usual visits, with the usual HCPs using, e.g., electronic versions of reflection sheets and use of telemedicine for instance Skype consultations if needed;
- Involving parents by offering both common and individual GSD-Y visits with foci on the parties' attention and shared responsibility for blood sugar management by theoretical and practical insight into autonomous motivation;
- Integrating GSD-Y as a part of transition programmes into adult clinics, thereby supporting adolescents and parents in transferring responsibility to increase adolescents' autonomous motivation for diabetes management; and
- Exploring the balance of benefits and costs in offering GSD-Y as part of extra diabetes care and treatment compared to conventional outpatient visits for adolescents with poor regulation.

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# Appendices

The following is included in the appendices:

## Appendix A

Summaries of the three Grounded Theories and presentation of figures  
The aim of each reflection sheet  
Reflection sheets for adolescents, parents and dieticians visits

## Appendix B

Tool for self-assessment and reflection  
Written test for HCPs

## Appendix C

The scales and their correspondence with numbers in the questionnaire  
The questionnaire

## Appendix D

The Case Report Form used at randomisation  
The Case Report Form for the GSD-Y group during the intervention  
The Case Report Form for the Control group during the control period

## Appendix E

Figure 1 Flowchart of Study A  
Figure 2 Randomisation period  
Figure 3 HbA1c levels during the study  
Table 1 Baseline Characteristics  
Table 2a, 2b Withdrawal analyses  
Table 3 Missing HbA1c values  
Table 4a, 4b Secondary outcomes  
Table 5 Hypoglycaemia rates and risks  
Table 6 Length of the study  
Table 7 Number of visits per sessions  
Table 8 Time from randomisation till first visit in the trial

## Appendix F

Flowchart of participants and data collection and sources in study B  
Interview guides  
Context, Mechanism and Outcome configuration  
Example of analysis process  
Figure of findings  
HbA1c levels for the nested sample

**Appendix G**

Information booklet for adolescents

Information booklet for parents

Consent forms

Invitation to participate in interviews

**Appendix H**

Timelines I & II

**Appendix I**

Papers I, II, III

## Appendix A

Summaries of the three Grounded Theories and presentation of figures

The aim of each reflection sheet

Reflection sheets for adolescents, parents and dieticians visits

## **Summaries of Zoffmann's three grounded theories.**

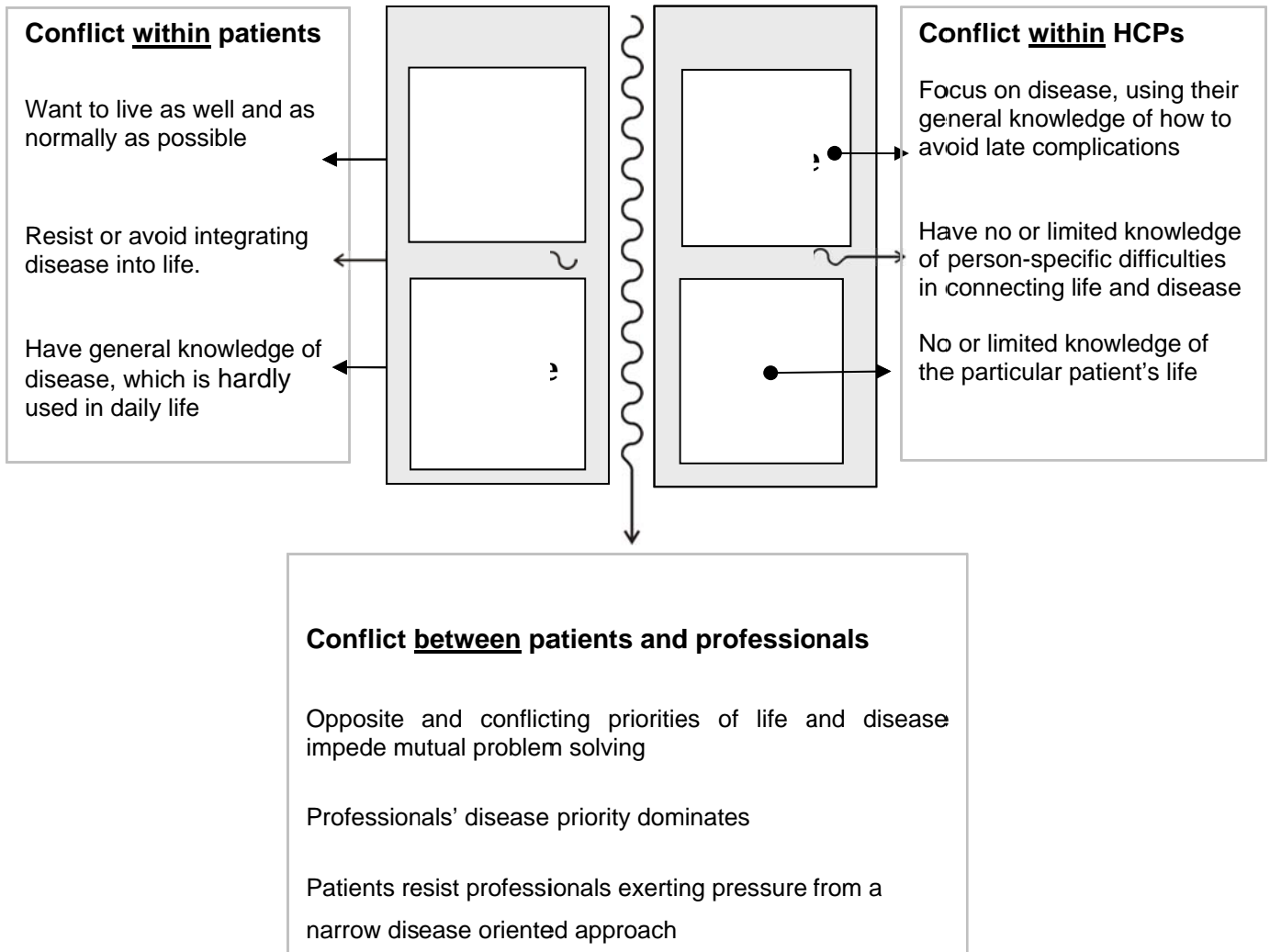
The development of the adult GSD was based on these three theories to overcome barriers in empowerment by interrupting inappropriate cooperation patterns between adult patients with type 1 diabetes and nurses.

### **Life Versus Disease in Difficult Diabetes Care: Conflicting Perspectives Disempower Patients and Professionals in Problem Solving**

The central finding in the first grounded theory was *Keeping Life and Disease Apart*, involving conflict lines within and between patients and professionals. The conflicts within patients consisted of attempting to live as well and as normally as possible while keeping disease at a distance. This made them prioritize life over diabetes. The conflicts within professionals were related to the dilemma of actually being interested in the patients' difficulties in living with the illness hindered by lack of knowledge of each patient's life. Having instead a large disease-specific knowledge, professionals tended to prioritize disease over life in their way of approaching the patients. This opposing life-disease prioritization between patient and professionals resulted in a conflict between them. The relationship between them was therefore dominated by the professionals' disease-over-life priority, which disempowered both parties in solving problems in difficult diabetes care. Three different approaches to problem solving influenced the conflicts differently. Conflicts remained unchanged in a compliance-expecting approach, deadlocked in a failure-expecting approach, and were resolved or diminished in a mutuality-expecting approach. The latter approach replaced the general conflict with situational mutual reflection and took advantage of a potential for change (82). Figure 1 below illustrates the findings in the first grounded theory *Keeping Life and Disease Apart*

Figur 1: Keeping life and disease apart

Life-versus-disease conflicts within and between patients and Health Care Providers (HCP) in difficult diabetes care



Zoffmann 2005(82)

### **Relationships and Their Potential for Change Developed in Difficult Type 1 Diabetes**

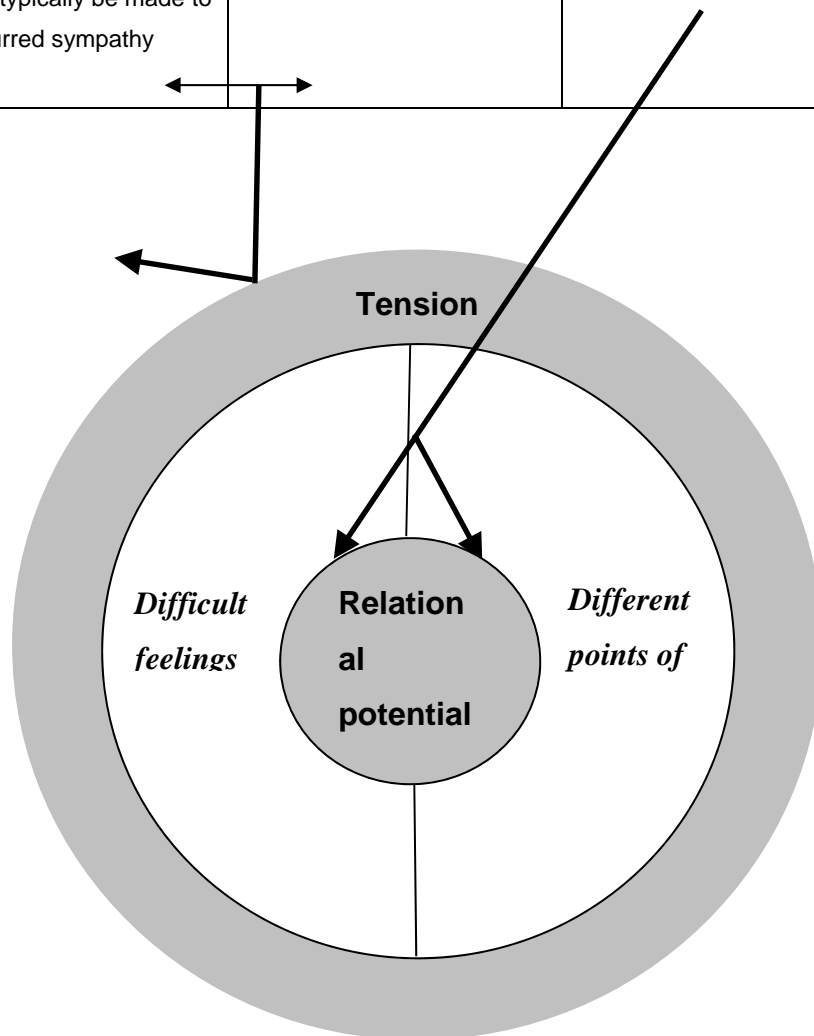
The central finding in the second grounded theory was *Relational Potential for Change*, involving three types of relationships. The kinds of relationships were identified and labelled according to the characteristics of the I-you boundaries during problem solving in clinical practice: 1) I-you-distant provider dominance, 2) I-you-blurred sympathy, and 3) I-you-sorted mutuality. The three types of relationship differed in a) scope of problem solving, b) the roles assigned to the patient and the professionals, c) use of difficult feelings and different points of view, and d) quality of knowledge achieved as the basis for problem solving and decision making. HCPs mostly shifted between the two first kinds of relationships, I-you-distant provider dominance and I-you-blurred sympathy, which was found to cause less effective relationships, interfering with a relational potential for change due to difficult feelings and different points of view. The first missed the potential for change because of the distance between the parties, and the second missed the potential for change by spontaneously covering over or diminishing the sources of tension which were difficult to tolerate, such as difficult feelings and different points of view. The third relationship, I-you-sorted mutuality, was only seen in few cases, but managed the tension and got access to the relational potential for change by actively addressing and exploring the sources of tension, difficult feelings and different points of views (83).

Figure 2 below illustrates the findings of the second grounded theory *Relational Potential for Change*.

Zoffmann 2007 (83)

Figur 2: Relational potential for change and its connections with the three relationships.

<b>I-you-distant provider dominance</b>	<b>I-you-blurred sympathy</b>	<b>I-you-sorted mutuality</b>
Miss the potential for change because of distance between the parties. If difficult feelings and different points of view are perceived and tension increases, a shift will typically be made to I-you-blurred sympathy	Miss the potential for change by covering over or diminishing sources of tension - difficult feelings and different points of views.	Access to relational potential for change by addressing and exploring the sources of tension - difficult feelings and different points of views.





### **A Person-Centred Communication and Reflection Model**

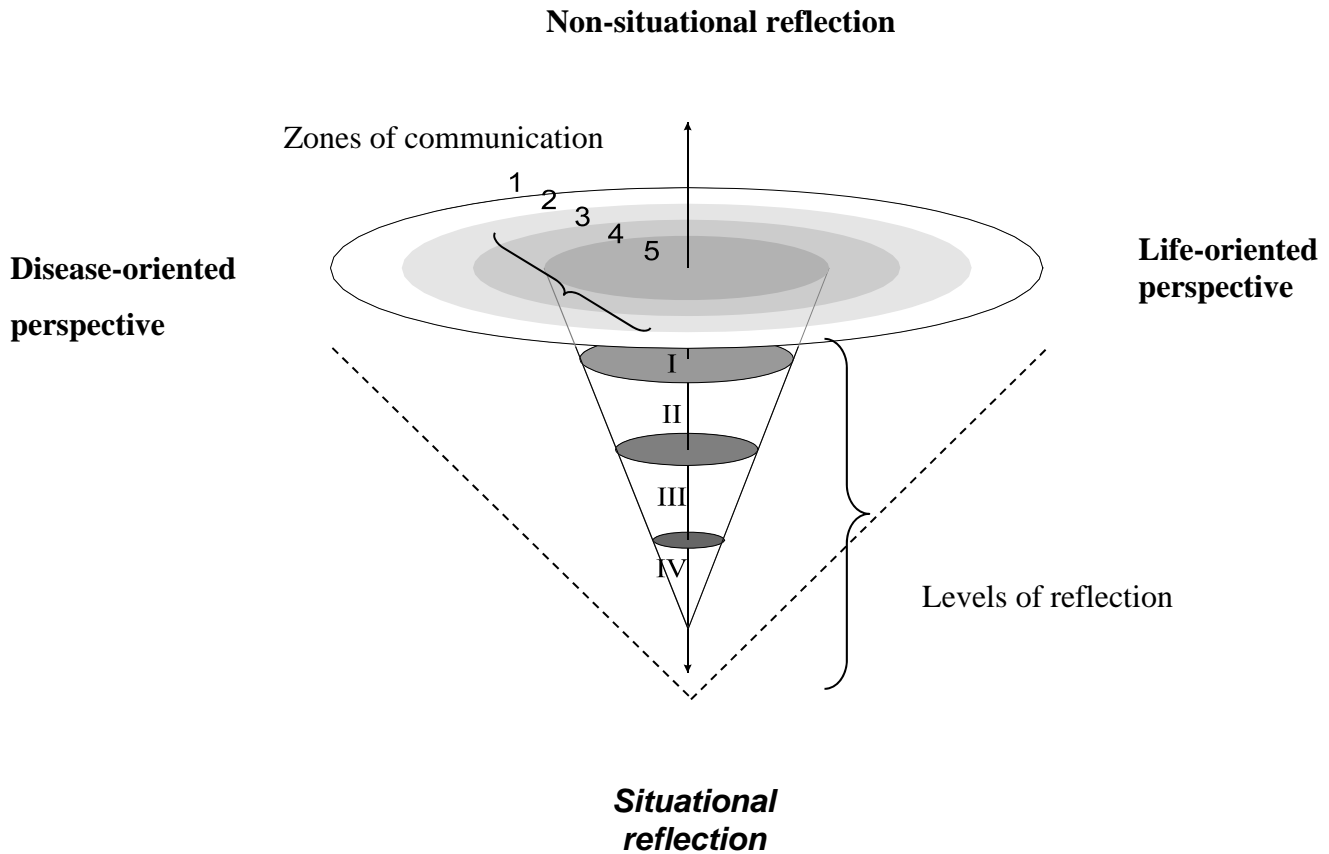
The central finding in the third grounded theory was *Co-creating Person-specific knowledge*, which required focused communication and situational reflection at a mutual level combined with a level of independent patient reflection. The latter helped patients gain insight into their own attitudes toward diabetes as a necessary step to changing it. Co-creating person-specific knowledge was a rare but important finding, as it constituted a crucial basis for effective and meaningful problem solving, and provided person specific insight into each patient's reaction to living with diabetes. A person-centred communication and reflection model was developed, which revealed important choices in communication and reflection that were decisive for whether shared decision making was achieved or not. Communication was focused when it addressed issues currently difficult or challenging for the patient in living with diabetes. Reaching situational reflection at a mutual level required that both patient and HCP were aware of the issue they were reflecting on, and were able to exchange thoughts and ideas about it to reach joint decisions. The model brings together the choices that patients and professionals can make in their communicative and reflective activities during problem solving and decision-making and it bridges the gap between patient-centered practice and evidence-based practice (84).

Figure 3 below illustrates the findings of the third grounded theory *Co-creating Person-specific knowledge*.

Zoffmann 2008 (84)

Figur 1: Person-Centred Communication and Reflection Model

<b>Zones of communication 1- 5</b>	1: Addressing unrelated issues.	4: Addressing issues related to the patient but currently not difficult.
	2: Addressing general health related issues.	5: Focused communication addressing issues currently difficult for the patient.
	3: Addressing issues of general significance for the patient group.	



Levels of reflection	Situational reflection	
	Health care professional's (HCP) activity	Patient's activity
I	Reflecting independently on observable signs of person-specific difficulties.	Being observed. Not engaged in HCP's reflection.
II	Reflecting independently or with colleagues on non-observable aspects of person-specific difficulties. Gathers information from the patient but does not inform the patient of the issues reflecting on or invite the patient to assess the difficulties. Conjectures remain unverified.	Contributing information, but not engaged in HCP's reflection or informed about the issues reflected on. Not asked to verify or assess assumed difficulties.
III	Engaged in mutual reflection with the patient, exchanging thoughts and ideas of explicit difficulties related to the patient's responses to living with the illness. Conjectures verified and knowledge of person-specific difficulties is co-created; importance, causes, meanings and possible solutions clarified.	Engaged in mutual reflection with HCP, verifying and exchanging thoughts and ideas of explicit difficulties related to living with the illness. Co-creating person-specific knowledge of the importance, causes, meanings and possible solutions.
IV	Though not participating in reflection, HCP can motivate the patient to start reflection e.g. by asking value clarifying questions or by pointing out possible inconsistencies in patient responses to illness.	Reflecting independently; autonomously clarifying and reassessing own responses to and stand on specific difficulties.

**The aim of each reflection sheet developed in adult diabetes care.**

**The number in the brackets refers to the adult order of reflection sheets. Those marked in red were not used in GSD-Y**

Findings in current care	Worksheets	The aim of each worksheet
<p>Patients showed up with reduced expectations at admission, having adapted to a purely disease-oriented scope and a passive patient role. Seldom had defined, conscious goals for hospital stay.</p>	<p><b>Invitation to work together (1a)</b></p> <p>One-to-one version</p> <p>Group version</p> <p>In start pack</p>	<p>To expand patients' expectations. Make them prepared to take an active role within the scope of their currently perceived difficulties in living with diabetes.</p>
<p>Unclear what decisions were made concerning issues to investigate and remedy during admission. Neither patients nor nurses were able to say what they had selected to work with or omit. Lack of clear decisions left the impression that everything could be worked with. Lack of selection caused lack of investigation.</p> <p>At discharge no agreements were made for future. Hospital stay appeared to be an isolated and closed period rather than part of a continuity.</p> <p>Patients experienced that the team in general did not know their situation well enough. For example, they perceived that nurses had gained knowledge which they did not pass on to the doctors. Patients</p>	<p><b>Progression form (1 b)<sup>1</sup></b></p> <p><i>Saved in the patient's medical record</i></p>	<p>A selection and sorting tool. Contains lists of problems perceived by patients and professionals, and a list of agreed problems to solve during hospital stay/ course. Reveals and legitimises different points of view of patients and professionals.</p> <p>Saves person specific knowledge for future care. Specifies goals agreed upon at discharge to be reached by next out-patient visit and the support needed from professionals and others.</p> <p>Informs members of the primary team, in order possibly to maintain continuity in the out-patient clinic.</p> <p>Provides the diabetes team with an overview of the issues chosen in</p>

<sup>1</sup> Sjøbakken, J. and Fleiner (Fleiner & Sjøbakken 2003) introduced the term 'I-you sorting' during courses in communication and change.

<p>viewed this negatively.</p> <p>Nurses experienced that doctors were seldom interested in learning what they knew about patients. When difficulties were presented in long and fairly unstructured narratives, doctors would lose interest after a short time.</p> <p>Patients frustrated over frequent staff changes.</p>		<p>order to mobilise diverse resources aiming at inter-disciplinary problem solving.</p> <p>Problems posed in a short and precise form verified by patients and acknowledged by the nurses. Gives person-specific difficulties a structure that is easy to convey.</p>
<p>Problematic issues or events earlier in the patient's life impeding current management of diabetes. Though nurses spent quite some time having patients talk about their life with diabetes, they often missed important time-related information e.g. How long had the patient been poorly regulated? When was the onset? Had there actually been longer periods of good regulation? How was this possible? Though wishing to tell their story, patients were tired of repeating it several times to different professionals.</p> <p>Patient number A4 and A11.</p>	<p><b>Important events and periods in your life with diabetes (2 a)<sup>2</sup></b></p> <p>In start pack</p> <p><i>Saved in the patient's medical record</i></p>	<p>Patients' stories are preserved in order to form a general view and promote identity. Makes patients aware of past, present and future. Hospital stay/ course provides choices important for future.</p> <p>Facilitates recall of important events and periods in past connecting them with glucose control. Patients have a chance to become aware of connections between life and disease not discovered previously.</p>
<p>Often nurses focused on general problems and doctors on disease oriented problems. Patients did not say what the real problem was for them. Sometimes a lot of time was spent talking about something actually irrelevant.</p>	<p><b>Present difficulties in living with your diabetes (2 b)<sup>3</sup></b></p> <p>In start pack</p>	<p>Draws patients' attention to current difficult issues. Invites them to express issues in their own words.</p>
<p>Patients were frequently not aware of certain areas inhibiting their problem solving in daily life. These areas could be painful or embarrassing for them to talk about or even think of. Sometimes they constituted blind spots. Patients seldom expected professionals to find these areas relevant.</p>	<p><b>Unfinished sentences</b></p> <p>- needs, values, experiences and opportunities (2 c)<sup>4</sup></p> <p>In start pack</p>	<p><b>Facilitates consideration and communication of difficult areas, reassessing what is really difficult for the patient.</b></p> <p><b>Gives quick information about many issues.</b></p>
<p>Many patients spontaneously described their situation by means of metaphors, which often revealed an overall attitude to having to live</p>	<p><b>A picture, a metaphor or expression for your life with diabetes (2 d)<sup>5</sup></b></p>	<p>Pictures, metaphors and set expressions can be regarded as a gift from deeper levels of the consciousness, which are generally difficult to reach but can reveal patients' overall attitudes to diabetes to both</p>

<sup>2</sup> From the many shades of life stories applied in health care, a life line version was adapted to diabetes (Frank 1996; Rybarczyk & Bellg 1997)

<sup>3</sup> Inspired by an open health concept developed by Wackerhausen (Wackerhausen 1994)

<sup>4</sup> A method inspired by values clarification (Steinberg 1986)

<sup>5</sup> Metaphors may reflect and maintain a positive or negative attitude to diabetes (Lakoff & Johnson 1980)

<p>with diabetes. Sometimes extremely negative or life restricting</p> <p>Patient number A1, A10, A11.</p>		<p>themselves and professionals. When expressed through drawings or words, such attitudes can be the subject of communication. If negative or self restricting, the attitude can be challenged or modified on the professionals' initiative</p>
<p>Some patients were intensely concerned about their disease and this constituted a considerable part of their problem. Apparently professionals found this reaction too difficult to talk about and accordingly did not comment on it (patient A11).</p> <p>Likewise it seemed difficult for them to approach the opposite problem of patients tending to neglect their diabetes.</p> <p>Patient A 11, B 17.</p>	<p><b>Room for diabetes in your life (2 e)</b></p>	<p>Patients asked to judge how much room diabetes currently takes up in their life by shading the corresponding area of an oval shape and asked to do the same for their intentions about how much room to give diabetes in future. Patients able to distinguish between negative and positive ways that diabetes can take up room. Provides a chance to make self-determined decisions about changing the room for diabetes in the short or long term, specifying the changes required. May help patients express their first acceptance of diabetes.</p>
<p>As diabetes behaviour affects many different aspects of daily life and time was limited, professionals lacked a broad view of each patient's lifestyle. Face to face communication was often of a general character and far from exhaustive. Feelings such as bad conscience or frustration seemed to mean that the slightest trace of a moralising tone in professionals' way of asking could mobilise resistance in patients.</p> <p>Changing lifestyle seemed to be treated as an event and not as a process. Consequently traditional ways of supporting lifestyle change only met the needs of people who were ready to change and not people who had not yet decided to change or people who needed help to maintain newly implemented changes.</p>	<p><b>Your experience with recommended ways of living (3 a)<sup>6</sup></b></p> <p>In start pack</p>	<p>Patients tick off whether they follow or do not follow 15 recommended behaviours and discuss this with professionals.</p> <p>A profile based on the number and kind of recommended rules that patients have integrated or not integrated into their life is quickly developed.</p> <p>Provides information on duration of started change and earlier failed attempts at changing.</p>
<p>Professionals lacked a broad view of which of the recommended rules for life patients were not following. In addition, they did not know about patients' readiness to change in specific areas. Time, energy and effort had till now been applied quite uncritically.</p> <p>Professionals were frustrated when their effort was wasted. Changes that had not been agreed could cause resistance to change in some people and in others resulted in attempts at change that were doomed</p>	<p><b>Your plans for changing your way of life (3 b)</b></p> <p>In start pack</p>	<p>Provides a quick overview of each person's needs and readiness to change.</p> <p>The questions signal respect for the patient's personal choices and accordingly facilitate autonomous motivation.</p>

<sup>6</sup> Prochaska's stages of change theory was used as a sort of screening tool to ascertain the need for and readiness to change separate areas of behaviour (Knudsen 1997).

<p>to failure because the decision was not self-determined.</p>		
<p>Patients were angry and frustrated that they were not asked about their experiences in earlier treatment. Patients did not express their experiences and suggestions when they were not invited to do so. However, patients often had some good ideas, which they kept returning to and using energy on as they became annoyed when not listened to.</p> <p>Many patients were afraid of the side effects of different kinds of medicine and experienced that doctors ignored this, referring to the small statistical risk of these side effects. Some felt that doctors regarded them as average patients from medical investigations. Patient number 1A, 8A, 11A.</p>	<p style="text-align: center;"><b>Own experience with different kinds of treatment (3 c)<sup>7</sup></b></p> <p style="text-align: center;">In start pack</p>	<p>Encourages patients to express ideas and good and bad experiences of different kinds of treatment.</p> <p>Patients' thoughts and ideas are listened to and discussed.</p> <p>Provides an overview of patients' experiences.</p>
<p>Professionals did not seem to notice conscious goals for BG-regulation even if they were actually stated. (Dyad 1)</p> <p>Patients did not have ownership of general goals for HbA1c stated by professionals. Difficult to translate HbA1c into blood glucose values and vice versa. Many had neither set personal goals for blood glucoses or HbA1c. Usually professionals did not know the patient's goals. Many patients regarded blood sugars as belonging to themselves and HbA1c as belonging to the professionals. HbA1c has developed a nickname - the "tell-tale test" – maintaining its role as the professionals' control tool and not as a tool for patients to use. Patients thus miss the HbA1c-value's long-term significance for prediction.</p>	<p style="text-align: center;"><b>Your ideal goals for daily blood glucoses (3d)</b></p>	<p>Asking patients about their goals indicates that you expect them to have some and intend to take those goals seriously. At the same time possible mistakes in translation of HbA1c-values to blood glucoses will be discovered and corrected.</p> <p>By renaming HbA1c the "landmark sample" you emphasize the importance of the test as the patients' guidance tool and tone down its role as the professionals' control tool.</p> <p>Scale provides opportunity to compare BG results and HbA1c.</p>
<p>Many patients did not test their blood sugar regularly and many did not test it after meals. They were therefore unaware of typical levels or variations.</p>	<p style="text-align: center;"><b>Blood glucoses as you know them in reality (3e)</b></p>	<p>By writing down 8 values from a typical day or question marks for times where they did not know the value, patients got an insight into their own knowledge of blood-glucoses. Having 8 measures they were also able to calculate a mean value translating it into HbA1c by imagining that all days were like a typical one. Comparing this value with the previously stated ideal, they arrived at the difference between their current level and own ideal.</p> <p>Scale provides possibility to compare BG results and HbA1c.</p>

<sup>7</sup> A power difference inevitably exists between patient and professional. According to Løgstrup's (Løgstrup 1997) power analysis, power is not to be avoided but is rather to be used appropriately. In the case of medicine, it is assumed that patients will not explicate their suggestions if they are not invited to do so.

<p>Patients warned about the risk of late complications due to high blood sugar without having a clear picture of the amount of risk at different levels. They were also unaware of the amount of risk for serious events of low blood sugar depending on different glucose levels. They were thus motivated to achieve a lower blood sugar more by threats than by actual awareness of the specific advantages or disadvantages of different levels.</p>	<p><b>Advantages and disadvantages of high and low blood sugar (3f)<sup>8</sup></b></p>	<p>Results from a DCCT study linking deterioration of eye complications on the one hand and serious events of low blood sugar on the other. Risk, stated in events per 100 years at risk, is illustrated by imagining 20 patients living 5 years at risk at three different HbA1c levels (5.5, and 7.0 and 10.5). Patients asked to consider the advantages and disadvantages drawing on their personal experience and taking situations in their daily life into account. Patients asked to set goals for their HbA1c at four intervals during the coming year.</p>
<p>Following firm requests by nurses, patients appeared to measure blood sugar during hospital stays for controlled reasons. Stopped measuring shortly after discharge. Some said that they stayed away from their appointment at an out-patient clinic if they had not checked blood glucoses as they were expected to do. Others said that they lied about their blood sugar and, for example, invented values or wrote down values measured months ago. Patients apparently tended to check blood glucoses for the sake of professionals.</p>	<p><b>Blood sugar checks and your reasons for checking (3g)<sup>9</sup></b></p>	<p>Asking patients to assign a letter to each self-measured blood sugar result depending on the motivation for testing, enables them to distinguish between and be critically aware of their own reasons for measuring. Patients are recommended not to measure for professionals' sake and rather to find their own reasons for measuring and developing curiosity about knowing how BG responds to certain behaviour or events.</p> <p>Scale provides possibility to convert mean BG results to HbA1c.</p>
<p>Professionals knew very little about patients' ways of solving problems.</p> <p>Frequently a discrepancy appeared to exist between patients' knowledge, goals and behaviour.</p>	<p><b>Current problem solving (4 a)<sup>10</sup></b></p>	<p>Professionals were supposed to know the patients' problem solving abilities regarding 1-3 issues. For each of these issues patients are guided through 4 pages and write their current 1) observations, 2) thoughts and feelings, 3) goals and 4) actions. Questions on these pages encourage patients to balance their own and others' interests, and short and long-term interests.</p>
<p>Professionals had till now only had a fragmented picture of fairly uncritically selected elements from a broad section of the patient's life and lacked an overview of the dynamics connected with a problem mutually identified and agreed on as worth solving.</p> <p>Professionals had till now not named the patient's problems</p>	<p><b>Dynamic judgment of current and future problem solving (4 b)</b></p>	<p>Problems are given a name, which both patient and professionals consider appropriate. Information from 4 a about the patients' observations, thoughts, feelings, goals and actions till now is transferred to 4 b giving an overview of the patient's ability to solve the problems. Both missing or weak and strong parts of the patient's problem solving will be visible for both parties and constitute the</p>

<sup>8</sup> According to Williams (Williams, Freedman, & Deci 1998) and Sheldon (Sheldon & Elliot 1999) internal motivation and self-concordant goals for blood glucose levels will enhance glucose control.

<sup>9</sup> Worksheet 3g was changed letting patients consider critically their own motivation to check blood sugars in order to facilitate the idea of autonomy support implementation.

<sup>10</sup> Bos's model of dynamic judgment building is regarded as being the core of Guided Self-Determination as it can advance the dynamics and coherence of assessment(Blumer 1969;Bos 2001).

systematically, causing them at times to discuss two different problems without being aware of it.	<i>Saved in the patient's medical record</i>	basis for mutual reflection, challenging and supporting the patient in expanded problem solving.
Patients had at times a fixed view of the advantages or disadvantages of certain issues. They thus seemed unable to discover contrasts and the fact that their own opposing interests might actually obstruct decision-making	<b>Pros and cons (4 c)<sup>11</sup></b>	Helps patients specify advantages and disadvantages connected with maintaining or changing a specific behaviour. Finding their own reasons to change or maintain behaviour increases autonomous motivation.
Despite having decided to change, carrying through and maintaining change was difficult. Even admitting the starting point appeared to be embarrassing. Often the magnitude of the intended change made patients tend to give up beforehand.	<b>More of (4 d)</b>	Is applied when patients have decided to implement a change requiring a measurable increase. Helps the patient specify and admit the starting point and take into consideration the facilitating or obstructing factors ahead. Helps them divide up the task by setting manageable goals without losing sight of the long term goal
Despite having decided to change, carrying through and maintaining change was difficult. Even admitting the starting point appeared to be embarrassing. Often the magnitude of the intended change made patients tend to give up beforehand.	<b>Less of (4 e)</b>	Is applied when patients have decided to implement a change requiring a measurable decrease. Helps the patient specify and admit the starting point and take into consideration the facilitating or obstructing factors ahead. Helps them divide up the task by setting manageable goals without losing sight of the long term goal
Sometimes difficult feelings provoked a fixed pattern in patients' behaviour. These were linked and were difficult to recognise and therefore to change.	<b>Mapping behaviour (4 f)<sup>12</sup></b>	By recognising a difficult feeling that provoked such a pattern and tracing step by step the behaviour provoked by this feeling, patients were able to see whether their behaviour affected their situation negatively. Furthermore, they were able to see steps for alternative behaviour.

<sup>11</sup> Worksheets 4c-e were developed by Arborelius(Arborelius 1992;Arborelius & Bremberg 1988)

<sup>12</sup> Developed by Newbern et al. and tested in life skills training of sub-groups(Newbern, Dansereau, & Pitre 1999)



Reflection sheets for adolescents  
Reflection sheets for parents  
Reflection sheets if seeing a dietician

**Reflection sheets  
for youth with Type 1 Diabetes**

## Overview of the reflection sheet handed out to youths in Hillerød and Glostrup

Working together- your life with diabetes – Session 1	Delivered	Discussed
1.a Invitation to work together	/	/
1.b 2 ways for using HbA1c	/	/
1.c Important events and periods in your life	/	/
1.d What do you find difficult at the present time living with your diabetes?	/	/
1.e Your plans for changing your way of life	/	/
<b>To be delivered after the draw to GSD-Young and discussed during session 1</b>		
Working together - your life with diabetes – Session 2	Delivered	Discussed
2.Unfinished sentences – values, experiences and needs	/	/
<b>To be delivered during session 1 and discussed during session 2</b>		
Your life with diabetes – Session 3	Delivered	Discussed
3.a Dividing responsibility	/	/
3.b A picture, metaphor, automatic thoughts about diabetes	/	/
3.c Room for diabetes in your life	/	/
3.d Blood sugar checks and your reasons for checking	/	/
<b>To be delivered during session 2 and discussed during session 3</b>		
Your life with diabetes – Session 4	Delivered	Discussed
4.a Your ideal blood glucose and actual blood glucose	/	/
4.b Advantages and disadvantages of high and low HbA1c	/	/
4.c Your plan for regulating your blood glucose – short- and long-term	/	/
<b>To be delivered during session 3 and discussed during session 4</b>		
Working to change – Session 5	Delivered	Discussed
5.a Common terms	/	/
5.b Current problem-solving (sheet 4 examined and started)	/	
<b>Common terms to be delivered during session 4 and discussed during session 5</b>		
<b>Current problem-solving be delivered <u>during</u> session 5</b>		
Working to change – Session 6	Delivered	Discussed
6.a Current problem-solving (sheet 4)		/
6.b Dynamic problem-solving	/	/
6.c Pros and Cons	/	/
<b>To be delivered during session 5 and discussed during session 6</b>		

Working to change – Session 7	Delivered	Discussed
7.a Common terms	/	/
7.b Current problem-solving (sheet 4 started)	/	/
<b>Common terms to be <u>delivered</u> during session 6 and discussed during session 7</b> <b>Current problem-solving to be delivered during session 7 and started</b>		
Working to change and final conversation – Session 8	Delivered	Discussed
8.a Dynamic problem-solving	/	/
8.b Pros and Cons	/	/
8.c Final agreement sheet and coming focus areas are noted	/	/
8.d Final sheet saved by agreement with the patient	/	/
<b>To be delivered during session 7 and discussed during session 8</b>		

## **Working together – your life with diabetes - Session 1**

- **Invitation to work together**
- **2 ways for using HbA1c**
- **Important events and periods in your life**
- **What do you find difficult at the present time - living with your diabetes?**
- **Your plans for changing your way of life**
- **Agreement sheet**

## Invitation to work together

We offer you a plan that runs throughout the coming year during which we work together in a new manner, and which will take place when you come for your outpatient clinic appointments. We are confident that this plan can mean a New Start in your life with diabetes. We call this year a “year of change.”

What should be the focus of our cooperation in working together?

- Whatever you find difficult with diabetes in your own and your parents’ daily life
- And you will also determine what we talk about

What roles do each of us have – yours, your parent’s and ours?

- Both your own, your parents’, and our knowledge and experience is needed
- Together we will aim at spending our time in the best possible way working on matters that we consider important
- Part of the time we will work separately, and at other times we will work together

How should we work together?

- It is OK for you, your mother, your father, and myself to perceive your situation differently
- Disagreeing is OK
- Having and showing emotions is OK
- It is necessary that we know and understand each other’s opinion

We will use different work sheets – but what are they for?

- You can use them for private reflection and for gaining insight into your situation – in peace and quiet
- We can use them to gain a general understanding of what is important in your situation
- They make it easier to talk about the things that can be difficult to talk about
- They help you, your parents and us to make decisions tailored to your needs and, therefore, more possible to be realized
- They help us to stay on-course as we progress

Through experience with other young people with Type 1 Diabetes who have used Guided Self Determination, we know that ....

- It is important that you give adequate time and energy to fill out the sheets both in-between and before your outpatient clinic appointments.
- It is important that you and your parents ensure that you always attend your scheduled outpatient clinic appointments during the next year.

Best regards,  
The Diabetes Team

**To use the HbA1c test (long-term test) in a retrospective way as a disclosure test**



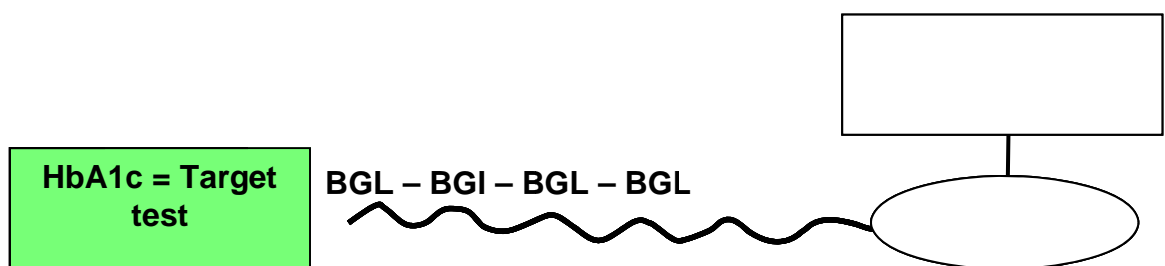
**BS – BS – BS!**

I might passively, accept the goal of the long-term test that my physician/nurse recommends.

I allow the long-term test to be used in a retrospectively way to discover, explore or disclose about how my blood sugar levels have been.

Depending on the outcome, I may feel that I am the good and accommodating patient or I feel that I have been exposed or unsuccessful. At the same time I may experience that my physician and nurse meet me with a lifted finger or are disappointed in me.

**To utilize the HbA1c test (long-term test) in a prospective way as a target test:**



I determine my own goal for HbA1c that I believe will be realistic and beneficial. I use the goal as a future point that I can aim at and achieve in my own pace. I am curious to find out how my blood glucose levels are because I want to know if I am heading in the right direction.

Source: Zoffmann 2004


Label:


## Important events and periods in your life with diabetes

State the **year** you were born

State the **year** you were diagnosed with diabetes

Indicate on the timeline the start and endpoints of longer periods in which:

your diabetes was well regulated (Write **V** or draw a thick line **on** the timeline) **V** 

your blood glucoses have been too **high** (write **H** on the line or draw a line **above** the timeline) 

you have been troubled by **low** blood glucoses (write **L** on the line or a wavy line **under** the timeline) **L** 

you have been troubled by **fluctuating** blood glucoses. (write **S** on the line or draw a wavy line **on** the timeline) **S** 

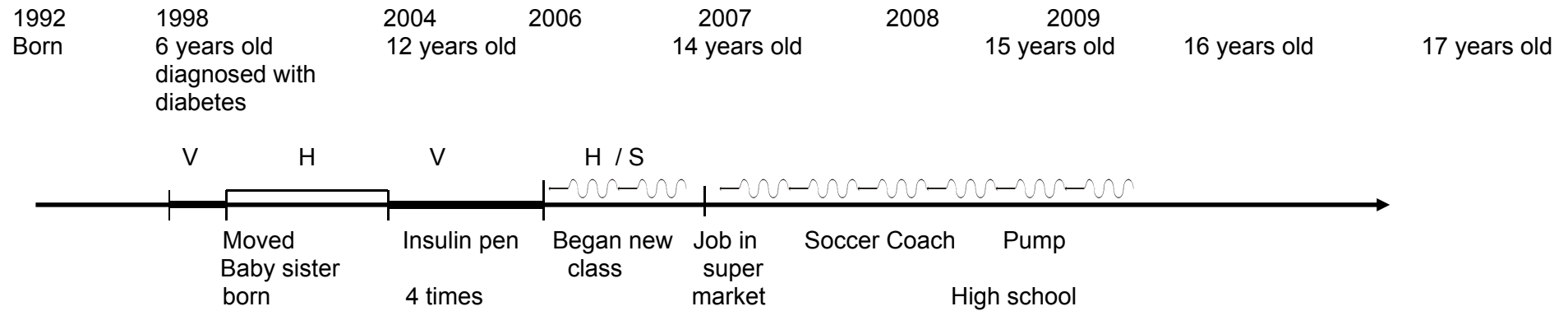


Write under the timeline the **reasons** you believe can explain periods with good or poor regulation. For example, note important **events or experiences** at home, in school, in your free time, or change of insulin medication, insuflon, pumps, etc. See an example on the next page.



## Example of patient with Type 1 Diabetes

“Important events and periods in your life with diabetes”



Source: Zoffmann 2004/GRH 2008

Label:

**What do you find difficult at the present time about living with your diabetes?**

**Write some key words:**

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## Plans for changes in everyday life

Many of the rules recommended to people with diabetes are difficult to fit into everyday life. Write an X in the left column next to all the sentences that fit your everyday life. Then write an X in the right column, stating if this is something you will change or will continue to do.

My everyday life is characterized by the fact that I: (mark with an X)		I wish to change this: (mark with an X)			I do not have plans to change this (mark with an X)
		Inside the first month	Inside the first ½ year	After the first ½ year	
	I do not eat the meals I need in relation to my treatment.				
	I do not have my insulin adjusted when what I drink and eat contains excessive carbohydrates				
	I eat too much when I have low blood glucoses				
	I do not exercise enough				
	Sometimes I do not take the insulin I need				
	Not often enough do I adjust insulin – or my diet – through exercise				
	I weigh too much				
	I smoke				
	I have alcohol consumption problems				
	I detect low blood glucoses too late				
	I do not investigate blood glucoses as recommended				
	I am often exposed to harmful stress				
	Once in a while I do not take other prescribed medicine				

- Mark the following sentences that are true for you:
  - Losing weight is not relevant for me because I have never been overweight.
  - Smoking is not relevant for me because I have not smoked during my period with diabetes.
  - I do not receive any medicine other except than insulin.

Source: Zoffmann 2004

## Agreement sheet for

\_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar ) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received \_\_\_\_\_ sheets

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment.

\_\_\_\_\_ **Date** \_\_\_\_\_ **Time** \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_

## **Reflection sheets for visit 2**

## **Working together - life with diabetes**

- **Unfinished sentences – values, experiences and needs**
- **Agreement sheet**

## Unfinished sentences – *values, experiences and needs*

Those, (for example classmates, friends, teachers, my mother, my father, sisters, family) who know the way I live, think that ...

The thing I am best at in relation to my diabetes is ...

The worst thing about having diabetes is ...

The thing I am worst at is ...

My diabetes has prevented me from ...

It must not prevent me from ...

In one year I will ...

I should not blame my diabetes for ...

When I am scheduled to visit the diabetes outpatient clinic, I think ...

I would like to learn more about ...

If I measure my blood sugar, it is because ...

One thing that can make problems at home is ...

I think that my friends and colleagues ...

One thing that I will try to change about myself is ...

A habit that I have a hard time getting rid of is ...

I find it difficult to stand against pressure from ...

I get good support from ...

I do not get enough support from ...

My diabetes has taught me that ...

The happiest day of my life was when ...

The saddest day of my life was when ...

The thing I wish for the most is ...

When I am at the end of my life I would like to look back on having....



**Agreement sheet for \_\_\_\_\_**

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

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Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received Sheet \_\_\_\_\_ :

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that I will think about and fill out before my next outpatient clinic appointment,

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_

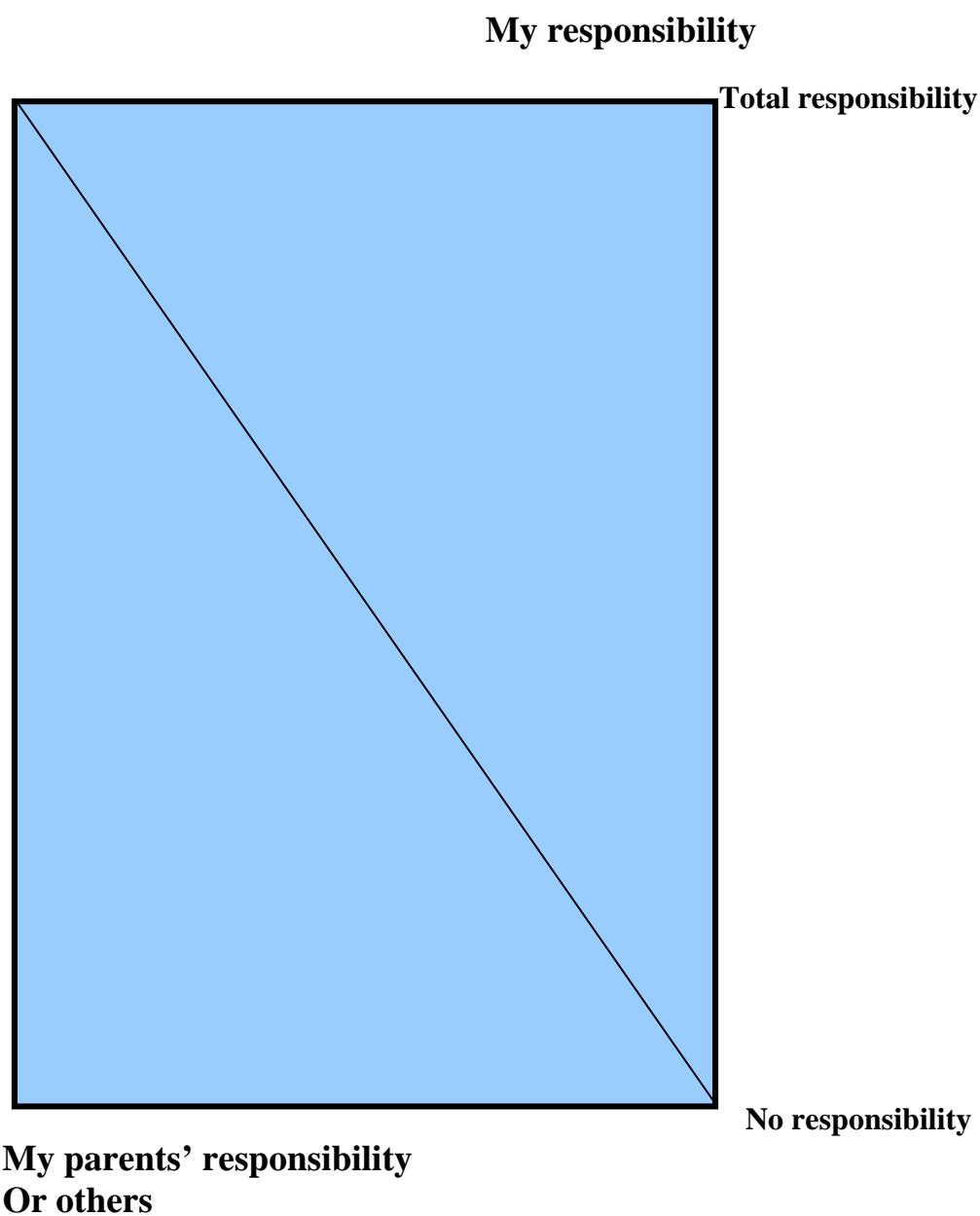
## **Reflection sheets for visit 3**

## **Your life with diabetes**

- **Dividing responsibility**
- **A picture, metaphor, automatic thoughts about diabetes**
- **Room for diabetes in your life**
- **Blood sugar checks and your reasons for checking**
- **Agreement sheet**

## Dividing Responsibility – How much and how

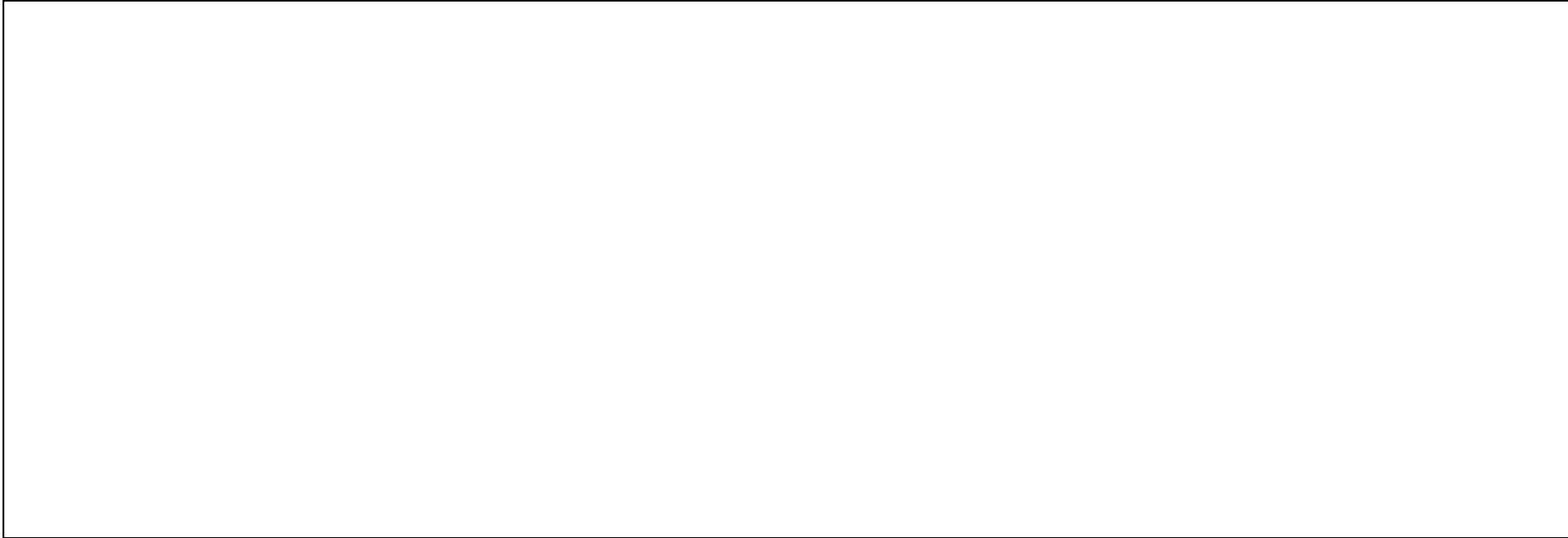
Indicate with an “X” at the right side of the box how much you feel that you take responsibility right now for your diabetes in your everyday life



Source: Olinder A 2009/GRH 2009

Label:

**Which pictures and thoughts usually appear in your mind when you think about it and remember that you must live with diabetes?**  
(Draw and/or write)



Source: Zoffmann 2004/GRH 2009

Room for diabetes in your life

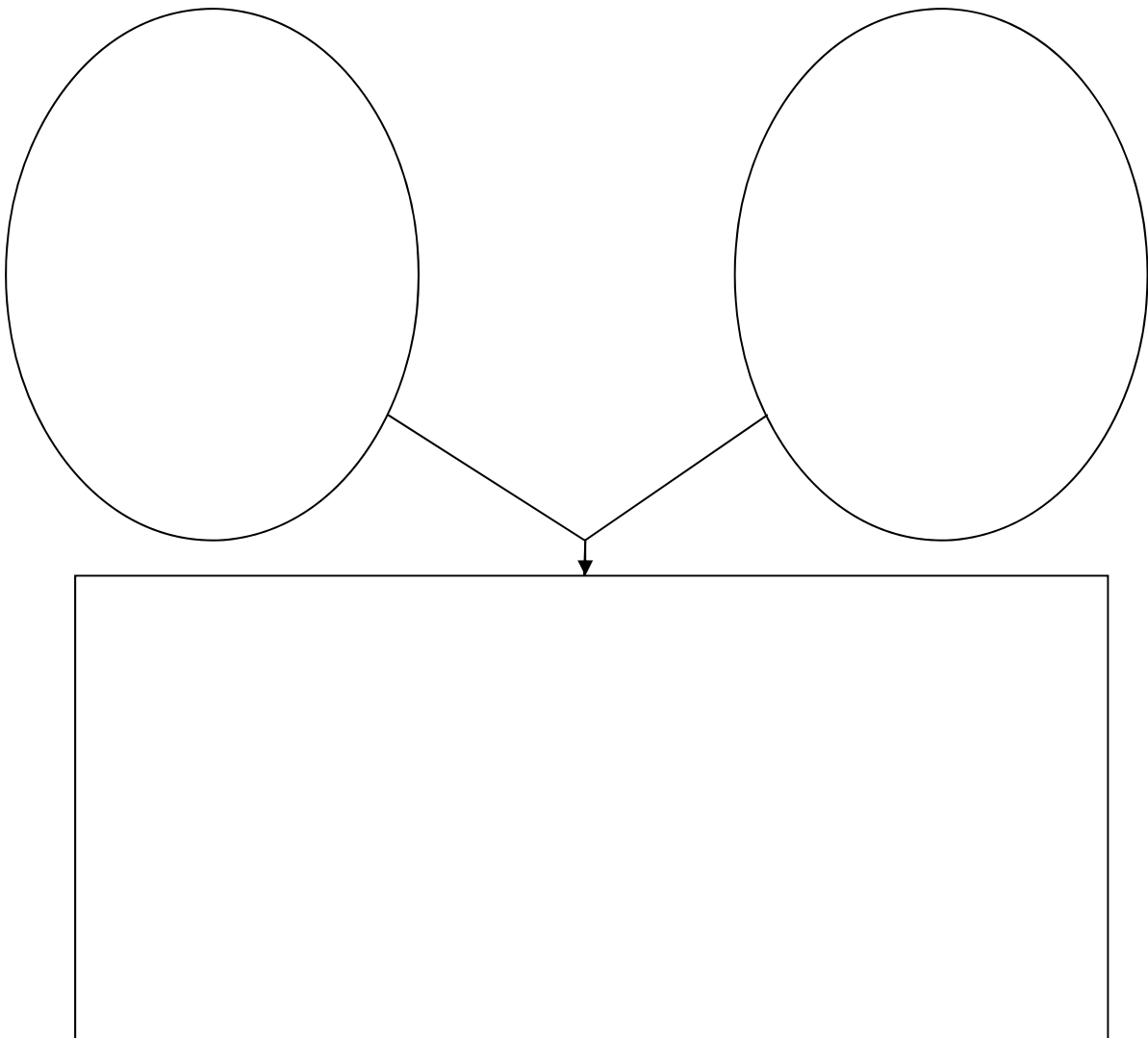
Label

**My diabetes has taken up  
this** much room until now

**My diabetes will take up  
this** much room in the future

*(mark the area diabetes fills now)*

*(mark the area diabetes will fill)*



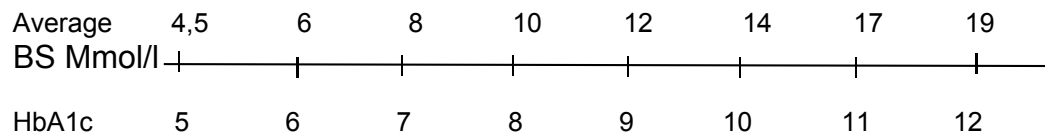
**Blood sugar checks and your reasons for checking**

Date	Breakfast		Lunch		Afternoon meal		Dinner		At bedtime	Middle of the night	Average
	Before	1½ hours after	before	1½ hours after	before	1½ hours after	before	1½ hours after			

Add one or more of the letters below to indicate your reasons for performing each blood sugar check. Average of all blood glucoses: \_\_\_\_\_

- A – Agreement with parents or others
- H – Detecting high blood glucoses
- J – For my own sake
- L – Preventing/detecting low blood glucoses
- M – For my sake
- N – Curiosity
- V – Habit is forming.

HbA1c: \_\_\_\_\_



Add a letter that fits you most

Source: Zoffmann 2004/GRH 2009

Agreement sheet for \_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received \_\_\_\_\_ sheets:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment,

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_



## **Reflection sheet for visit 4**

## **Your life with diabetes**

- **Your ideal blood glucose and actual blood glucose**
- **Advantages and disadvantages of high and low HbA1c**
- **Your plan for regulating your blood glucose – short and long term**
- **Agreement sheet**

## Your ideal blood glucose and actual blood glucoses

Patient label
---------------

### Your desired results of your daily blood glucoses

Date	Breakfast		Lunch		Afternoon meal		Dinner		At bedtime	Middle of the night	Average
	before	1½ hours after	before	1½ hours after	before	1½ hours after	before	1½ hours after			

Average of ideal-BG:

--

### Your blood glucoses results as you know them in real life

Date	Breakfast		Lunch		Afternoon meal		Dinner		At bedtime	Middle of the night	Average
	before	1½ hours after	before	1½ hours after	before	1½ hours after	before	1½ hours after			

Average of actual BG:

--

Mark your ideal and actual blood glucoses →

BG Mmol/l	4,5	6	8	10	12	14	17	19
HbA1c %	5	6	7	8	9	10	11	12

Source: Zoffmann 2004

## Your plan for BG-regulation – short-term and long-term

HbA1c (long-term blood sugar) Result before GSD-Y: _____ %
---

HbA1c as you wish it at the following times



HbA1c		HbA1c		HbA1c		HbA1c	
Goal	Result	Goal	Result	Goal	Result	Goal	Result
_____	_____	_____	_____	_____	_____	_____	_____
Date		Date		Date		Date	

State the situations where you especially wish to avoid low blood sugar:

---



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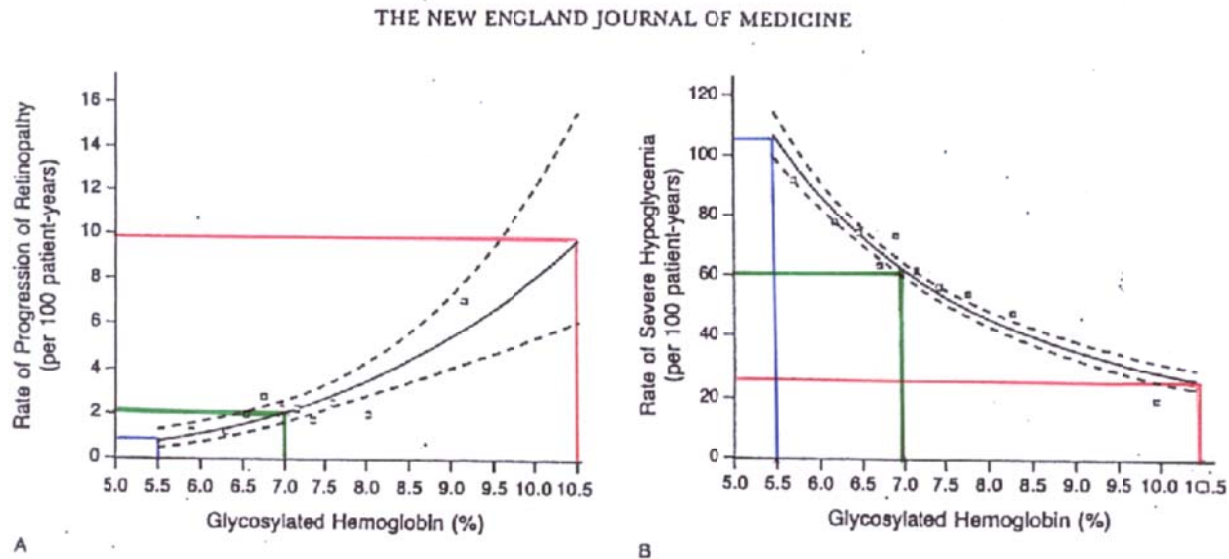


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# Advantages and disadvantages of blood sugar regulation

What do we actually know about Type 1 Diabetes?

*The New England Journal of Medicine*



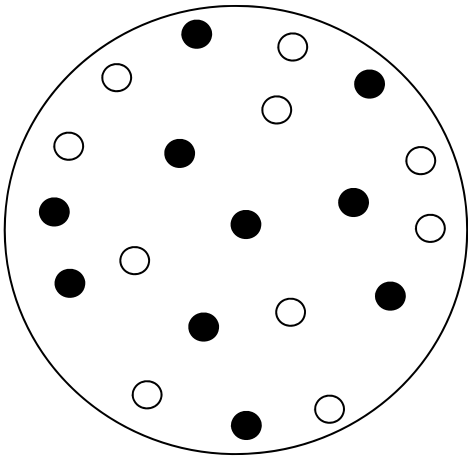
The higher the HbA1c, the greater is the known risk of developing lasting changes, for instance in the eyes. The lower the HbA1c, the greater the risk of serious situations with low blood sugar (for instance situations where you cannot manage without the help of others)

**Curves show how often this happens during 100 patient years:**

- i.e. for 100 persons during a 1-year period
- or for 20 persons during a 5-year period
- or for one person during a 100-year period

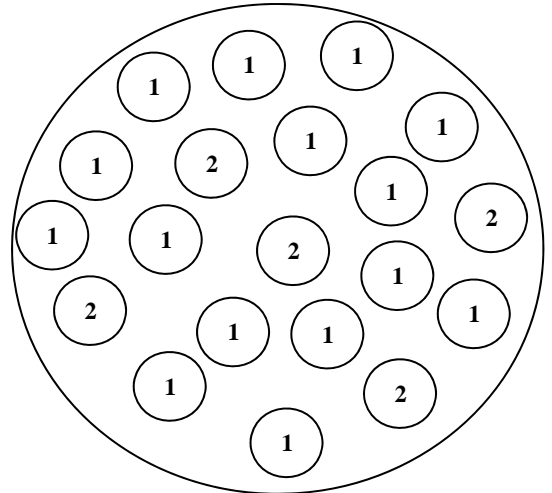
**With adults.**  
Instances of new registered lasting changes in eyes\* (Type 1 Diabetes)

**With adults.** Serious instances of low blood sugar\*\*, insulin instances that require help from others (**Type 1 Diabetes**)

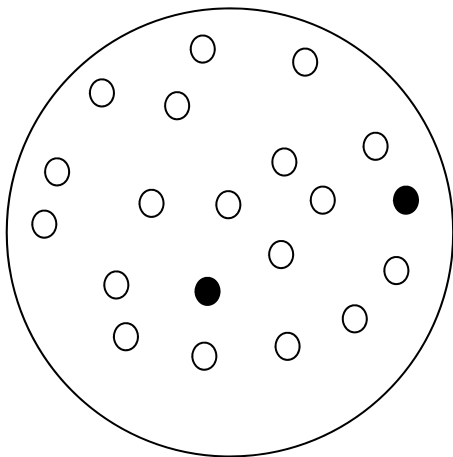


10 instances in 5 years for a group of 20

HbA1c  
**10,5%**

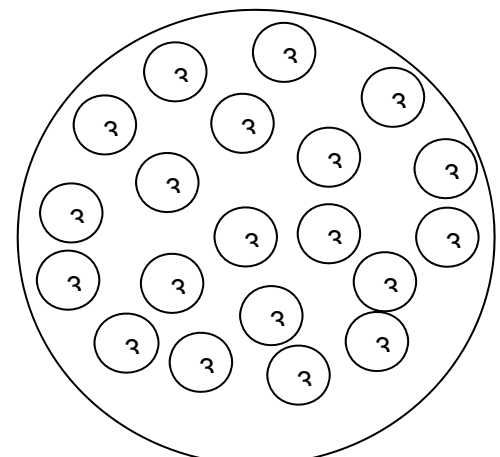


1 instance in 5 years for all 20 and 2 instances for a few

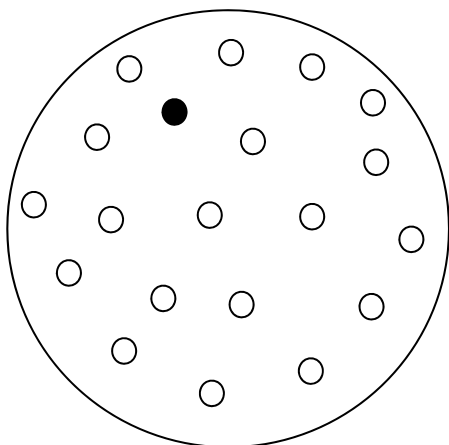


In 5 years, 2 instances in a group of 20 people

HbA1c  
**7,0 %**

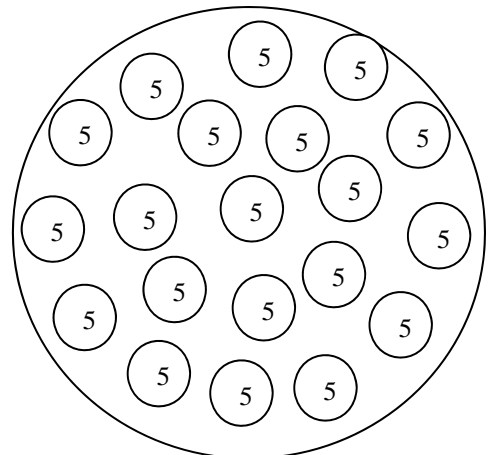


In 5 years, 3 instances for all 20 people



In 5 years, 1 instance in a group of 20 people

HbA1c  
**5,5 %**



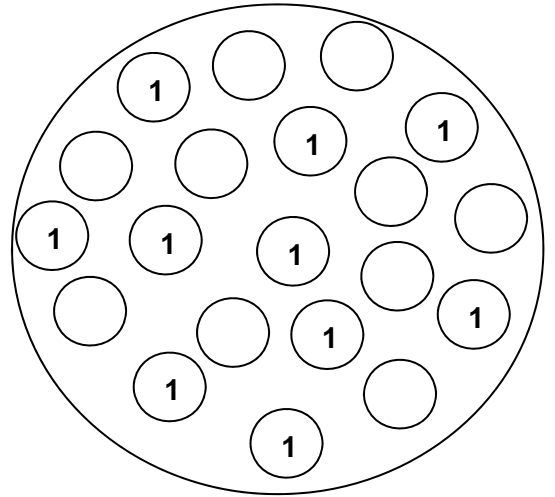
In 5 years, 5 instances for all 20 people

\* Does not mean that you are blind, but display a new deterioration that has been registered in one eye over a period of ½ year, and does not disappear.

\*\* Insulin instances, not where you collapse, but you cannot manage to eat or drink without help from others.

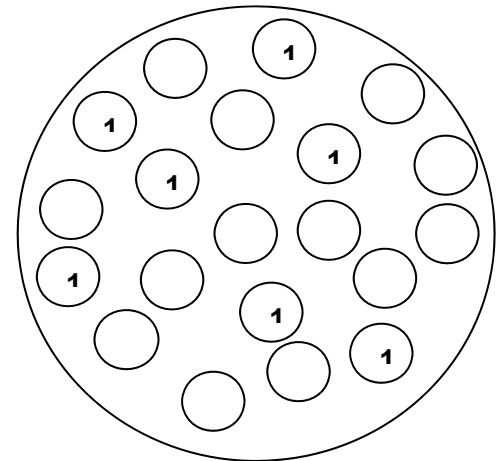
# Insulin shock with consciousness - youth ages 13-18 years with Type 1 Diabetes

HbA1c  
>10,0%



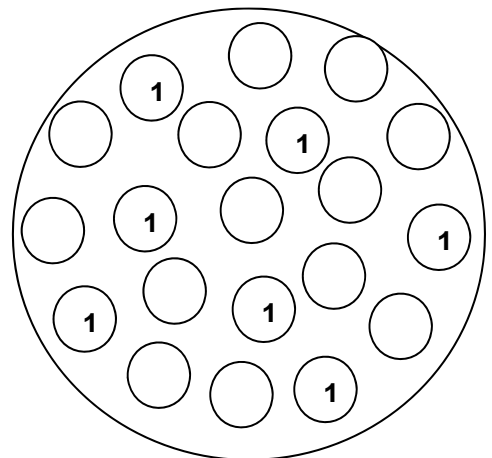
In 5 years, 1 instance for 10 out of 20 young people

HbA1c  
7,0%



In 5 years, 1 instance for 7 out of 20 young people

HbA1c  
<6,0%



In 5 years, 1 instance for 7 out of 20 young people

Source: Danish Children's Diabetes Register 2008. Conclusion: Insulin shock happens most seldom in young people with an HbA1c below 7%. There are no records showing risks of eye changes and/or effects on kidneys at high / low HbA1c. However, it is expected to be equal to the adult's risks for developing complications. (GRH & Zoffmann 2009)

**Agreement sheet for** \_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar ) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received Sheet \_\_\_\_\_ :

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment.

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_



**Reflection sheet  
for visit 5**

### **Working to change**

- **Common term(s)**
- **Patient's list**
- **HCPs' list**
- **Current problem-solving – to be delivered and started together during Conversation 5 after Common terms.**
- **Agreement sheet**

## Choosing and defining a difficulty/challenge in your life with diabetes

Our independent lists that may be different:

Your list:

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HCPs' list:

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Our common term  
that will be correct,  
adequate, and  
acceptable:

---

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# Current problem/challenge solving

A name for what is causing you problems – The thing that is difficult is .....

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## Your observations

How long have you experienced this?

How often do you experience this?

Has it increased or decreased over time?

When do you notice the problem the most?

When do you notice the problem the least?

The thing that is difficult is.....

## Your thoughts and feelings

What do you think this problem/challenge is related to?

---

What makes it worse?

What makes it better?

What does it stop you from doing?

What do you achieve by it?

How much does it affect you?

The thing that is difficult is.....

## **Your goals and intentions**

### **What is important to you? – What are you aiming for?**

What can you/other people gain by solving the problem?

In the short term?

In the long term?

What can you/other people lose by solving the problem?

In the short term?

In the long term?

Have you decided whether you want to solve the problem completely or only partly?

If partly – which parts?

The thing that is difficult is:.....

**Your actions**

Which partially successful attempts have you made in order to solve the problem?

When?

How often?

Have you had unsuccessful attempts?

Who helped you?

—

Who have you lacked help from?

Who have you asked for help?

—

Who would you have liked to have asked for help?

Label:

**Your observations**

## **Dynamic Problem-solving**

**New goals and intentions**

### **Expanded problem solving**

What have you noticed?

**Problem-solving to date**

Your goals until now?

**The thing that is difficult is:**

Your thoughts and feelings?

What have you done until now?

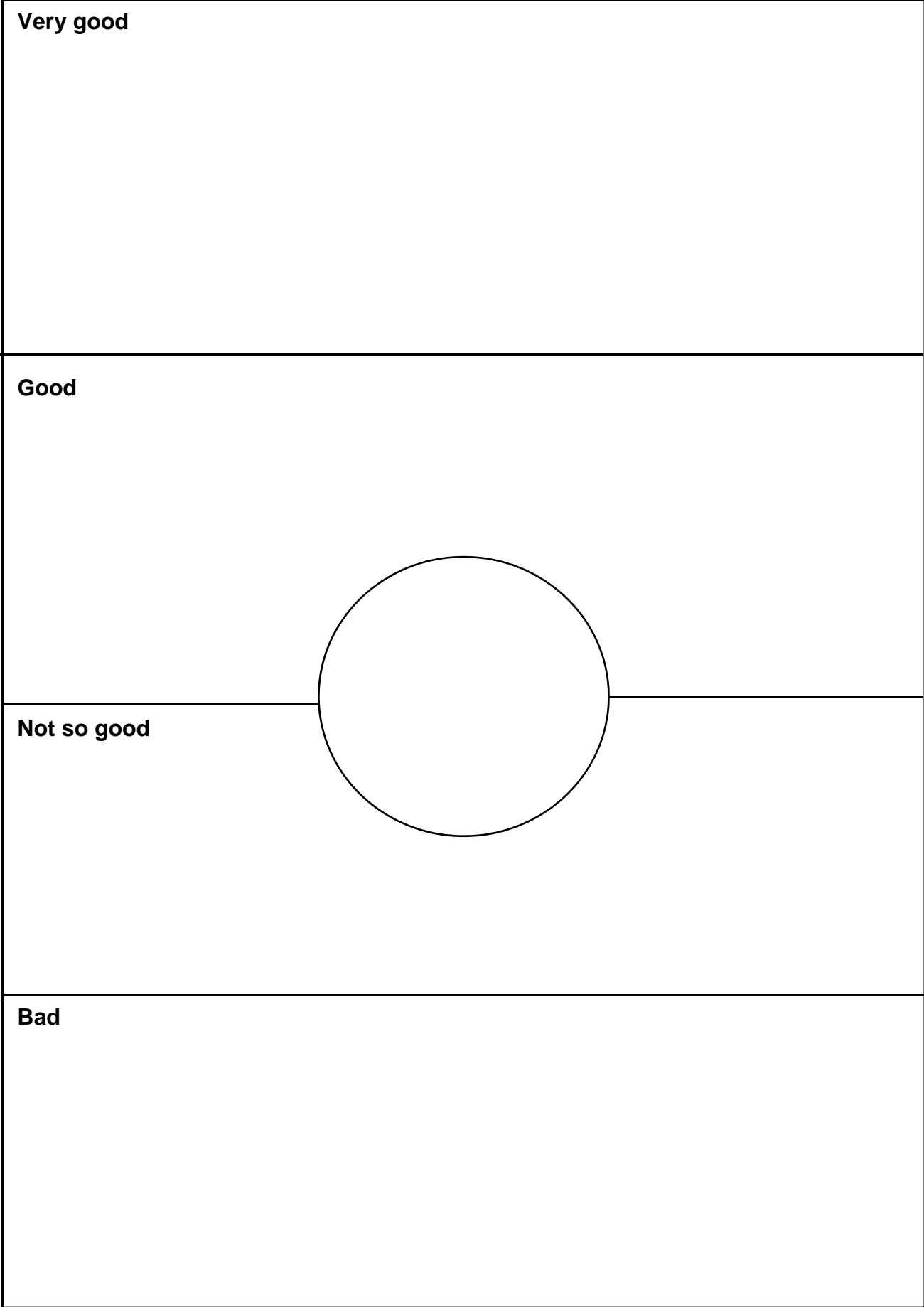
**New thoughts you discover**

**New ideas for action from now on**

Source: Zoffmann 2004



Label:



**Agreement sheet for** \_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received Sheet \_\_\_\_\_ :

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment.

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_

**Reflection sheet  
for visit 6**

## **Working to change**

- **Current problem-solving (4 sheets)**
- **Dynamic problem-solving**
- **Pros and Cons**
- **Agreement sheet**

# Current problem-solving

A name for what is causing you problems – the thing that is difficult is.....

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---

## Your observations

How long have you experienced this?

How often do you experience this?

Has it increased or decreased over time?

When do you notice the problem the most?

When do you notice the problem the least?

The thing that is difficult is.....

## Your thoughts and feelings

What do you think the problem/challenge is related to?

---

What makes it worse?

What makes it better?

What does it stop you from doing?

What do you achieve by it?

How much does it affect you?

The thing that is difficult is.....

## **Your goals and intentions**

### **What is important to you? – What are you aiming for?**

What can you/other people gain by solving the problem?

In the short term?

In the long term?

What can you/other people lose by solving the problem?

In the short term?

In the long term?

Have you decided whether you want to solve the problem completely or only partly?

If partly – which parts?

The thing that is difficult is:.....

**Your actions**

Which partially successful attempts have you made in order to solve the problem?

When?

How often?

Have you had any unsuccessful attempts?

Who helped you?

-

Who have you lacked help from?

Who have you asked for help?

-

Who would you have liked to have asked for help?



Label:

Your observations

## Dynamic Problem-solving

New goals and intentions

### Expanded problem solving

What have you noticed?

Problem-solving to date

Your goals until now?

The thing that is difficult is:

Your thoughts and feelings?

What have you done until now?

New thoughts you discover

New ideas for action from now on

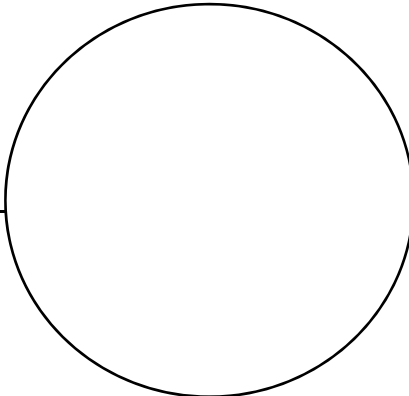
Label:

**Very good**

**Good**

**Not so good**

**Bad**



**Agreement sheet for** \_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar ) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received Sheet \_\_\_\_\_ :

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment.

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_

## **Reflection sheet for visit 7**

## **Working to change**

- **Common term (s)**
- **Patient's list**
- **HCP's list**
- **Current problem-solving – to be delivered and started together during Conversation 7 after Common terms.**
- **Agreement sheet**

## Choose and name the difficulties/challenges in your life with diabetes

**Our independent lists that may be different:**

Your list:

HCP's list:

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---

---

---

Our common term  
that will be correct,  
adequate, and  
acceptable:

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---

---

# Current problem/challenge solving

A name for what is causing your problem –The thing that is difficult is.....

---

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## Your observations

How long have you experienced this?

How often do you experience this?

Has it increased or decreased over time?

When do you notice the problem the most?

When do you notice the problem the least?

The thing that is difficult is.....

### Your thoughts and feelings

What do you think the problem/challenge is related to?

---

What makes it worse?

What makes it better?

What does it stop you from doing?

What do you achieve by it?

How much does it affect you?



The thing that is difficult is.....

## **Your goals and intentions**

### **What is important to you? – What are you aiming for?**

What can you/other people gain by solving the problem?

In the short term?

In the long term?

What can you/other people lose by solving the problem?

In the short term?

In the long term?

Have you decided whether you want to solve the problem completely or only partly?

If partly – which parts?

The thing that is difficult is:.....

**Your actions**

Which partially successful attempts have you made in order to solve the problem?

When?

How often?

Any unsuccessful attempts?

Who helped you?

-

Who have you lacked help from?

Who have you asked for help?

-

Who would you have liked to have asked for help?

Label:

**Your observations**

## **Dynamic Problem-solving**

**New goals and intentions**

### **Expanded problem solving**

What have you noticed?

**Problem-solving to date**

Your goals until now?

**The thing that is difficult is:**

Your thoughts and feelings?

What have you done until now?

**New thoughts you discover**

**New ideas for action from now on**

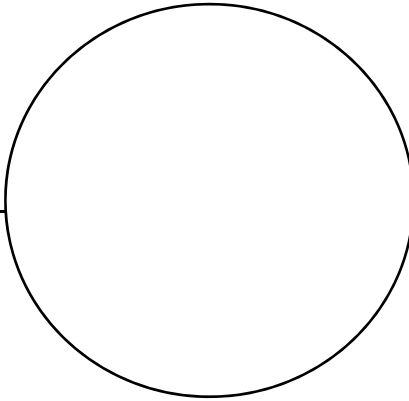
Label:

**Very good**

**Good**

**Not so good**

**Bad**



**Agreement sheet for** \_\_\_\_\_

During the period from now until my next outpatient clinic appointment, I have chosen to work with:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Possible change in insulin \_\_\_\_\_

My own long-range goals with HbA1c (long-term blood sugar ) \_\_\_\_\_

My own short-range goals with HbA1c (long-term blood sugar) \_\_\_\_\_

Other \_\_\_\_\_

Today I have received Sheet \_\_\_\_\_ :

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

that I will think about and fill out before my next outpatient clinic appointment,

\_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Email (optional): \_\_\_\_\_ Cell phone (optional) \_\_\_\_\_

**Reflection sheet  
for visit 8**

## **Working to change**

- **Dynamic problem-solving**
- **Pros and Cons**
- **Final agreement sheet and coming focus areas**

**Label:**

**Your observations**

## **Dynamic Problem-solving**

**New goals and intentions**

### **Expanded problem solving**

What have you noticed?

**Problem-solving to date**

Your goals until now?

**The thing that is difficult is:**

Your thoughts and feelings?

What have you done until now?

**New thoughts you discover**

**New ideas for action from now on**



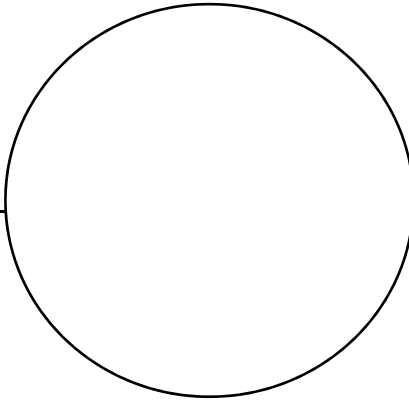
Label:

**Very good**

**Good**

**Not so good**

**Bad**



Label

Final Agreement Sheet date: \_\_\_\_\_

**Which problems/challenges have I worked with until now?**

**Which problems/challenges have been solved?**

**Which problems/challenges will I continue to work with?**

My list	Nurse/ Physician's list
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____
_____	_____

**We agree that in-between and during the next outpatient appointment, I will start working with:**

---

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**My short-term goal for long-term blood sugar: \_\_\_\_\_ and my long-term goal: \_\_\_\_\_**  
Source: GRH 2009/Zoffmann 2009

## **Reflection Sheet for parents**

## Reflection sheet, handed out to adolescent's parents at Hillerød and Glostrup

Being parents to a child with diabetes – Parent-session 1	Delivered	Discussed
1.a Unfinished sentences – values, experiences and needs (Mother)	/	/
1.b Unfinished sentences – values, experiences and needs (Father)	/	/
1.c Room for diabetes in your life (Mother)	/	/
1.d. Room for diabetes in your life (Father)	/	/
1.e Common terms (Mother and/ Father)	/	/
Working to change – Parent session 2	Delivered	Discussed
2.a. Current problem/challenge-solving (4th Sheet)	/	/
2.b Dynamic problem-solving	/	/
2.c Pros and Cons	/	/
To be delivered during session 1 and discussed during session 2 ,		

## Unfinished sentences – *about values, experiences, and needs* (Mother)

Those who know our way of handling diabetes think that ...

The thing we are best at in relation to diabetes is ...

The worst thing about having a child with diabetes is ...

The thing I am worst at is ...

My child's diabetes has prevented her/him from ...

I must not prevent my child from ...

In one year I will ...

We should not blame diabetes for ...

When my child is scheduled to visit the diabetes outpatient clinic, I think ...

I would like to learn more about ...

If my child measures her/his blood sugar, it is because ...

One thing that can give problems at home is ...

I think that my child's classmates and friends ...

One thing that I would like my child to try to change about herself/himself is ...

One thing that I would like to change about myself is ...

One thing that I would like my husband/partner to change about himself is ...

A habit I have a hard time getting rid of is ...

I think my child finds it difficult to withstand pressure from ...

My child gets good support from ...

My child does not get enough support from ...

Diabetes has taught me that ...

The happiest day of my life was when ...

The saddest day of my life was when ...

The thing I most wish for is ...

When my child becomes an adult, I will want to look back and see that I have ...

## Unfinished sentences – about values, experiences, and needs (Father)

Those who know our way of handling diabetes think that ...

The thing we are best at in relation to diabetes is ...

The worst thing about having a child with diabetes is ...

The thing I am worst at is ...

My child's diabetes has prevented her/him from ...

I must not prevent my child from ...

In one year I will ...

We should not blame diabetes for ...

When my child is scheduled to visit the diabetes outpatient clinic, I think ...

I would like to learn more about ...

If my child measures her/his blood sugar, it is because ...

One thing that can give problems at home is ...

I think that my child's classmates and friends ...

One thing that I would like my child to try to change about herself/himself is ...

One thing that I would like to change about myself is ...

One thing that I would like my wife/partner to change about herself is ...

A habit I have a hard time getting rid of is ...

I think my child finds it difficult to withstand pressure from ...

My child gets good support from ...

My child does not get enough support from ...

Diabetes has taught me that ...

The happiest day of my life was when ...

The saddest day of my life was when ...

The thing I most wish for is ...

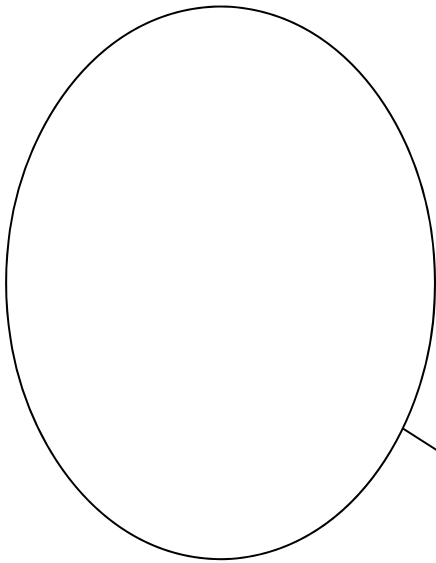
When my child becomes an adult, I will want to look back and see that I have ...



## Room for diabetes in your life (Mother)

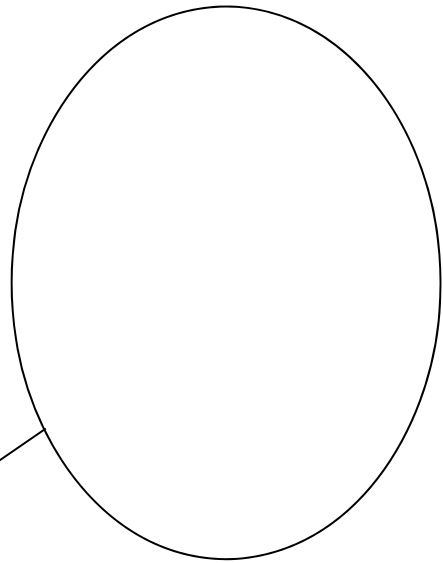
My child's diabetes has taken up this much room until now

(mark the area diabetes fills)

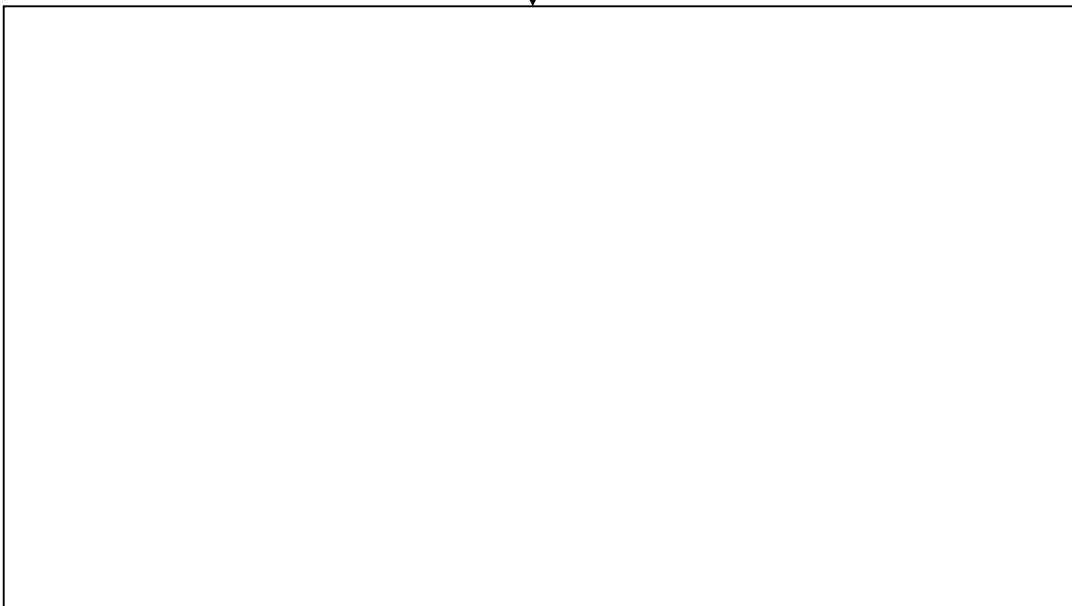


My child's diabetes will take up this much room in the future

(mark the area diabetes will fill)



What is the difference?



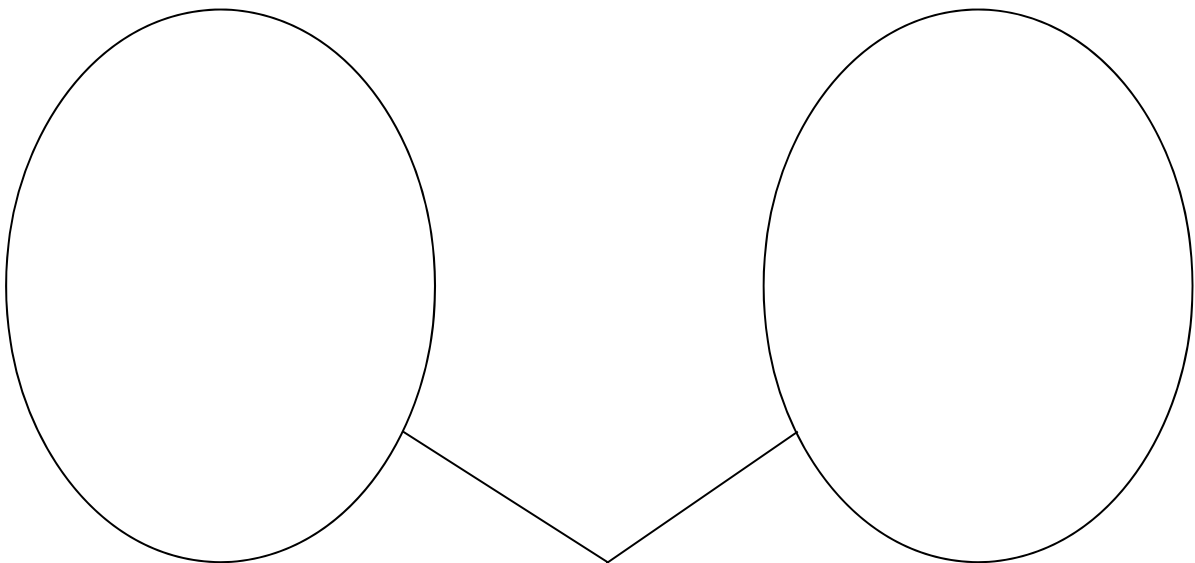
## Room for diabetes in your life (Father)

My child's diabetes has taken up this much room until now

(mark the area diabetes fills)

My child's diabetes will take up this much room in the future

(mark the area diabetes will fill)



What is the difference?

A large, empty rectangular box with a thin black border, intended for the user to write their response to the question 'What is the difference?'.

# Current problem/challenge solving

A name for what is causing you problems – The thing that is difficult is .....

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## Your observations

How long have you experienced this?

How often do you experience this?

Has it increased or decreased over time?

When do you notice the problem the most?

When do you notice the problem the least?

The thing that is difficult is.....

## Your thoughts and feelings

What do you think this problem/challenge is related to?

---

What makes it worse?

What makes it better?

What does it stop you from doing?

What do you achieve by it?

How much does it affect you?

The thing that is difficult is.....

## **Your goals and intentions**

**What is important to you? – What are you aiming for?**

What can you/other people gain by solving the problem?

In the short term?

In the long term?

What can you/other people lose by solving the problem?

In the short term?

In the long term?

Have you decided whether you want to solve the problem completely or only partly?

If partly – which parts?

The thing that is difficult is:.....

## Your actions

Which partially successful attempts have you made in order to solve the problem?

When?

How often?

Have you had unsuccessful attempts?

Who helped you?

—

Who have you lacked help from?

Who have you asked for help?

—

Who would you have liked to have asked for help?

Source: Zoffmann 2004/GRH 2009

Label:

**Your observations**

## **Dynamic Problem-solving**

**New goals and intentions**

### **Expanded problem solving**

What have you noticed?

**Problem-solving to date**

Your goals until now?

**The thing that is difficult is:**

Your thoughts and feelings?

What have you done until now?

**New thoughts you discover**

**New ideas for action from now on**

Source: Zoffmann 2004

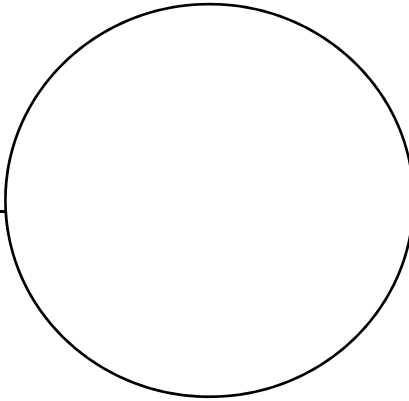
Label:

**Very good**

**Good**

**Not so good**

**Bad**





**Reflection Sheet for  
use with Dietitian session**

**Overview of Reflection Sheet, handed out to adolescents at Hillerød and Glostrup (Herlev) in connection with a dietitian's session.**

<b>Cooperation regarding diet and diabetes – for Session 1</b>	<b>Delivered</b>	<b>Discussed</b>
<b>1.a What do you currently find demanding or difficult in connection with your diet and diabetes?</b>	/	/
	<b>Filled out</b>	<b>Discussed</b>
<b>1.b Review of 500 and 100 rule</b>	/	/
<b>1.c How do I get Rapid and what I eat and drink to match</b>	/	/
	<b>Delivered</b>	<b>Discussed</b>
<b>1.d Experiment 1 (a situation at home)</b>	/	/
<b>1.e Experiment 2 (a situation away from home)</b>	/	/
<b>Working together with diet and diabetes – for Session 2</b>	<b>Delivered</b>	<b>Discussed</b>
	/	/
	<b>Delivered</b>	<b>Discussed</b>
<b>2.a Experiment 1 (a situation at home)</b>	/	/
<b>2.b Experiment 2 (a situation away from home)</b>	/	/
<b>Working together with diet and diabetes – for Session 3</b>	<b>Delivered</b>	<b>Discussed</b>
	/	/
	<b>Delivered</b>	<b>Discussed</b>
<b>3.a Experiment 1 (a situation at home)</b>	/	/
<b>3.b Experiment 2 (a situation away from home)</b>	/	/
<b>Other:</b>		

Name \_\_\_\_\_ date \_\_\_\_\_

### Sheet for dietitian's session

**What do you find demanding or difficult in relation to your food and diabetes?**

**Write down some keywords for use during the conversation with the dietitian:**

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Name: \_\_\_\_\_ date: \_\_\_\_\_

**The 500 – Rule: Used to calculate how much insulin I must use for what I eat or drink.**

I calculate by dividing 500 with the average of total units insulin I need daily.

Example: (50 units/day)  $500 \div 50 = 10$  grams carbohydrate

My actual calculation:

On an average, I need \_\_\_\_\_ units daily

500 divided by \_\_\_\_\_ units = \_\_\_\_\_ grams carbohydrate

This means that I need 1(one) unit Rapid, every time I eat/drink  
\_\_\_\_\_ grams carbohydrate

**The 100 – Rule: I can use if, just before I eat, I want to adjust the amount of insulin according to my blood sugar level that is either too high or too low (also called insulin sensitivity)**

I calculate by dividing 100 with the average of the total units insulin I need daily.

Example: (50 units/day)  $100 \div 50 = 2$  mmol/l per unit Rapid

My actual calculation:

On an average, I need \_\_\_\_\_ units daily

100 divided by \_\_\_\_\_ units = a blood sugar reduction of  
\_\_\_\_\_ mmol/l

This means that my blood sugar falls \_\_\_\_\_ mmol every time I take 1 unit Rapid

Source: GRH 2009/Zoffmann 2009

Name: \_\_\_\_\_ date: \_\_\_\_\_

## How do I get Rapid to match what I eat and drink?

My blood sugar falls by \_\_\_\_\_ when I take one unit Rapid.

Each time I eat/drink \_\_\_\_\_ grams carbohydrate, I must take \_\_\_\_\_ units Rapid

My examples	Breakfast	Mid-morning	Lunch	Afternoon	Dinner	After dinner
<b>Total sum carbohydrate</b>						
The Rapid I should take for what I eat and drink.						
Example of what my blood sugar was yesterday before I ate.						
Rapid I should take in order to correct my blood sugar						
Rapid I should take in total for what I eat and drink						

Source: GRH 2009/Zoffmann 2009

Name: \_\_\_\_\_ Date: \_\_\_\_\_

## How do I get Rapid and candy, smoothies, cakes, fruit, potato chips, fast-food, etc., to match?

My blood sugar falls by \_\_\_\_\_ when I take one unit Rapid.

Each time I eat/drink \_\_\_\_\_ grams carbohydrates, I must take \_\_\_\_\_ units Rapid

Things that I like are, for example:				
<b>Total sum carbohydrate</b>				
<b>The Rapid I should take for what I have chosen to eat and drink.</b>				

Name: \_\_\_\_\_ Date: \_\_\_\_\_

## Experiment 1 (a situation at home)

Describe where you were, who you were with, and what you did:

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My blood sugar falls by \_\_\_\_\_ when I take one unit Rapid.

Each time I eat/drink \_\_\_\_\_ grams carbohydrates, I need \_\_\_\_\_ units Rapid

Food/snack/drink/ candy/fruit/ ice-cream	My blood sugar before	The number of units Rapid I took in order to correct	Units of Rapid I took for what I ate	My Blood sugar 1½ -2 hours after	Comments

Source: GRH 2009/Zoffmann 2009

Name: \_\_\_\_\_ Date: \_\_\_\_\_

## Experiment 2 (a situation away from home)

Describe where you were, who you were with, and what you did:

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My blood sugar falls by \_\_\_\_\_ when I take one unit Rapid.  
Each time I eat/drink \_\_\_\_\_ grams carbohydrates, I need \_\_\_\_\_ units Rapid

Food/snack/drink/ candy/fruit/ ice-cream	My blood sugar before	The number of units Rapid I took in order to correct	Units of Rapid I took for what I ate	My Blood sugar 1½ -2 hours after	Comments



## **Appendix B**

Tool for self-assessment and reflection

Written test for HCPs

## **‘Reflection on action’ tool for assessment and supervision of HCPs use of GSD-Y**

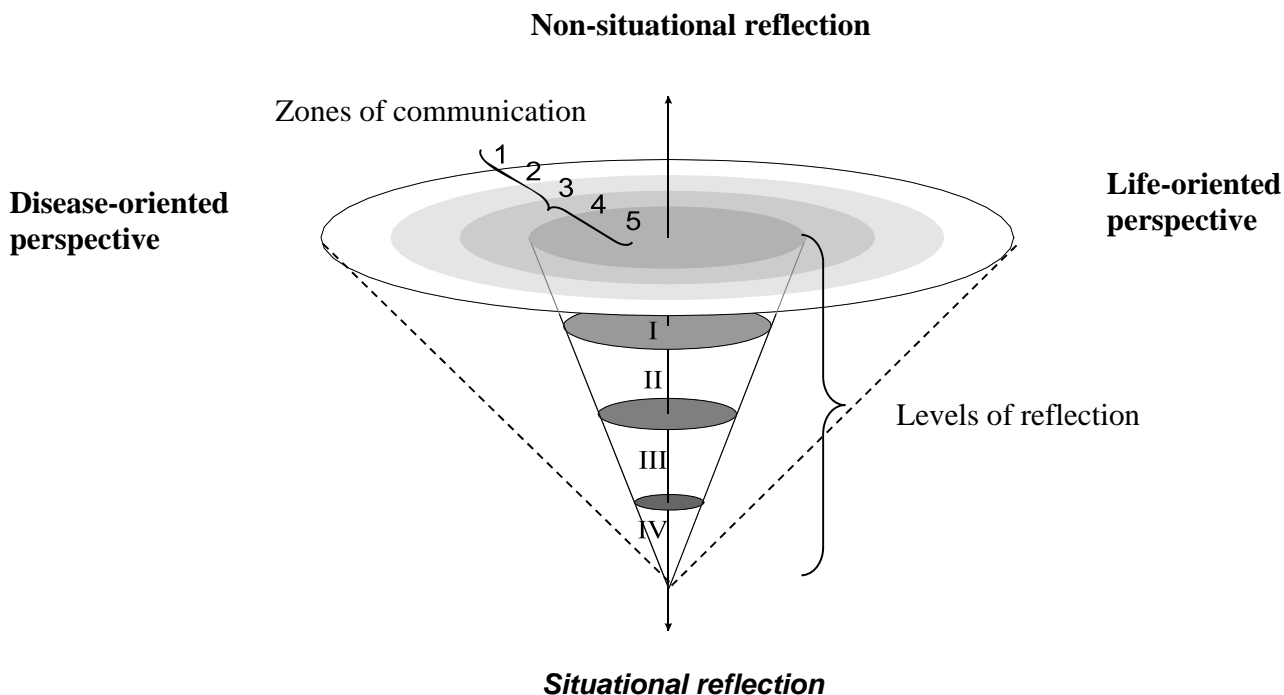
**Can you identify in the transcription where you have used mirroring, please put a mark in the text that illustrates an example.**

**Can you identify in the transcription where you have used active listening, please put a mark in the text that illustrates an example.**

**Can you identify in the transcription where you have used values clarifying responses, please put a mark in the text that illustrates an example.**

**When you look at the Person-Centered communication and reflection model, where would you consider your communication has taken place?**

<b>Zones of communication</b> 1- 5	1: Addressing unrelated issues.	4: Addressing issues related to the patient but currently not difficult.
	2: Addressing general health related issues.	5: Focused communication addressing issues currently difficult for the patient.
	3: Addressing issues of general significance for the patient group.	



Situational reflection		
Levels of reflection	Health care professional's (HCP) activity	Patient's activity
I	Reflecting independently on observable signs of person-specific difficulties.	Being observed. Not engaged in HCP's reflection.
II	Reflecting independently or with colleagues on non-observable aspects of person-specific difficulties. Gathers information from the patient but does not inform the patient of the issues reflecting on or invite the patient to assess the difficulties. Conjectures remain unverified.	Contributing information, but not engaged in HCP's reflection or informed about the issues reflected on. Not asked to verify or assess assumed difficulties.
III	Engaged in mutual reflection with the patient, exchanging thoughts and ideas of explicit difficulties related to the patient's responses to living with the illness. Conjectures verified and knowledge of person-specific difficulties is co-created; importance, causes, meanings and possible solutions clarified.	Engaged in mutual reflection with HCP, verifying and exchanging thoughts and ideas of explicit difficulties related to living with the illness. Co-creating person-specific knowledge of the importance, causes, meanings and possible solutions.
IV	Though not participating in reflection, HCP can motivate the patient to start reflection e.g. by asking value clarifying questions or by pointing out possible inconsistencies in patient responses to illness.	Reflecting independently; autonomously clarifying and reassessing own responses to and stand on specific difficulties.

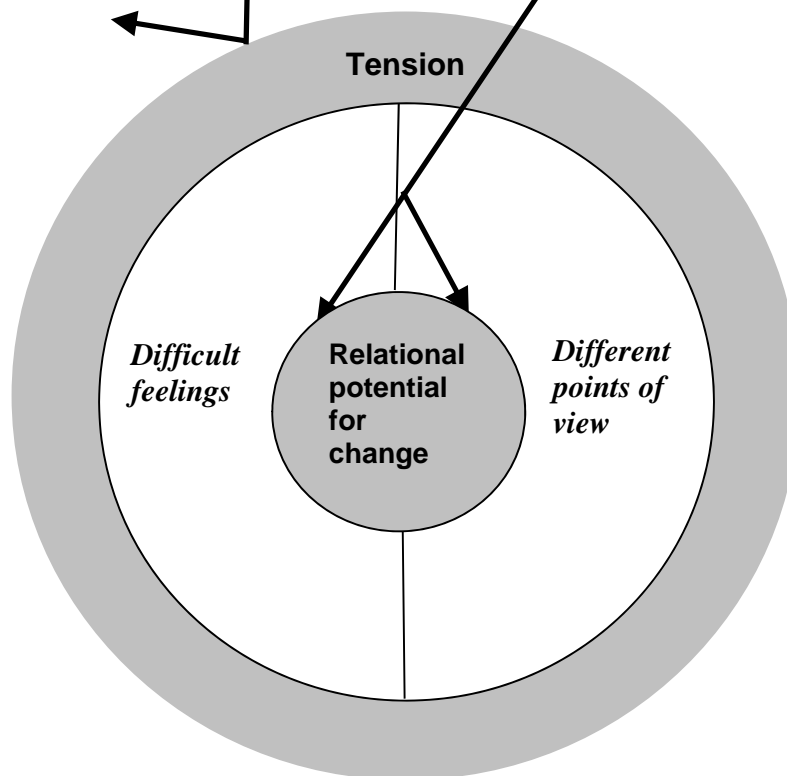
Zoffmann 2008(84)

**When you think of your conversation and read your transcription and you look at the different ways of relationships how would you consider your relationship was?**

Relational potential for change and its connections with the three relationships.

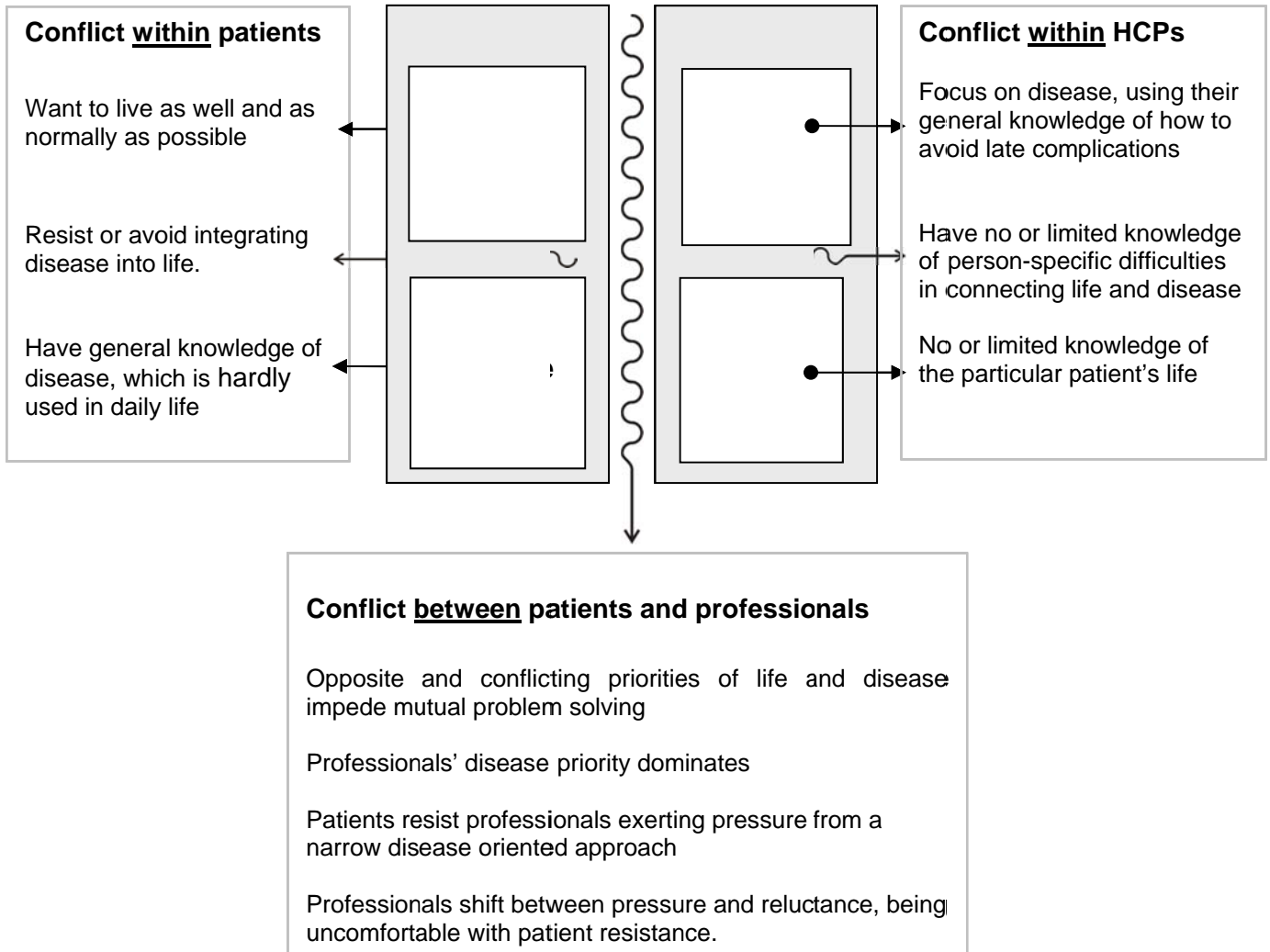
<b>I-you-distant provider dominance</b>	<b>I-you-blurred sympathy</b>	<b>I-you-sorted mutuality</b>
Miss the potential for change because of distance between the parties. If difficult feelings and different points of view are perceived and tension increases, a shift will typically be made to I-you-blurred sympathy	Miss the potential for change by covering over or diminishing sources of tension - difficult feelings and different points of views.	Access to relational potential for change by addressing and exploring the sources of tension - difficult feelings and different points of views.

Zoffmann 2007(83)



**When you think on your conversation and read your transcription and you look at the different conflict lines where can you identify signs of conflicts within the patient, within yourself, between you and the patient?**

Keeping life and disease apart



**Zoffmann 2005(82)**

## Final written test for HCPs

### Questions about the method Guided Self-Determination-Youth

Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Please mark an "X" next to the answer you feel is correct.**

1. The method GSD-Youth is being further developed on the basis of

- Grounded theories developed from empirical studies among adults with Type 1 Diabetes
- Surveys among adults with Type 1 Diabetes
- Literature Studies among children and youth with Type 1 Diabetes

2. One of Vibeke Zoffmann's 3 theories describes three different types of relation-forms:

- Keeping life and disease apart
- Relation potential for change
- Person-specific communication and reflection models

3. One of Vibeke Zoffmann's 3 theories describes three different types of approaches to problem-solving:

- Keeping life and disease apart
- Relation potential for change
- Person-specific communication and reflection models

4. One of Vibeke Zoffmann's 3 theories describes a life-oriented and disease-oriented view of the patient's situation as well as a situational and non-situational approach:

- Keeping life and disease aparte
- Relation potential for change
- Person-specific communication and reflection models

5. What kind of knowledge forms the basis for decision-making according to the method GSD-Youth?

- General knowledge
- Evidence-based knowledge
- Person-specific knowledge

6. GSD-Youth builds on the Empowerment Philosophy and thus views the Patient's potential for development in the following way:

- The patient's potential for development, is provided by the professional through knowledge
- The patient's potential for development is inherent
- The patient's potential for development is not active until the professional defines the patient's problem and solution.

7. The Patient is empowered when:

- The patient has sufficient knowledge to make rational choices, has the control and resources to implement these choices in his/her own life, as well as to evaluate the efficacy of these choices.
- The professional has given the patient sufficient knowledge to make rational choices, and the professional has given the patient added control and resources so he/she can integrate the disease in his/her own life in the best possible way.
- The patient and the professional use a compliance-expecting approach to problem-solving.

8. Behavioral changes in the patient last longer if the inappropriate behavior is identified by:

- The professionals or the parents
- The patient
- Through research results showing general inappropriate behavior related to the specific diagnosis.

9. GSD-Youth is a method:

- That facilitates meaningful and effective problem-solving between patient, parent and professionals
- That facilitates meaningful and effective problem-solving solely for the patient
- That facilitates meaningful and effective problem-solving based on general observations about diabetes.

10. In the process that involves problem-solving, it is important in the method GSD-Youth to:

- Identify and term person-specific issues
- Be familiar with the most general issues related to this category of patients
- Identify and term the general issues related to this category of patients and parents.

11. The method GSD-Youth contributes by:

- Erasing differences between the patient's, parents', and professionals' perspectives
- Differentiating between the patients, parents' and the professionals' perspectives
- Strictly following the patient's perspective.

12. The method GSD-Youth intentionally invites the patient and the professional to engage in the following form of relationship:

- I-you-blurred sympathy
- I-you-sorted mutuality
- I-you-distanced professional dominance

13. With the method GSD-Youth, the following approach to problem-solving is the optimal way to reach the patient:

- Compliance-expectant approach
- Failure-expectant approach
- Mutuality expecting approach

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**The following questions do not have a list of answer options for you to select. You must explain and describe your own answers.**

14. What is Mirroring?

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15. Write a Mirroring for the following statement

"I know exactly what it takes. I just need to pull myself together and start measuring more blood glucoses when I'm in school"

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16. What is Active Listening?

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17. Write an Active Listening for the following statement

"I know exactly what it takes. I just need to pull myself together and start measuring more blood glucoses when I'm in school"

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18. What is Value Clarification?

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19. Write a Value Clarification answer for the following statement

"I know exactly what it takes. I just need to pull myself together and start measuring more blood glucoses when I'm in school"

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**Please complete the following sentences:**

When I need to speak with youth who repeatedly show up without having measured their blood glucoses, and their HbA1c continues to rise, I think

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21. When I need to speak with the parents of poorly regulated youth, I think

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Thank you for your answers!

## **Appendix C**

The scales and their correspondence with numbers in the questionnaire

The questionnaire

## Overview of the scales

Scales	Outcome	Ranging	Examples	Scores
The Perceived Competence Scale (PCD) 5-item	Experience of own competence	Ranging from 1 (strongly disagree) to 7 (strongly agree)	<i>"I feel confident in my ability to manage my diabetes"</i>	Produces a total sum score from 5- 35. A high sum score represents a high level of perceived competence
The Health-Care Climate Questionnaire (HCCQ) 5 -item	Perceptions of autonomy support from HCP	Ranging from 1 (strongly disagree) to 7 (strongly agree)	<i>"I feel that my HCPs have provided me choices and options about handling my diabetes"</i>	Produces a total sum score from 5-35. A high sum score represents a high level of perceived autonomy support
The Treatment Self-Regulation Questionnaire (TSRQ) 21-item Consists of 3 subscales	The degree in which patients' behaviour is self-determined	Ranging from 1 (strongly disagree) to 7 (strongly agree)	<i>(I) Autonomous; "It's exciting to try to keep my blood sugar in a healthy range"</i> <i>(II) Controlled; "I want my HCP to think I am a good patient"</i> <i>(III) A-motivated; "I do not know why I do try – I will not be successful"</i>	Produces sum scores for each of three subscales, Autonomous from 8-56, Controlled 9-63, Amotivated 4-28. High sum scores indicate high levels of autonomy, controlled or amotivated behaviour. A Relative Autonomy Index is calculated by subtracting the controlled scores from the autonomous scores. The higher relative autonomy index the higher is motivation based on autonomy compared to control
The Problem Areas In Diabetes scale (PAID) 20-item	Perception of current emotional burden of diabetes related issues	Ranging from 0 (not a problem) to 4 (serious problem)	<i>"Feelings of guilt or anxiety when you get off track with your diabetes management"</i>	Produces a total score from 0-100 by summing up and multiplying this sum by 1.25. Higher scores indicate greater emotional distress. Cut points: ≥30 elevated distress ≥40 serious distress
The Perception of Parents Scale (POPS) 26-item Consists of 2 sub-scales, mothers & fathers	Perception of autonomy support and involvement from parents	Ranging from 1 (not at all true) to 7 (very true)	<i>(I) Mother/Father Autonomy Support; "My mother/father allows me to decide things for myself"</i> <i>(II) Mother/Father Involvement; "My mother/father finds time to talk with me"</i>	Produces a total sum score for each of the two subscales. Autonomy from 7-49, Involvement from 6-42. High sum scores represent a high level of mother/father autonomy support/involvement
The WHO5 Well-Being Index 5-item	Emotional Well-being	Ranging from 0 (not present) to 5 (constantly present).	<i>"I have felt cheerful and in good spirits for the last two weeks"</i>	Produces a total score from 0-100 by summing up and multiplying this sum by 4. Higher scores indicate greater emotional distress. Cut points: < 50 poor emotional well-being ≤ 28 indicate depression

**The scales and their corresponding number in the questionnaire**

Scales	Question number
HCCQ (5 items)	17,18,19,20,21
TSRQ (21 items) Autonomy subscale Controlled subscale Amotivation subscale	23,25,29,32,35,38,40,41 22,26,27,28,30,31,33,36,39 24,34,37,42
PCD (5 items)	43,44,45,46,47
PAID (20 items)	48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67
POPS (26 items) Mother autonomy Mother involvement Father autonomy Father involvement	68,69,71,73,75,77,79 70,72,74,76,78,80 81,82,84,86,88,90,92 83,85,87,89,91,93
WHO5 (5 items)	94,95,96,97,98

# QUESTIONNAIRE

- concerning you and your diabetes



# QUESTIONNAIRE

**Dear Teenager,**

Thank you for taking the time to fill out this questionnaire!

Your answers provide a clear picture of how you currently feel about your diabetes, and how you feel you are being helped in order to live with the disease.

In addition to the one page with introductory questions, the questionnaire is divided into 6 different topics:

- 1) Your diabetes and your diabetes treatment.
- 2) Your visits in the diabetes outpatient clinic.
- 3) Taking care of your diabetes.
- 4) Possible problems connected to your diabetes.
- 5) Your experience of your parent's involvement and support for you.
- 6) Your well-being with diabetes.

Please answer the questions in the order in which they appear, and follow the instructions given along the way.

Mark with an **X** next to the answer that you think is most true. You may only make one mark per question.

It is important that ...

- you answer all the questions
- you answer as honestly as possible
- it is only you who is answering

If you find it difficult to find the perfect answer, please choose the answer you think is the closest match.

The time needed to fill out the questionnaire is approximately 15 to 20 minutes.

If you have any questions or comments, please feel welcome to contact

**Ph.D. Student Gitte R. Husted**

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mail: [gihu@hih.regionh.dk](mailto:gihu@hih.regionh.dk)  
tlf. 20 26 43 39, weekdays between 9.00 – 15.00

Nr.

## INTRODUCTORY QUESTIONS:

1. What is your CPR. number? \_\_\_\_\_ - \_\_\_\_\_

2. Are you a:  girl  boy

3. Date for filling out the questionnaire: \_\_\_\_\_ / \_\_\_\_\_ - 2011/2012

4. Your type of living accommodation?

- I live with my parents
- I live with my mother
- I live with my mother and her boyfriend
- I live with my father
- I live with my father and his girlfriend
- I live alone
- I live at a boarding school
- Other \_\_\_\_\_

5. Your education?

- I am attending primary school
- I am attending high school
- I am attending HHX, HTX, HF
- Other \_\_\_\_\_

6. Please state your height? \_\_\_\_\_ cm

7. Please state your weight? \_\_\_\_\_ kg

# 1) YOUR DIABETES AND YOUR DIABETES TREATMENT

8. How long have you had diabetes? \_\_\_\_\_ months/years

9. How do you take your insulin?
- I use a pen
  - I have an insuflon
  - I have a pump

10. Which insulin type(s) do you use?

Insulin name:

Rapid-acting: \_\_\_\_\_

Slow-acting: \_\_\_\_\_

11. State your current insulin usage for a typical day:

Number of units:

Morning: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Noon: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Afternoon: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Evening: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Bedtime: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Extra: Rapid-acting \_\_\_\_\_

Slow-acting \_\_\_\_\_

Only if you use a pump:

Basic dosage \_\_\_\_\_



12. How often do you forget or omit to take your insulin?

- Daily
- One to four times a week
- One up to more times a month
- Never, or almost never

13. Do you measure your own blood sugar

- Yes       No

14. How many times have you measured your blood sugar during the past 7 days?

\_\_\_\_\_times

15. How often do you adjust your insulin dosage according to your measurements

- Daily
- One or more times a week
- One or more times a month
- Never or almost never

16. How secure do you feel about adjusting your insulin?

- Very insecure
- Fairly insecure
- Fairly secure
- Very secure

## 2) YOUR VISIT TO THE DIABETES OUTPATIENT CLINIC

The next section contains a series of phrases that refer to your visits to the doctor, nurse and dietician (staff) at your diabetes outpatient clinic.

The phrases are about how you felt during the conversation, and how the staff interacted with you. Staff will typically have various ways to deal with patients, and we would like to know more about how you felt when speaking with them about your diabetes.

We ask that you be honest and sincere. Please tick beneath the answer that best fits your level of agreement.

Work quickly and answer all items as best you can.

		Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree
17.	I feel that my health practitioners have provided me choices and options about handling my diabetes							
18.	I feel understood by my health practitioners with respect to my diabetes							
19.	My health practitioners convey confidence in my ability to make changes necessary to control my diabetes							
20.	My health practitioners encourage me to ask questions about my diabetes							
21.	My health practitioners try to understand how I see my diabetes before suggesting a new way to do things							

## 3) TAKING CARE OF YOUR DIABETES

There are many different reasons why young people with diabetes take their medication, check their blood sugar, eat right and exercise regularly.

Please consider the following statements and indicate to what extent you agree or disagree with each statement, using the scale below.

A.	I take my medications for diabetes and check my glucoses because:	Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree
22.	Other people would be mad at me if I didn't							
23.	I find it a personal challenge to do so							
24.	I don't know why I'd try – I won't be successful							
25.	I personally believe that controlling my diabetes will improve my health.							
26.	I would feel guilty if I didn't do what my health practitioner said							
27.	I want my health practitioner to think I'm a good patient							
28.	I would feel bad about myself if I didn't							
29.	It's exciting to try to keep my glucose in a healthy range							

30.	I don't want other people to be disappointed in me							
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B.	The reason I follow my diet and exercise regularly is that:	Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly disagree	Moderately agree	Strongly agree
31.	Other people would be upset with me if I don't							
32.	I personally believe that these are important in remaining healthy							
33.	I would be ashamed of myself if I didn't							
34.	It's easier to do what I'm told than to think about it							
35.	I've carefully thought about my diet and exercising and believe it's the right thing to do							
36.	I want others to see that I can follow my diet and stay fit							
37.	I don't know why; I'd just do it because my health practitioner said so							
38.	I feel personally that watching my diet and exercising are the best for me							
39.	I'd feel guilty if I didn't watch my diet and exercise							
40.	Exercising regularly and following my diet are choices I really want to make							
41.	It's a challenge to learn how to live with diabetes							
42.	I'm not sure why I'd follow a diet or exercise, I'll wait and see							

	Mark the answer that indicates your level of agreement with that statement	Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly disagree	Moderately agree	Strongly agree
43.	I feel confident in my ability to manage my diabetes							
44.	I now feel capable of handling my diabetes							
45.	I am able to do my own routine diabetic care now							
46.	I feel confident discussing my diabetes with my health provider							
47.	I am able to meet the challenge of controlling my diabetes							

## 4) POSSIBLE PROBLEMS CONNECTED WITH YOUR DIABETES

	<b>Which of the following diabetes issues are currently a problem for you?</b>	<b>Not a problem</b>	<b>Minor problem</b>	<b>Moderate problem</b>	<b>Somewhat serious problem</b>	<b>Serious problem</b>
48.	Not having clear and concrete goals for your diabetes care?					
49.	Feeling discouraged with your diabetes treatment plan?					
50.	Feeling scared when you think about living with diabetes?					
51.	Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat)?					
52.	Feelings of deprivation regarding food or meals?					
53.	Feeling depressed when you think about living with diabetes?					
54.	Not knowing if your mood or feelings are related to your diabetes?					
55.	Feeling overwhelmed by your diabetes?					
56.	Worrying about low blood sugar reactions?					
57.	Feeling angry when you think about living with diabetes?					
58.	Feeling constantly concerned about food and diabetes?					
59.	Worrying about the future and the possibility of serious complications?					
60.	Feelings of guilt or anxiety when you get off track with your diabetes management?					
61.	Not 'accepting' your diabetes?					
62.	Feeling unsatisfied with your diabetes health care providers?					
63.	Feeling that diabetes is taking up too much of your mental and physical energy every day?					
64.	Feeling alone with your diabetes?					
65.	Feeling that your friends and family are not supportive of your diabetes management efforts?					
66.	Coping with complications of diabetes?					
67.	Feeling 'burned out' by the constant effort needed to manage diabetes?					

## 5) YOUR EXPERIENCE OF PARENT INVOLVEMENT AND THEIR SUPPORT FOR YOU

Please answer the following questions about your mother and father. If you do not have contact with one of your parents (for example, your father), but there is another adult of the same gender living with your house (for example a stepfather), then please answer the questions about that other adult.

If you have no contact with one of your parents, and there is not another adult of that same gender with whom you live, then leave the questions about that parent blank.

Please enter an X under the numbers that you feel match you most.

	Questions about your mother	1 Strong-ly disagree	2	3	4 Partially agree	5	6	7 Strong-ly agree
68.	My mother seems to know how i feel about things.							
69.	My mother tries to tell me how to run my life.							
70.	My mother finds the time to talk with me.							
71.	My mother, whenever possible, allows me to choose what to do							
72.	My mother doesn't seem to think of me often.							
73.	My mother listens to my opinion or perspective when I've got a problem.							
74.	My mother spends a lot of time with me.							
75.	My mother allows me to decide things for myself.							
76.	My mother often seems too busy to attend me.							
77.	My mother insists upon my doing things her way.							
78.	My mother is not very involved with my concerns.							
79.	My mother is usually willing to consider things from my point of view.							
80.	My mother puts time and energy into helping me.							

	<b>Questions about your father</b>	<b>1</b> Strongly disagree	<b>2</b>	<b>3</b>	<b>4</b> Partially agree	<b>5</b>	<b>6</b>	<b>7</b> Strongly agree
81.	My father seems to know how i feel about things.							
82.	My father tries to tell me how to run my life.							
83.	My father finds the time to talk with me.							
84.	My father, whenever possible, allows me to choose what to do							
85.	My father doesn't seem to think of me often.							
86.	My father listens to my opinion or perspective when I've got a problem.							
87.	My father spends a lot of time with me.							
88.	My father allows me to decide things for myself.							
89.	My father often seems too busy to attend me.							
90.	My father insists upon my doing things her way.							
91.	My father is not very involved with my concerns.							
92.	My father is usually willing to consider things from my point of view.							
93.	My father puts time and energy into helping me.							

## 6) YOUR WELL BEING WITH DIABETES

The last questions relate to how you have felt in general during the past 2 weeks.

For each of the 5 statements, please enter an X in the field that comes closest to how you felt during the past two weeks.

	<b>During the past two weeks...</b>	<b>All of the time</b>	<b>Most of the time</b>	<b>More than half of the time</b>	<b>Less than half of the time</b>	<b>Some of the time</b>	<b>At no time</b>
94.	I have felt cheerful and in good spirits						
95.	I have felt calm and relaxed						
96.	I have felt active and virgorous						
97.	I woke up feeling fresh and rested.						

98.	My daily life has been filled with things that interest me.							
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**HOW HAVE YOU EXPERIENCED YOUR PARTICIPATION IN THIS PROJECT?**

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Thank you for your answers!

## **Appendix D**

The Case Report Form used at randomization

The Case Report Form for GSD-Y adolescents during the intervention period

The Case Report Form for Control adolescents during the control period



## Case Report Form at Randomisation time

Project:

Life Skills with Type 1 Diabetes

Guided Self-Determination – Youth

Hospital: \_\_\_\_\_

Test Subject CPR No:	Project Number	Contact Person		
<b>Criteria for inclusion</b>			YES	NO
Youth aged 13-18 years with poorly controlled Type 1 Diabetes, defined by an average HbA1c $\geq$ 7,5.0% during the last year and the last measurement $\geq$ 8.0%				
Duration of Diabetes is minimum 1 year from starting the study				
One parent / guardian / other adult would like to participate in outpatient visits				
The youth does not have the possibility of having a parent or another adult / guardian attend outpatient visits				
The youth and participating parents / adults all speak, read, write and understand Danish				
<b>Criteria for exclusion</b>			YES	NO
Mental-health problems in the youth or in both parents				
Critical illness in the youth or parents				
Youth or parents is currently undergoing psychiatric/psychological treatment/examination				
Has participated in a preliminary trial course				
The youth or parent / guardian do not agree to participate				
<b>Participant acceptance</b>			YES	NO
Statement of Consent is signed by the contact person				
Statement of Consent is signed by the patient, who is above 15 years of age				
Acting Statement of Consent is signed by one of the parents/guardian for the patient who is under 15 years of age				
Statement of Consent for parent participation is signed by at least one parent				
Copies of the Statements of Consent are created and delivered to the patient and parents				
The original Statement of Consent is inserted in the journal				

Date: \_\_\_\_\_ Signature

HCP: \_\_\_\_\_

**Case Report Form for GSD-Y Visit (one sheet was filled in at each visit)**

Name: \_\_\_\_\_

Project no: \_\_\_\_\_ GSD-Youth: \_\_\_\_\_

Cpr. no. \_\_\_\_\_

Date: \_\_\_\_\_

Contact person: \_\_\_\_\_

Visit no.	Brought and completed sheets	Brought sheets but not completed. Will complete alone in the waiting room	Brought sheets but not completed. To be completed together with HCP.	Forgot the sheets	Forgot sheets. New sheets provided. Completed alone	Forgot sheets. New sheets provided. Completed together with med HCP.	Delivery of new sheets for Visit 2	Desires a break	Does not want additional sheets

Visit no.	Patient alone	Patient and both parents	Patient and mother	Patient and father	Patient and another	Parents alone	Mother alone	Father alone	Absent	Cancelled
Participants										

Visit no.	No. of hypo reactions * since previous visit	No. of keto with hospitalization since previous visit	Change of insulin type	Change of injection method, if yes, state change	Change of insulin Doses	Other

\* Mild (insulin-sensing) where the person feels the low blood sugar and can treat it, is recorded with the number 1

\* Moderate (insulin reaction) where the person can feel the low blood sugar, but needs help from others for treatment, is recorded with the number 2

\* Severe (insulin shock), when glucose levels are so low that the person is unconscious or has convulsions, is registered with number 3

## Case Report Form for control visits (one sheet was filled in at each visit)

Name: \_\_\_\_\_  
 Cpr. no. \_\_\_\_\_  
 Date: \_\_\_\_\_

Project no: \_\_\_\_\_ GSD-Y Control: \_\_\_\_\_  
 Contact person: \_\_\_\_\_

Visit no:	Patient alone	Patient and both parents	Patient and mother	Patient and father	Patient and another	Parents alone	Mother alone	Father alone	Absent	Cancelled
Participants										

Visit no.	No. of hypo reactions * since previous visit	No. of keto with hospitalization since previous visit	Change of insulin type	Change of injection method, if yes, state change	Change of insulin doses	Other

\* Light (insulin-sensing) where the person feels the low blood sugar and can treat it, is recorded with the number 1

\* Moderate (insulin reaction) where the person can feel the low blood sugar, but needs help from others for treatment, is recorded with the number 2

\* Severe (insulin shock), when glucose levels are so low that the person is unconscious or has convulsions, is registered with number 3

## **Appendix E**

Figure 1 Flowchart of study A

Figure 2 Randomisation period

Figure 3 HbA1c levels during the study

Table 1 Baseline Characteristics

Table 2a, 2b Withdrawal analyses

Table 3 Missing HbA1c values

Table 4a, 4b Secondary outcomes

Table 5 Hypoglycaemia rates and risks

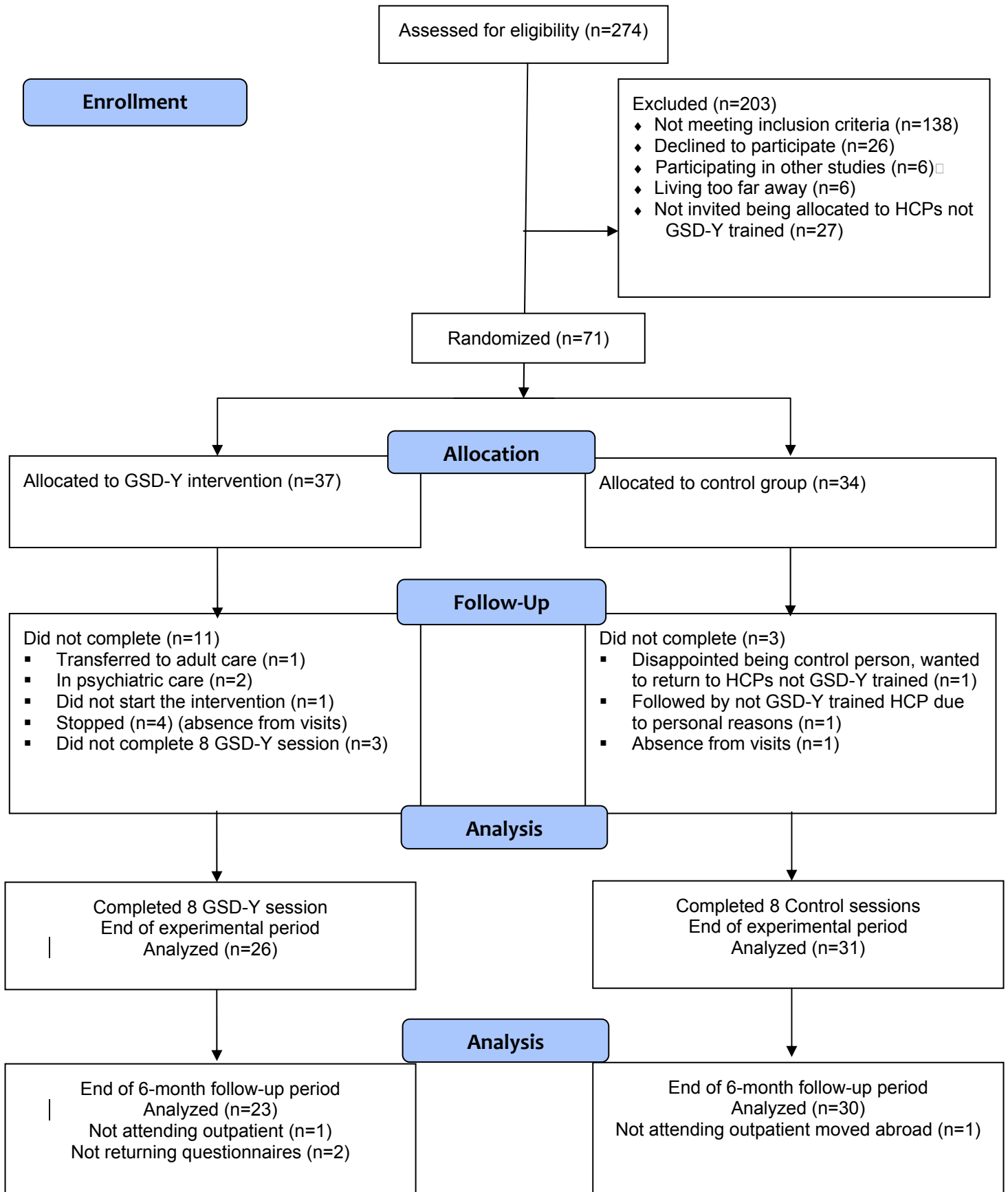
Table 6 Length of the study

Table 7 Number of visits per sessions

Table 8 Time from randomisation till first visit in the trial

Figure 1

### CONSORT Flow Diagram



**Figure 2** When each HCP passed the final fidelity tests and how long time it took for each HCP to enrol the adolescents in the study.

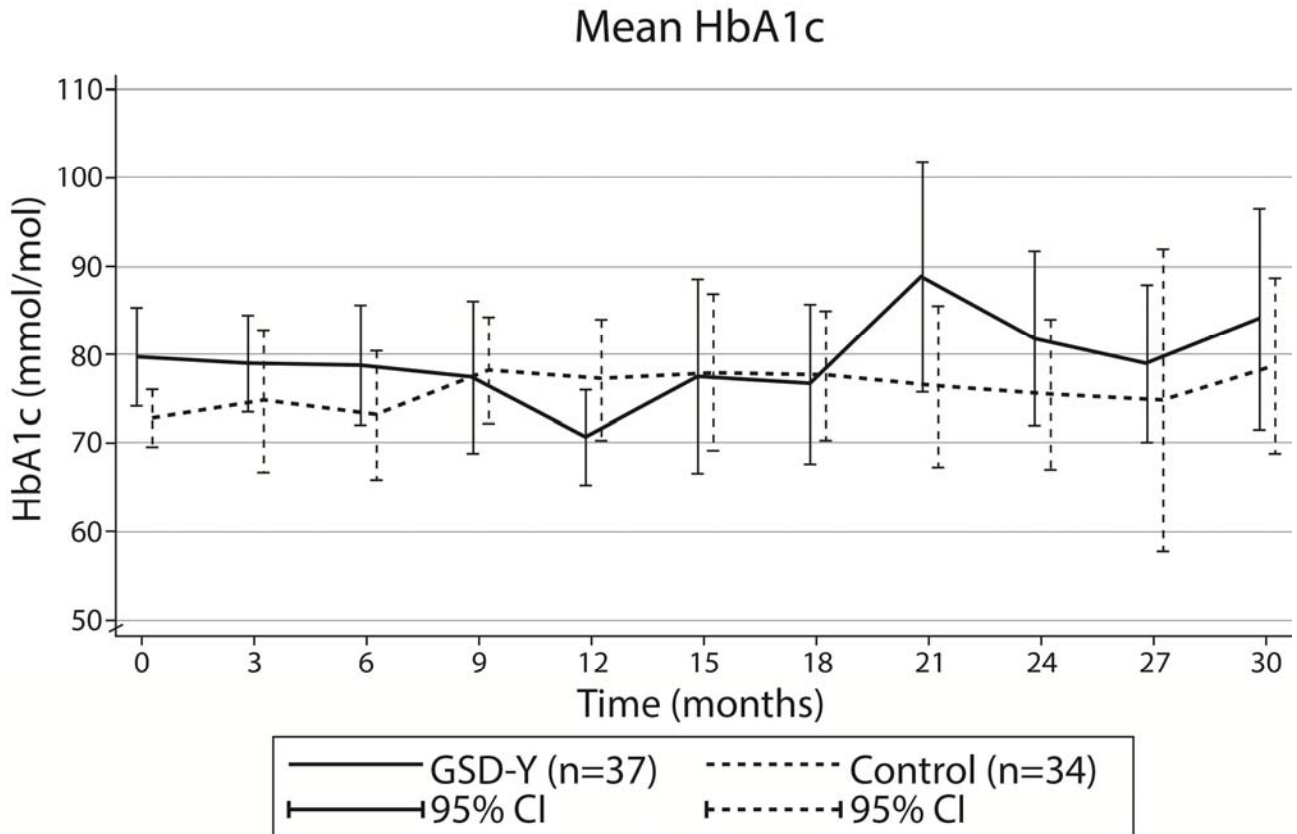
	2009					2010												In total
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
HCP1		1 Pt	1 Pt		1 Pt	2 Pt		1 Pt			1 Pt	1 Pt		1 Pt	2 Pt			<b>10 Pt</b>
HCP2	1 Pt	2 Pt	1 Pt	1 Pt		1 Pt		2 Pt						1 Pt				<b>9 Pt</b>
HCP3		1 Pt		2 Pt	1 Pt			2 Pt			2 Pt		3 Pt					<b>10 Pt</b>
HCP4	1 Pt	4 Pt	1 Pt	1 Pt	1 Pt		1 Pt		1 Pt					1 Pt				<b>10 Pt</b>
HCP5		1 Pt			5 Pt	3 Pt	1 Pt					2 Pt	2 Pt					<b>13Pt</b>
HCP6		4 Pt		1 Pt	1 Pt	1 Pt							1 Pt	1 Pt	1 Pt			<b>10 Pt</b>
HCP7					1 Pt		2 Pt				1 Pt		2 Pt	3 Pt		1 Pt		<b>9 Pt</b>
Dietician 1		1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt
Dietician 2			1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt	1 Pt

HCP: health care provider (physicians (5,6), nurses (1,2,3,4,7) and dieticians (1,2)) . Pt: number of patients enrolled

- The month in which each HCPs passed the final tests
- The number of patients randomised to the study in a specific month
- Dieticians did not enrol adolescents to the study, but should also pass the final tests

**Figure 3**

HbA1c levels in the GSD-Y and the control groups during 30 months of trial



The figure shows an error bar diagram of the mean of HbA1c (mmol/mol) as a function of time and the adolescents' group membership. It appears that the levels of the two groups are quite close and that both curves are relatively flat. This impression is confirmed by the results of the mixed-model analysis which showed that there was no significant difference between the mean HbA1c levels of the two groups,  $p$  of main effect of intervention = 0.86, no significant change over time in the mean values of the groups neither overall,  $p$  of main effect of time = 0.65, nor interaction between time and intervention,  $p$  = 0.55.



**Table 1 Clinical and demographic baseline characteristics of the adolescents.** GSD-Y: Guided Self-Determination-Youth group. CON: control group. SMBG: self-monitored blood glucose. MIT: multiple insulin injections. CSII: continuous subcutaneous insulin infusion. Data are presented as mean±SD (number of patients (%)).

	<b>GSD-Y</b>	<b>CON</b>
	<b>37</b>	<b>34</b>
n (% females)	22 (62)	21 (60)
Age (years)	14.9±1.5	14.6±1.3
BMI (kg/m <sup>2</sup> )	22.1±2.9	22.3±4.0
Age at onset of diabetes (years)	8.8±2.9	9.2±3.7
Duration of diabetes (years)	6.1±3.0	5.3±3.4
HbA1c (mmol/mol)	79.9±16.6	72.8±9.4
HbA1c (%)	9.5±3.7	8.8±3.0
SMBG (number per week)	28±14	33±18
Insulin dose (IU per kg per day)	1.2±0.6	1.0±0.5
MIT, n (%)	25 (68)	22 (65)
CSII, n (%)	12 (32)	12 (35)
Living with both parents, n (%)	16 (62)	21 (70)
Ethnicity		
Danish, n (%)	31 (84)	25 (74)
Other, n (%) *	6 (16)	9 (26)
Education		
Danish public school (0-10 grades), n (%)	23 (62)	25 (74)
Secondary education, n (%) **	8 (22)	5 (15)
Other schools, n (%) ***	6 (16)	4 (11)

\*Turkey, Somalia, Sweden, France, Russia, Morocco, Afghanistan, Poland, Tunisia, Pakistan

\*\*Gymnasium, Higher Preparatory Examination (HF), Higher Commercial Examination Program (HHX), Higher Technical Examination Program (HTX)

\*\*\*Continuation school

**2.a. Withdrawal analyses.** Baseline comparisons between GSD-Y adolescents who completed the intervention (n=26) and those who did not (n=11), and between Control adolescents who completed the control period (n=31) and those who did not (n=3).

	<b>GSD-Y 26</b>	<b>GSD-Y 11</b>	<b>p-value</b>	<b>Control 31</b>	<b>Control 3</b>	<b>p-value</b>
n (% females)	16 (62)	6 (55)	0.69	19 (61)	2 (67)	0.99
Age (years)	14.7 ± 1.4	15.5 ± 1.4	0.18	14.6 ± 1.3	14.7 ± 1.2	0.93
BMI (kg/m <sup>2</sup> )	21.8 ± 2.7	22.9 ± 3.6	0.32	22.2 ± 4	22.7 ± 5.8	0.97
Age at onset of diabetes (years)	8.3 ± 3.2	10.0 ± 1.8	0.04	9 ± 3.7	11 ± 3.6	0.34
Duration of diabetes (years)	6.4 ± 3.3	5.4 ± 2.3	0.50	5.5 ± 3.4	3.7 ± 2.9	0.30
HbA1c (%)	9.7 ± 1.8	9.5 ± 1.5	0.96	9.1 ± 0.9	9.4 ± 1.3	0.77
SMBG (number per week)	28 ± 14	33 ± 15	0.73	33 ± 19	42 ± 21	0.44
Insulin dose (IU per kg per day)	1.2 ± 0.6	1.2 ± 0.7	0.87	1.0 ± 0.5	1.1 ± 0.2	0.42
MIT, n (%)	18 (69)	7 (64)		19 (38)	3 (100)	
CSII, n (%)	8 (31)	4 (36)	0.74	12 (61)	0	0.18
Living with both parents, n (%)	16 (62)	7 (65)	0.90	21 (68)	3 (100)	0.54
Ethnicity						
▪ Danish, n (%)	22 (85)	9 (82)		25 (81)	2 (67)	
▪ Other, n (%) *	4 (15)	2 (18)		9 (29)	1 (33)	
Education						
▪ Danish public school (0-10 grades), n (%)	18 (69)	6 (55)		22 (71)	3 (100)	
▪ Secondary education, n (%) **	5 (19)	3 (27)		5 (16)		
▪ Other schools, n (%) ***	3 (12)	2 (18)		4 (13)		

SMBG: self-monitored blood glucose. MIT: multiple insulin injections. CSII: continuous subcutaneous insulin infusion. Data are mean±SD (number of patients (%))

Chi<sup>2</sup> tests were used for sex, living situation and treatment in the GSD-Y group while Fisher's tests were used for these variables in the control group. Mann Whitney tests were used for all tests in the GSD-Y and the control group except for diabetes at onset because a normal distribution was identified and t-tests were therefore chosen.

\* Turkey, Somalia, Sweden, France, Russia, Morocco, Afghanistan, Poland, Tunisia, Pakistan,\*\* Gymnasium, Higher Preparatory Examination (HF), Higher Commercial Examination Programme (HHX), Higher Technical Examination, Programme (HTX)\*\*\* Continuation school

**Table 2 b Withdrawal analysis of life skills scales**

Baseline comparisons between GSD-Y adolescents who completed the intervention (n=26) and those who did not (n=11), and between Control adolescents who completed the control period (n=31) and those who did not (n=3).

	<b>GSD-Y 26</b>	<b>GSD-Y 11</b>	<b>p-value</b>	<b>Control 31</b>	<b>Control 3</b>	<b>p-value</b>
PAID, MD, (scores 0-100)	28 (20-39)	21 (10-30)	0.13	27 (10-36)	10 (8-45)	0.80
HCCQ, MD,(scores 5-35)	32 (28-34)	32 (27-33)	0.99	31 (28-33)	34 (21-35)	0.49
PCD, MD (scores 5-35)	25 (20-28)	28 (20-32)	0.41	28 (22-32)	31 (25-34)	0.41
TSRQ, MD Autonomy (scores 8-56)	46 (39-50)	45 (43-50)	0.51	46 (39-50)	47 (43-50)	0.66
TSRQ, MD Control (scores 9-63)	44 (36-48)	33 (31-46)	0.12	39 (35-48)	38 (31-46)	0.66
TSRQ, MD Amotivation (scores 4-28)	12 (10-15)	9 (8-11)	0.10	10 (9-12)	8 (8-15)	0.64
TSRQ, MD Index Scores -51,-47))	3 ((-3)-6)	10 (4-15)	0.06	3 ((-2)-9)	8 (4-10)	0.25
POPS, MD Autonomy Mother (scores 7-49)	35 (30-38)	36 (32-40)	0.23	37 (32-41)	34 (28-35)	0.36
POPS, MD, Autonomy Father (scores 7-49)	34 (25-39)	35 (31-40)	0.50	35 (28-39)	37 (33-43)	0.32
POPS, Mean, Involvement Mother (scores 6-42)	33 ± 5.5	-	-	32 ± 5.2	-	-
POPS, Mean, Involvement Father (scores 6-42)	32 ± 8.1	-	-	29 ± 6.5	-	-
WHO5, MD, min/max scores (scores 0-100)	60 (52-72)	61 (40-80)	0.72	68 (48-76)	80 (72-84)	0.13

Data are median and range (number of patients (%))

Mann Whitney tests were used except for TSRQ Autonomy in the GSD-Y group because a normal distribution was identified and t-tests were therefore chosen

**Table 3 Missing HbA1c values**

Percentage of missing HbA1c values as a function of time of measurement (time) and the intervention group to which the adolescent was assigned. Overall 57% of the values planned to be measured are missing. A logistic regression of per cent missing values on time and intervention and their interaction showed that time and intervention did not interact ( $p = 0.75$ ). However, there was a significant main effect of time (the missingness increased with time,  $p = 0.039$ ) while the missingness was not related to the intervention ( $p = 0.12$ ).

Per cent missing HbA1c values as a function of intervention group and time of measurement relative to time of randomization<sup>a</sup>

<b>Time/month</b>	<b>GSD-Y</b>	<b>Control</b>	<b>Marginal means</b>
3	38%	71%	54%
6	57%	53%	55%
9	41%	56%	48%
12	60%	41%	51%
15	65%	59%	62%
18	54%	56%	55%
21	60%	59%	59%
24	65%	56%	61%
27	68%	68%	68%
30	60%	58%	59%
Total	57%	58%	57%

- a) Logistic regression of missingness (1 if value was missing and 0 otherwise) on time and intervention showed P of intervention = 0.12; P of time = 0.039. Interaction between time and intervention was not significant (P = 0.75)

**Table 4a. Results of the life skills questionnaires.** The results were taken at baseline, at the end of intervention, and at the end of the 6-month follow-up period in the Guided Self-Determination-Youth group (GSD-Y) and in the treatment as usual control group (CON). Data are presented as means±standard errors (SE) (number of patients).

Quantity	Min-max Scores	Baseline		End of intervention		End of follow-up	
		GSD-Y	CON	GSD-Y	CON	GSD-Y	CON
PCD	5-35	24±1.1 (37)	26±1.0 (34)	26±1.3 (26)	28±0.9 (30)	28±1.3 (23)	28±1.3 (30)
HCCQ	5-35	31±0.6 (37)	30±0.9 (34)	32±0.8 (26)	31±0.6 (30)	32±1.3 (23)	31±1.1 (30)
TSRQ autonomy	8-56	45±1.1 (37)	44±1.3 (34)	47±0.95 (26)	43±1.3 (30)	46±1.3 (23)	44±1.3 (29)
TSRQ control	9-63	40±1.4 (37)	41±1.7 (34)	40±1.5 (26)	41±2.1 (30)	37±2.3 (23)	40±2.1 (29)
TSRQ amotivation #	4-28	11±0.6 (37)	11±0.6 (34)	9.1±0.7 (26)	11±0.9 (30)	8.6±0.9 (23)	11±0.8 (29)
TSRQ autonomy index (autonomy – control)	-51- +47	4.8±1.6 (37)	3.6±1.3 (34)	6.9±1.4 (26)	1.6±1.3 (30)	9.0±2.2 (23)	3.8±2.1 (29)
POPS autonomy support mother	7-49	35±1.0 (35)	35±1.3 (34)	37±1.5 (24)	35±1.3 (24)	40±1.2 (21)	37±13 (29)
POPS autonomy support father	7-49	34±1.5 (33)	33±1.3 (32)	36±1.8 (24)	34±1.5 (24)	36±2.1 (21)	33±1.7 (29)
POPS involvement mother	6-42	33±1.0 (34)	32±0.8 (34)	34±1.6 (24)	33±1.2 (30)	36±1.2 (21)	33±1.1 (29)
POPS involvement father	6-42	31±1.6 (32)	28±1.1 (32)	31±1.8 (24)	30±1.4 (28)	32±1.8 (21)	29±1.4 (29)
PAID	0-100	29±2.3 (34)	24±3.1 (34)	28±3.3 (26)	28±4.0 (29)	26±3.6 (22)	22±3.5 (30)
WHO5 index	0-100	60±2.8 (36)	66±3.3 (34)	60±4.2 (26)	61±3.6 (30)	56±4.8 (23)	62±3.4 (30)

# p=0.0013 by mixed model analysis; family-wise error controlled by Holm's method (Bretz F, Hothorn T, Westfall P. Multiple comparisons using R CRC: Press Chapman & Hall; 2011). (ref number in thesis: 150 )

**Table 4b.** Results of the mixed model analyses with repeated measures of primary and secondary outcomes. P of (1) main effect of project, of (2) main effect of follow-up, of (3) project dependent effect of follow-up and of (4) main effect of professional health care person is shown. Results obtained when the analyses are adjusted for effect of professional (Prof) and of baseline value.

Outcome	Project <sup>a</sup>	Follow-up	Project*Follow-up	Professional <sup>a</sup>
Log(HbA1c) <sup>b</sup>	0.85	0.10	0.68	0.038
Blood sugar measurements in one week <sup>b</sup>	0.94	0.97	0.95	0.87
PAID <sup>b</sup>	0.85	0.31	0.64	0.27
HCCQ <sup>c</sup>	0.81	0.76	0.99	0.40
PCD <sup>c</sup>	0.32	0.82	0.089	0.045
TSRQ auto <sup>d</sup>	0.017 <sup>e</sup>	0.93	0.64	0.11
TSRQc ontrol <sup>d</sup>	0.48	0.17	0.80	0.47
TSRQa mot <sup>d</sup>	0.0010 <sup>f</sup>	0.94	0.52	0.14
TSRQautoindex <sup>d</sup>	0.020 <sup>e</sup>	0.20	0.98	0.89
POPS-auto-mother <sup>d</sup>	0.036 <sup>e</sup>	0.07	0.66	0.48
POPS-auto-father <sup>b</sup>	0.068	0.52	0.11	0.87
POPS-inv-mother <sup>d</sup>	0.23	0.34	0.32	0.37
POPS-inv-father <sup>d</sup>	0.51	0.98	0.63	0.76
WHOS <sup>d</sup>	0.71	0.61	0.37	0.05

- a) If P of follow-up and P of Project\*follow-up were both > 0.05 then the analysis was repeated without the terms Project and Project\*follow-up included in the model. In that case it is the P value from the latter analysis that is shown in the column
- b) Four distributions were examined: at end of study in each intervention group and at end of follow-up in each intervention group. In each group the normality was tested using Shapiro Wilk's test ( $p \leq 0.01$ ). One of the four distributions differed significantly from normality. But it was judged from a graphical analysis that the approximation to normality was reasonably good
- c) More than one of the four distributions examined (see footnote b) differed significantly from normality. The approximation to normality was deemed poor. As a sensitivity analysis a non-parametric test (Mann-Whitney) comparing the distributions between the intervention groups at end of intervention and at end of follow-up was done. In all cases P was  $\geq 0.10$
- d) Using Shapiro Wilk's test none of the four distributions (see footnote b) differed significantly from normality
- e)  $P < 0.05$  before Holms test

- f)  $P < 0.00128$  (To preserve a family wise error rate of less than 0.05 the significance level is adjusted to 0.00128 using Holm's test)



**Table 5. Hypoglycaemia event rates.**

Comparison between the intervention groups of the distributions of the event rates of various types of hypoglycaemia experienced during the intervention period. For each of the four hypoglycaemia categories the distributions of the rates were defined as the number of events over the time of observation/day are compared between the groups using a non-parametric test (Mann-Whitney).

Type of hypoglycaemia	Intervention group	N	Mean rate	Maximum rate (minimum rate always 0.0000)	P of Mann-Whitney test
All	GSD-Y	26	0.0026	0.0140	0.80
	Control	30	0.0070	0.1040	
Severity 1	GSD-Y	26	0.0023	0.1000	0.80
	Control	30	0.0070	0.1000	
Severity 2	GSD-Y	26	0.00037	0.0042	0.34
	Control	30	0.00029	0.0060	
Severity 3	GSD-Y	26	0.00027	0.0023	0.34
	Control	30	0.00015	0.0029	

**Hypoglycaemia risks.**

Comparison of the risk of experiencing each of three types of hypoglycaemia (graded according to increasing severity) and any hypoglycaemia irrespective of severity between the intervention groups

Type of hypoglycaemia	Group	N (% risk)	Relative risk <sup>a</sup> (adjusted estimate) <sup>b</sup> (95% CI)	P of Cochran Mantel-Haenszel test
All	GSD-Y	13 (50)	1.15 (0.87) (0.66 to 2.02)	0.62
	Control	13 (43)		
Severity 1	GSD-Y	10 (39)	0.96 (0.72) (0.50 to 1.85)	0.91
	Control	12 (40)		
Severity 2	GSD-Y	4 (15)	2.31 (1.74) (0.46 to 11.6)	0.30
	Control	2 (7)		
Severity 3	GSD-Y	4 (15)	2.31 (1.74) (0.46 to 11.6)	0.30
	Control	2 (7)		

a) Risk of GSD-Y group/risk of Control group

b) If one were to assume that the risk of experiencing at least one attack was directly proportional to the length of observation and one was to correct the point estimates accordingly using the mean length of the intervention period (see table 6) the risk of the GSD-Y group should be adjusted by  $458/608 = 0.753$ . This would result in a relative risk of  $50 \bullet 0.753/43.3 = 0.87$  in row 2 etc.

Severity 1: Mild (insulin-sensing) where the person feels the low blood sugar and can treat it

Severity 2: Moderate (insulin reaction) where the person can feel the low blood sugar, but needs help from others for treatment

Severity 3: (insulin coma), when glucose levels are so low that the person is unconscious or has convulsions

**Table 6** Comparison of the distributions of length/day of periods (intervention/control period and follow-up period) between the GSD-Y and the Control group

Period	Intervention group	Mean	SD	10 Percentile (PC)	25 PC	50 PC	75 PC	90 PC	P of difference
Intervention	GSD-Y	608	125	412	525	604	675	788	< 0.0005
	Control	458	111	322	362	435	540	631	
Follow-up	GSD-Y	216	59	161	182	203	231	327	0.14 <sup>a</sup>
	Control	246	83	160	183	229	300	403	

- a) P of t-test. Since P of Levene's test for equal variances was 0.06 for the follow-up period unequal variances were assumed in the t-test

**Table 7.** Overview of number of visits used per session in the GSD-Y and the control group to complete the trial.

Group	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8
<b>GSD-Y</b>								
Number of visits per session	1.4 ± 0.9	1.4 ± 1.0	1.3 ± 0.6	1.3 ± 0.7	1.9 ± 1.1	1.9 ± 1.2	1.6 ± 0.8	1.2 ± 0.7
<b>Control</b>								
Number of visits per session	1.0 ± 0.0	1.0 ± 0.1	1.0 ± 0.2	1.0 ± 0.0	1.0 ± 0.0	1.1 ± 0.3	1.0 ± 0.0	1.3 ± 0.7

Values are presented as mean ± standard deviation.

The table shows that especially GSD-Y session 5 and 6 required more visits than the other sessions. At session 5 & 6 the reflection sheets concerning dynamic problem-solving are discussed.

**Table 8.** Time since randomisation date till each group had their first visit in the trial

Group	Duration in days from randomisation till the first visit
<b>GSD-Y group N=37</b>	55 ± 36
<b>Control N=34</b>	61 ± 38

Values are presented as mean ± standard deviation.

The control group took longer time to get to their first visit since randomisation time

## **Appendix F**

Flowchart of participants and data collection and sources of study B

Interview guides

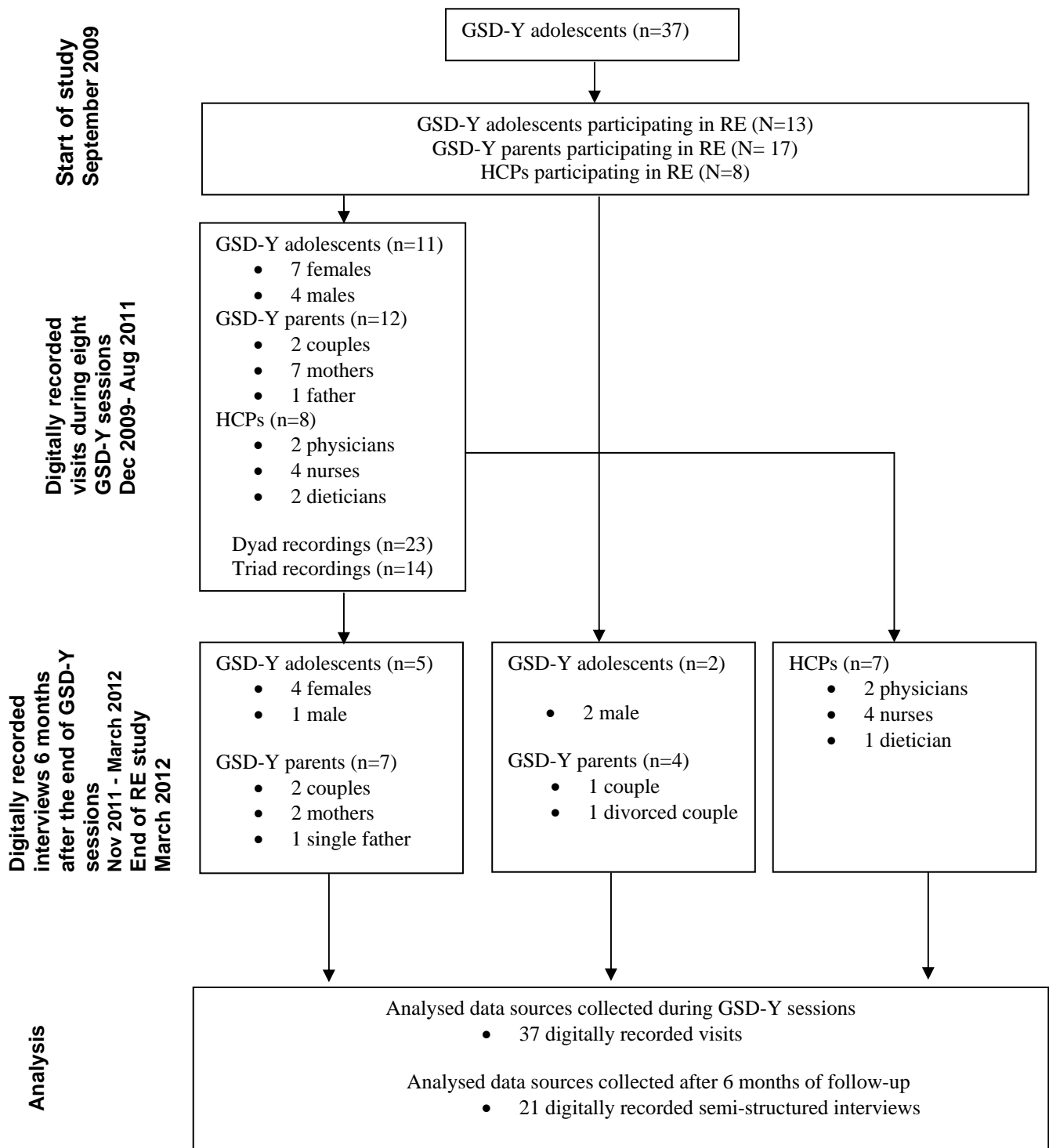
Table showing the Context, Mechanism and Outcome configurations

Example of analysis process

Figure of findings

HbA1c levels

**Figure 2. Overview of the study period, participants and data sources used for the qualitative, realistic evaluation of the GSD-Y.**



Dyads: adolescents and health care providers

Triads: adolescents, mother and/or father and health care provider

RE: realistic evaluation

## **Interviewguide adolescents**

What is the first thing that comes to your mind when you think back upon your participation in the project?

How have you experienced participating in this project?

In the questionnaire your answer to this question was ..... - can you say something more?

Can you give an example of this?

## **Reflection sheets**

When you look at your reflection sheets again what is the first thing that comes to your mind

Pros and cons in using them– can you give some examples

Have some sheets been more important to you than others – examples

Have you discovered anything new about yourself that you had not thought about previously – an example?

What do you think about filling them out beforehand – what was your experience?

What do you think about the amount of sheets?

If you were to point out some sheets that could be spared - which one would it be?

## **Cooperation with HCPS**

Is there any difference for you in attending outpatient visits compared to previously

– examples?

Does using sheets make any difference for you in the outpatient visits compared to previous visits without?

Pros and cons in using sheets at visits – examples?

Can you give an example of a concrete thing that has changed after using the sheets?

Did you discover any differences for your HCPs in using reflection sheets – if in what way?

What do you do if you do not agree with your HCPs now? What did you do previously – an example?

## **Cooperation with parents**

How much did your parents participate in the GSD-Y program?

Pros and cons for you in the way they participated? - and for them? – examples?

Have you discovered anything new about your parents?

What do you do e.g. if you need help to manage high numbers - an example

What do you do if you do not agree with your parents' advice – an example

Do you experience that your and your parents' participation in GSD-Y have influenced the way you interact concerning your diabetes today?

Can you give an example of a concrete thing that has changed?

## **Cooperation with peers**

When I look at your reflection sheets, I can see, that you worked on changing how to manage diabetes when e.g., together with your friends /at school– can you say something more about it?

Can you give an example of how it worked out?

## **Autonomous motivation for blood sugar measurement and management**

When is it important to you to know your numbers?

Who decides when you do blood sugars - is that different from previously?

How do you use your results – an example?

When I look at your HbA1c results during the program it has changed from x till y

What do you think is the reasons for this change?

What have you missed in the project?

Is there anything you want to tell before we stop the interview?

### **Interviewguide Parents**

What is the first thing that comes to your mind when you think back upon your own participation in the project?

What is the first thing that comes to your mind when you think back upon your son/daughters participation in the project?

In the questionnaire your answer to; '*Do you have any comments about your or your teenager's participation in the project?*' was ..... - can you say something more  
Can you give an example of this?

### **Reflection sheets**

When you look at your reflections sheets again what is the first thing that comes to your mind

Pros and cons in using them – can you give some examples?

Have some sheets been more important to you than others – examples?

What do you think about the amount of sheets?

Have you discovered anything new about yourself that you had not thought about previously – an example?

### **Cooperation with HCPs**

How did you experience your own GSD-Y visits?

Was there any difference in your cooperation with HCPs compared to previous visits – examples?

Pros and cons – examples

How much did you participate in your son/daughters visits?

Pros and cons – examples?

How did you experience your son/daughter's interaction with HCPs during the project compared to previously?

Pros and cons for him/her and for you – examples?

Have you discovered anything new about your son/daughter which you had not thought about previously – an example?

### **Autonomy support in cooperation with son/daughter**

What do you do if she/he asks for help e.g. managing high numbers - an example?

What do you do if you e.g. do not agree with your son/daughter's way to handle her diabetes – an example?

Who decides e.g. when he/she does blood sugars - is that different from previously?

How does he/she use the results – an example?

Can you tell me if you experience that you and your son/daughter's participation in the project have influenced your ability to support him/her to live with diabetes today?

Can you give an example of a concrete thing that has changed?

When I look at your son's /daughter's HbA1c results during the program it has increased/decreased from x.x till y.y

What do you think are the reasons for this change?

Have you any idea why the project helped/ did not help?

Is there anything you have missed in the project being a parent to a teenager with diabetes?

Is there anything you want to tell before we stop the interview?

### **Interview HCPs**

What is the first thing that comes to your mind when you think back upon your participation in the project (GSD-Y)?

What is the biggest difference for you doing GSD-Y visits compared to usual visits?

Can you give an example?

What is the best in using GSD-Y – an example?

What is the worst in using GSD-Y – an example?

### **Reflection sheets**

When you look at his/hers reflections sheets again what is the first thing that comes to your mind?

What is the difference for you using sheets in outpatient visits compared to usual visits?

Pros and cons in using reflection sheets - can you give some examples?

Pros and cons for adolescents in using them - can you give some examples?

Have some sheets been more important to you than others?

Have some sheets been more important to him/her and their parents than others?

Have you discovered anything new about him/her which you had not known before – an example?

Your experience, concerning the amount of sheets and filling in beforehand?

### **Cooperation with adolescents and autonomy support**

How would you describe your interaction with adolescents when running GSD-Y visits compared to usual visits - examples of efficient and non-efficient interaction?

When he/she measures blood today, who do you think takes the initiative?

How do you experience that he/she uses the results – an example?

What do you do if you e.g do not agree with the adolescent's way of handling diabetes – an example?

When I look at his/hers HbA1c/scores results during the program it has changed from x.x till y.y

Have you any idea why the project helped/ did not help on this?

### **Cooperation with parents**

GSD-Y parents were offered 2 visits using specific sheets for these visits – what is your experience from these visits?

Pros and cons of parents visits – examples?

When you look at their reflection sheets – what comes to your mind?

When you think back - have you discovered anything new about the parents, which you had not known before – an example?

How would you describe your interaction with the parents?

How would you describe parental GSD-Y visits' influence on cooperation patterns between GSD-Y adolescents and their parents in your opinion – e.g. blood sugar measurements?

### **Cooperation with peers**

When I look at the reflection sheets, I can see, that some of the topics you and xx have focused on are how to manage diabetes e.g., when together with friends /at school

Can you give an example of how you worked on it?

### **Overall evaluation and self-assessment**

Overall, do you think it has had any impact on patients' self-management skills and parents' involvement having participated in GSD-Y?



If you look at your own performance in supporting your patients and parents – do you consider that your professional scope to act upon has become different using GSD-Y – an example?  
Did following the GSD-Y programme prevent you from doing things that you wanted to do? –an example?  
Do you prefer the conventional way to run the visits?

To what extent do you find that you have been able to exploit possibilities provided by the GSD-Youth method in connection with your patient-cases?  
What would it require for you to be able to use the method 100%?

Adolescents answered an open-ended question in the questionnaire formulated; ‘How has your experience participating in this project been?’ The answers from your adolescents were .....  
What do you think about their answers?

Their parents also answered an open-ended question in the questionnaire formulated ‘Do you have any comments about your or your teenager’s participation in the project?’  
What do you think about their answers?  
How do you interpret their answers?

Some parents have told that they have experienced that their adolescents have matured due to the project. Some adolescents have stressed that they have started to accept diabetes as a part of them – what are your comments to this?

Is there anything you want to tell before we stop the interview?

Eight conjectured CMO configurations proposed prior to the intervention, including the eight life skills outcomes (1-8), ordered chronologically according to when they were expected to appear during the process of change.

CMO	Context identified through previous research	Enabling mechanisms activated by GSD-Y	Expected life skills outcomes
CMO-1	Content of outpatient visits are predetermined by the HCPs' routines in conducting outpatient clinics.	When filling in reflection sheets, adolescents increase their readiness to participate actively in own visits. They become aware of and clarify concrete topics they want to talk about.	1) Adolescents are conscious about what they want to talk about at the outpatient clinics.
CMO-2	Adolescents often have difficulties in communicating openly and honestly with HCPs and parents because they are aware that they do not always manage their diabetes as they are told.	By writing down or drawing their thoughts and feelings, adolescents are enabled to express them. Unexpected insight into each other's perspectives by sharing thoughts, feelings and observations gives mutual understanding and respect.	2) Adolescents communicate openly and honestly with HCPs and parents.
CMO-3	Adolescents do not always perceive HCPs and parents as collaborative partners when having difficulties in managing diabetes.	Good experiences from mutual reflection with HCPs and parents increases the adolescents' readiness to listen to them and benefit from their input.	3) Adolescents are conscious of parents' and HCPs' resources and take advantage of these resources in learning self-management of diabetes.
CMO-4	Adolescents often have difficulties in managing diabetes when with friends, at school or away from home because they avoid being perceived as different from their peers.	Through mutual situational reflection, adolescents share concrete difficulties in daily life with HCPs. Through shared insight into the difficulties, new ideas for solutions appear - ready for agreement on experiments.	4) Adolescents prevent or resolve conflicts or problems with diabetes in daily life outside the home or at home with support from parents and HCPs.
CMO-5	To be liked by others, adolescents might ignore or deliberately choose not to measure blood sugar or take insulin.	Through mutual reflection together with HCPs, adolescents train their ability to communicate about their own barriers to measure blood sugar and take insulin in front of their peers in daily life situations.	5) Adolescents have insight into new ways to handle situations and relate constructively to the disease and their own reactions. They now explain reasons for diabetes actions to their friends.
CMO-6	Goals for blood glucose and HbA1c are mostly defined by HCPs or parents and seldom decided in a concordant way by the adolescents.	Insight into own values and reasons to accomplish good glycaemic control combined with clearly translated evidence makes it easier for the adolescents to pose self-concordant goals for HbA1c .	6) Adolescents express their own goals for blood glucose and HbA1c.
CMO-7	HCPs and/or parents are striving for good glycaemic control. Therefore, they may unwillingly obstruct the adolescents' development of autonomous motivation and instead potentially foster passivity, ill health and lack of motivation.	Shared insight into own reasons for wanting or not wanting to change diabetes management patterns makes it easier to overcome barriers in each adolescent's life.	7) Adolescents develop autonomy-based motivation for blood glucose measurement, registration and regulation (HbA1c decreases).
CMO-8	Conflicts between life and disease both within and between adolescents, parents and HCPs are often not identified or solved at outpatient clinic visits.	Shared insight into person-specific life-disease conflicts and a mutual approach to problem solving help resolve conflicts.	8) Adolescents start to integrate the disease into their lives.

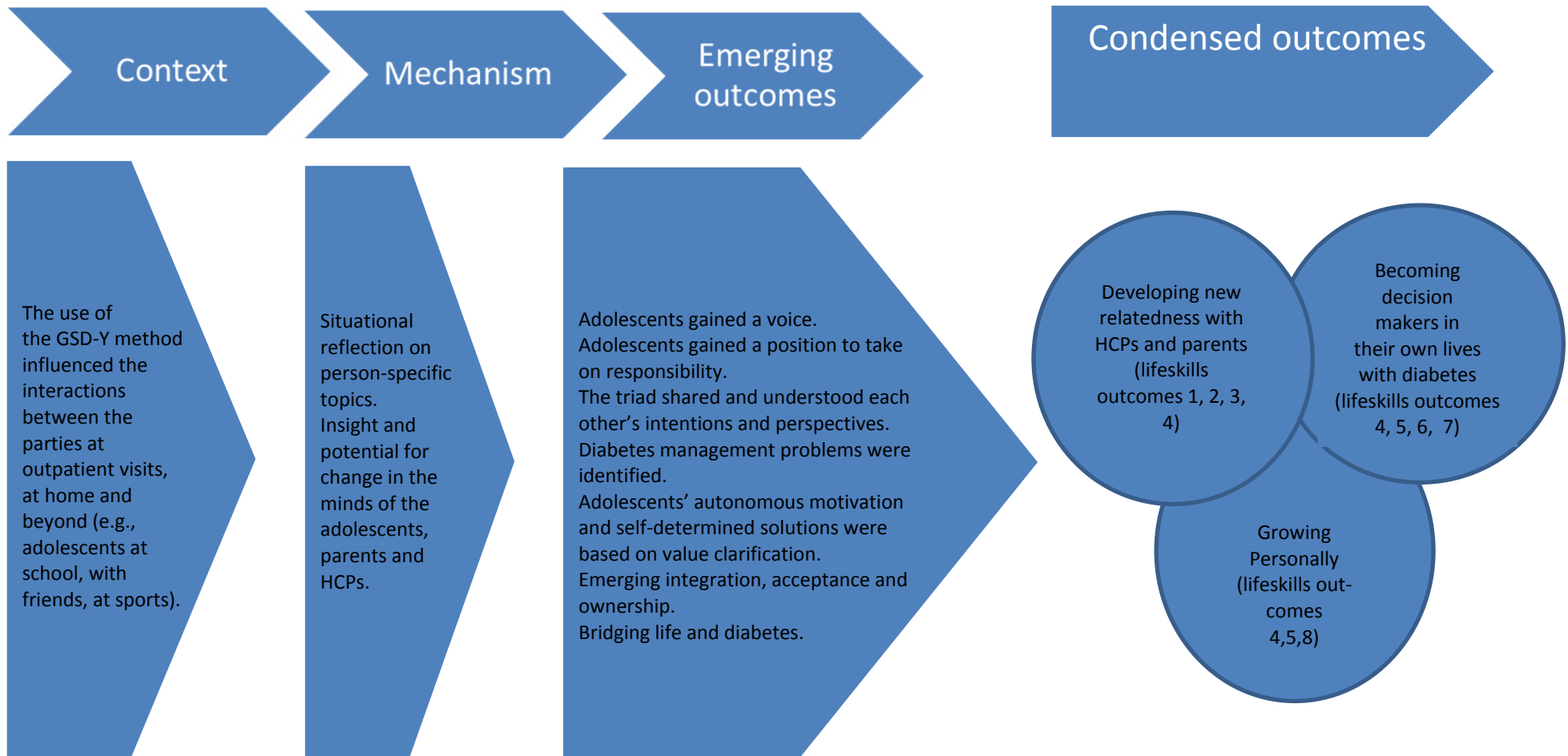
CMO: C = context, M = mechanism, O = outcome

An example of the analysis process of CMO-2, adolescents communicating openly and honestly with HCPs. The table illustrates what worked for whom, in what circumstances and how. CMO: Context, mechanism and outcome.

CMO-2	Context before experiences by participant	Constraining mechanisms	Enabling mechanisms	Context after experiences by participants	Codes	Emerging outcomes	Condensed outcome
Adolescents are able to communicate openly and honestly with HCPs	<p>I had a kind of feeling that they [the nurse and the physician] had read a book about what it was like to have diabetes. Well, it's so and so, to control it (A1)</p> <p>Before it was just more a general talk with her [nurse] (A13)</p> <p>I felt like a patient and not a human person (A2)</p> <p>She [Physician] did not talk to me; it was more orientated towards my parents (A12)</p>	<p>Not person-specific problem-solving attitude</p> <p>Controlling language</p> <p>Not being invited to participate in dialogue</p> <p>Not being seen as the person they felt they were</p> <p>Not being invited to participate in dialogue</p>	<p>Reflection sheets in combination with advanced communication skills created the conditions for activating situational and mutual reflection, leading to shared insight into adolescents' way of managing daily challenges</p> <p>Feeling being taken seriously</p> <p>Honest communication</p> <p>Insight into each other's intentions and perspectives</p> <p>Active in own visits</p> <p>Feeling ownership of problems</p> <p>Shared reflection and focused communication</p>	<p>Now it is much more like a conversation than just someone [nurse or physician] who sits and dictates you (adolescent) (A1)</p> <p>It becomes more on their own terms rather than just me shoving it down their throats (HCP1 nurse)</p> <p>Now it is more specific to my condition and problems (A13)</p> <p>It's not me who needs to solve the problems – it's their problems (HCP2 nurse)</p> <p>We became much closer to each other. Now she [HCP1 nurse] was not only my nurse. She was also familiar with me and interested in what was best for me (A2)</p> <p>So it relates more to the young person's problem than it does to my own need to inform (Dietician)</p> <p>The last few times, I was the one who said, 'Today I would like to talk about this and that' (A1)</p> <p>I had [previously] spoken with the mother and father, so he did not really participate. But here (during the project) he was the one who presented what he had thought about at home. He was the one who came with proposals (HCP6 physician)</p>	<p>From monologue to dialogue</p> <p>From isolated thoughts to sharing thoughts</p> <p>From resistance to starting to consider different diabetes management solutions</p>	<p>Giving voice to adolescents and HCPs</p> <p>Adolescents gain a position to take on responsibility</p> <p>Sharing and understanding each other's intentions and perspectives</p>	Developing new relatedness with HCPs

**Figure of findings.**

The figure illustrates how the use of GSD-Y was found to influence the interaction between the participants. The emerging outcomes were condensed into three main outcomes. The predefined eight life skills outcomes (1-8) were connected to the three condensed outcomes as shown in the circles. The circles illustrate that the condensed outcomes influenced each other in the development of life skills by the adolescents.



**Table 6.** Overview of adolescents who participated in the qualitative realistic evaluation. HbA1c levels are shown at baseline end of trial, and at six-month follow-up. Number of visits and months spent to complete eight GSD-Y sessions for those who participated in interviews is shown. Number of collected digital recordings from each adolescent's during the intervention period and individual interviews are given.

Pt	Sex	HbA1c baseline mmol/mol	HbA1c end of GSD-Y mmol/mol	HbA1c at 6 months follow-up mmol/mol	No. of visits to complete 8 GSD-Y sessions/in months	No. digital recordings with nurse or physician	No. digital recordings with dietician	Interview with adolescent	Interview with **M/F	Interview with HCPs
A1	F	63	62	83	12/20	3	1	Yes	M	HCP1
A2	F	68	68	70	11/16	1	0	Yes	M+F	HCP1
A3	M	78	*	*	*	3	0	No	No	HCP5
A4	F	65	78	75	14/20	2	0	Yes	M+F	HCP2
A5	F	65	60	58	9/11	1	0	Yes	M	HCP3
A6	F	78	*	*	*	3	0	No	No	–
A7	F	73	*	*	*	3	2	No	No	–
A8	F	69	*	*	*	3	3	No	No	–
A9	M	125	*	*	*	2	0	No	No	–
A10	M	81	*	*	*	2	2	No	No	–
A11	M	144	105	107	12/19	3	3	Yes	F	HCP2 & Dietician 2
A12	M	77	73	69	9/14	0	0	Yes	M+F	HCP6
A13	M	67	74	75	8/17	0	0	Yes	M+F	HCP4

Pt= A1 and so forth is a code for the participating adolescents. These numbers are equal to the numbers in Paper III.

\* Adolescents who had not completed their sessions when interviews started, \*\* M = mother, \*\* F = father.

HCP1 is mentioned twice in connection with interview but interviewed once and talked about all the adolescents she had had during the trial.

## **Appendix G**

Information booklet for adolescents

Information booklet for parents

Consent forms

Invitation to participate in interviews

**Information for Youth 13-18 years of age regarding the research project:**

**Guided Self-Determination-Youth  
at the Hospitals of Hillerød and Glostrup**



**What we offer**

We invite you to participate in a research project developed to investigate whether teenagers and their parents can get better support to live with diabetes in their daily lives, and additionally achieve improved long-term test results, when the diabetes staff work with you in an alternative way.

**What is Guided Self-Determination-Youth**

Guided Self-Determination-Youth (GSD-Youth) is a new way to collaborate during visits to the diabetes outpatient clinic. GSD-Youth will help you and us to identify your and your parents' main challenges or problems in an everyday life with diabetes. The Guided Self-Determination-method has been tested on adults with Type 1 Diabetes. These participants improved the quality of living a life with diabetes and achieved better long-term test results.

We have now retailored the method to match youth, in collaboration with 22 youths aged 13-18 years, all with Type 1 Diabetes, and their parents. All of these participants are connected with the children's diabetes outpatient clinics of Glostrup and Hillerød.

### **Who can participate?**

The participants in this research project are composed of 68 youth with Type 1 Diabetes aged 13-18 years and their parents from Glostrup and Hillerød Hospitals' children's diabetes outpatient clinics. You have been chosen because you have been a Type 1 Diabetes patient for at least one year and have had a long-term average blood glucose (HbA1c) of 7.5 or above during the past year and above 8.0 registered at the last measurement.

### **What does your participation involve?**

You and the 67 other participants will be divided into two equal groups. The groups are created completely at random, and the group you and your parents join will be totally based on which envelope you pick out at the outpatient visit. No matter which group you join, you and your parents will meet your permanent diabetes staff at your outpatient visits.

**One of the groups** will be offered the Guided Self-Determination-Youth method (GSD-Youth). This means that before, and between outpatient visits, you must fill out and complete various sheet-forms about your thoughts and experiences in relation to your life with diabetes. Additionally, your parents will fill out various sheets about their thoughts and experiences in relation to being parents of a teenager with diabetes. The sheets will help you, your parents, and the diabetes staff to detect and focus on the things that, in your specific situation, are difficult or challenging in your everyday life.

Conversations taking place during outpatient visits will build on the answers in the sheets. The visits will encompass a number of types:

- You and your parents speak with the diabetes staff together
- You speak alone with the diabetes staff
- Your parents speak alone with the diabetes staff two times.

We expect each visit to last approximately one hour.

**The second group of teenagers and parents** are offered outpatient visits as they are accustomed to, i.e., both the content and the length of their visits remain the

### **What does it require of you to participate**

**No matter which group you belong to**, you must make sure that you come to 8 outpatient visits over the next year. The first 4 visits take place approximately every 4th to 6th week, and the remaining four visits approximately every second month.

Visits are determined from each visit to the next so they fit your schedule, your parents' schedules, and that of the diabetes staff.

### **Does Guided Self-Determination-Youth work?**

In order to determine if the GSD-Youth approach works, the diabetes personnel collects information via a questionnaire and measures and records the long-term test (HbA1c) as usual during the coming year. At the end, results from the group applying the GSD-Youth approach are compared to results from the group that continued with the normal outpatient visits. This means that no matter which group you belong to, you must give your consent that you will:

- Participate in the project
- Participate in a survey today, right after completion of the project, and 6 months after completion of the project.



- Allow your long-term blood sugar results (HbA1c) to be measured and recorded today, and at least every 3 months during the next year and a half .

In addition to the above, the group that is offered Guided-Self-Determination-Youth, may be asked:

- To allow 1 or 2 of the outpatient visits during the next year to be audio-recorded by the diabetes staff.
- That you and your parents may be interviewed separately, after the end of the project, at a time that suits both you and the project leader Gitte R. Husted.

If the method displays positive effects, the group that did not apply the method will be offered a Guided Self-Determination-Youth course at the end of the research period.

### **Does participation pose any risks?**

We have judged that there will be no risks to you by participating in this research project. Previous application of the method on adults with Type 1 Diabetes has helped them to achieve better quality of everyday life with diabetes plus a lower long-term blood sugar.

### **What do you get?**

You are helping to test if a new method works to help youth with Type 1 Diabetes. Your involvement can enable diabetes staff to discover if there is an alternative way to help you and your parents to live with diabetes in your everyday lives and thereby provide you, and future families, the support they need during the teenage years. If the method works, the knowledge and experience gained through the participation of you and your parents will enable other children to use the method in diabetes outpatient clinics in Denmark. The content of your conversations about diabetes with staff, including responses to the questionnaires, will remain anonymous and will not identify you when the project's results are communicated.

The results will be published both in English and Danish journals. Diabetes staff and patient groups will be offered training in how to use the method.

### **Your rights and your parents' rights as participants in the project:**

- Participation is completely voluntary and can only start after you have received both written and oral information about the research project from the diabetes staff and have signed a consent form
- You may at any time withdraw from the research project, even after you have given your oral or written consent for participation. Withdrawal from the research project will have no impact on your future engagements in the diabetes outpatient clinic
- All information you provide that appears in the research project is subject to confidentiality
- Storage of information about you is subject to laws concerning the processing of personal data and the laws defining patients' legal status.

We hope that this written information has given you sufficient insight into what it means to participate in this research project. If you would like to know more, please feel very welcome to contact one of the following persons:

#### **Glostrup**

Departmental Staff Physician Ph.D. Jannet Svensson, Children's Diabetes Outpatient Clinic Glostrup, tlf. 43233023

Staff Nurse Jeanne Maibom, Children's Diabetes Outpatient Clinic Glostrup, tlf. 43232987

#### **Hillerød**

Departmental Staff Physician Lene Lyngsøe, Children's Diabetes Outpatient Clinic Hillerød, tlf. 48297157

Staff Nurse Susanne Lisbjerg, Children's Diabetes Outpatient Clinic Hillerød, tlf. 48294321

Staff Nurse Kirsten Hald Boldrel, Children's Diabetes Outpatient Clinic Hillerød, tlf. 48294321

**Responsible for the research project:**

Project Leader, Nurse and Ph.D. student Gitte R. Husted, employed at Children's Ward, Hillerød Hospital. Can be contacted at tlf. 48296295 or email [gihu@hih.regionh.dk](mailto:gihu@hih.regionh.dk)

If you and your parents wish to participate, please fill out the enclosed consent forms. If you are under 15 years of age, one of your parents must provide both verbal and written consent for your participation. If you are above 15 years of age, both you and one of your parents must individually provide oral and written consent for your participation. Following this, you must fill out the questionnaire and deliver the complete set to the diabetes staff.

Sincerely,

The Diabetes team at Hillerød and Glostrup Children's Ward  
Project Leader and PhD student Gitte R. Husted



## Guided Self-Determination-Youth Research Project at Hillerød and Glostrup Children's Diabetes Outpatient Clinic Parent Information

### **What we offer**

We invite you to participate in a research project developed to investigate whether teenagers and their parents can get better support to live with diabetes in their daily lives, and additionally achieve improved HbA1c (blood glucoses control), when the diabetes staff work with you in an alternative way.

### **What is Guided Self-Determination-Youth**

Guided Self-Determination-Youth (GSD-youth) is a new way to collaborate during visits to the diabetes outpatient clinic. GSD-Youth will help your teenager, yourselves and us to identify your main challenges or problems in an everyday life with diabetes. The cooperation-method has been tested on adults with effective results when used by people with Type 1 Diabetes. Participants improved the quality of their lives with diabetes and achieved better glycemic control (HbA1c long-term). The same method has now been developed for youth and for their parents. The actual development process took place in collaboration with 22 youths, aged 13-18 years, all with Type 1 Diabetes, together with their parents, and with staff from the children's diabetes outpatient clinics of Glostrup and Hillerød.

### **Who can participate**

The participants in this research project will be 68 youth with Type 1 Diabetes aged 13-18 years and their parents from Glostrup and Hillerød Hospital's children's diabetes outpatient clinics. You have been chosen because your teenage child has been a Type 1 Diabetes patient for at least one year and has had a long-term average blood glucose (HbA1c) of 7.5 or above during the past year and above 8.0 registered at the last measurement.

### **What does your participation involve**

68 teenagers and their parents will be divided into two equal groups. The groups are created completely at random, based on which envelope your teenage child picks out at the outpatient visit. No matter which group you join, you will still meet your current permanent diabetes staff at your outpatient visits.

**One of the groups** of teenagers and parents will be offered the Guided Self-Determination-Youth method (GSD-Youth). This means that before and between outpatient visits your teenager must complete various sheet-forms about his/her thoughts and experiences in relation to life with diabetes. Additionally, you as parents will fill out various sheets about your thoughts and experiences in relation to being parents of a teenager with diabetes. These sheet-forms will help you and the diabetes staff to detect and focus on the things that, in your specific situation, are difficult or challenging in your everyday life. Conversations taking place during outpatient visits will be based on the answers in the sheets. The visits will alternate between:

- speaking with the diabetes staff together
- your teenager speaks alone with the diabetes staff
- you as parents speak alone with the diabetes staff two times.

We expect each visit to last approximately one hour.

**The second group of teenagers and parents** are offered outpatient visits as they are accustomed to, i.e., both the content and the length of their visits remain the same.

### **What is required of you to participate**

No matter which group you belong to, you must make sure that your teenage child comes to 8 outpatient visits over the next year. The first 4 visits take place approximately every 4th to 6th week, and the remaining visits approximately every second month. Parents of youth in the group applying the GSD-Youth approach must additionally come alone twice. Visits are determined from each visit to the next so they fit your schedule and that of the diabetes staff.

### **Does Guided Self-Determination-Youth work**

In order to determine if the GSD-Youth approach works, the diabetes staff collects information via a questionnaire and measures and records the long-term test (HbA1c) as usual during the coming year. At the end, results from the group applying the GSD-Youth approach are compared to results from the group that continued with the normal outpatient visits.

This means that, no matter which group you belong to, you must give your consent that you will:

- Participate in the project
- Let your teenager participate in a survey today, immediately after completion of the project, and 6 months after completion of the project.
- Let your teenager's long-term blood sugar results (HbA1c) be measured and recorded today, and at least every 3 months during the next year and a half.

In addition to the above, the group that is offered Guided-Self-Determination-Youth, may be asked to:

- Allow 1 or 2 of the outpatient visits during the next year to be audio-recorded by the diabetes staff.
- Allow you and your teenager to be interviewed separately after the end of the project, at a time that suits both you and the project leader Gitte R. Husted.

You may participate in the project, even if you do not wish to attend interviews at the end.

If the method displays positive effects, both in terms of everyday-life quality and in a lower long-term blood sugar (HbA1c) for the teenager, the group that did not apply the method will be offered a Guided Self-Determination-Youth course at the end of the research period.

### **Does participation pose any risks?**

We have judged that there will be no risks to you from participating in this research project. Previous application of the method with adults has not resulted in adverse effects or complications. Instead, it has helped participants to achieve better quality of everyday life with diabetes plus lower long-term blood sugar (HbA1c).

### **What do you get?**

You are helping to test whether a new method works to help youth with Type 1 Diabetes and their parents. Your involvement can enable diabetes staff to discover if there is an alternative way to help you and your teenager to live with diabetes in your everyday lives and to achieve better glucose control. The goal is to provide you and future families with the support required during the typically difficult teenage years. If the method works, the knowledge and experience gained through your participation will enable other children to use the method in diabetes outpatient clinics in Denmark. The content of your conversations about diabetes with staff, including responses to the questionnaires, will remain anonymous and will not indicate your identity when the project's results are communicated. The results will be published both in English and Danish journals. Diabetes staff and patient groups will be offered training in how to use the method.

### **Your rights as a participant in the project:**

- Participation is completely voluntary and can only start after you have received both written and oral information about the research project from the diabetes staff and have signed a consent form
- You may at any time withdraw from the research project, even after you have given your oral or written consent for participation. Withdrawal from the research project will have no impact on your future engagements in the diabetes outpatient clinic
- All information you provide that appears in the research project, is subject to confidentiality
- Storage of information about you is subject to laws concerning the processing of personal data and the laws defining patients' legal status.

We hope that this written information has given you sufficient insight into what it means to participate in this research project. If you would like to know more, please feel very welcome to contact one of the following persons:

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Staff Nurse Susanne Lisbjerg, Children's Diabetes Outpatient Clinic Hillerød, tlf. 48294321  
Staff Nurse Kirsten Hald Boldrel, Children's Diabetes Outpatient Hillerød, tlf. 48294321

**Responsible for the research project:**

Project Leader, Nurse and Ph.D. student Gitte R. Husted, employed at Children's Ward, Hillerød Hospital. The research project is a part of a Ph.D. study program at the University of Copenhagen. Can be contacted at tlf. 48296295 or email [gihu@hih.regionh.dk](mailto:gihu@hih.regionh.dk)

**The Project steering committee group:**

Senior Researcher, Ph.D., Vibeke Zoffmann, Steno Diabetes Center, Gentofte  
Research leader, cand.cur. Dr. Med. Science, Bente A. Esbensen, Glostrup Hospital  
Professor, Dr. Med. Birger Thorsteinsson, Department of Cardiology, Hillerød Hospital  
Chief Physician, Dr. Med. Eva Hommel, Steno Diabetes Center, Gentofte

If you wish to participate, please fill out the enclosed consent forms. If your teenager is under 15 years of age, one of the parents must provide both verbal and written consent for both your teenager's, and your own participation. If your teenager is above 15 years of age, both the parents and the teenager must individually provide oral and written consent to participate.

Sincerely

The Diabetes Team at Hillerød and Glostrup Children's Ward  
Project Leader and PhD student Gitte R. Husted

**Informed consent and Substituted Consent  
for participation in the research project  
Life Skills for Youth with Type 1 Diabetes**

## **Informed parent consent for participation in a research project**

The research project title: Life Skills for Youth with Type 1 Diabetes

### **Declaration from the diabetes nurse/physician:**

I hereby declare that the person whose name is signed below has received written and verbal information about the research project and has had the opportunity to ask questions. To the best of my knowledge, the person below has received adequate information, including an overview of both the advantages and disadvantages, in order to make an informed choice.

I have informed the person signed below that the responsible person and project leader is Gitte R. Husted.

\_\_\_\_\_ Date \_\_\_\_\_ Signature

### **Declaration from parents who participate:**

I have read the written information regarding the research project and have been briefed verbally in a language that I understand. I know enough about the goals, methods, advantages and disadvantages to be able to give my consent for participation. I have been informed that it is voluntary to participate and that I can withdraw my consent and leave the project at any time without further explanation. I have been informed that my withdrawal will not affect my future engagements in the outpatient clinic, my rights for treatment, or other entitlements.

I consent to participate in the research project and have received a copy of the written information for my own use together with a copy of this consent form.

Participant's name: \_\_\_\_\_

\_\_\_\_\_ Date \_\_\_\_\_ Signature

## **Informed consent by youth over 15 years of age for participation in a research project**

The research project title: Life Skills for Youth with Type 1 Diabetes

### **Declaration from the diabetes nurse/physician:**

I hereby declare that the person whose name is signed below has received written and verbal information about the research project and has had the opportunity to ask questions. To the best of my knowledge, the person below has received adequate information, including an overview of both the advantages and disadvantages, in order to make an informed choice.

I have informed the person below that the responsible person and project leader is Gitte R. Husted.

\_\_\_\_\_ Date \_\_\_\_\_ Signature



**Declaration from youth over 15 years of age who participate:**

I have read the written information regarding the research project and have been briefed verbally in a language that I understand. I know enough about the goals, methods, advantages and disadvantages to be able to give my consent for participation. I have been informed that it is voluntary to participate and that I can withdraw my consent and leave the project at any time without further explanation. I have been informed that my withdrawal will not affect my future engagements in the outpatient clinic, my rights for treatment, or other entitlements.

I consent to participate in the research project and have received a copy of the written information for my own use together with a copy of this consent form.

Participant's name: \_\_\_\_\_

\_\_\_\_\_ Date \_\_\_\_\_ Signature

**Substituted Consent for youth under 15 years of age for participation in a research project**

The research project title: Life Skills for Youth with Type 1 Diabetes

**Declaration from the diabetes nurse/physician:**

I hereby declare that the person whose name is signed below, and who is giving Substituted Consent, has received written and verbal information about the research project and has had the opportunity to ask questions. To the best of my knowledge, the person below who is giving Substituted Consent has received adequate information, including an overview of both the advantages and disadvantages, in order to make an informed choice.

I have informed the person below that the responsible person and project leader is Gitte R. Husted.

\_\_\_\_\_ Date \_\_\_\_\_ Signature

**Declaration from the person giving Substituted Consent:**

I have read the written information regarding the research project and have been briefed verbally in a language that I understand. I know enough about the goals, methods, advantages and disadvantages to be able to give my Substituted Consent for participation. I have been informed that it is voluntary to participate and that I can withdraw my consent, so that my child leaves the project at any time. I have been informed that my withdrawal will not affect my child's future engagements in the outpatient clinic, his/her rights for treatment, or other entitlements.

I hereby give my consent that : \_\_\_\_\_ ( your child's name) may participate in the research project, and has received a copy of the written information for own use together with a copy of this consent form.

Name of person giving Substituted Consent: \_\_\_\_\_

\_\_\_\_\_ Date \_\_\_\_\_ Signature

**Children's Ward**

Section B1521

Dyrehavevej 29  
3400 Hillerød

**Entrance** 15A  
**Section** B1521

**Telephone** 48 29 43 33  
**Direct** 48 29 62 95  
**Fax** 48 29 43 10

Telephone hours Mon.-Fri. 10-12 and Mon.-Thurs.14-15

Date: 4th November 2011

XXXXXXXXXX

**Dear xxxxx**

First, I would like to express my thanks for your participation in the project Guided Self-Determination-Youth.

I am contacting you because, as the project manager, I wish to interview you about your experiences with the project. Selected from among those who participated, 6-10 youth and their parents will be interviewed.

The interview will last 1½ -2 hours, and can be conducted at a location that suits you best – either at your home or in the outpatient clinic at Hillerød Hospital/Glostrup Hospital.

I would like to begin the interview by speaking with xxxx, followed by a talk alone with your parents, and finally with all three of you together.

I would also like your permission to audio record our conversations. Whatever we speak about will remain confidential and anonymous.

I will contact you during next week to arrange a possible appointment. You are also very welcome to contact me in order to make an appointment. I can be reached by e-mail: [gihu@hih.regionh.dk](mailto:gihu@hih.regionh.dk), or by phone: 48296295 or cellphone: 20264339.

I hope you will share your experiences with me. Your input will contribute to our assessment of the value of the tested method: Guided Self-Determination-Youth, and will help us determine whether it should be offered in the future to other young people with Type 1 Diabetes.

Kind Regards,

Gitte R. Husted  
Nurse & Ph.D.-Student  
The Children's Ward  
Hillerød Hospital  
Telephone: 48296295 or 20264339  
gihu@hih.regionh.dk

# Appendix H

## Timelines

Timeline and overview of the activities during 2007-2009 where the adjustment, development of GSD-Y and GSD-Y training of HCPs took place

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
2007			2 nurses start in outpatient		2 nurses start in outpatient	1 nurse starts in outpatient	Outpatient clinic closed	Introduction to GSD in Hillerød & Herlev			Course I Hillerød & Herlev	
2008	A central diabetes nurse dies in Hillerød	Course II Hillerød & Herlev  Re-organization of the diabetes team in Hillerød starts	Start of practical training	Course III Hillerød & Herlev  Individual supervision/training  Strike among Danish nurses from mid-April	Strike continues	End of strike mid-June	Outpatient clinic closed	No GSD-Y training	Course IV Hillerød & Herlev  Re-start of practical training  GRH partly care leave	Practical training  Individual supervision/training  Meetings with HCPs  GRH partly care leave	Course V Hillerød & Herlev  Practical training  Individual supervision and training  GRH partly care leave	Practical training  Individual supervision/training  Meetings with HCPs  GRH partly care leave
2009	Practical training  Individual supervision and training  Meetings with HCPs  GRH partly care leave	Course VI part I Hillerød and Herlev participated separately  Practical training  Individual supervision/training  Meetings with HCPs	Practical training  Individual supervision/training  Meetings with HCPs  HCP long term off sick	Practical training  Individual supervision/training  Meetings with HCPs  HCP long term off sick	Practical training  Individual supervision/training  Meetings with HCPs  Face validity of questionnaire	Course VI part II Hillerød and Herlev participated separately  Practical training  Individual supervision/training  Meetings with HCPs  Face validity of questionnaire	Outpatient clinic closed	8 HCPs passed GSD-Y tests  Face validity of questionnaire  <b>First patient randomized</b> at end of August QUAN data collection starts Experimental period starts				1 HCPs passed GSD-Y tests

Weekly meetings took place in Herlev. In Hillerød meetings took place monthly. In Hillerød GRH was available 4 days a week 2008-2013.

Timeline and activities during intervention and follow-up. Further education: HCPs were absent minimum once a week and had time off work in connection with their final exam (10-14 days).

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
2009							Outpatient clinic closed	<b>First patient randomised</b>  Quantitative data collection starts  Intervention period starts	Individual supervision  Meetings with HCPs  1 HCP starts further education 2009-2010	Individual supervision  Meetings with HCPs  3 HCP on conference abroad	Individual supervision  Meetings with HCPs	<b>Start of qualitative data collection</b>  Individual supervision  Meetings with HCPs
2010	Digitally recordings  Meetings with HCPs  Individual supervision	Digitally recordings  Meetings with HCPs  Individual supervision	Digitally recordings  Meetings with HCPs  Individual supervision	Digitally recordings  Meetings with HCPs  1 HCP starts further education Apr-June	Digitally recordings  Meetings with HCPs  Individual supervision	Digitally recordings  Meetings with HCPs  Individual supervision	Outpatient clinic closed	Digitally recordings  Meetings with HCPs  Individual supervision	Digitally recordings  Meetings with HCPs  Individual supervision 1 HCP further education 2010-2011	Digitally recordings  3 HCP on conference abroad  Individual supervision  Meetings with HCPs	<b>Last patient randomised</b>  Digitally recordings  Individual supervision  Meetings with HCPs	Digitally recordings  Meetings with HCPs  Individual supervision
2011	Digitally recordings  Individual supervision  Meetings with HCPs	Digitally recordings  Individual supervision  Meetings with HCPs	Digitally recordings  Individual supervision  Meetings with HCPs	Digitally recordings  Individual supervision  Meetings with HCPs  Financial savings – reduction in staff among nurses	Digitally recordings  Individual supervision  Meetings with HCPs  1 HCP long term off sick	Digitally recordings  Individual supervision  Meetings with HCPs  1 HCP long term off sick	Outpatient clinic closed	Glostrup outpatient moves to Herlev Hospital  Individual supervision  1 HCP maternity leave start  Meetings with HCPs	GSD-Y visits on hold in Herlev  Individual supervision  Meetings with HCPs	GSD-Y visits starting slowly up in Herlev  Individual supervision  3 HCPs on conference abroad  Meetings with HCPs	Interview starts  Individual supervision  Meetings with HCPs	Interview  Individual supervision  Meetings with HCPs
2012	Interview  Meetings with HCPs	Interview  Meetings with HCPs	<b>End of qual data collection</b> Meetings with HCPs	Meetings with HCPs	Meetings with HCPs	Meetings with HCPs	Outpatient clinic closed	End of intervention period Meetings with HCPs	Meetings with HCPs	3 HCP on conferences abroad	Meetings with HCPs	Meetings with HCPs
2013	Meetings with HCPs	Meetings with HCPs					Last data follow-up delivered					

## Appendix I

Paper I

Paper II

Paper III

STUDY PROTOCOL

Open Access

# Improving glycaemic control and life skills in adolescents with type 1 diabetes: A randomised, controlled intervention study using the Guided Self-Determination-Young method in triads of adolescents, parents and health care providers integrated into routine paediatric outpatient clinics

Gitte R Husted<sup>1\*</sup>, Birger Thorsteinsson<sup>1</sup>, Bente Appel Esbensen<sup>2</sup>, Eva Hommel<sup>3</sup> and Vibeke Zoffmann<sup>3</sup>

## Abstract

**Background:** Adolescents with type 1 diabetes face demanding challenges due to conflicting priorities between psychosocial needs and diabetes management. This conflict often results in poor glycaemic control and discord between adolescents and parents. Adolescent-parent conflicts are thus a barrier for health care providers (HCPs) to overcome in their attempts to involve both adolescents and parents in improvement of glycaemic control. Evidence-based interventions that involve all three parties (i.e., adolescents, parents and HCPs) and are integrated into routine outpatient clinic visits are lacking. The Guided Self-Determination method is proven effective in adult care and has been adapted to adolescents and parents (Guided Self-Determination-Young (GSD-Y)) for use in paediatric diabetes outpatient clinics. Our objective is to test whether GSD-Y used in routine paediatric outpatient clinic visits will reduce haemoglobin A1c (HbA1c) concentrations and improve adolescents' life skills compared with a control group.

**Methods/Design:** Using a mixed methods design comprising a randomised controlled trial and a nested qualitative evaluation, we will recruit 68 adolescents age 13 - 18 years with type 1 diabetes (HbA1c > 8.0%) and their parents from 2 Danish hospitals and randomise into GSD-Y or control groups. During an 8-12 month period, the GSD-Y group will complete 8 outpatient GSD-Y visits, and the control group will complete an equal number of standard visits. The primary outcome is HbA1c. Secondary outcomes include the following: number of self-monitored blood glucose values and levels of autonomous motivation, involvement and autonomy support from parents, autonomy support from HCPs, perceived competence in managing diabetes, well-being, and diabetes-related problems. Primary and secondary outcomes will be evaluated within and between groups by comparing data from baseline, after completion of the visits, and again after a 6-month follow-up. To illustrate how GSD-Y influences glycaemic control and the development of life skills, 10-12 GSD-Y visits will be recorded during the intervention and analysed qualitatively together with individual interviews carried out after follow-up.

**Discussion:** This study will provide evidence of the effectiveness of using a GSD-Y intervention with three parties on HbA1c and life skills and the feasibility of integrating the intervention into routine outpatient clinic visits.

**Danish Data Association ref nr. 2008-41-2322**

**Trial registration: ISRCTN54243636**

\* Correspondence: [gihu@hih.regionh.dk](mailto:gihu@hih.regionh.dk)

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## Background

Type 1 diabetes in adolescents is a challenge for the teenagers, their parents and the diabetes health care providers (HCPs) [1]. Despite new medical treatment modalities, the prognosis for childhood-onset type 1 diabetes remains poor [2,3]. The number of life years lost remains unchanged over the last four decades at approximately 17 years for a child diagnosed with type 1 diabetes at the age of 10 years [4]. Keeping blood glucose levels as close to normal as possible from as early in the disease as possible is known to prevent or postpone late diabetic complications [5-8]. The recommended target for haemoglobin A1c (HbA1c) in adolescents with type 1 diabetes is less than 7.5% without increasing the occurrence of hypoglycaemia [9]. However, adolescents typically do not maintain the necessary degree of diabetes self-management or the recommended HbA1c levels [10,11]. In Denmark, 31% of affected adolescents meet the recommended HbA1c threshold [12]. Although late diabetic complications are rarely seen during adolescence, there is evidence that their pathogenesis begins soon after diagnosis and accelerates during puberty [13,14].

### Challenges faced by adolescents trying to integrate diabetes into their lives

Most adolescents experience difficulties integrating the diabetes regimen into their lives; they confront significant conflicts between the need for diabetes management and psychosocial developmental needs and challenges [1,15]. Belonging to a peer group and fitting into the group's social norms and behaviours may be perceived as more important to the quality of a teenager's life than diabetes treatment [16]. Avoiding taking care of the disease as advised by HCPs and parents often leaves the adolescents with feelings of guilt, a conflicted conscience and frustration [17]. At the same time, they have conflicting experiences of being watched over, blamed and controlled by their parents [18], while also being vulnerable to the disease [19] and still needing guidance from their parents to manage the daily treatment [20-22]. This increases conflicts and deteriorates adolescent-parent collaboration and adolescent self-management [23,24]. From the adolescent's point of view, striving for independence and self-management of the disease is known to present a considerable stress [25,26].

### Challenges faced by parents in transferring responsibility

During adolescence, the responsibility for the management of diabetes should gradually be transferred from parents to adolescents [1,27]. Some parents are, however, reluctant to transfer responsibility for diabetes management, as they doubt the adolescents' abilities to self-manage their diabetes [28,29]. Other parents leave all responsibility for

managing the disease to their adolescents, trying to avoid conflicts or expecting them to be competent because of their age and the amount of time since diagnosis [30]. Both approaches may lead to poor glycaemic control [31,32]. A constructive form of parental involvement comprising guidance and supervision, shared knowledge and shared responsibility yields better glycaemic control [33]. However, systematic education and guidance on how to be a constructive and supportive parent is not currently offered as part of routine care [34,35].

### Challenges faced by health care providers in their interactions with adolescents and parents

HCPs view adolescence as a difficult time in which the processes of managing diabetes, providing guidance and eliciting cooperation from adolescents and their parents are complex [36-38]. Apart from optimising medical treatment for diabetes, HCPs should aim to effectively navigate the interaction between adolescents struggling to find their identity separate from their parents and parents concerned about their child's difficulties combining teenage life with diabetes self-management [39]. HCPs should encourage parental involvement that facilitates adolescents' independent decision-making through a gradual transfer of responsibility and management of the disease [40-42]. However, current diabetes education and routine outpatient clinic visits seem to have little effect on conflict resolution, transfer of responsibility, self-management skills, and better glycaemic control [43].

### Interventions

According to Anderson [24] and Delamater [44], psychosocial and behavioural family-based controlled interventions improve self-management, glycaemic control and family relationships. However, these interventions were carried out separate from routine paediatric outpatient clinic visits. Three randomised controlled studies have partly been integrated into routine paediatric outpatient clinics [43,45,46], and two of these studies included parents (Laffel [46] and Murphy [43]). Grey and colleagues have shown that coping skills training delivered to small groups of adolescents combined with intensive diabetes management improved quality of life and glycaemic control [45]. Laffel and colleagues have shown that a family-focused teamwork intervention run by a trained research assistant increased family involvement and prevented worsening of glycaemic control [46]. Murphy and colleagues have shown potential benefits on parental involvement and glycaemic control in a structured education programme for adolescents and parents in small groups, but further studies are in progress to confirm these findings [43].

In searching for a method that could be applied by HCPs and adapted to adolescents and their parents, we chose Guided Self-Determination (GSD), which has reduced HbA1c (by 0.4%) and improved life skills in adults with persistently poor glycaemic control of type 1 diabetes [47]. We adjusted GSD to adolescents and their parents (GSD-Young, named GSD-Y hereafter) for use in paediatric diabetes outpatient clinics by the adolescents' usual HCPs. The current trial of GSD-Y is the first to evaluate the effect of an intervention involving both adolescents and parents that is carried out in routine outpatient clinics with HCPs from the adolescents' usual interdisciplinary diabetes team.

We hypothesize that using GSD-Y in routine paediatric outpatient diabetes clinics will reduce HbA1c concentrations and improve adolescents' life skills compared with those in a control group.

### Objectives

1) To test whether GSD-Y can be integrated into routine paediatric outpatient diabetes clinics in a collaboration between adolescents, their parents and the interdisciplinary diabetes HCPs.

2) To test whether GSD-Y reduces HbA1c and improves life skills in adolescents with type 1 diabetes.

3) To illustrate how GSD-Y influences developing life skills in adolescents supported by their parents and their HCPs.

### Methods/Design

#### Ethical Approval

The trial will be performed in accordance with the recommendations guiding nurses in clinical research involving human participants (Helsinki Declaration). The project was reviewed by the Danish National Committee on Biomedical Research Ethics on April 17, 2009 as registry- and interview-based research (REC; reference number, 0903054 document number, 230436).

#### Type of study

This study is a life-skills intervention using a mixed methods design comprised of a randomised controlled trial and a nested qualitative evaluation [48]. Objective 2 will be met through the quantitative component, whereas Objectives 1 and 3 will be met through the qualitative component. The use of a quantitative and a qualitative approach in combination increases the opportunity for a complementary evaluation, which provides a better understanding of GSD-Y's potential to influence the process of improving glycaemic control and life skills than using either approach alone. The quantitative component evaluates the effect of GSD-Y, whereas the qualitative component has two purposes: a) to elucidate the factors that affect how well GSD-Y is implemented in routine

clinics and perhaps affects the outcomes, and b) to provide a detailed understanding of how GSD-Y works in triads carried out as part of routine care delivered by the adolescents' usual HCPs.

The protocol is summarised in a flowchart (Figure 1).

#### Setting

The study takes place at 2 paediatric outpatient clinics at 2 hospitals in the capital region of Denmark: Glostrup, with the largest diabetes outpatient clinic in Denmark (480 patients) and Hillerød, with the third largest diabetes outpatient clinic in Denmark (171 patients).

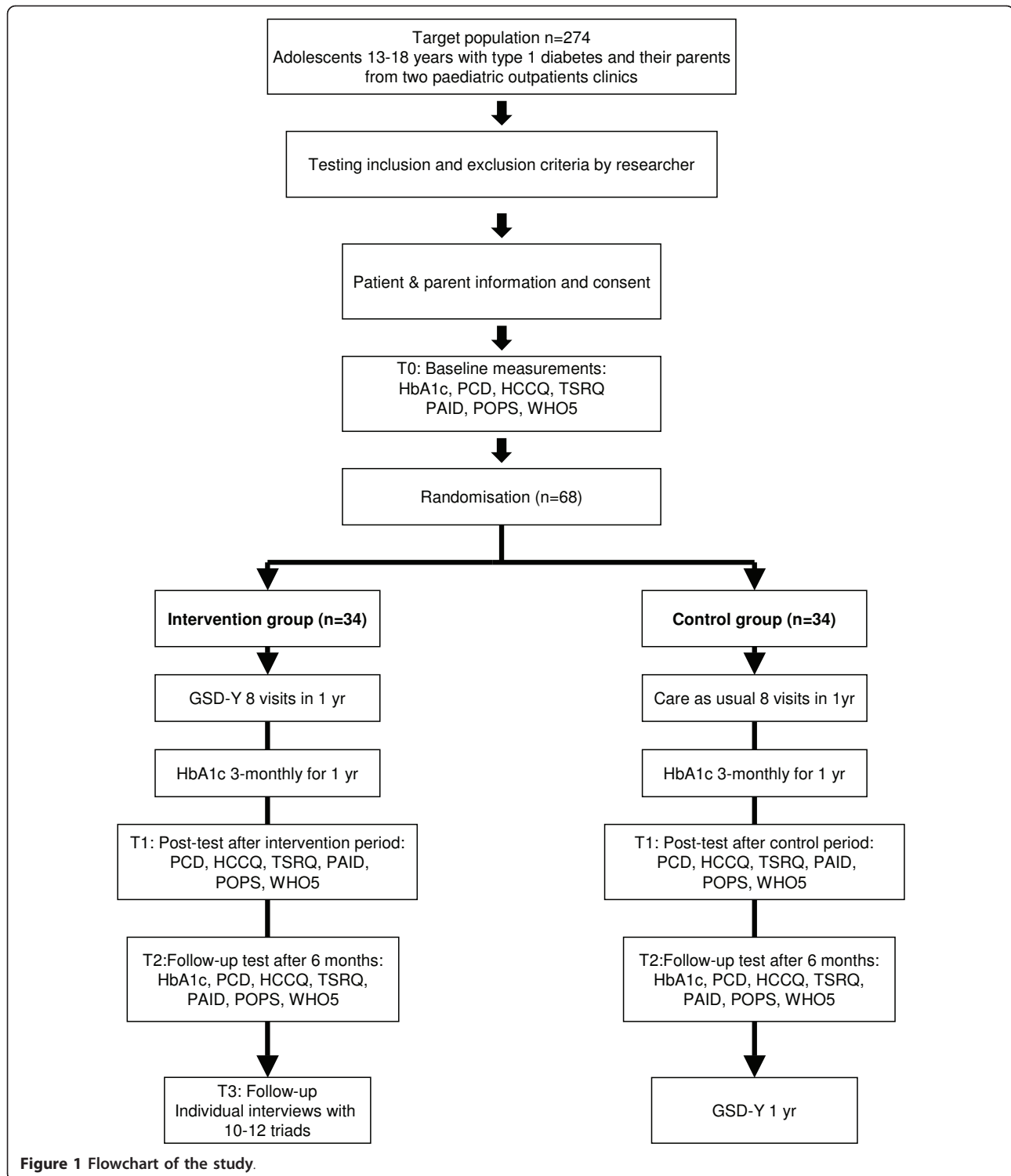
Two paediatric physicians, 5 paediatric diabetes nurses and 2 dietitians (HCP hereafter), trained and tested in using GSD-Y, will recruit adolescents with type 1 diabetes and conduct the GSD-Y intervention as part of their routine outpatient clinic visits.

#### Guided Self-Determination-Young: theoretical and conceptual frameworks

GSD is a problem-solving and decision-making method designed to overcome barriers to empowerment in adult patient-provider interactions, and these barriers are explained by three grounded theories [49-51]. GSD has a formal theoretical foundation in life-skills theory [52,53], empowerment [54] and motivational theory of self-determination [55,56].

GSD-Y is aimed at improving glycaemic control and increasing adolescents' life skills. Life skills is defined as "those personal, social, cognitive and physical skills that enable people to control and direct their lives and develop the capacity to live with and produce change in their environment" [47,52,57]. In GSD-Y, the acquisition of life skills is considered to be a developmental process, where the adolescents are intended to start to accept and integrate diabetes into their lives and to become autonomously motivated to handle the challenges the life of a teenager with type 1 diabetes demands. To be autonomously motivated means, for example, that adolescents check their blood sugar because they find it important personally, rather than doing it on the initiative of parents or HCPs [56].

Because part of developing life skills is making self-determined decisions [52], Self-Determination Theory (SDT) has a central role in GSD-Y. According to SDT, self-determined behaviour requires the fulfilment of three needs: competence, autonomy and relatedness. An environment that is autonomy-supportive is necessary to foster the fulfilment of these needs [56]. A feeling of competence occurs when a person perceives that he or she meets optimal challenges and is able to master them effectively. Autonomy is perceived when people experience a sense of choice, endorsement and volition to act in accordance with their interests and values. The need



for relatedness refers to the warmth and caring received through interactions with others, resulting in a general sense of belonging [56]. However, by applying pressure in their striving for good glycaemic control, parents and HCPs may unwillingly obstruct the adolescents'

development of competence, autonomy and relatedness, potentially fostering passivity, ill-being and amotivation [58].

In our study, the adolescents' need for relatedness is satisfied when they feel a sense of belonging with parents

and HCPs because there is an atmosphere where talking openly and honestly about their difficulties living with diabetes is legitimised, and adolescents still feel that they are cared for unconditionally. Satisfaction of the need for autonomy occurs when the adolescents perceive that parents and HCPs try to understand their perspective, acknowledge their feelings, and act in a non-judgmental way by minimizing the use of controlling language and behaviour. This creates an autonomy-supportive environment for decision-making, which helps adolescents act in congruence with their values and interests. Satisfying the need for relatedness and autonomy paves the way for fulfilling the need for competence in diabetes management. Adolescents will believe that they succeed in managing diabetes because parents and HCPs are aware of their current competence and accept their shifting readiness to take responsibility for their diabetes.

#### **Guided Self-Determination-Young: essentials in GSD-Y**

GSD-Y consists of 18 semi-structured reflection sheets for adolescents (Table 1) and 5 reflection sheets for parents (Table 2). In addition, 4 new semi-structured reflection sheets have been developed for visits with dieticians (Table 3). The semi-structured reflection sheets are based on theories such as dynamic judgement building [59], values clarification [60] and the trans-theoretical stages of change theory [61], all of which enhance the development of life skills as described above.

Before each appointment, adolescents and parents complete the reflection sheets (Table 1, 2, 3). The first reflection sheet includes a written invitation for adolescents and their parents to take part in mutual problem solving (Table 1) [50]. While this component of the sheet clarifies that the knowledge of all three parties is important and legitimises different points of view, it

**Table 1 Reflection sheets for adolescents**

<b>1. visit</b>	<b>Your life with diabetes from beginning to now</b>
<b>Reflection sheets</b>	Written invitation to work together in a new way Two ways to look at HbA1c Important events and periods in your life What do you find difficult at present living with your diabetes? Your plans for changing your way of life Agreement on things to work with till next visit
<b>2. visit</b>	<b>Values and opportunities</b>
<b>Reflection sheets</b>	Unfinished sentences: needs, values, experiences and opportunities? Agreement on things to work with till next visit
<b>3. visit</b>	<b>Diabetes in your life - now and in the future</b>
<b>Reflection sheets</b>	Blood sugar checks and your reasons for checking A picture or a metaphor, or expression describing your life with diabetes Room for your diabetes in your life Shared responsibility for your diabetes in daily life between you and your parents Agreement on things to work with till next visit
<b>4. visit</b>	<b>Different ways to look upon numbers</b>
<b>Reflection sheets</b>	Your blood-sugar numbers as you would wish them to be and as you know them from experience Evidence for advantages and disadvantages of high and low blood sugar Your plan for blood sugar regulation in the short and long run Situations where you want to avoid low blood sugar Agreement on things to work with till next visit
<b>5. visit</b>	<b>Problem-identification</b>
<b>Reflection sheets</b>	Current problem-solving Agreement on things to work with till next visit
<b>6. visit</b>	<b>Problem solving and options of new ways to self-management</b>
<b>Reflection sheets</b>	Dynamic problem-solving Pros and cons Agreement on things to work with till next visit
<b>7. visit</b>	<b>Problem-identification</b>
<b>Reflection sheets</b>	Current problem-solving Agreement on things to work with till next visit
<b>8. visit</b>	<b>Problem solving and options of new ways to self-management</b>
<b>Reflection sheets</b>	Dynamic problem-solving Pros and cons Solved problems and subjects to continue to work with in future outpatients appointments

**Table 2 Reflection sheets for parents**

<b>1. visit</b>	<b>Your life as a parent to an adolescent with type 1 diabetes</b>
<b>Reflection sheets</b>	Unfinished sentences: needs, values, experiences and opportunities? Room for your adolescents' diabetes in your life Current problem-solving
<b>2. visit</b>	<b>Problem identification and solving - options of new ways to shared decision making</b>
<b>Reflection sheets</b>	Dynamic problem-solving Pros and cons

also states that the adolescents are seen as the final problem solvers, and parents and HCPs are seen as facilitators.

By filling in reflection sheets with their own words and drawings, adolescents and their parents systematically explore and express their individual and common difficulties and experiences with diabetes in daily life. Thus prepared for appointments in the outpatient clinics, adolescents and their parents are guided by trained GSD-Y HCPs to communicate openly and reflect mutually by sharing and respecting each other's observations, thoughts and feelings as a starting point for a constructive collaboration in a caring relationship. This model adds shared insight to previous patterns of diabetes management, which yields a platform for identifying unknown resources in both adolescents and parents and discovering new strategies for problem-solving between the three parties. This paves the way for agreements and concrete arrangements about how to test new problem-solving strategies in the time between outpatient appointments. At the outpatient appointments, the triad evaluates their experiences with these strategies.

The overall aim is for adolescents and parents to identify concrete potential for change [47] and to avoid adolescents, parents or HCPs entering alliances with one another against the third party.

To use the reflection sheets with adolescents and parents, HCPs must be able to practice advanced communication skills such as mirroring [62], active listening [63,64] and values clarification [60]. Furthermore, HCPs should be able to support autonomy in their way of providing information and research-based knowledge of

diabetes treatment and management (e.g., evidence on risks incurred by high and low blood sugar levels).

#### **GSD-Y training programme for HCP**

To meet Objective 1, HCPs participated in a training programme (Additional file 1 ). The programme consisted of lessons in the formal theoretical basis of GSD, knowledge of barriers to empowerment in patient-provider relationships that GSD was designed to overcome and apparatuses in GSD-Y. Furthermore, they practiced using the semi-structured reflection sheets supported by their advanced communication skills using role-playing with simulated adolescents and parents, but also with real adolescents with type 1 diabetes and parents who agreed to participate in this training process. These adolescents and parents did not participate in the intervention trial. HCPs were taught and supervised by GRH and VZ. Finally, their formal theoretical foundation and ability to use GSD-Y were approved by GRH before the start of the trial.

#### **Endpoints of the study**

##### **Primary outcome**

HbA1c.

##### **Secondary outcomes**

a. Development of life skills in adolescents with type 1 diabetes

(i) Experience of feeling competent in managing diabetes, (ii) experience of HCPs being autonomy-supportive versus controlling, (iii) motivation for diabetes management, (iv) ability to manage diabetes-related distress, (v) involvement and support for autonomy from parents, (vi) well-being.

**Table 3 Reflection sheets for visits at the dietician**

<b>1. visit</b>	<b>Present challenges regarding food, snacks and insulin</b>
<b>Reflection sheets</b>	What do you find demanding or difficult at present regarding your food living with your diabetes?  Experiments: An easy situation and a difficult situation as you experience it where you try to get food/snacks and insulin to fit together
<b>2. visit</b>	<b>Evaluation of experiments</b>
<b>Reflection sheets</b>	Did it work? Why if and why if not?  New experiments to work with till next visit or ending

b. Diabetes outcomes directly related to patient management

(i) Insulin delivery/number of injections/insulin types, (ii) number of self-monitored blood glucose values, (iii) hypoglycaemic episodes (frequency and severity), (iv) admissions to hospital and reasons for admissions (e.g. episodes of ketoacidosis, hypoglycaemia).

c. Diabetes outcomes indirectly related to patient management

(i) Attendance at intervention or control sessions, (ii) parental participation.

### Sample size calculation

The size of the study was based on the primary outcome measure HbA1c. According to a power calculation, an absolute difference of 1.0% in HbA1c between the GSD-Y group and the control group (power 0.8; two-sided level of significance 0.05) could be detected with 26 patients in each group. This calculation was based on a standard deviation of the HbA1c value of 1.3% from a study of coping skills training [45]. To compensate for an attrition rate of 25%, we aimed to recruit 68 patients.

### Enrolment

#### Inclusion criteria

All adolescents aged 13-18 years who have had type 1 diabetes for more than one year will be invited to participate together with their parents if they meet the following criteria:

- HbA1c  $\geq$  8.0% at the last visit before entry into the study and
- Average HbA1c  $>$  7.5% during the last year before entry into the study.

#### Exclusion criteria

Adolescents will be excluded from participating in the study if they meet any of the following criteria:

- Diagnosed with a psychiatric disease
- Consulting a psychologist at the time of recruitment
- Unable to understand, talk or read Danish.

### Randomisation

Adolescents and parents willing to participate and fulfilling the inclusion criteria will be randomised to either an intervention group ( $n = 34$ ) (GSD-Y) or a control group ( $n = 34$ ) (standard care), using stratified randomisation by the adolescent's usual HCP. Randomisation will be performed using sealed envelopes. Neither adolescents nor the HCPs can possibly be blinded to the study. The adolescents in the control group will be offered the GSD-Y intervention after the study has concluded (14-18 month wait-list design).

### Consent

Consent to participate in the study will be obtained by the adolescents' usual HCP. After informed written

consent is obtained from the adolescent and at least one parent, adolescents will be randomised into either the intervention or the control group. The adolescent or their parents remain free to withdraw at any time during the study without giving reasons and without prejudicing further treatment. If a participant withdraws consent from further study participation, their data will remain on file and will be included in the final study analysis if the consent for use of the data is not withdrawn; if consent for use of data is also withdrawn, data will be destroyed immediately.

### Intervention group

The GSD-Y intervention will be delivered by the adolescent's usual HCP in individual settings for a total of 8 visits during an 8- to 12 month period. Each of the 8 visits will last for 1 hour and will include specific reflection sheets, and each visit will cover a specific topic (Table 1). Parents will be invited to participate. However, at least one of the visits can take place without the parents if the involved parties agree. The purpose is to create a safe environment where the adolescents can talk about personal affairs that are confidential and not known by their parents, yet are pertinent to their ability to manage their diabetes (e.g. smoking, drugs, boy/girlfriend). After this type of visit, the adolescents and HCPs will agree on what should be told to the parents, who should tell, and when.

In addition to the visits together with their adolescents, parents will also be offered two visits alone with the adolescents' usual HCPs. The reason for this is to create an environment where the parents can talk about how to act in an autonomy-supportive manner and how to manage their adolescents' shifting readiness to take responsibility for the management of the disease. The first of these parent/HCP visits will be offered after 3 months, and the second will be offered after 6 months. Both of the visits will include specific reflection sheets, and both visits will cover a specific topic (Table 2). After these visits, the parents and HCPs will agree on what should be told to the adolescents, who should tell, and when.

Adolescents will be referred to the dietician if needed. The need for referral will be made by the adolescent, the parents and their HCPs based on the completed reflection sheets from visits 1 and 2. The meeting with the dietician can take place with or without the parents, as decided by the involved parties. Each referral to the dietician involves at least two visits. Each visit is supported by special reflection sheets and covers a specific topic (Table 3).

The adolescents and parents keep their original semi-structured reflection sheets and a copy is put in their file.

### Control group

The control group receives standard care including a number of outpatient visits equal to that of the intervention group: eight visits during an 8 to 12 month period, with a standard duration per visit of 30 to 45 minutes, depending on the hospital.

### Duration

The trial will last from 14 to 18 months for both groups including the 6-month follow-up measurements. The first adolescent began the study in September 2009, and the last adolescent will finish the study in April 2012.

### Data Collection, Measurements and Analysis Quantitative component

#### Primary outcome

HbA1c will be collected as a routine clinical measurement every third month, which is a standard practice. The capillary blood samples for HbA1c from both hospitals are being analysed at the same department of clinical biochemistry using Variant Analysis Mode, TOSOH Automated Glycohaemoglobin Analyzer HLC-723 G8 (normal range 4.3% - 5.8%).

#### Secondary outcome a

Danish versions of 6 scales were compiled in one questionnaire (Table 4). The questionnaires will be completed by the adolescents at the outpatient clinics and placed in a closed envelope before being returned to the personal HCPs at the following timepoints: 1) baseline before randomisation, 2) after the end of the intervention/control period (8-12 months), and 3) after a 6-month follow-up period (ranging between 14 and 18 months from the time of entry into the trial).

The scales included the following:

- Perceived competence for diabetes management (PCD), assessing patients' experiences of feeling able to manage their diabetes successfully [65]
- Health Care Climate Questionnaire (HCCQ) assessing the degree to which patients believed their HCPs to be autonomy-supportive versus controlling in providing general treatment [65]
- Treatment Self-Regulation Questionnaire (TSRQ) assessing the motivation for diabetes management and the degree to which behaviours tended to be self-determined. The TSRQ consists of three subscales; (I) Autonomous, (II) Controlled, (III) A-motivated [66]
- Problem Areas In Diabetes (PAID) assessing diabetes-related distress including a wide range of feelings related to living with diabetes and its treatment, including guilt, anger, depressed mood and fear [67]
- The Perception of Parents Scale (POPS) [68] assessing adolescents' perceptions of their parents' autonomy support and involvement

- WHO-5 Well-being Index capturing emotional well-being in the last two weeks (WHO-5) [69].

The scales were translated and harmonised in accordance with recommended guidelines [70]. Internal consistency was measured for all 6 scales and proved to be good. Cronbach's  $\alpha$  ranged from 0.76-0.94 for the Danish versions of the HCCQ, PCD and TSRQ for adults, [47]; the Cronbach's  $\alpha$  for the English version for adolescents of the WHO5 was 0.82 [69], 0.96 for the PAID [71] and 0.88 for the POPS Autonomy support from mothers and fathers [58]. Face validity of the Danish versions was tested in 8 adolescents between 13 and 18 years of age with type 1 diabetes.

#### Secondary outcomes b and c

Regarding secondary outcomes b and c, a case report form will be completed at every outpatient visit by the adolescents' HCPs. Furthermore, demographic data will be collected at baseline, after the intervention/control period and at the 6-month follow-up.

### Analysis

To meet Objective 2 and test if GSD-Y effectively reduces HbA1c and improves life skills in adolescents with type 1 diabetes, we will analyse HbA1c and quantitative data from the questionnaires using PAWS Statistics18 for Windows (SPSS Chicago, IL, USA). Statistical analyses will include frequency, mean, standard deviation and confidence intervals. Comparisons of primary and secondary outcomes for the two groups will be conducted comparing data at baseline, at the end of the study, and after a 6-month follow-up period using appropriate parametric tests for variables fulfilling the normal distribution criteria or appropriate non-parametric tests for variables not fulfilling the normal distribution criteria. A Bonferroni correction for multiple testing will be performed.

Improvement of life skills will be defined as increases in HCCQ-scores, TSRQ-scores on autonomy or in relative autonomy index (formed by subtracting TSRQ-scores on control from TSRQ-scores on autonomy), PCD, POPS, WHO-5 and frequency of SMBG per week, and decreases in TSRQ-scores on amotivation, PAID scores and HbA1c. Differences within the GSD-Y group and between the GSD-Y group and the control group will be calculated at the end of the intervention (8-12 months) and after a 6-month follow-up period.

### Qualitative component

#### Data collection

Ten to twelve adolescents from the intervention group and their parents and HCPs will be followed during the intervention period. To ensure that we follow triads who face significant challenges, we will select them on

**Table 4 Adolescent measures and outcome**

Scales	Outcome	Ranging	Examples	Scores
The Perceived Competence Scale (PCD) 5-item	Experience of own competence	Ranging from 1 (strongly disagree) to 7 (strongly agree)	"I feel confident in my ability to manage my diabetes"	Produces a total sum score from 5- 35. A high sum score represents a high level of perceived competence
The Health-Care Climate Questionnaire (HCCQ) 5 -item	Perceptions of autonomy support from HCP	Ranging from 1 (strongly disagree) to 7 (strongly agree)	"I feel that my HCPs have provided me choices and options about handling my diabetes"	Produces a total sum score from 5-35. A high sum score represents a high level of perceived autonomy support
The Treatment Self-Regulation Questionnaire (TSRQ) 21-item Consists of 3 subscales	The degree in which patients' behaviour is self-determined	Ranging from 1 (strongly disagree) to 7 (strongly agree)	(I) Autonomous; "It's exciting to try to keep my blood sugar in a healthy range" (II) Controlled; "I want my HCP to think I am a good patient" (III) A-motivated; "I do not know why I do try - I will not be successful"	Produces sum scores for each of three subscales, Autonomous from 8-56, Controlled 9-63, Amotivated 4-28. High sum scores indicate high levels of autonomy, controlled or amotivated behaviour. A Relative Autonomy Index is calculated by subtracting the controlled scores from the autonomous scores. The higher relative autonomy index the higher is motivation based on autonomy compared to control
The Problem Areas In Diabetes scale (PAID) 20-item	Perception of current emotional burden of diabetes related issues	Ranging from 0 (not a problem) to 4 (serious problem)	"Feelings of guilt or anxiety when you get off track with your diabetes management"	Produces a total score from 0-100 by summing up and multiplying this sum by 1.25. Higher scores indicate greater emotional distress. Cut points: ≥30 elevated distress ≥40 serious distress
The Perception of Parents Scale (POPS) 26-item Consists of 2 sub-scales, mothers & fathers	Perception of autonomy support and involvement from parents	Ranging from 1 (not at all true) to 7 (very true)	(I) Mother/Father Autonomy Support; "My mother/father allows me to decide things for myself" (II) Mother/Father Involvement; "My mother/father finds time to talk with me"	Produces a total sum score from 13-91 in each subscale. High sum scores represent a high level of mother/father autonomy support/involvement
The WHO5 Well-Being Index 5-item	Emotional Well-being	Ranging from 0 (not present) to 5 (constantly present).	"I have felt cheerful and in good spirits for the last two weeks"	Produces a total score from 0-100 by summing up and multiplying a sum score by 4. Higher scores indicate greater emotional distress. Cut points: < 50 poor emotional well-being ≤ 28 indicate depression

the basis of high PAID scores and low WHO-5 scores at baseline, which indicate difficulties with life skills.

Data will be collected during the intervention period by recording two or three outpatient appointments between 1) adolescent, parent and HCP, 2) adolescent and HCP, and 3) parent and HCP.

Individual interviews will be carried out and recorded with the above-mentioned triads after the intervention's endpoint measures at a 6-month follow-up visit using a semi-structured interview guide [72] prepared on the

basis of both listening to the recordings from outpatient visits and the definition of life skills [57,73].

#### Parameters and analysis

To meet Objective 1, the analysis of the recorded outpatient visits and the individual interviews will explore how adolescents, parents and HCPs experience the following:

- the implementation of GSD-Y in routine clinics (e.g. appropriateness, feasibility, the triads' receptiveness, factors affecting implementation)



- usefulness of components of GSD-Y and additional support required for sustained uptake
- sustainability of GSD-Y and issues to consider in extending the model to adolescents in general with diabetes or other chronic disorders

To meet Objective 3, the analysis will also explore and illustrate how GSD-Y influences the process of adolescents developing life skills supported by their parents and their HCPs. Because the intervention is theory-driven [74], the analytical framework is predominantly deductive, based on theories on life skills [57,73], self-determination theory [56], empowerment [54], values clarification [60], Zoffmann's grounded theories [49-51] and the way we expect these skills to be recognized in the interactions between adolescents, parents and HCPs in the qualitative evaluation as operationally described below. However, the analysis will also be inductive in its use of the constant comparative method and theoretical sampling [75] to expand the existing GSD theory to build a cumulative body of theory because the evaluation of GSD-Y is the first to evaluate a version involving three parties.

Data from the recorded outpatient clinics and the individual interviews will be transcribed verbatim. NVivo 8 software will be used to facilitate the analysis. To maximise the validity of our findings, at least two researchers will participate in the analysis.

Improvement of life skills after participating in the intervention group will be defined if we recognize that the adolescents have met the following benchmarks:

- start to integrate the disease into their lives (i.e., if they talk about having a good teenage life without being enclosed by diabetes and are still well regulated).
- develop autonomously based motivation for blood glucose measurement, registration and regulation, because they think it is important and not because it is either imposed by parents/HCPs or driven by an "I should do" feeling.
- express their own goals for blood glucose and HbA1c regulation, and there is consistency between their objectives, values and behaviours.
- are conscious about what they want to talk about at the outpatient clinics.
- have insight into new ways to handle situations and relate constructively to the disease and their own reactions (e.g., instead of ignoring or deliberately choosing not to take insulin preventively, they now explain to their friends why they either opt out of eating certain foods or measure blood sugar and take insulin in advance.
- are able to communicate openly and honestly with parents and HCPs because there is an atmosphere where it is permissible and possible to be honest without experiencing condemnation.

- prevent or resolve conflicts or problems with diabetes in daily life outside the home and at home with support from parents and HCPs.
- are conscious about parents' and HCPs' resources and seek advice from their parents and HCP when needed and take advantage of these resources in learning self-management of diabetes.

### Confidentiality

The study was approved by the Danish Data Association ref nr. 2008-41-2322. All information collected during the course of the study will be kept strictly confidential in accordance with Danish Data Association rules. The study will comply with all aspects of the Danish Data Association. Operationally, this will include consent from adolescents and parents to record the adolescents' personal details including name and date of birth and consent from adolescents and parents for the data collected for the study to be used to develop new research.

### Organization and Supervisors

A supervisory group comprising the co-authors of the present paper was established and is responsible for the project. The group will meet with the project leader (GRH) four times each year until the study is finished. The meetings will provide an opportunity to discuss the research design, methods for data collection, schedules, data analyses, outcomes and statistical challenges.

The day-to-day management of the study will be led by the project leader. Every week the project leader will meet with the involved HCPs who are running the intervention. These meetings will provide the opportunity to discuss current challenges regarding using the GSD-Y in routine outpatient clinical care.

### Additional material

**Additional file 1: Appendix 1.** Content of GSD-Y training of paediatric diabetes HCPs.

### List of Abbreviations Used

HCP: health care providers; GSD-Y: guided self-determination - young; HbA1c: glycosylated haemoglobin

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#### Authors' contributions

All authors have read and approved the final manuscript. VZ is involved in the conception of the study and its implementation. VZ and BT have contributed to the design of the study and VZ, BT and BAE to development of the protocol. GRH drafted the manuscript with all authors providing critical review and final approval.

#### Declaration of competing interests

The authors declare that they have no competing interests.

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**Effect of guided self-determination youth intervention integrated into outpatient visits  
versus treatment as usual on glycemic control and life skills:  
a randomized clinical trial in adolescents with type 1 diabetes**

Running head: GSD-Y in adolescent type 1 diabetes.

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## **Abstract**

**Background:** Providing care for adolescents with type 1 diabetes is complex, demanding, and often unsuccessful. To improve care, Guided Self-Determination (GSD), a life skills approach proven effective when caring for adults with type 1 diabetes, was revised for adolescents, their parents, and interdisciplinary health care providers (HCP) to create GSD-Y (Youth). We evaluated the impact of GSD-Y after it was integrated into pediatric outpatient visits versus treatment as usual focusing on glycemic control and the development of life skills in adolescents with type 1 diabetes.

**Methods:** Seventy-one adolescents (mean age, 15 years; mean duration of diabetes, 5.7 years; mean HbA1c, 77 mmol/mol, (9.1%), upon study entry) from two pediatric departments were randomized into a GSD-Y group (n=37, GSD-Y was provided during individual outpatient sessions) versus a treatment as usual group (n=34). The primary outcome was the HbA1c measurement. The secondary outcomes were life skills development (assessed by self-reported psychometric scales), self-monitored blood glucose levels, and hypo- and hyperglycemic episodes. The analysis followed intention-to-treat.

**Results:** Fifty-seven adolescents (80%) completed the trial, and 53 (75%) completed a 6-month post-treatment follow-up. No significant effect of GSD-Y on HbA1c could be detected in a mixed model analysis after adjusting for the baseline HbA1c levels and the identity of the HCP (p=0.85). GSD-Y significantly reduced the amotivation for diabetes self-management (p=0.001). Compared with the control group, the trial completion was prolonged in the GSD-Y group (p<0.001), requiring more visits (p=0.05) with a higher rate of non-attendance (p=0.01). GSD-Y parents compared with control parents participated in less of the adolescents' visits (p=0.05).

**Conclusion:** Compared with treatment as usual, GSD-Y did not improve the HbA1c levels but decreased the adolescents' amotivation for diabetes self-management.

**Trial registration:** ISRCTN 54243636.

**Keywords:** Type 1 diabetes mellitus, adolescents, outpatient clinic, hospital, clinical trials, randomization, empowerment.

## **Background**

Managing type 1 diabetes during adolescence is a complex and demanding process that is often unsuccessful [1,2]. The importance of good glycemic control for preventing or postponing the long-term complications of diabetes has been well established [3]. Although late diabetic complications are rarely observed during adolescence, these pathogeneses begin to develop soon after diagnosis and accelerate during puberty [4]. In adolescents with type 1 diabetes, the target for glycemic control is an HbA1c level  $<58$  mmol/mol (7.5%) and an absence of frequent hypoglycemia [5]. Currently, 31% of adolescents in Denmark achieve this target (overall mean HbA1c, 70 mmol/mol, 8.6%) [6]. This result emphasizes the need for new methods to address the complexity of treating and caring for diabetes during adolescence.

Improvements in glycemic control during adolescence are associated with the involvement of parents and healthcare providers (HCPs) through a constructive and autonomy-supportive relationship that leads to self-determined management of the disease [7]. Behavioral and psychosocial interventions to improve self-management and glycemic control have had only a moderate effect [8], and only a few interventions involving parents have been integrated into conventional outpatient care [9-11].

Guided Self-Determination (GSD), a life skills approach developed to facilitate empowerment in the patient-provider relationship, has been shown to be effective in group training for adults with type 1 diabetes and persistently poor glycemic control, reducing HbA1c by 3 mmol/mol (0.4%) and increasing their life skills [12]. GSD functions as a shared decision-making and mutual problem-solving method involving the use of semi-structured reflection sheets [13] in combination with mirroring, active listening, and value-clarifying



responses, which lead to focused communication and situational reflection [14]. Life skills are defined as “those personal, social, cognitive and physical skills that enable people to control and direct their lives and develop the capacity to live with and produce change in their environment” [15]. The core principle in GSD is to support patients in clarifying and expressing their difficulties and mobilizing their own potential for change in interactions with autonomy-supportive HCPs. Instead of being told what to do by HCPs, GSD guides patients and HCPs in shared decision-making, whereby patients find solutions that align with their own values [14].

We adjusted GSD into GSD for adolescents and their parents (Guided Self-Determination-Youth (GSD-Youth (Y))) and fully integrated this method into pediatric diabetes outpatient clinics run by the adolescents’ usual interdisciplinary HCPs [13]. The aim of our randomized clinical trial was to test whether GSD-Y reduced HbA1c levels and improved life skills in adolescents with type 1 diabetes compared with conventional outpatient diabetes care.

## **Methods**

### ***Study design***

The study was a randomized clinical trial with a mixed methods design. The protocol has been previously published [13]. Here, we present the results from the quantitative portion of the trial.

### ***Participants***

From September 2009 through November 2010, adolescents with type 1 diabetes attending 2 Danish pediatric outpatient clinics at 2 hospitals in the Capital Region of Denmark were recruited for the trial if they met the following eligibility criteria: a) aged 13–18 years; b) had

been diagnosed with type 1 diabetes for >1 year; c) had engaged in insulin therapy since the onset of the disease; d) had recorded levels of HbA1c  $\geq 64$  mmol/mol (8.0%) at the last evaluation before entry into the trial (determined from medical records), and had maintained an average HbA1c  $>58$  mmol/mol (7.5%) during the year prior to inclusion, with values collected from the Danish National Diabetes Register for Children (DanDiabKids) [6] and manual searches of local medical records; e) had not been diagnosed with any psychiatric disease; f) were not engaged in psychological treatment at the time of recruitment; and g) had the ability to speak and understand Danish. Parents were included if they spoke, read, and wrote Danish, did not have severe illnesses, did not have mental problems, and were not currently undergoing psychiatric or psychological treatment. The criteria for discontinuation from the trial included the voluntary withdrawal of consent or—at the discretion of the investigator—the occurrence of severe concomitant disease or non-compliance with the trial protocol. The criterion for HCPs to participate in the trial was at least 1 year of experience in a diabetes pediatric outpatient clinic at the beginning of the intervention. The HCPs were GSD-Y trained and tested for their abilities to provide GSD-Y correctly in triads of adolescents, parents, and HCPs prior to the start of the trial [13]. The adjustment and implementation of GSD-Y lasted 18 months. Husted (GRH) and Zoffmann (VZ) adjusted the adult GSD to the GSD-Y version [16,17], ensuring that the language and reflection sheets were suitable for use in the triads.

Written informed consent was obtained from all adolescents and parents of minors (younger than 15 years of age) prior to enrollment by the adolescents' usual HCP. The trial protocol was reviewed by the Danish National Committee on Biomedical Research Ethics in April 2009 as a registry- and interview-based research study (REC; reference number 0903054;

document number 230436). The study was registered with the Danish Data Association (ref number 2008-41-2322) and with the Current Controlled Trials registry (ISRCTN54243636).

The adolescents were stratified according to their usual HCPs and were randomized in blocks. The generation of the allocation sequence was determined according to when the adolescents had their regularly scheduled outpatient appointments. A case report form (CRF) was used on the day of randomization to ensure that the adolescents fulfilled the eligibility criteria. The adolescents were randomized using opaque sealed envelopes containing a twice-folded piece of paper indicating the group assignment; these assignments were prepared in blocks of 4, each comprising 2 GSD-Y intervention assignments and 2 usual-care assignments. The 4 envelopes in each block were randomly mixed and then consecutively numbered from 1 to 4 by GRH. In collaboration with VZ, GRH supervised the HCPs during randomization. Because of the nature of the intervention, neither the adolescents nor the HCPs could possibly be blinded to the group allocation after randomization. All participating adolescents provided a blood sample for HbA1c measurement while in the clinic before the randomization. Baseline characteristics are presented in Table 1.

*Table 1 here*

### ***GSD-Y intervention***

Two pediatric physicians, 5 pediatric diabetes nurses, and 2 dieticians (HCPs) provided the GSD-Y intervention as part of their conventional outpatient clinical care. The intervention was divided into 8 sessions scheduled over an 8- to 12-month period with a standard duration of 1 hour per session in an individual setting. The intervention consisted of 18 semi-structured reflection sheets for adolescents, 5 for parents, and 6 sheets if the patient were

visiting a dietician [13]. Before each visit, the adolescents and parents completed their individual reflection sheets with regard to different predefined main topics that related to their lives with diabetes (e.g., “*Room for your diabetes*” or “*Room for your teenager’s diabetes in your life*”). The details of all predefined topics are published elsewhere [13]. By completing the reflection sheets using their own words and drawings, the adolescents and parents systematically explored and expressed their individual and shared difficulties with diabetes in session. The GSD-Y sessions functioned as life-skills training [18] in 6 steps: (i) establishing a mutual relationship with clear I-you borders, also called I-you-sorted mutuality [19]; (ii) self-exploration; (iii) self-understanding; (iv) shared decision-making; (v) action; and (vi) feedback from action.

GSD-Y adolescents were referred to a dietician if the reflection sheets completed after session 1 or 2 indicated such a need. Each referral to a dietician was anticipated to involve a minimum of 2 sessions in addition to the planned 8 sessions.

The parental GSD-Y sessions with HCPs were scheduled twice during the experimental period (after 3 and 6 months), with a typical duration of 1 hour per session.

The adolescents and parents kept their original semi-structured reflection sheets, and copies were placed in the adolescents’ medical records.

### ***Treatment-as-usual control group***

The control group’s 8 sessions were scheduled across an 8- to 12-month period, with a maximum standard duration of 45 minutes (usually 30 to 45 minutes). They were referred to

a dietician, according to usual practice. Because no guidelines were available for this procedure, each HCP independently decided when referral to a dietician was needed.

## ***Outcomes***

### **Primary outcome**

The primary outcomes were HbA1c levels measured at baseline and every third month during the trial. The HbA1c levels from both hospitals were analyzed at the same department of clinical biochemistry using the Variant Analysis Mode of the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (normal range 23 to 40 mmol/mol, 4.3% to 5.8%). As the HbA1c analyses in Scandinavia were found to be falsely high due to problems with a freeze-dried calibrator, these values were consequently decreased by 2.7 mmol/mol (0.24%), following recommended guidelines [20].

### **Secondary outcomes**

- a. The development of life skills in adolescents with type 1 diabetes was measured according to increases in the following factors: (i) perceived competence in managing diabetes [21]; (ii) perceived autonomy support from the HCPs [22]; (iii) autonomous motivation for diabetes management [23]; (iv) the ability to manage diabetes-related distress [24]; (v) involvement and autonomy support from parents [25]; and (vi) patient well-being [26].
- b. The diabetes outcomes directly related to patient management included the following issues: (i) insulin delivery (continuous subcutaneous insulin infusion [CSII] or multiple daily injections [MDI]); (ii) the number of self-monitored blood glucose (SMBG) values during the prior (last) week; (iii) hypoglycemic episodes (frequency and severity); and (iv) admissions to the hospital and the reasons for the admissions (e.g., episodes of ketoacidosis or hypoglycemia).

c. The diabetes outcomes that were indirectly related to patient management included (i) attendance at the intervention or control sessions and (ii) parental participation.

Because of the absence of a universal scale with which to measure the development of life skills in individuals with diabetes, we applied the Danish versions of 6 scales consistent with the theoretical framework of GSD [27]. One scale, the Perception of Parental Support (POPS) scale [25], was translated into Danish following recommended guidelines [28]. The scales comprised the 20-item Problem Areas In Diabetes (PAID) questionnaire a 5-point scale measuring the perceived burden of diabetes-related problems [24]; the 5-item Health Care Climate Questionnaire questionnaire (HCCQ) which measures the degree to which the patients experience autonomy support from their HCPs [22]; the 5-item Perceived Competence in Diabetes Scale (PCD) which measures the degree of competence perceived by patients in managing their diabetes [21]; the 21-item Treatment Self-Regulation Questionnaire (TSRQ) which comprises 3 subscales measuring the patients' motivations for taking diabetes medication, checking glucose levels, following their diets and exercising regularly with the results scored as autonomous (originated from the self), controlled (pressured or coerced by intrapsychic or interpersonal forces), or amotivated (having no intention to change and often feel unable to change) [23]; two subscales of the Perception of Parents Scale (POPS), a 7-point Likert scale consisting of 26 items in total (13 items for mothers and 13 items for fathers) that assess adolescents' perceptions of their parents' autonomy support and involvement [25] ; and the 5-item World Health Organization-5 scale (WHO5), which assesses emotional well-being [26]. Improvement in life skills was defined as a significant increase in scores on HCCQ, PCD, TSRQ autonomy, TSRQ relative autonomy index (formed by subtracting the TSRQ-scores on control from the TSRQ-scores

on autonomy), POPS, and WHO5 and a significant decrease in scores on PAID, TSRQ control and TSRQ amotivation.

The scales are presented in Table 2. Details of the scales and scores have been published elsewhere [13]. The face validity of all scales was tested in 8 adolescents with type 1 diabetes (not included in the randomized part of the trial) before starting the trial; no changes were needed. The scales were compiled into 1 questionnaire and completed by the adolescents in the clinic at baseline, before randomization, at the end of the experimental period, and after a 6-month follow-up period.

The CRFs were used to collect the secondary diabetes outcomes (b+c) during the experimental period and were completed at every outpatient clinic visit by the adolescents' usual HCPs, except for the number of SMBG measurements, which were self-reported when the adolescents completed the questionnaires. The number and severity of hypoglycemic episodes since the last visit were recorded, distinguishing between mild (treatable by the patient), moderate (requiring help from others), or severe (the patient was unable to assist in his/her own care, was semiconscious or unconscious, or was comatose) [29]. The plasma glucose levels at the time of the hypoglycemic episodes were unavailable. Demographic data were collected from adolescents at baseline.

### ***Statistical analysis***

A power calculation, which was based on an absolute difference of 11 mmol/mol (1.0%) in the primary outcome HbA1c between the GSD-Y and control groups, a standard deviation of HbA1c of 1.3%, as reported in a study on coping skills training [30], a power of 0.80, and a 2-tailed significance test at the 0.05 level, indicated that 26 patients would be needed in each group. To allow for 25% attrition, we aimed to recruit 68 adolescents.

Intention-to-treat analyses were used with 2-tailed tests at the 0.05 significance level. Holm's test was used to control the family-wise error rate [31].

The analyses of the primary outcome and each of the 14 continuous life skills outcomes were performed using a linear mixed model with repeated measures that assumed an unstructured covariance matrix. The primary result was based on a model that included an indicator for the intervention (I, reference group 2), an indicator for the follow-up (F, 0 for the end of the experiment and 1 for the follow-up time point), the interaction between the 2 indicators (I\*F), the protocol-specified stratification variable, and the baseline value of the dependent variable (HbA1c). Two hypotheses were tested: (i) that the intervention had an effect on the mean level of the dependent variable (HbA1c) at the end of the experiment that was sustained until follow-up (main effect of I); and (ii) that the intervention changed the level of the dependent (HbA1c) variable from the end of the experiment until follow-up (interaction between intervention and follow-up). Thus, a significant main effect of the intervention in the presence of an insignificant main effect of follow-up and insignificant interaction between follow-up and intervention would suggest that the intervention had an immediate effect that was neither augmented nor blunted during the follow-up period. Two additional exploratory analyses were conducted: (i) an analysis without adjusting for the stratification variable (HCP); and (ii) an analysis with an additional adjustment of the baseline value of log(HbA1c) to adjust for severity of the disease. The rate data were compared between the groups using a non-parametric Mann-Whitney U-test. The binary quantities were compared using the Cochran-Mantel-Haenszel test of relative risk. The ordinal data were compared between the groups using the Cochran-Armitage test for trends at the end of the experiment and at the end of the follow-up. The mixed model with repeated measures utilizes all observed values and



provides unbiased estimates under the condition that the data are missing at random (i.e., that the missingness of the data does not depend on the unmeasured values).

The fact that the HbA1c levels were measured relatively routinely in the adolescents allowed a supplementary post hoc analysis of the HbA1c levels, which was designed to investigate the constant periods and the frequencies of observation of the HbA1c levels. We compared the time series of the 2 groups, including the HbA1c level measurements obtained every third month starting with the measurement obtained 3 months following randomization and covering a period of 30 months, to ensure that the period of experimental and control intervention was included for all patients. The results were subjected to a repeated-measures mixed-model regression analysis. The Akaike information criterion was used to choose between an autoregressive model of first order AR (1) and a compound symmetric covariance matrix because convergence was not obtained using an unstructured matrix. We tested for a main effect of intervention, a main effect of time, and an interaction between the 2 models, controlling for the baseline HbA1c level and the HCP. The data were analyzed using SPSS version 17.

## **Results**

A total of 71 of the 274 adolescents with type 1 diabetes were randomized to either the GSD-Y intervention group (n=37) or the control group (n=34) (Figure 1). We allocated equal numbers of GSD-Y and control adolescents to each physician and nurse—approximately 10 adolescents to each professional. A total of 138 adolescents did not meet the eligibility criteria (first because of not meeting the HbA1c level criterion, second because of language barriers, and third because of current psychological or psychiatric treatment or possible psychiatric disorders). Twenty-seven eligible adolescents were not invited because they were

usually treated by HCPs who had not been GSD-Y trained; 26 eligible adolescents declined to participate; 6 participated in other projects, and 6 lived far away and normally only attended the outpatient clinic 3 to 4 times yearly.

*Figure 1 here*

A comparison of the baseline characteristics between the groups suggests that the randomization was successful for all variables except for the HbA1c level, for which the mean value was somewhat lower in the control group (Table 1).

Fifty-seven adolescents (80%) completed the trial, 26 in the GSD-Y group and 31 in the control group. Fifty-three (75%) adolescents provided 6-month follow-up data, 23 in the GSD-Y group and 30 in the control group. The duration of the experimental period was significantly longer in the GSD-Y group than in the control group ( $608 \pm 125$  days versus  $458 \pm 111$  days,  $p < 0.0005$ , mean  $\pm$  SD). The duration of follow-up did not differ significantly between the groups ( $216 \pm 59$  days versus  $246 \pm 83$  days,  $p = 0.14$ ).

### ***Primary outcome***

The baseline HbA1c values were  $80 \pm 3$  mmol/mol ( $9.5 \pm 0.3\%$ ) in the GSD-Y group and  $73 \pm 2$  mmol/mol ( $8.8 \pm 0.1\%$ ) in the control group (mean  $\pm$  SE). At the end of the trial, the HbA1c levels were  $80 \pm 3$  mmol/mol ( $9.5 \pm 0.3\%$ ) in the GSD-Y group versus  $76 \pm 2$  mmol/mol ( $9.1 \pm 0.2\%$ ) in the control group. After a 6-month follow-up, the results were  $82 \pm 3$  mmol/mol ( $9.6 \pm 0.3\%$ ) in the GSD-Y group versus  $79 \pm 3$  mmol/mol ( $9.4 \pm 0.3\%$ ) in the control group. The mixed model analysis showed neither a significant main effect of the intervention ( $p = 0.85$ ) nor any significant interaction between follow-up and intervention ( $p = 0.68$ ). The mixed

model exploratory analysis of the time course of HbA1c during the first 30 months following the randomization revealed no significant main effect for the intervention ( $p=0.86$ ), no significant main effect for time ( $p=0.65$ ), and no significant interaction between time and intervention ( $p=0.55$ ). Figure 2 shows the means plus/minus 2 SDs in each group as a function of time during the 30-month period.

*Figure 2 here*

### ***Secondary outcomes***

The results of the mixed model analyses on the life skills scores controlling for baseline values and the effect of HCPs showed a significant main effect of the GSD-Y intervention on Treatment Self-Regulation Questionnaire (TSRQ) amotivation ( $p=0.001$ ), TSRQ autonomy ( $p=0.017$ ), TSRQ autonomy index ( $p=0.020$ ), and POPS autonomy mother support ( $p=0.036$ ). The main effect of follow-up and the interaction between the intervention and the follow-up was clearly insignificant in all instances. After adjusting the significance level according to Holm's method [31], only the main effect of the GSD-Y intervention on TSRQ amotivation ( $p=0.0010$ ) at the end of the intervention remained significant (Table 2).

*Table 2 here*

There were no significant differences between the GSD-Y group versus the control group concerning the number of SMBG measurements taken during the experimental period ( $32\pm 14$  versus  $32\pm 13$  measurements per patient per week,  $p=0.89$ ) or at follow-up ( $31\pm 13$  versus  $31\pm 19$ ,  $p=0.88$ ). The occurrence of mild, moderate, and severe hypoglycemic episodes during the experimental period were 0.60, 0.13, and 0.08 episodes, respectively, per patient per year

in the GSD-Y group versus 2.4, 0.11, and 0.02 episodes, respectively, per patient per year in the control group. No significant between-group differences were observed concerning the risk of hypoglycemia (mild,  $p=0.91$ ; moderate,  $p=0.30$ ; severe,  $p=0.30$ ) or the rate of events (mild,  $p=0.80$ ; moderate,  $p=0.34$ ; severe,  $p=0.34$ ) during the experimental period. Insulin regimens, insulin doses, admissions to hospital, and occurrences of ketoacidosis did not differ between the groups (data not shown).

All but 1 GSD-Y adolescent required more than 8 visits to complete the 8 sessions. The median number of visits was 12 (range, 8-16) in the experimental group compared with 8 (range, 7-12) in the control group ( $p=0.001$ ). Neither the GSD-Y group patients nor the control group patients showed up for all scheduled outpatient sessions. The GSD-Y group had more non-attendance incidents yearly compared with the control group ( $0.9\pm 1.1$  versus  $0.4\pm 0.6$  missed visits,  $p=0.02$ ), but the yearly number of cancellations did not differ between the 2 groups ( $1.1\pm 1.1$  versus  $0.8\pm 1.4$  cancellations,  $p=0.07$ ). The parents of the GSD-Y adolescents participated in fewer sessions than the parents of the control adolescents (median, 3.5 versus 7 visits,  $p=0.05$ ). Twenty-three (68%) of the GSD-Y parents attended 1 parental GSD-Y session (at a median of 6 months; range, 2-14), and 11 parents (30%) attended 2 parental GSD-Y sessions (at a median of 13 months; range, 5-20).

More GSD-Y adolescents (50%) were referred to the dietician compared with 11% in the control group. Each GSD-Y adolescent completed 1 to 6 visits, whereas each control adolescent had 1 visit.

The reflection sheets were completed by all 26 GSD-Y adolescents, except for 2 sheets identifying the patterns and motivations for blood sugar management behaviors (3.d and 4.a [13]), which were not used by 10 participants (39%).

## Discussion

When integrated into routine pediatric outpatient diabetes visits, GSD-Y had no significant effect on the primary outcome of HbA1c compared with treatment as usual. GSD-Y seemed to significantly decrease the level of amotivation for diabetes self-management at the end of the experimental period compared with the control group, an effect that was maintained at follow-up. No other life-skills outcomes and no diabetes outcomes directly related to patient management were significantly influenced by the GSD-Y intervention compared with treatment as usual.

Our HbA1c results aligned with the results from 3 recently published randomized clinical trials that also included treatment-as-usual outpatient visits [9-11]. In the Development and Evaluation of a Psychosocial Intervention in Children and Teenagers Experiencing Diabetes (DEPICTED) trial—a diabetes training program for pediatric diabetes teams that is based on motivational interviewing—26 secondary and tertiary care pediatric diabetes services in the UK were evaluated [9]. This intervention included 359 young people with type 1 diabetes (aged 4–15 years) and their main caregivers; the program showed no effect on HbA1c levels 1 year after training compared with 334 patients in the control group. In the 18-month Families and Adolescents Communication and Teamwork Study (FACTS), the effectiveness of a family-centered group education program was studied in 158 adolescents with type 1 diabetes (aged 11-16 years) [10]. Six 90-min monthly sessions were attended by adolescents and parents. After 18 months (12 months post-intervention), there was no significant difference in the HbA1c levels compared with the 147 adolescents in the control group. In a 2-year trial, Katz and coworkers randomized 153 adolescents (aged 8-16 years) with type 1 diabetes into 3 groups: (i) receiving standard care, (ii) receiving monthly outreach by a care ambassador, or (iii) receiving monthly outreach by a care ambassador and participating in a

family-focused psychoeducational intervention [11]. No significant differences in HbA1c levels were detected among the groups after 2 years.

In the DEPICTED trial, the HbA1c levels did in fact increase in both groups during the trial (from 79 to 83 mmol/mol (9.4 to 9.7%) in the intervention group and from 77 to 80 mmol/mol (9.2 to 9.5%) in the control group) [9], and similar findings were observed in FACTS [10] and the trial by Katz and coworkers [11]. In our trial, the HbA1c levels increased in the control group (from 73 to 76 mmol/mol [8.8 to 9.1 %]) at the end of the experimental period) but were unchanged in the GSD-Y group (80 mmol/mol, 9.5 %) from baseline until the end of the experimental period. It is well known that HbA1c levels normally increase during adolescence [32]. In the DanDiabKids Registry, the HbA1c levels increased from 66 to 73 mmol/mol (8.2 to 8.8%) in adolescents with type 1 diabetes who were between the ages of 12 and 18 years, or at an average of 1 mmol/mol (0.12%) per year (Svensson J, DanDiabKids Registry, unpublished data 2012). Whether our finding of an unchanged average HbA1c level in the GSD-Y group during the trial period represents a true difference from the increase in the control group or is a coincidence remains to be determined.

In adults, the original 16-hour, nurse-led GSD group training had a statistically significant impact on HbA1c levels from 3 to 12 months [12]. Group interventions in adolescents have been found to be associated with improved glycemic control compared to individual interventions [8,33]. The lack of an effect of GSD-Y on HbA1c in our study could, therefore, be attributed to our individual approach. However, in FACTS, poor attendance at group education sessions delivered in a routine clinic was a major challenge [10]. The authors suggested that more personalized educational approaches might be required to support and

motivate families struggling to integrate the demands of intensive insulin regimens into their daily lives [10], a statement that seems to be somewhat contradicted by our findings that GSD-Y is a personalized, motivating approach. The non-significant results of the 4 trials ([9-11] and the present trial) appear to be related to the more complex conditions that are at play among adolescents compared with adults. Adolescents' crave conformity. That fact, their lack of acceptance of the disease [34] and their perception of resistance against their parents [35] are important factors to consider in achieving good glucose management. These competing difficulties may have resulted in less attention to the reflection sheets. One-third of the GSD-Y participants did not complete 1 or 2 of these reflection sheets, which were designed to identify the adolescents' patterns of motivation for blood sugar management [12]. In adults, these specific reflection sheets may have had an important impact on the decrease of HbA1c [27]. Another distinction from the trial in adults was that the GSD-Y adolescents required more time and additional visits to complete the 8 GSD-Y sessions and had a higher rate of non-attendance than the control group. We speculate that the extended time between the GSD-Y sessions and an excessively lengthy intervention period may have reduced the momentum of the intervention to impact glucose management behavior [36], this consideration is also mentioned in the report from Katz and colleagues study [11].

GSD-Y significantly decreased amotivation at the end of the intervention compared with treatment as usual. A significant main effect of the intervention in the presence of an insignificant main effect of follow-up and insignificant interaction between follow-up and intervention suggests that the intervention had an immediate effect that was neither augmented nor blunted during the follow-up period. This result may seem paradoxical considering the aforementioned difficulties in complying with the intervention. A decrease in amotivation indicates that GSD-Y adolescents felt motivated to identify the reasons for



diabetes self-management in which they believed [23], which is an important sign of developing life skills [18]. To be autonomously motivated means that people perceive themselves as choosing to follow their treatment for personally meaningful reasons and freely chosen goals, rather than because of controlled reasons, such as *'I ought to'* or *'I should,'* or amotivational feelings of helplessness, such as *'I do not know why I do try – I will not be successful'* [37]. Because amotivation has been regarded as a sign of hopelessness and a predictor of psychological distress and depression [38], decreasing amotivation seems to be important for a constructive approach to diabetes self-management [39]. Surprisingly, the decreased amotivation was not found to be accompanied by significantly increased parental (POPS) or HCPs' autonomy support (HCCQ). By applying pressure for better diabetes management, parents and HCPs may unwittingly obstruct the adolescents' motivations for treating the disease and instead foster resistance, passivity, and amotivation for developing self-management skills [40-42]. One explanation of the decrease in amotivation may be that GSD-Y parents participated less in their adolescents' visits than the control parents. Thus, GSD-Y adolescents may have been enabled to become more engaged in their own diabetes care. We also speculate whether the decrease in amotivation was influenced by the use of reflection sheets being perceived as motivating unto themselves and keeping HCPs from promoting controlled motivation attitudes. Another explanation may be that the GSD-Y adolescents received more visits during a longer period. This explanation may have contributed to better possibilities to decrease their amotivation. However, none of the other life skills outcomes were influenced by the time differences between the intervention and the control group.

Our study demonstrated no significant effects on the remaining life skills parameters when Holm's correction [31] was implemented. The lack of significant differences in the scales

between the groups may have been due to the sample size. Accordingly, type II errors cannot be excluded.

The present trial has several strengths. First, we used stratified randomization, which reduced selection bias by ensuring that GSD-Y and control adolescents were followed by equally GSD-Y-skilled HCPs. Second, we chose the same primary and secondary outcomes that were used in adults precisely because they had been proven sensitive to capture the effect of GSD in adults [12]. Thus, it was possible to test whether an effect occurred in adolescents.

However, the feasibility of integrating a complex intervention in a complex health-care system may be questioned because the participants followed the protocol in neither the experimental nor the control group. A pilot study might have captured some of the difficulties involved in integrating GSD-Y into usual outpatient visits [43], but we did not choose to do so because we would have been left with too few adolescents for the randomized trial.

Several limitations may have threatened the internal and, hence, the external validity of our trial. First, we used allocation concealment by employing opaquely sealed envelopes [44,45]. Although they were consecutively numbered, we cannot exclude the possibility that the allocation sequence was compromised [44,45]. When the expected adolescents did not show up as scheduled or needed time to consider their participation until the following visit, the next adolescent who fulfilled the inclusion criteria was invited and randomized if his or her consent to participate was given. Second, the present trial could not be blinded because of the nature of the intervention, which may have biased our results [44,45]. Moreover, because each HCP practiced both the experimental and the control intervention, we cannot exclude a spillover effect caused by the GSD-Y training of all HCPs. Third, we did not assess some of the secondary outcomes (b+c) during the follow-up. The GSD-Y impact on, for instance, the

occurrence and the risks of hypoglycemia could, therefore, only be assessed during the experimental period. Furthermore, it may also be considered a limitation that HbA1c was chosen as the primary outcome both at the end of the experimental period and at the follow-up because the time of the experimental period differed significantly between the 2 intervention groups. HbA1c is, however, considered to be the ‘gold standard’ when researching outcomes in adolescents with type 1 diabetes as an indicator of diabetes management [46,47]. To compare our results with similar trials, we chose this outcome variable. However, no effect of the experimental intervention was detected by using HbA1c in our trial.

## **Conclusions**

No effect of GSD-Y on HbA1c was identified in our trial. Our results can be questioned because the intervention was not followed as strictly as was intended. Together with previous research [9-11], the result underscores the difficulties involved in developing effective treatments integrated into the usual care provided to adolescents. Presently, GSD-Y should not be integrated into outpatient visits in its current format if the only purpose is to improve glycemic control. Whether the positive finding of decreased amotivation in the GSD-Y group can be sustained for longer periods or replicated remains to be determined.

## **List of abbreviations**

BAE:	Bente Appel Esbensen
BT:	Birger Thorsteinsson
CG:	Christian Gluud
CRF:	Case Report Form
CSII:	Continuous subcutaneous insulin infusion

DanDiabKids: Danish National Diabetes Register for Children

EH: Eva Hommel

HbA1c: Glycated Haemoglobin A1c (a difference of 1% is equivalent to 11 mmol/mol)

HCCQ: Health Care Climate Questionnaire

HCP: Health care providers

GRH: Gitte Reventlov Husted

GSD: Guided Self-Determination

GSD-Y: Guided Self-Determination-Youth

MDI: Multiple Daily Injections

PW: Per Winkel

PAID: Problems Area In Diabetes

PAR: Participatory Action Research

PCD: Perceived Competence in Diabetes

POPS: Perception Of Parental Support

SDT: Self-Determination theory

SMBG: Self-monitored blood glucose measurements

TSRQ: Treatment Self-Regulation Questionnaire

VZ: Vibeke Zoffmann

WHO5: Emotional Well-Being Scale

### **Competing interests**

The authors declare that they have no competing interests.

### **Author contributions**

GRH drafted the manuscript. GRH and PW analyzed the data. VZ, BT, BAE, EH, PW and

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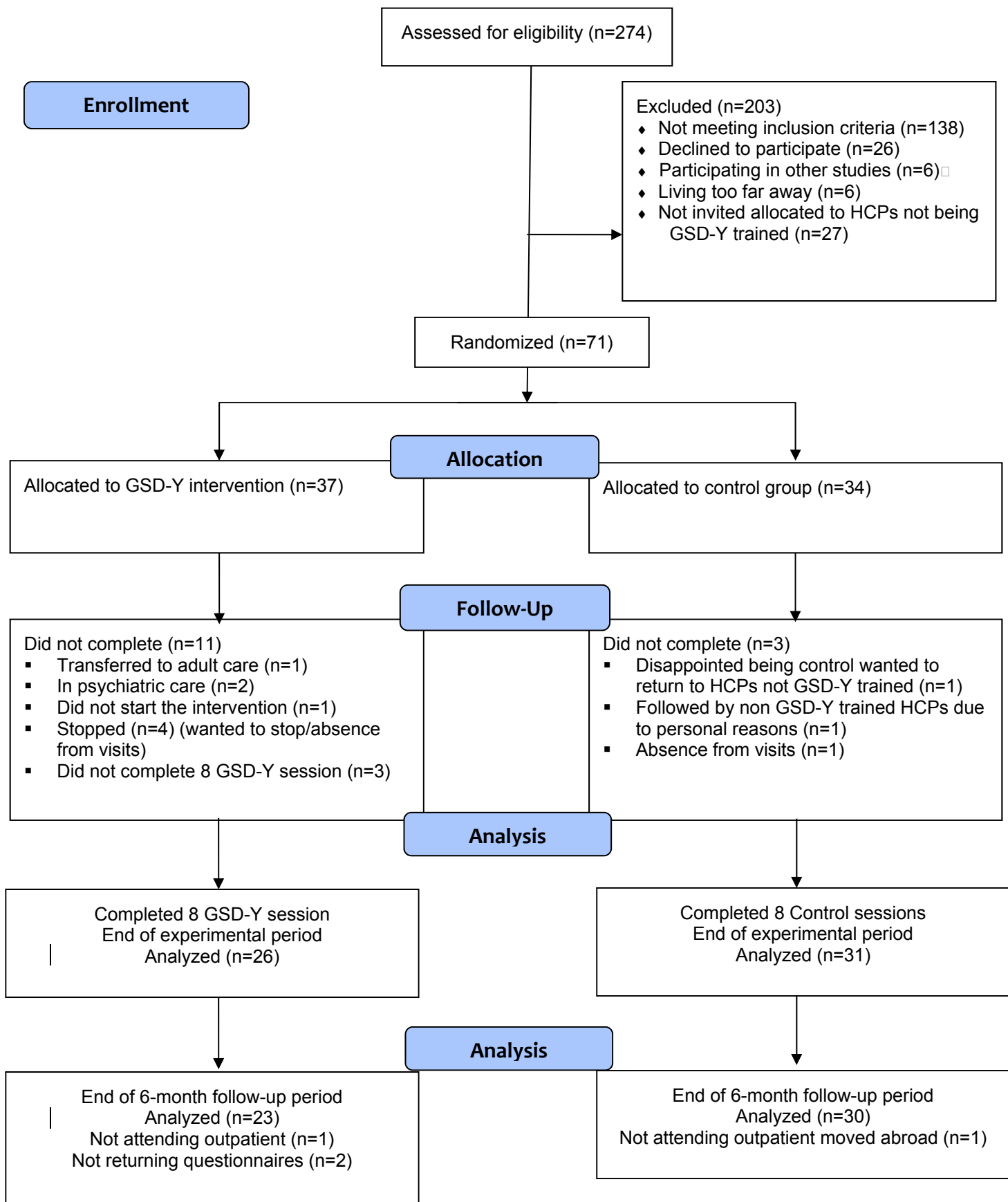
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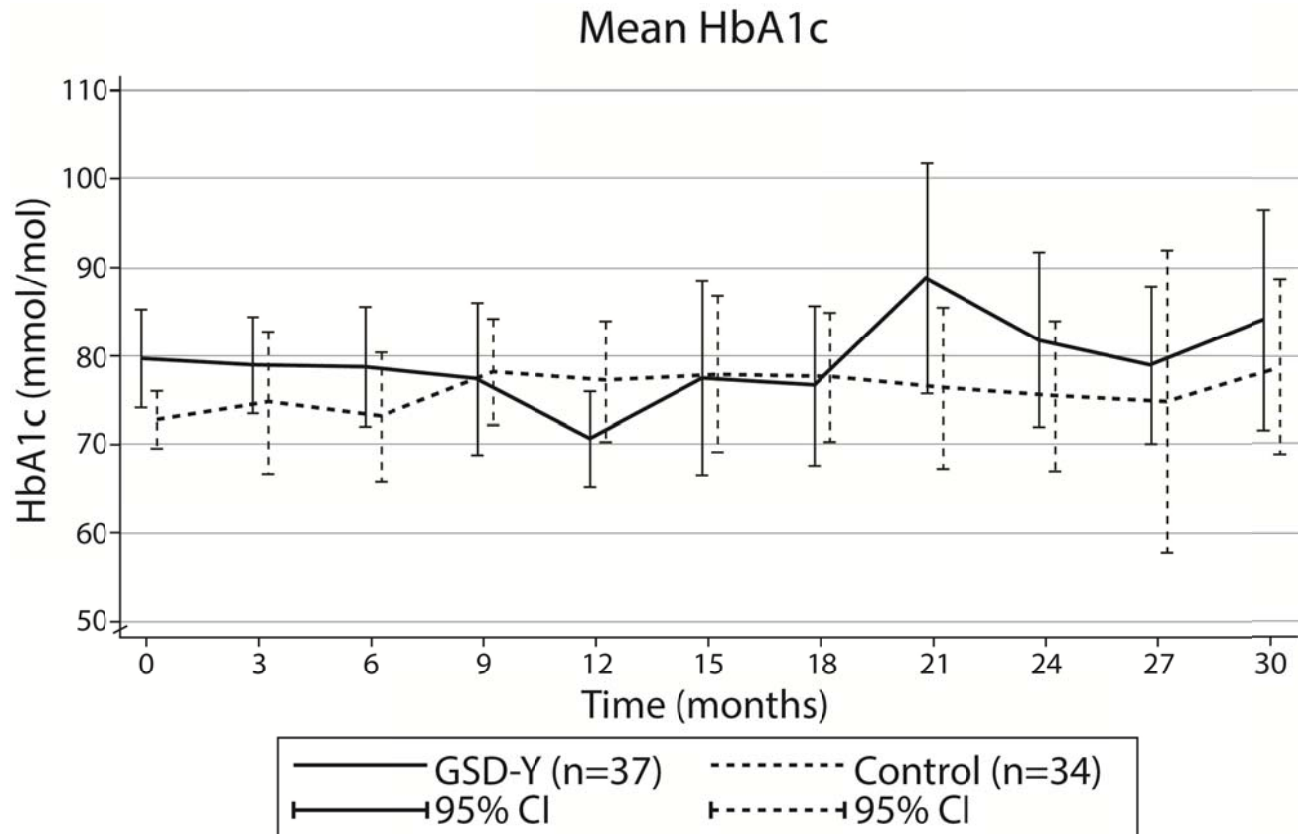
Figure 1

### CONSORT Flow Diagram



**Figure 2**

HbA1c levels in the GSD-Y and the control groups during 30 months of trial



The figure shows an error bar diagram of the mean of p-HbA1c/mmol/mol as a function of time and the adolescents' group membership. It appears that the levels of the two groups are quite close and that both curves are relatively flat. This impression is confirmed by the results of the mixed model analysis which showed that there was no significant difference between the mean levels of the two groups (P of main effect of intervention = 0.86), no significant change over time in the mean values of the groups neither overall (P of main effect of time = 0.65) nor in individual groups (P of interaction between time and intervention = 0.55).

**Table 1. Clinical and demographic baseline characteristics of the adolescents.** GSD-Y: Guided Self-Determination-Youth group. CON: control group. SMBG: self-monitored blood glucose. MIT: multiple insulin injections. CSII: continuous subcutaneous insulin infusion. Data are presented as means±SDs (number of patients (%)).

	<b>GSD-Y</b> <b>37</b>	<b>CON</b> <b>34</b>
n (% females)	22 (62)	21 (60)
Age (years)	14.9±1.5	14.6±1.3
BMI (kg/m <sup>2</sup> )	22.1±2.9	22.3±4.0
Age at onset of diabetes (years)	8.8±2.9	9.2±3.7
Duration of diabetes (years)	6.1±3.0	5.3±3.4
HbA1c (mmol/mol)	79.9±16.6	72.8±9.4
HbA1c (%)	9.5±3.7	8.8±3.0
SMBG (number per week)	28±14	33±18
Insulin dose (IU per kg per day)	1.2±0.6	1.0±0.5
MIT, n (%)	25 (68)	22 (65)
CSII, n (%)	12 (32)	12 (35)
Living with both parents, n (%)	16 (62)	21 (70)
Ethnicity		
Danish, n (%)	31 (84)	25 (74)
Other, n (%) *	6 (16)	9 (26)
Education		
Danish public school (0-10 grades), n (%)	23 (62)	25 (74)
Secondary education, n (%) **	8 (22)	5 (15)
Other schools, n (%) ***	6 (16)	4 (11)

\*Turkey, Somalia, Sweden, France, Russia, Morocco, Afghanistan, Poland, Tunisia, Pakistan

\*\*Gymnasium, Higher Preparatory Examination (HF), Higher Commercial Examination Program (HHX), Higher Technical Examination Program (HTX)

\*\*\*Continuation school

**Table 2. Results of the life-skills questionnaires.** The results were taken at baseline, at the end of intervention, and at the end of the 6-month follow-up period in the Guided Self-Determination-Youth group (GSD-Y) and in the treatment as usual control group (CON). Data are presented as means±standard errors (SE) (number of patients).

Quantity	Min-max Scores	Baseline		End of intervention		End of follow-up	
		GSD-Y	CON	GSD-Y	CON	GSD-Y	CON
PAID	0-100	29±2.3 (34)	24±3.1 (34)	28±3.3 (26)	28±4.0 (29)	26±3.6 (22)	22±3.5 (30)
HCCQ	5-35	31±0.6 (37)	30±0.9 (34)	32±0.8 (26)	31±0.6 (30)	32±1.3 (23)	31±1.1 (30)
PCD	5-35	24±1.1 (37)	26±1.0 (34)	26±1.3 (26)	28±0.9 (30)	28±1.3 (23)	28±1.3 (30)
TSRQ autonomy	8-56	45±1.1 (37)	44±1.3 (34)	47±0.95 (26)	43±1.3 (30)	46±1.3 (23)	44±1.3 (29)
TSRQ control	9-63	40±1.4 (37)	41±1.7 (34)	40±1.5 (26)	41±2.1 (30)	37±2.3 (23)	40±2.1 (29)
TSRQ amotivation #	4-28	11±0.6 (37)	11±0.6 (34)	9.1±0.7 (26)	11±0.9 (30)	8.6±0.9 (23)	11±0.8 (29)
TSRQ autonomy index (autonomy – control)	-51- +47	4.8±1.6 (37)	3.6±1.3 (34)	6.9±1.4 (26)	1.6±1.3 (30)	9.0±2.2 (23)	3.8±2.1 (29)
POPS autonomy support mother	7-49	35±1.0 (35)	35±1.3 (34)	37±1.5 (24)	35±1.3 (24)	40±1.2 (21)	37±13 (29)
POPS autonomy support father	7-49	34±1.5 (33)	33±1.3 (32)	36±1.8 (24)	34±1.5 (24)	36±2.1 (21)	33±1.7 (29)
POPS involvement mother	6-42	33±1.0 (34)	32±0.8 (34)	34±1.6 (24)	33±1.2 (30)	36±1.2 (21)	33±1.1 (29)
POPS involvement father	6-42	31±1.6 (32)	28±1.1 (32)	31±1.8 (24)	30±1.4 (28)	32±1.8 (21)	29±1.4 (29)
WHO5 index	0-100	60±2.8 (36)	66±3.3 (34)	60±4.2 (26)	61±3.6 (30)	56±4.8 (23)	62±3.4 (30)

# p=0.0013 by mixed model analysis; family-wise error controlled by Holm's method (Bretz F, Hothorn T, Westfall P. Multiple comparisons using R CRC: Press Chapman & Hall; 2011).



## **Adolescents Developing Life Skills for Managing Type 1 Diabetes: A Qualitative, Realistic Evaluation of a Guided Self-Determination-Youth Intervention**

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**Running head:** Life skills in adolescents with type 1 diabetes

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### **Author contributions**

All authors meet at least one of the following criteria (recommended by the ICMJE:

[http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html)) and have agreed on the final version:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- Drafting the paper or revising it critically for important intellectual content

**Danish Data Association ref nr. 2008-41-2322**

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**Trial Registration: ISRCTN54243636**

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## **ABSTRACT**

**Aim.** To explore and illustrate how the Guided Self-Determination-Youth method influences the development of life skills in adolescents with type 1 diabetes supported by their parents and health care providers.

**Background.** Evidence-based methods that accomplish constructive cooperation between adolescents with poorly controlled type 1 diabetes, their parents, and health care providers are needed. We adjusted an adult life skills intervention comprising reflection sheets and advanced communication for use by adolescent-parent-professional triads in outpatient visits.

**Design.** A qualitative realistic evaluation design comprising eight context-mechanism-outcome configurations directed the analysis of the Guided Self-Determination-Youth's influence on adolescent-parent-professional triads to evaluate what worked for whom, how and in what circumstances. Thirteen adolescents aged 13-18 years diagnosed with type 1 diabetes for  $\geq$  one year and having poor glycaemic control participated together with 17 parents and 8 health care providers. Data were collected from December 2009 until March 2012 and consisted of digitally recorded outpatient Guide Self-Determination-Youth visits collected during the intervention period (11.5-24.5 months) and semi-structured interviews at 6-month follow-up.

**Findings.** Emerging life skills in adolescents were identified as 1) developing new relatedness with health care providers and parents; 2) becoming decision-makers in their own lives with diabetes; and 3) growing personally. Reflection sheets combined with health care providers' advanced communication were central in promoting mutual problem solving.

**Conclusion.** A life skills approach turned outpatient visits into person-specific visits with improved cooperation patterns within the triads. Combining reflection sheets and advanced communication skills supported adolescents in beginning a process of developing life skills.

**Keywords:** Type 1 diabetes; adolescents; autonomy-supportive intervention; nursing; outpatient clinic; decision-making

## **SUMMARY STATEMENT**

### **Why is this research needed?**

- Adolescents with type 1 diabetes struggle with difficulties in integrating the disease into their lives.
- Parents and health care providers may unwillingly suppress adolescents' motivation to start taking responsibility for the disease, which may foster resistance and reduced motivation.
- In adults with type 1 diabetes, Guided Self-Determination improved life skills; no interventions integrated into usual care have yet changed unconstructive cooperation patterns between adolescents, parents and health care providers.

### **What are the key findings?**

- A Guided Self-Determination version was adjusted and developed to youth (GSD-Y) and integrated into usual outpatient clinic visits involving adolescents with type 1 diabetes and their parents.
- The adolescents develop a new relatedness with health care providers and parents, becoming decision-makers in their own lives and start to grow personally.
- The use of semi-structured reflection sheets in combination with health care providers' use of mirroring, active listening and values-clarifying responses seem to support development of life skills in adolescents.

### **How should the key findings be used to influence practice and research?**

- Health care providers are able to practice a life skills approach in outpatient clinic visits, which supports them in conducting person-specific and meaningful visits.
- GSD-Y should be further explored in the care of adolescents with other chronic conditions.
- Further research is needed to develop a GSD-Y parental protocol to meet parents' different needs for guidance in supporting the development of life skills by their adolescents.

## **Introduction**

Type 1 diabetes (T1D) is a demanding disease for adolescents, parents and involved health care providers (HCPs) (Court *et al.* 2009). Parents and HCPs might prioritise good glycaemic control to prevent complications, but adolescents might struggle with integrating diabetes into their lives (Suris *et al.* 2004). By applying pressure for better diabetes management, parents and HCPs may unwillingly quash the adolescents' motivation for managing the disease. This pressure may foster resistance and passivity, which may hinder self-management skill development (Niemiec *et al.* 2006, Leonard *et al.* 2005, Christian *et al.* 1999). Guided Self-Determination (GSD) is a method for improving cooperation between adolescents, parents and HCPs that is applicable in conventional outpatient visits and can improve life skills in adults (Zoffmann & Kirkevold 2012, Zoffmann & Lauritzen 2006). Life skills have been used as outcomes for individual behavioural change among adolescents in health-promotion programmes (Gilchrist *et al.* 1987, Moote & Wodarski 1997, Botvin & Griffin 2002). Therefore, we assumed that the GSD's life skills approach could be suitable in a paediatric diabetes context.

## **Background**

### **Guided self-determination and life skills: theoretical framework**

GSD is a shared decision-making and mutual problem-solving method involving semi-structured reflection sheets (R-sheets) and advanced communication skills, which lead to focused communication and situational reflection (Zoffmann 2004). The method was developed link empowerment, which is regarded as a philosophy of the interaction between an HCP and a patient (Anderson & Funnell 2000), and life skills (Nutbeam 1998), which are considered outcomes of individual diabetes care (Zoffmann & Kirkevold 2012). GSD was developed

(Zoffmann 2004) through programmatic qualitative research (Sandelowski 1997). A synthesis of three grounded theories constituted the theoretical foundation for GSD (Zoffmann & Kirkevold 2012), along with formal theories such as empowerment (Anderson & Funnell 2000), self-determination theory (Deci & Ryan 1985), life skills theory (Mullen 1985), stages of change theory (Prochaska *et al.* 2002) and values theory (Steinberg & Andresen 1981).

During the development of GSD, Zoffmann (VZ) recognised the method as an approach to developing life skills that were defined as ‘those personal, social, cognitive and physical skills that enable people to control and direct their lives and develop the capacity to live with and produce change in their environment’ (Nutbeam 1998, p. 121). GSD functions as life skills training (Mullen 1985) in six steps: 1) establish a mutual relationship with clear I-you borders, also called I-you-sorted mutuality (Zoffmann & Kirkevold 2007); 2) self-exploration; 3) self-understanding; 4) shared decision making; 5) action; and 6) feedback on action. At its core, GSD supports patients in clarifying and expressing their difficulties and mobilising their own potential for change in interactions with HCPs that support patient autonomy. Rather than being told what to do, patients find solutions that agree with their own values (Zoffmann & Kirkevold 2012).

A theory-driven evaluation showed that establishing I-you-sorted mutuality also involves resolving a life-versus-disease conflict (Zoffmann & Kirkevold 2005) and accomplishing person-centred communication and reflection (Zoffmann *et al.* 2008). A randomised controlled trial (RCT) revealed the effect of GSD on HbA1c control and psycho-social functioning in adults 3-12 months after participating in a 16-hour, nurse-driven GSD group training session (Zoffmann & Lauritzen 2006).



## **Guided Self-Determination - Youth**

Two of the authors (GRH and VZ) adjusted GSD to GSD-Y inspired by participatory action research (Beringer & Fletcher 2011), which confirmed that language and R-sheets were suitable for use in adolescent-parent-HCP triads. GSD-Y consists of 18 semi-structured R-sheets for adolescents, five for parents and six for visits with a dietician, if needed. VZ & GRH taught GSD-Y to all HCPs in five courses (a total of 44 lessons). HCPs were subsequently supervised by GRH, who observed how GSD-Y worked when nine HCPs each used all R-sheets with two adolescents and their parents. These observations indicated that GSD-Y positively influenced cooperation in adolescent-parent-HCP triads. To ensure fidelity to GSD-Y, HCPs should pass a test (Husted *et al.* 2011) confirming the correct use of R-sheets and communication skills, such as mirroring (Clabby & O'Connor 2004), active listening (Gordon & Kragh 1999) and value-clarifying responses (Steinberg & Andresen 1981).

## **The study**

### ***Aim***

The aim of this study was to explore and illustrate influenced developing life skills in adolescents with T1D when supported by their parents and HCPs.

### ***Design***

A qualitative realistic evaluation (RE) design was chosen (Pawson & Tilley 1997). The RE was embedded in an RCT that tested the effect of GSD-Y (manuscript submitted).

### ***Sample and participants***

The study took place at two paediatric diabetes outpatient clinics in the Capital Region of Denmark. We purposely sampled (Patton 2002) adolescents for qualitative RE from both clinics among those randomised to the GSD-Y intervention (n=37) to capture different needs for developing life skills. Participants were adolescents aged 13-18 years diagnosed with T1D  $\geq$  1 year prior with poorly controlled diabetes (HbA1c  $\geq$  64 mmol/mol) at study entry and an average HbA1c  $\geq$  58 mmol/mol during the prior year. None of them had psychiatric diagnoses or were consulting a psychologist at the time of recruitment, and all were able to understand, speak and read Danish. The included parents were also able to speak, read and write Danish, did not have severe illnesses or mental problems and were not currently undergoing psychiatric or psychological treatment. HCPs had at least one year of experience in paediatric diabetes outpatient clinics prior to the intervention. In total, 13 adolescents of varying age, sex, living situation, diabetes duration and HbA1c level at baseline, along with their parents and HCPs, participated (Table 1).

Table 1 here

### ***The GSD-Y intervention***

GSD-Y consisted of eight GSD-Y sessions delivered during outpatient visits (8-14, table 1) by the adolescents' usual physician, nurse or dietician in individual settings (Figure 1). Each session was scheduled for one hour (usually 30-45 minutes) and included different semi-structured R-sheets that related to their lives with diabetes (Husted *et al.* 2011). To address the parents' challenges, they were offered two sessions alone with the HCP. The adolescents were offered

one session alone to facilitate conversation about confidential personal affairs. In preparation for each outpatient visit, the adolescents and parents filled in the R-sheets.

Figure 1 here

### ***Data collection***

We digitally recorded GSD-Y sessions of 11 adolescent-parent-HCP triads during their outpatient visits but acknowledged that interviews might disturb the RCT segment of the study. Therefore, the interviews took place after quantitative data were delivered, six months after the adolescents completed their eighth session. Due to a delay, only five of the 11 triads had completed all the sessions when the qualitative data collection had to be finalised. To increase the amount of information gained from the interviews, two additional triads were selected, although no GSD-Y sessions with these triads were recorded. In total, 37 (45-60-minute) audio files from the outpatient visits allowed us to explore the intervention period, and 21 interviews (60-90 minutes) were explored to evaluate how the adolescents, parents and HCPs experienced GSD-Y (Figure 2). All interviews were conducted by GRH over a four-month period; the interviews were conducted with the adolescents individually and parents together in their homes, except for one family who wished to come to the hospital. HCPs' interviews were conducted at the hospital. The adolescents and parents were not acquainted with GRH prior to the interviews. The participants' R-sheets supported their memory in the semi-structured interviews, which were based on open-ended questions concerning the intervention and its influence on their daily life. For example, questions directed to the adolescents included, '*When you look at your reflection sheets again, what is the first thing that comes to your mind?*' followed by, '*What difference has*

*it made for you to attend outpatient visits using reflection sheets compared to previous visits?’*  
followed by asking, *‘Please, give an example of this.’*

Figure 2 here

### ***Ethical considerations***

The study was reported to the Danish Data Protection Agency (2008-41-2322), the Ethics Committee of the Capital Region of Denmark (REC; reference number 0903054, document number 230436) and Trials Registration (ISTCTN54243636) and performed in accordance with the ethical recommendations of the Helsinki Declaration. Signed consent was obtained for adolescents and in addition for parents if adolescents were less than 15 years old. Information leaflets stated that data would be treated confidentially and anonymously and that the adolescents could withdraw from the study with no consequences for their treatment and care at the outpatient clinic.

### ***Methodology***

The methodology was based on RE, a theory-driven approach that evaluates how expected changes occur, to evaluate ‘what works for whom, in what circumstances and in what respect, and how’ (Pawson & Tilley 1997, Pawson & Tilley 2004). We considered RE a valuable supplement to the RCT’s ability to determine to what degree GSD-Y had an effect when applied to a new context (Allen *et al.* 2012). RE intends to develop ‘transferable and cumulative lessons from research,’ and therefore suggests that evaluators ‘orient their thinking to Context-Mechanism-Outcome pattern configurations’ (CMOs) based on the study’s theoretical framework prior to the start of the intervention (Pawson & Tilley 1997, p. 217).

*Context* refers to interpersonal and social relationships connected to situations and localities (Pawson & Tilley 1997, p. 58). *Mechanisms* are how participants interpret and act upon an intervention and are not directly observable (Pawson & Tilley 1997). Mechanisms can be ‘constraining’ when an intervention fails and/or ‘enabling’ when an intervention is successful in a particular context (Pawson & Tilley 1997). Because GSD-Y was based on the adult version (Zoffmann & Kirkevold 2012), the *outcome* was expected to be that adolescents would start developing life skills (Nutbeam 1998). We operationalised life skills in eight outcomes (Husted *et al.* 2011) and incorporated them into eight conjectured CMO configurations (Table 2) based on evidence from paediatric contexts and GSD mechanisms identified in adult care (Zoffmann & Kirkevold 2012).

Table 2 here

### ***Data analysis***

Data from the outpatient visits and interviews were transcribed verbatim by a secretary, controlled by GRH and managed using N’Vivo software (version 8). The analysis was a four-step process.

First, the transcriptions from the outpatient visits were read several times. Text was extracted according to each of the conjectured eight CMO configurations (Table 2) and coded deductively and inductively (Pawson & Tilley 1997, p. 218). Codes were compared within each participant and subsequently across sub-groups of adolescents, parents and HCPs; these comparisons identified an activation of individual and common mechanisms. Second, the transcribed interviews were analysed using the same procedure from step one. The codes from

GSD-Y visits were compared with codes from interviews, showing that the interaction pattern between the parties had changed. Third, text and codes from steps one and two were sorted in a table according to each CMO configuration. Participants' experiences of the context before and after the intervention revealed changes and both constraining and enabling mechanisms. Codes were formulated based on their experiences; for example, in experiences related to CMO-2, *'adolescents are able to communicate openly and honestly with HCP'* was coded *'from monologue to dialogue'*, *'from isolated thoughts to sharing thoughts'* or *'from resistance to starting to consider different diabetes management solutions'* (Table 3).

All codes were compared, and several observed outcomes were related to the GSD-Y sessions expressing what worked in GSD-Y, for whom, in what circumstances and how.

Table 3 here

Fourth, the induced and deduced outcomes from each of the eight CMO patterns were compared and discussed by the research team, and finally condensed into three outcomes which were identified together with their connection to the eight predefined life skills outcomes (Figure 3).

### **Rigour**

Credibility was obtained by purposeful sampling among those who completed the intervention and by combining two different data sources (recorded GSD-Y-visits and interviews). In particular, we considered the digitally recorded visits as important in establishing credibility, as they verified what actually happened during the visits. Dependability was determined through

GRH's and VZ's independent analyses and subsequent discussions of the findings until a consensus was reached. Confirmability was ensured by discussing the findings primarily with Esbensen (BAE) and also with all the authors (Guba 1981). Due to the thoroughness of RE, these findings may be theoretically transferrable to understanding and intervening in interaction patterns between adolescents, parents and HCPs in other clinical subpopulations with chronic disease.

## **Findings**

The combination of recorded GSD-Y visits and interviews with all participants illustrated how a process of developing life skills in adolescents with T1D was launched by involving adolescents first and parents second in decision-making and problem solving during the sessions. The importance of the R-sheets was emphasised by all the participants, whereas the importance of HCPs' advanced communication skills was seen as an aid to alleviate tension and act constructively when adolescent-parent conflicts occurred during visits (Table 4).

Table 4 here

The HCPs used GSD-Y R-sheets in combination with mirroring, active listening and value-clarifying responses in their communication with adolescents and parents. The HCPs noticed that this increased their ability to focus on the difficulties that were perceived as important by adolescents instead of the former tendency to solely provide information. A dietician reflected on this ability during her interview:

Dietician 2: They [adolescents] get a chance to talk about what they feel is difficult, so it relates more to the young person's problem than it does to my own need to inform.

The circumstances in each family were, however, more or less complex. The adolescents' ability to develop life skills manifested at different levels, which did not always include improved HbA1c. The development of life skills based on the eight CMOs was found to be interdependent and was condensed into three outcomes for adolescents: 1) *developing new relatedness with HCPs and parents*, 2) *becoming decision-makers in their own lives with diabetes* and 3) *growing personally* (Figure 3). The findings are detailed below. M1-13 and F1-13 are mothers and fathers, respectively, to adolescents A1-13. The adolescents' ages at the time of the GSD-Y visits or interviews were recorded.

Figure 3 here

### **Developing new relatedness with HCPs and parents**

#### ***Developing new relatedness with HCPs***

The outpatient visits changed from being dominated by the HCPs and focused on general aspects of diabetes management to being person-specific. The adolescents expressed that they were met with an interest in sharing and understanding their perspectives regarding difficulties that they believed had not been previously considered. The adolescents attributed this change to using their completed R-sheets, which gave them a voice and motivated them to actively participate during the visits. They felt that they were being seen and listened to as the person they were and not just 'as a patient' (A2). This change was illustrated by an 18-year-old girl in the interview:



A1: It is much more like a conversation than just someone who sits and dictates what you should do. You feel you want to be part of it when you can be involved in discussing suggestions. The last few times, I was the one who said, ‘Today I would like to talk about this and that.’

The fact that adolescents were able to take responsibility for the visit’s content was surprising to the HCPs, as expressed by a physician reflecting on her visits with a 15-year-old boy during her interview:

HCP6: I had [previously] spoken with the mother and father, so he did not really participate. But [during the intervention] he was the one who presented what he had thought about at home.

### ***Developing new relatedness with parents***

Sharing observations, thoughts and feelings with HCPs helped the adolescents reconsider previous perceptions of their parents’ intentions and responses to their difficulties in managing diabetes. This change altered previous behaviours, such as quarrels and disagreements, and adolescents considered listening to the parents or involving them in solving difficulties. An example of a deadlocked interaction pattern regarding blood sugar management and its resolution was illustrated by a 14-year-old girl and her mother during their first visit:

M6: I would like to hear your values [blood sugar], but when you say all the values on top of each other, it does not help at all.

A6: .... Then say so instead of leaving!

M6 (Shouting): But I tried!

A6: No, you didn't (crying).

The nurse's use of value-clarifying responses allowed her to take a neutral role in helping the adolescent and her mother reconsider their own parts in the conflict, as illustrated by the following conversation:

HCP1: What if each of you could change one thing about the way you talk about it [blood sugar] – what would it be?

A6: I would stop interrupting.

M6: I would think a bit more about what I say. I can sometimes sound tougher than I really mean to.

At the last visit, both the adolescent and her mother expressed that their cooperation had improved ('Now we are doing this together') (A6).

In some cases, however, the parents' own difficulties prevented them from helping their adolescent. Using the R-sheets, a 15-year-old boy told his parents and the physician that he experienced living with the disease as carrying a stone around his neck. Despondency among his parents kept them from agreeing on how to best support him—either by taking over or letting him learn by trial-and-error (A3). Despite the boy's openness due to the GSD-Y sessions, the complexity of the parents' disagreement in this triad was too serious to be remedied. This family never completed the intervention.

Altogether, the adolescents experienced a shift from feeling controlled to receiving support from their parents without being afraid of being told off. 'It was about realising that she

[mother] did what she did to help me and not to just be after me' (A2). This change in perspective was supported by the HCPs. With their new communication skills, they changed their perception of having to solve problems for adolescents and parents to acknowledging that it was both important and possible to support them in reaching a mutual understanding. This was described by a nurse during her interview:

HCP2: Now I have more options concerning communicating. It's not me who needs to solve the problems - it's their problems. But I want to help shed light on it and try to help them see things from various angles. They are the ones who must find a way.

### **Becoming decision-makers in their own lives with diabetes**

The adolescents began a process of becoming decision-makers in their own lives with diabetes. After identifying diabetes management problems through R-sheets, they began talking openly and honestly with HCPs and reassessed their prior reasons for avoiding managing their disease. In some triads, the parents had overlooked their adolescents' readiness to speak for themselves: 'I have certainly underestimated him concerning how responsible he actually is' (M12). In other triads in which the adolescents feared being perceived as different from their friends, the GSD-Y sessions helped them reconsider ways of managing their diabetes. Some started discussing possible behavioural changes with their HCPs, and others dared to conduct experiments that increased their ability to act autonomously and with self-determination. Feedback from such an experiment was given to a nurse during an outpatient visit by a 17-year-old boy who had measured his blood sugar in front of his friends:

HCP2: You decided that you would take insulin and measure blood sugar in front of your friends. What did they say?

A8: They asked a lot, 'Does it hurt?', 'How often must you do it?', and so forth. I was afraid that they would say I was not one of them. But then it was nothing like that. It was a wonderful feeling that went through my body. So, now I know I can do it in front of them.

Instead of telling the adolescents the number and timing of blood sugar tests that should be performed, HCPs supported them in setting their own goals and making their own decisions about why and when to do it. 'It becomes more on their own terms rather than just me shoving it down their throats' (nurse HCP1). Previous reasons for measuring blood glucose had often been external, such as avoiding being scolded or preventing quarrels. Our idea of applying evidence on the exact benefits of good glycaemic control in a meaningful way and supporting them in measuring their glucose for their own sake reduced their resistance to measuring blood sugar. This was experienced by a 16-year-old girl as follows:

A4: I measure much more than before. I can see now much more clearly that these measurements are really important for me.

A process of integrating the disease into their lives appeared to occur at different levels: in the adolescents' minds, 'It [the diabetes] used to be like a burden, while now it has become a part of me' (A4). For others, this integration process changed their actions by making them think ahead and consider how to handle situations such as sports. This was illustrated by a 15-year-old boy at his interview:

A12: I don't think so much about it anymore. Remember sugar and remember the cell phone. I believe that it's those sheets that helped me. Sometimes, they [my parents] would look inside my bag [previously]. They don't do that anymore.

Parents connected their adolescents' increased decision-making skills with HCPs' emphasis on supporting the adolescents in taking ownership of their disease: 'I think he has accepted having diabetes after his talk with the physician' (M12).

GSD-Y did not always help parents and adolescents in accomplishing balanced responsibility for diabetes management. In four triads (A1, A4, A12, A13), parents became aware that they might have intervened too little because they were uncertain how they could be supportive without taking too much control, as illustrated by a father to a 16-year-old boy at the interview:

F13: We have probably been more lax than we should have. Looking back, it would have been nice if we had talked [during the project] about the best way to provide support without taking over again.

### **Growing personally**

The adolescents began a process of personal growth. The focused communication as well as mutual and independent reflection helped them to gain insight into their internal conflicts between life and diabetes: 'I feel that I have become a different person - much more open about it all' (A4). This insight released a potential for change in their minds, which supported them in

starting to bridge life and diabetes: ‘It used to be me against diabetes – now we have become a team’ (A1). Some were able to transfer these skills to their life as a whole, even if their glycaemic control had not yet improved satisfactorily, as explained by a 17-year-old boy at the interview:

A11: If I had not participated [in GSD-Y], my life would probably not be as good as it is today in relation to diabetes. It has certainly helped me to gain insight into my own life. I explore things deeply in relation to why I think as I do, and why I behave as I do, also in relation to ordinary life.

Parents noticed that their adolescents had changed. Some were unsure whether it was because of GSD-Y, merely the natural developmental process or a combination of the two. However, they all stated at the interviews that personal growth had taken place, as exemplified by the mother of an 18-year-old girl:

M1: I think that she has gradually grown during this project. It is perhaps because you can put it into words [R-sheets], and so you feel better in terms of your self-esteem.

From the HCPs’ viewpoint, the adolescents had changed. Like the parents, they were aware that the changes could be ascribed to both the GSD-Y and the normal developmental process. In considering whether signs of change were identical among adolescents in the control group, the HCPs reflected on how using the GSD-Y had influenced the adolescents’ development. A physician elaborated during her interview:

HCP5: I think it has taught them to reflect on and speak about what is truly happening, so I think it has made them more mature.

## **Discussion**

We explored and illustrated how GSD-Y initiated change by activating mechanisms in adolescent-parent-HCP triads (Table 4). The triads emphasised the importance of R-sheets and a change in communication patterns by involving the adolescents in mutual problem solving. The changes agreed with operationalised life skills as stated in the eight CMOs. The interdependence of these outcomes is evidenced from the three condensed outcomes identifying adolescents' emerging life skills: 1) developing new relatedness with HCPs and parents, 2) becoming decision makers in their own lives with diabetes and 3) growing personally.

The new relatedness with HCPs preceded a new relatedness with parents and the ability of both HCPs and parents to refrain from controlling behaviours (Ryan & Deci 2000). This motivated the adolescents to share observations, thoughts and feelings to identify personal barriers to diabetes management. Previous studies demonstrated that a lack of relatedness and controlling communication by parents and HCPs have a negative impact on adolescents' diabetes self-management skills (Scholes *et al.* 2012, Anderson *et al.* 2002a, Dashiff *et al.* 2008). In contrast, an autonomy-supportive relatedness reduced familial conflicts and increased diabetes self-management (Anderson *et al.* 2002b, Wiebe *et al.* 2005). Our findings support the importance of relatedness and involving adolescents as contributors to the development of self-determined behaviour (Ryan & Deci 2000), which is central in developing life skills (Gilchrist *et al.* 1987). Notably, as also observed in adult care, the combination of R-sheets and HCPs'

communication skills was powerful for promoting conflict resolution through a mutual approach to problem solving in the triads (Zoffmann & Kirkevold 2012).

The adolescents' ability to become decision-makers in their own lives with diabetes was an important finding because decision making is part of developing life skills (Gilchrist *et al.* 1987). It was also important that this development was accompanied by HCPs' and parents' increased awareness of the adolescents' readiness and competence to speak and make decisions. Discrepant perceptions of adolescent competence between adolescents and their parents have been identified in previous studies (Husted 2006, Alderson *et al.* 2006) and can reduce adolescent motivation for developing self-management skills (Miller & Drotar 2003). Researchers have disputed whether adolescents can make proper decisions until they reach a certain age, such as 15 (Mann *et al.* 1989) or 17 years (Hanna *et al.* 2003, Viklund *et al.* 2007). In contrast, a review concluded that competent adolescent decision-making depends on parent and HCP attitudes rather than the adolescent's age (Mårtenson & Fägerskiöld 2008). The importance of HCP and parent attitudes was supported by a study of 55 children and adolescents, in which HCPs' and parents' communication styles and behaviours actually hindered adolescent participation in decision making (Coyne & Gallagher 2011). Our findings support the conclusions of Mårtenson and Fägerskiöld (2008) and Coyne and Gallagher (2011), as we found that 13–18-year-old adolescents showed an increased ability to make autonomously motivated decisions after the new relatedness was established with HCPs and, subsequently, with parents. Researchers have advocated for methods that facilitate independent decision-making among adolescents (Silverstein *et al.* 2005, Hanna *et al.* 2003). However, such methods have not been available to HCPs. It appears that GSD-Y may be an effective tool for that purpose.



In this study, the adolescents underwent personal growth, which is also part of life skill development (Gilchrist *et al.* 1987). We acknowledge that the adolescents were also undergoing an age-specific developmental process during the intervention period (Steinberg & Morris 2001). However, adolescents, parents and HCPs unanimously emphasised that the adolescents increased their resources to take on responsibility during the intervention. We consider this as a sign of empowerment that supports the crucial nature of helping adolescents prevent or reduce internal conflicts to stop the development of helpless feelings and depressive symptoms (Grey *et al.* 2002, Dantzer *et al.* 2003). Insight into their own abilities seemed to release the potential for change. As found in adult care, this occurred via four stages: in the person's mind, in a supportive relationship, in the diabetes team and in daily life (Zoffmann 2004, p. 112).

One of the differences between GSD-Y and other similar interventions integrated into outpatient visits (Laffel *et al.* 2003, Murphy *et al.* 2012, Robling *et al.* 2012) was the power of the R-sheets. Their semi-structured format ensured that adolescents and parents could state what was important to each of them. In allowing initiation by the adolescents, these R-sheets supported their autonomy, which has also been identified in adult care (Zoffmann & Kirkevold 2012). Our findings support the previously identified importance of meeting parents' needs for supervision (Maas-van Schaaijk *et al.* 2011, Howe *et al.* 2012, Scholes *et al.* 2012). Based on the mostly positive changes in adolescent-parent cooperation patterns observed in our study, the principles of GSD-Y seem promising as a foundation for such support.

### **Limitations**

We were only able to select seven triads for interviews due to time limits and to avoid disturbing the RCT part of the study, which was not completed at the time of data collection. Interviews

with adolescents who required more time to complete the intervention might have provided insight into the mechanisms of GSD-Y over a longer period.

## **Conclusion**

This research shows that the use of a life skills approach, GSD-Y, made outpatient visits person-specific and meaningful, improving cooperation patterns in the triads by combining R-sheets and advanced communication skills. GSD-Y helped adolescents, HCPs and parents discover the adolescents' resources and reflect on their internal reasons for behavioural changes. GSD-Y helped adolescents begin a process of developing life skills with or without decreasing HbA1c. We regard good glycaemic control as an important indicator of life skills. Whether GSD-Y had a significant effect on glycaemic control and psychosocial functioning will be determined by the RCT segment of the study.

## **Recommendations**

Overall, GSD-Y was effective in adolescent-parent-HCP triads for improving the life skills of adolescents with T1D. Further methodological refinements might be needed to help parents support their adolescents in maintaining glucose control over the long term.

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## **Figure legends**

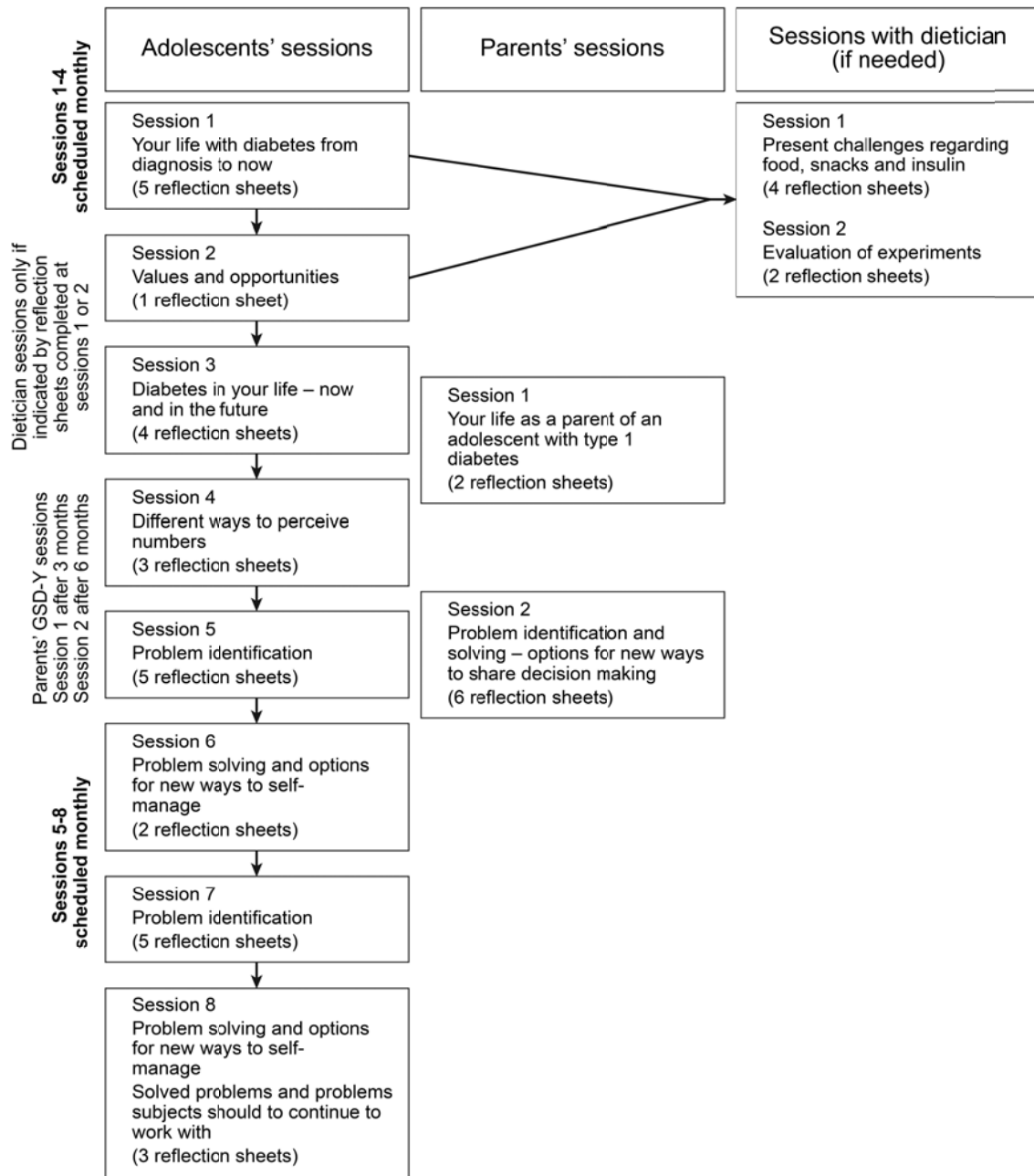
**Figure 1.** Overview of the main content of eight GSD-Y sessions for adolescents, two GSD-Y sessions for parents and, if needed, two sessions with dieticians.

**Figure 2.** Overview of the study period, participants and data sources used for the qualitative, realistic evaluation of the GSD-Y.

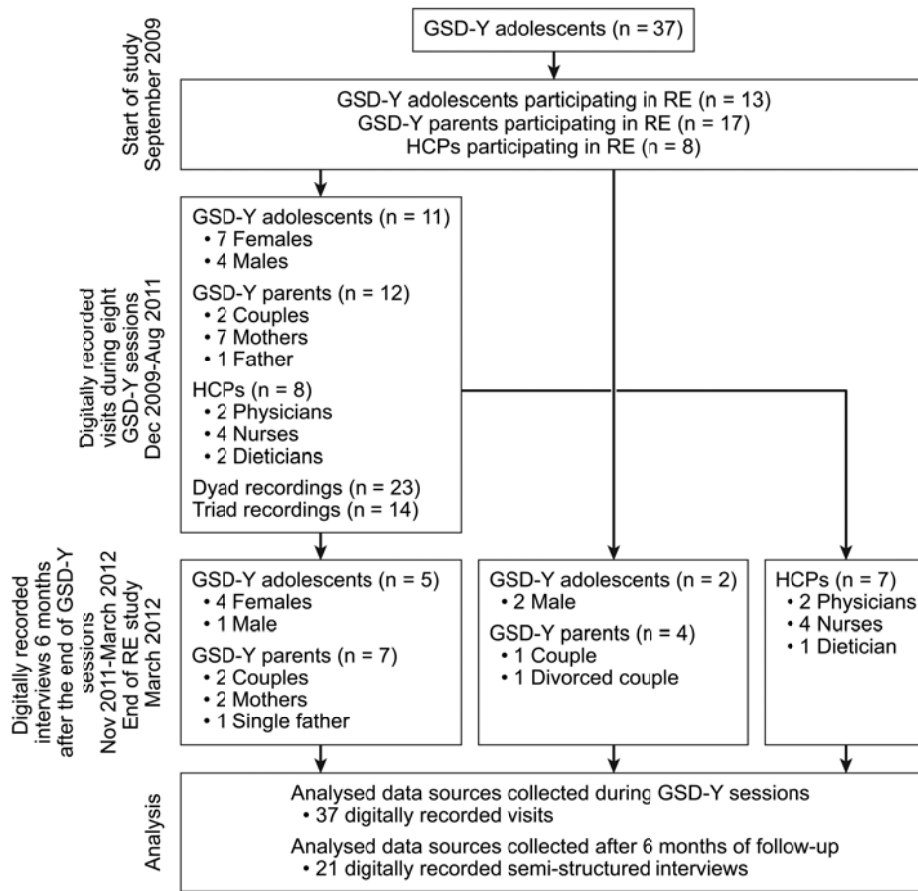
**Figure 3.** Illustrates how the use of GSD-Y was found to influence the interaction between the participants. The emerging outcomes were condensed into three main outcomes. The predefined eight life skills outcomes (1-8) were connected to the three condensed outcomes as shown in the circles. The circles illustrate that the condensed outcomes influenced each other in the development of life skills by the adolescents.



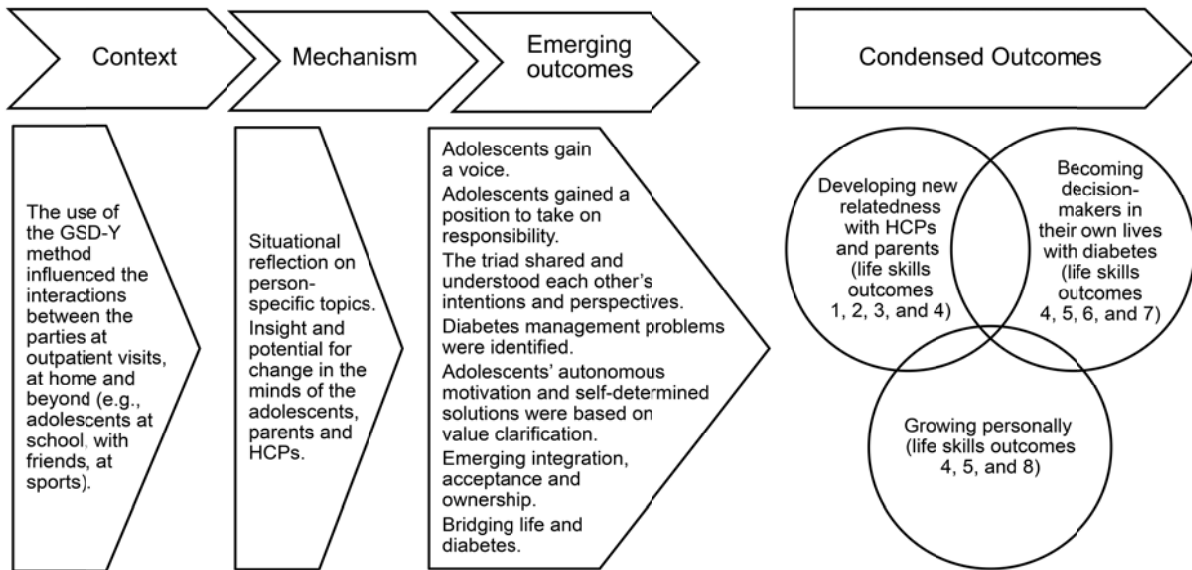
**Figure 1**



**Figure 2**



**Figure 3**



## Tables

Table 1. Characteristics of adolescents, parents and health care providers participating in the qualitative evaluation by GSD-Y.

<b>Adolescents participating in the qualitative evaluation</b>	<b>Total sample</b>	<b>Interview sample</b>
Adolescents (n)	13	7
Females/males (n)	7/6	4/3
Mean age in years, SD (min-max)	14.7±1.4 (13-17)	15.6±1.5(14-18)
Mean age at onset of diabetes in years, SD	7.6±3.1	6.6±3.5
Mean duration of diabetes in years, SD	7.1 ±3.7	9.0±3.3
Median HbA1c mmol/mol (min-max)	73 (63-144)**	75 (58-107)***
Living in two-parent family/living in single-parent family (n)	6/7	4/3
Ethnicity, Danish/other ethnicity*	12/1	7/0
Median visits to complete 8 GSD-Y sessions (range)	-	11 (8-14)
Median months to complete 8 GSD-Y sessions (range)	-	17.5 (11.5-20.5)
<b>Parents participating in the qualitative evaluation</b>	<b>GSD-Y sessions</b>	<b>Interviews</b>
Couples (n)	2	4
Mothers (n)	7	2
Fathers (n)	1	1
Mothers' mean age in years, SD (min-max)	47±7.7 (35-58)	50±6.6 (41-58)
Fathers' mean age in years, SD (min-max)	49±7.5 (41-59)	51±7.7 (41-59)
<b>HCPs participating in the qualitative evaluation</b>	<b>GSD-Y sessions</b>	<b>Interviews</b>
Number of HCPs (n)	8	7
Females (n)	8	7
Mean age in years, SD (min-max)	47.4±7.6 (36-62)	48.0±8.1 (36-62)
Mean years of experience in paediatric diabetes outpatient clinics at start of trial, SD (min-max)	14.3±10.0 (3-25)	14.7±10.3 (3-25)

\* One adolescent had a Middle Eastern background, and the parents did not participate.

\*\* HbA1c at baseline

\*\*\* HbA1c at 6-month follow-up

Table 2. Eight conjectured CMO configurations proposed prior to the intervention, including the eight life skills outcomes (1-8), ordered chronologically according to when they were expected to appear during the process of change.

<b>CMO</b>	<b>Context identified through previous research</b>	<b>Enabling mechanisms activated by GSD-Y</b>	<b>Expected life skills outcomes</b>
CMO-1	Content of outpatient visits are predetermined by the HCPs' routines in conducting outpatient clinics.	When filling in reflection sheets, adolescents increase their readiness to participate actively in own visits. They become aware of and clarify concrete topics they want to talk about.	1) Adolescents are conscious about what they want to talk about at the outpatient clinics.
CMO-2	Adolescents often have difficulties in communicating openly and honestly with HCPs and parents because they are aware that they do not always manage their diabetes as they are told.	By writing down or drawing their thoughts and feelings, adolescents are enabled to express them. Unexpected insight into each other's perspectives by sharing thoughts, feelings and observations gives mutual understanding and respect.	2) Adolescents communicate openly and honestly with HCPs and parents.
CMO-3	Adolescents do not always perceive HCPs and parents as collaborative partners when having difficulties in managing diabetes.	Good experiences from mutual reflection with HCPs and parents increases the adolescents' readiness to listen to them and benefit from their input.	3) Adolescents are conscious of parents' and HCPs' resources and take advantage of these resources in learning self-management of diabetes.
CMO-4	Adolescents often have difficulties in managing diabetes when with friends, at school or away from home because they avoid being perceived as different from their peers.	Through mutual situational reflection, adolescents share concrete difficulties in daily life with HCPs. Through shared insight into the difficulties, new ideas for solutions appear - ready for agreement on experiments.	4) Adolescents prevent or resolve conflicts or problems with diabetes in daily life outside the home or at home with support from parents and HCPs.
CMO-5	To be liked by others, adolescents might ignore or deliberately choose not to measure blood sugar or take insulin.	Through mutual reflection together with HCPs, adolescents train their ability to communicate about their own barriers to measure blood sugar and take insulin in front of their peers in daily life situations.	5) Adolescents have insight into new ways to handle situations and relate constructively to the disease and their own reactions. They now explain reasons for diabetes actions to their friends.
CMO-6	Goals for blood glucose and HbA1c are mostly defined by HCPs or parents and seldom decided in a concordant way by the adolescents.	Insight into own values and reasons to accomplish good glycaemic control combined with clearly translated evidence makes it easier for the adolescents to pose self-concordant goals for HbA1c.	6) Adolescents express their own goals for blood glucose and HbA1c.
CMO-7	HCPs and/or parents are striving for good glycaemic control. Therefore, they may unwillingly obstruct the adolescents' development of autonomous motivation and instead potentially foster passivity, ill health and lack of motivation.	Shared insight into own reasons for wanting or not wanting to change diabetes management patterns makes it easier to overcome barriers in each adolescent's life.	7) Adolescents develop autonomy-based motivation for blood glucose measurement, registration and regulation (HbA1c decreases).
CMO-8	Conflicts between life and disease both within and between adolescents, parents and HCPs are often not identified or solved at outpatient clinic visits.	Shared insight into person-specific life-disease conflicts and a mutual approach to problem solving help resolve conflicts.	8) Adolescents start to integrate the disease into their lives.

CMO: C = context, M = mechanism, O = outcome

Table 3. Example of the analysis process of CMO-2, adolescents communicating openly and honestly with HCPs. The table illustrates what worked for whom, in what circumstances and how.

CMO-2	Context before experiences by participant	Constraining mechanisms	Enabling mechanisms	Context after experiences by participants	Codes	Emerging outcomes	Condensed outcome
Adolescents are able to communicate openly and honestly with HCPs	I had a kind of feeling that they [the nurse and the physician] had read a book about what it was like to have diabetes. Well, it's so and so, to control it (A1)	Not person-specific problem-solving attitude Controlling language Not being invited to participate in dialogue	Reflection sheets in combination with advanced communication skills created the conditions for activating situational and mutual reflection, leading to shared insight into adolescents' way of managing daily challenges	Now it is much more like a conversation than just someone [nurse or physician] who sits and dictates you (adolescent) (A1) It becomes more on their own terms rather than just me shoving it down their throats (HCP1 nurse) Now it is more specific to my condition and problems (A13) It's not me who needs to solve the problems – it's their problems (HCP2 nurse)	From monologue to dialogue	Giving voice to adolescents and HCPs	Developing new relatedness with HCPs
	I felt like a patient and not a human person (A2)	Not being seen as the person they felt they were	Feeling being taken seriously Honest communication Insight into each other's intentions and perspectives	We became much closer to each other. Now she [HCP1 nurse] was not only my nurse. She was also familiar with me and interested in what was best for me (A2) So it relates more to the young person's problem than it does to my own need to inform (Dietician)	From isolated thoughts to sharing thoughts	Adolescents gain a position to take on responsibility	
	She [Physician] did not talk to me; it was more orientated towards my parents (A12)	Not being invited to participate in dialogue	Active in own visits Feeling ownership of problems Shared reflection and focused communication	The last few times, I was the one who said, 'Today I would like to talk about this and that' (A1) I had [previously] spoken with the mother and father, so he did not really participate. But here (during the project) he was the one who presented what he had thought about at home. He was the one who came with proposals (HCP6 physician)	From resistance to starting to consider different diabetes management solutions	Sharing and understanding each other's intentions and perspectives	

CMO: Context, mechanism and outcome

**Table 4. Content of GSD-Y sessions and the activities and mechanisms seen in the triads during the change process launched by GSD-Y**

	<b>Introduction: Preparation at home or during the visit</b>	<b>Sessions 1-3: Your life with diabetes from beginning to now. Values and opportunities. Diabetes in your life now and in the future</b>	<b>Session 4: Different ways to look at numbers</b>	<b>Sessions 5-8: Problem identification, problem solving and options of new ways to self-manage</b>	<b>Sessions in which parents participated with adolescents (1-8)</b>
<b>GSD-Y intervention</b>	<p>Written invitation to work together was discussed.</p> <p>(R-sheets) for self-exploration and discovery of person-specific challenges:                      -Two ways to look at HbA1c                      -Important events...                      -Difficulties at present                      -Plans for changes</p> <p>Adolescents who are referred to a dietician also used R-sheets with the dietician.</p>	<p>R-sheets filled in with adolescents' words or drawings were used during the visits.</p> <p>-Unfinished sentences                      -Room for diabetes in your life -                      Picture or thoughts about diabetes</p> <p>Dialogue was supported by HCPs' communication skills</p> <ul style="list-style-type: none"> <li>- Mirroring</li> <li>- Active listening</li> <li>- Value-clarifying responses</li> </ul>	<p>Distinctions between using the HbA1c test as a disclosure test or a target test. Dividing responsibility for diabetes.</p> <p>Own reasons to measure SMBGs and posing autonomy-based BG-goals.</p> <p>Translation of risks of eye complications and serious hypoglycaemic events in order to promote self-concordant HbA1c goals.</p>	<p>Two individual lists were formed, by adolescents and HCPs, comprising their independent assessments of what was difficult or challenging for the adolescent.</p> <p>From the lists, they chose one problem/challenge and agreed on a name for it to be further explored and mapped in Dynamic Problem Solving, which is central in GSD-Y and provides thorough reflection on observation, thoughts, goals and actions, according to the selected challenge</p> <p>Completed dynamic problem solving and thereby reached a deeper insight and overview of their own reactions in daily life together with other people. This gave an overview of their situation and a basis for deciding what to change.</p> <p>Sheets with observations, thoughts, goals and actions gave shared understanding of the adolescents' way of making decisions together with family and friends. HCPs supplemented with ideas in the final Dynamic Problem Solving sheet.</p>	<p>R-sheets for parents allow for their self-exploration and discovery of person-specific challenges and their own reactions on being parents to adolescent with T1D.</p> <p>Value-clarifying responses were applicable when conflicts between adolescents and parents appeared.</p> <p>Shared understanding in the triad of the adolescents' challenges in life with diabetes.</p>
<b>Adolescents' activities and mechanisms</b>	<p>Most of them worked with R-sheets at home. Discovered aspects they often were not aware of before. Clarified values.</p>	<p>Adolescents read aloud their words or explained their drawings on the R-sheets. This increased their ability to communicate openly about difficulties. Felt that HCPs listened to and took them seriously.</p>	<p>Told about concrete situations in which they avoided measuring BG or taking insulin in front of their friends or school mates. Created experiments about this and shared their experience concerning these experiments with HCPs.</p>	<p>Completed dynamic problem solving and thereby reached a deeper insight and overview of their own reactions in daily life together with other people. This gave an overview of their situation and a basis for deciding what to change.</p>	<p>Might tell about disagreements and unresolved conflicts with parents. If parents were present they might start arguing with them. Supported by HCPs, adolescents reconsidered their own reactions and often found alternative solutions.</p>
<b>HCPs' activities and mechanisms</b>	<p>If R-sheets were not completed at home, most HCPs supported adolescents in doing it during the visit. Others asked them to do it before next visit, which meant that either an extra visit was needed or extra sheets should be discussed next time.</p>	<p>Heard, saw or read aloud what adolescents found challenging/difficult in daily life. Realised that exploring the adolescents' difficulties was more important than their prior "need" to inform. Used new communication skills to support the adolescents in exploring difficult issues.</p>	<p>Supported the adolescents' in describing daily life difficulties in glucose management and supported them in creating experiments and giving feedback from these experiments.</p> <p>They supported adolescents in aiming for HbA1c goals that were consistent with their own life values.</p>	<p>Sheets with observations, thoughts, goals and actions gave shared understanding of the adolescents' way of making decisions together with family and friends. HCPs supplemented with ideas in the final Dynamic Problem Solving sheet.</p>	<p>Was able to alleviate tension caused by conflicts and used value-clarifying responses to support parents' and adolescents' self-reflection and ability to find alternative solutions.</p> <p>Became aware that they should not solve the problem but rather support the adolescents and parents in solving them.</p>
<b>Parents' activities and mechanisms</b>	<p>Some parents reminded their adolescents to fill in R-sheets.</p>	<p>If present, they listened to their adolescents express challenges they often had not been aware of before.</p>	<p>Often found concrete ways they could support glucose management.</p>	<p>Parents were involved if part of the problem appeared to be their behaviour. Helped them to change.</p>	<p>Parents might start arguing with the adolescents as well. Supported by the HCP, parents reconsidered their own reactions and found alternative solutions.</p>