Ph.D. Thesis
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Self-Management in Diabetes Care:
The importance of self-care management intervention in chronically ill patients diagnosed with diabetes

University of Southern Denmark, Odense
Faculty of Health Sciences
2010
Preface

In the autumn 2003, the head group at Odense University Hospital, Denmark decided to intensify the health prevention and promotion efforts of the hospital by the establishment of three research-based model projects. The Department of Endocrinology M at the hospital made itself available for a model project at the Diabetes Clinic. A Health Technology Assessment (HTA) project was designed in collaboration between Department of Applied Research and HTA, Department of Quality and Department of Endocrinology at the hospital. The aim of the HTA was to examine the impact of an individual self-management program to promote diabetes self-care and thereby hopefully prevent progression of diabetes complications among patients diagnosed with type 1 and type 2 diabetes mellitus.

This thesis is part of the HTA project and comprises assessments of the technology aspect and patient aspect of the HTA. The thesis is based on research work carried out from December 2005 to June 2010 at the Diabetes Clinic and consists of a meta-analysis regarding the existing evidence on self-management intervention in diabetes, a clinical randomized controlled trial regarding the effect of a self-management program and an explorative study regarding patients’ understanding and experience of diabetes self-management following the self-management program.

The research was performed under the supervision of Jan Erik Henriksen, chief consultant, MD, PhD, Clinical Associate Professor, The Institute of Clinical Research, Faculty of Health Sciences, University of Southern Denmark and Department of Endocrinology M, Odense University Hospital, and Lis Wagner, Dr.PH, RN, Professor, The Research Unit of Nursing, Institute of Clinical Research, Faculty of Health Sciences, University of Southern Denmark.

The thesis is based on the following papers:


II. Rosenbek Minet LK, Lønvig EM, Henriksen JE, Wagner L. The Experience of Living With Diabetes Following a Self-Management Program Based on Motivational Interviewing. Qualitative Health Research 2010 (Accepted for publication)

III. Rosenbek Minet LK, Wagner L, Lønvig EM, Henriksen JE. The effect of motivational interviewing intervention on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education program: a randomized controlled trial (Submitted for publication)
Acknowledgement

The research work in connection with this thesis has involved a great number of people, whom I am indebted to and I wish to thank them all for their help and support.

First and foremost, I am grateful to all the study patients for their willingness to participate in the study. Without them the study would never have been made.

A special thanks to my supervisors Jan Erik Henriksen and Lis Wagner for their support in my educational journey throughout the whole Ph.D.-study. You have both been scientifically strong sparring partners, and your constructive criticism has been essential for this work.

Henning Beck-Nielsen (formerly head of Department of Endocrinology) believed in the project idea from the very beginning, and I thank him for letting me be part of his research group.

I am grateful to Else-Marie Lønvig, Kristian Kidholm and Lise Kvistgaard at the Department of Applied Research and HTA and the Department of Quality for their warm welcome. Thanks for your enthusiasm and valuable advice during the whole project period. A special thanks to Else-Marie Lønvig who has worked very hard to make this project possible in the first place.

The study included an intensive training program for the multidisciplinary team carrying out the counseling program. I am truly grateful to Inge Kamp, Ewa Romanczuk, Iben Eggertsen, Trine Flemming Larsen, Gitte Kramer and Bettina Nielsen who were ready to change their approach to motivational interviewing and participating in the training program. A special thanks to Lene Sjöberg for your huge involvement in training the team members and for sharing your experiences in motivational interviewing with us.

Next, I thank my fellow PhD students at the Department of Endocrinology for constructive discussions and socializing. Thanks to the Qualitative Group at the Research Group of General Practice, the Methodological Group at Health, Man and Society, and Journal Club at the Research Unit of Nursing, University of Southern Denmark, for good discussions on relevant methodological, theoretical and analytical issues. I owe my sincere thanks to my office colleague Dorthe Nielsen.
whose dedication to research work has been an inspiration. Thanks also for your assistance with the focus group interviews.

Thanks to the staff at the Diabetes Clinic Department of Endocrinology for co-operation and assistance with assessment of clinical measurements. I appreciate the help I have received from research secretary Elsebeth Byrge who kindly made the randomization of the study participants. Thanks to Claire Gudex and Lise Stark for language editing of the manuscript.

I acknowledge Werner Vach at Freiburg University Medical Center for substantial support with the statistical analyses and interpretation of the data. Thanks to Grant Corbett at Behavior Change Solutions in Canada for helpfully answering my questions and providing advice concerning the theoretical approach underpinning motivational interviewing.

Last but not least I would like to tank my dear husband Jørgen Kristian Minet for helping me with the creation of my Access Database. I cherish your support and encouragement through the good times and the bad times during the project – to my two beloved children Johanna and Frederik, I could not have accomplished this without the love of both of you.

The financial support provided by grants from The National Board of Health, Funen County, Danish Association of Diabetes, Odense University Hospital, University of Southern Denmark and TRYG Fonden was also essential.
Abbreviations
BP, Blood Pressure
CI, Confidence Interval
DKK, Danish Crowns
Ghb, Glycated Hemoglobin
HbA1c, Glycated Hemoglobin
HTA, Health Technology Assessments
LDL, Low-density lipoprotein
LOCF, Last Observation Carried Forward
MeSH, Medical Subject Headings
MI, Motivational Interviewing
MINT, Motivational Interviewing Network of Trainers
MITI, Motivational Interviewing Treatment Integrity
OHA, Oral Hypoglycemic Agents
PAID, Problem Areas in Diabetes
PCDS, Perceived Competence for Diabetes Scale
QUOROM, Quality of Reporting of Meta-analyses
RCT, Randomized controlled trial
SD, Standard Deviation
SPSS, Statistical Package for the Social Sciences
WHO, World Health Organization
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1. Introduction

During the last twenty years the prevalence of diabetes has increased dramatically in many parts of the world and the disease is now a worldwide public health problem. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030\(^1\). In Denmark at the end of 2007 proximately 240,000 people had been diagnosed with diabetes\(^2\). The mortality rate is higher among people with diabetes than among the rest of the population with an excess mortality of 65 % in 2007\(^3\). Excess mortality is mainly due to diabetes-related diseases developed because of poorly controlled diabetes. The socioeconomic impact of diabetes and diabetes care in Denmark is estimated to be about 22 billion DKK per year in 2008 including the health sector’s annual cost for treating diabetes and diabetes-related diseases\(^4;5\). Moreover, the social costs of production due to diabetes represents another 9.5 billion DKK yearly\(^4\). The increasing prevalence of the disease and hereby also increasing social costs combined with the fact that the disease is associated with increased morbidity and mortality emphasizes the importance of effective diabetes care.

1.1 Type 1 and type 2 diabetes mellitus

Diabetes is a metabolic disease that is diagnosed on the basis of sustained high concentration of glucose in the blood. According to the World Health Organization (WHO) the current diagnostic criteria for diabetes are: 1) plasma glucose concentration measured after an overnight fast above 7.0mmol/l and/or 2) plasma glucose concentration measured two hours after a 75g oral glucose load above 11.0mmol/l\(^6;8\). Diabetes occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. Type 1 diabetes results from autoimmune mediated destruction of the beta cells of the pancreas\(^9\). Insulin is vital for individuals with type 1 diabetes to avoid ketoacidosis, coma and death. Type 2 diabetes is characterized by resistance to the action of insulin and disorder of insulin secretion, either of which may be the predominant feature\(^9\). Individuals with this type of diabetes do not need insulin to survive. Type 2 diabetes, which is the most common type, is often a result of excess body weight and physical inactivity in genetically predisposed individuals\(^10\). Over time, diabetes can increase the risk of health-related problems including blindness, kidney damage, nerve damage, amputation of lower limbs and cardio vascular disease\(^3\). Although diabetes cannot be cured, the disease can be managed by non-pharmacological and pharmacological strategies, where improvements in glycaemic control are important factors in delaying the onset and progression of diabetes-related complications\(^11;12\).
1.2 Self-management and self-care

Treatment of diabetes leading to improved control is a 24-hour-a-day activity and often includes changes in lifestyle, most of which patients with diabetes must provide for themselves on a daily basis. Self-management of diabetes involves a number of considerations and choices that the patient with diabetes must make on a daily basis. It requires that patients are able to reconcile their resources, values and preferences with a therapeutic regimen of a healthy diet, exercise, no smoking, low alcohol intake, glucose monitoring and, for some patients, medication. Self-management of diabetes is closely connected to the self-care concept, which can be related to the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health, and well-being. The self-care concept in this thesis is inspired by Orem theory of self-care and is seen as a health resource in the individual. The Orem theory of self-care as a fundamental need in humans is based on the values of autonomy and independence. In Orem’s understanding, self-care is a learned and purposeful activity of the individual that requires a certain level of maturity enabling the individual to perform effective, purposeful, controlled and consistent actions. The theory also encompasses healthcare providers to help a person with their actual or potential self-care deficits. In this thesis self-care is seen as context dependent ability. Therefore, the self-care activity is not only a process directed inwards affected by personal conditions, but the ability to conduct self-care is also affected by interpersonal and external conditions. Thus, the context and the dynamics of available resources determine the conduct of self-care activities.

1.3 Self-management education

The patient’s own role in diabetes treatment and recognition of the need to educate patients in diabetes self-management has long been considered to be important. The concern about educating patients to take care of their diabetes began more than 100 years ago and was emphasized with the publication of the Diabetic Manual for the Doctor and Patient by Elliot Proctor Joslin in 1918. Since then several guidelines for diabetes care including education have been developed, among these The World Health Organization’s guideline for a national program for diabetes mellitus, which stressed the importance of developing effective patient education programs to maintain the health and quality of life of individuals with diabetes. Managing the daily care of diabetes seems to be a challenging task for many patients, and a patient’s ability to be involved in the daily routine of diabetes care seems to be grounded in psychological, motivational as well as educational factors. Diabetes self-management intervention has emerged as a resource to assist patients in
managing daily diabetes care through dissemination of information and facilitation of self-management behaviors. Knowledge about the disease and specific lifestyle guidelines is necessary but not an adequate factor to facilitate the appropriate behavioral changes\textsuperscript{20,21}. In the development of education intervention there has therefore been an interest in identifying approaches that could strengthen the individuals’ beliefs in their own competency to handle their diabetes, and hopefully thus enabling them to control the disease\textsuperscript{22}. This indicates a need for health professionals to focus on the patients, their lives and their health problems, rather than on the disease and disease management in diabetes treatment. The individual’s ability to conduct self-care activities and to assume responsibility for daily diabetes care are supposed to be reflected in good outcomes, which make the patients less prone to diabetes-related complications.

1.4 Previous research in diabetes self-management intervention

The increase of diseases with a multifactorial aetiology including a strong social component in prosperous countries has given rise to research in health prevention and health promotion\textsuperscript{23,24}. With regard to diabetes, the research in this area has focused mainly on how to encourage people with diabetes to undertake a prolonged regime of self-management. Previous systematic reviews and meta-analyses sought to find evidence that self-management intervention using educational or behavioral strategies stimulates the individual’s performance of diabetes self-care to increase target behavior actions such as blood glucose monitoring, diet care, physical activity and medical care among adults (Table 1). These studies indicated modest but significant improvements in glycaemic control in educational and behavioral interventions in diabetes\textsuperscript{24-31}, although, the improvement on glycaemic control seemed to decrease over time\textsuperscript{25,28,30}. The effect of self-management intervention on reduction in glycated hemoglobin seemed to be affected by baseline values of HbA1c, i.e. the higher baseline values of HbA1c, the greater the reduction\textsuperscript{24,25,32}. There was no strong evidence that interventions to improve self-management behaviors were effective in reducing morbidity and mortality among patients with diabetes. Studies to substantiate the effectiveness for self-management intervention to affect long-term behavior are therefore needed\textsuperscript{29}. Effects on other outcomes such as lipids, weight and blood pressure varied\textsuperscript{26,28,29} indicating the need for more studies to establish knowledge in this area. This was also true for research on psychological factors\textsuperscript{25,26,32}, though there was indication that psychological distress tends to fall among patients with diabetes who receiving psychological therapy\textsuperscript{28}. The organization of self-management intervention including methodological strategies was not well expounded. The contact time (time in hours) between healthcare professional and patient, however, seemed to have an influence on the
results\textsuperscript{30}, and strategies based on case management seemed to be more robust in improving glycaemic control compared to other quality improvement strategies for type 2 diabetes\textsuperscript{24}.

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Number</th>
<th>Subjects</th>
<th>Tested intervention</th>
<th>Follow-up</th>
<th>Effect on glycaemic control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norris 2001\textsuperscript{29}</td>
<td>Systematic review of 54 RCTs</td>
<td>-</td>
<td>Type 2 diabetes</td>
<td>Self-management training</td>
<td>6 months or less</td>
<td>Self management training tend to demonstrate positive effect on glycaemic control</td>
</tr>
<tr>
<td>Norris 2002\textsuperscript{29}</td>
<td>Meta-analysis of 31 trials</td>
<td>4263</td>
<td>Type 2 diabetes</td>
<td>Self-management education</td>
<td>0 months More than 4 months</td>
<td>A reduction of 0.76 % immediate after intervention and 0.26 % after more than 4 months in G hb in favor of intervention</td>
</tr>
<tr>
<td>Gary 2003\textsuperscript{41}</td>
<td>Meta-analysis of 18 RCTs</td>
<td>2720</td>
<td>Type 2 diabetes</td>
<td>Educational and behavioral intervention</td>
<td>1-26 months</td>
<td>A reduction of 0.43% in total G hb, H bA1, or H bA1c in favor of intervention</td>
</tr>
<tr>
<td>Ismail 2004\textsuperscript{41}</td>
<td>Systematic review and meta-analysis of 12 trials</td>
<td>522</td>
<td>Type 2 diabetes</td>
<td>Psychological therapy</td>
<td>1-6 months (one study had 12 months follow-up)</td>
<td>A reduction of 0.76 % in glycated hemoglobin in favor of intervention</td>
</tr>
<tr>
<td>Norris 2005\textsuperscript{41}</td>
<td>Subgroup meta-analysis of 4 RCTs</td>
<td>347</td>
<td>Type 2 diabetes</td>
<td>Lifestyle and behavioral intervention</td>
<td>12-24 months</td>
<td>A reduction of 0.3 % in glycated hemoglobin in favor of intervention</td>
</tr>
<tr>
<td>Deakin 2005\textsuperscript{41}</td>
<td>Meta-analysis of 11 RCTs</td>
<td>1532</td>
<td>Type 2 diabetes</td>
<td>Group-based self-management diabetes education programs</td>
<td>4-6 months 24 months</td>
<td>A short-term and long-term reduction of 1.4 % and 1.0 % in H bA1c, respectively, in favor of intervention</td>
</tr>
<tr>
<td>Shojania 2006\textsuperscript{41}</td>
<td>Meta-regression of 24 trials</td>
<td>28,410</td>
<td>Type 2 diabetes</td>
<td>Quality improvement strategies</td>
<td>13 months</td>
<td>A reduction of 0.42 % in glycated hemoglobin in favors of intervention</td>
</tr>
<tr>
<td>SBU 2009\textsuperscript{25}</td>
<td>Meta-analysis of 25 trials</td>
<td>6278</td>
<td>Type 1 and type 2 diabetes</td>
<td>Individual and group based patient education</td>
<td>6 months 12 months</td>
<td>A reduction of 0.5 % at 6 months and 0.16 % at 12 months in H bA1c in favors of individual based intervention. A reduction of 0.6 % at 6 months and 0.4 % at 12 months in H bA1c in favor of group based intervention. Insufficient scientific base for conclusion in type 1 diabetes</td>
</tr>
<tr>
<td>Duke 2009\textsuperscript{32}</td>
<td>Meta-analysis of 12 RCTs or CCTs</td>
<td>1359</td>
<td>Type 2 diabetes</td>
<td>Individual patient education</td>
<td>6-18 months</td>
<td>No significant improvements in H bA1c in favor of individual education</td>
</tr>
</tbody>
</table>

Although importance has been attach to the patient’s role in diabetes treatment, knowledge about how patients with diabetes experience self-management intervention programs aimed to promote self-care activities has not been well elaborated. We know from previous qualitative research evaluating interventions to improve self-management among patients with diabetes that self-management activities consist of a complex and dynamic set of processes that are deeply embedded in the individual’s unique life situation\textsuperscript{33}. This research indicated that support from diabetes specialist nurses and family caregivers are a prerequisite for managing diabetes. A study evaluating patient education found that behaviors rather than physiological outcomes need to be rewarded if self-management changes are to be encouraged and maintained\textsuperscript{34}. Cooper et al. argued
that there is a lack of support for the self-monitoring practice in the healthcare system. There was some evidence that multiple lifestyle modifications are beneficial in promoting diabetes self-management\textsuperscript{35}. Previous research has also suggested that patient involvement\textsuperscript{36}, cultural adaptation\textsuperscript{37}, family involvement\textsuperscript{38} and individualization\textsuperscript{39,40} are important factors in the development of interventions seeking to increase self-management among patients with diabetes.

There has been a keen interest in examining the impact of different kinds of patient education programs’ on diabetes self-management but the long-term effect of such programs is still unknown\textsuperscript{21,41}. In spite of that it is widely accepted that diabetes education is not only required in the first few months following diagnosis but is an important component of ongoing diabetes care due to the onerous requirements for self-care that demands multiple daily decisions in order to balance diet, physical activity and medications\textsuperscript{42}. Critical assessment of the impact of self-management education requires further research based on rigorous methods in high quality studies with a large number of participants, long-term follow-up on the effectiveness and well-defined interventions\textsuperscript{25,26,32}. A Danish Health Technology Assessment suggested that long-term effects on progression of diabetes probably requires intensive and lengthy training efforts\textsuperscript{21}. Furthermore, a literature review on patient education with emphasis on methods and effects concluded that the existing knowledge in patient education is insufficiently substantiated in comparison to the method and effect measurements\textsuperscript{43}. Further understanding of how self-management intervention supports the patient in dealing with diabetes in everyday life is also imperative for implementation of diabetes treatment aiming at improving and maintaining self-care activities\textsuperscript{41}.

2. Objectives

The objective of the present Ph.D. thesis was to study the importance of self-care management intervention in people diagnosed with diabetes. With this in mind, the aim was:

1. To assess the variations in the effectiveness of different self-care management interventions on glycaemic control indexed by glycated hemoglobin (HbA1c). (Paper I)

2. To examine the mediating effect of different study characteristics on the effect size, with specific focus on the difference between an educational intervention to the management of type 2 diabetes and a behavioral psychosocial intervention. (Paper I)

3. To explore and describe the lived experience of patients living with diabetes following a one-year self-management intervention based on motivational interviewing. We placed
particular focus on self-care activities and patients’ expectations and experiences of treatment. (Paper II)

4. To study the effect of a one-year intervention program based on motivational interviewing on glycaemic control and competence of management in patients diagnosed with type 1 or type 2 diabetes after attending a group education program. (Paper III)

3. Methods

This chapter describes how and under what conditions the empirical data underlying this thesis have been produced. The thesis is based on a meta-analysis of the available literature on the efficacy of self-management intervention, focus group interviews of patients with diabetes following a self-management program and a randomized study of the efficacy of a self-management program. Empirical data were gathered procedurally over a period of five years. The various methods for collecting empirical data were processed simultaneously, but in the actual analysis work, the data were separated between methods. It has of course been possible to use reflections about data across methods. In the discussion chapter we reflected on selection and deselection concerning the different methods.

3.1 Meta-analysis

3.1.1 Data Sources and Searches

We searched in the following electronic databases: MEDLINE (1952 to 2007), EMBASE (1980-2007), CINAHL (1982-2007), PsycINFO (1967-2007), Cochrane Library (1980-2007), SveMed+ (1977-2007), Bibliotek.dk (- 2007) and Web of Sciences (- 2007). Text word and controlled terms such as MeSH terms in Medline were applied. The following search terms were used: ‘Diabetes Mellitus’ was used to identify health condition. Since self-care treatment can be labeled with different terms, we used ‘self-care’, ‘education’, ‘self-management’, ‘empowerment’, ‘health behavior’, ‘self-care behavior’, ‘life style’, ‘health promotion’, ‘coping’, and ‘compliance’ to identify the intervention. ‘Clinical trials’ or ‘intervention studies’ were used to identify studies of the appropriate design. The search was restricted to humans and adults (over 18 years of age). Although only studies published in English or Nordic language were included in the analysis, there was no language restriction in the search strategy. The reference lists of all relevant studies were assessed and searched for additional studies. Likewise previously conducted meta-analyses on the
effect of non-pharmacological intervention in patients with diabetes were reread in the search for additional studies. No attempts were made to identify unpublished studies.

3.1.2 Study selection

Our protocol was implemented with reference to the QUOROM guidelines. Studies qualified for inclusion were randomized controlled trials because this study design generally supports high validity in testing the effectiveness of health technologies. All studies included tested the effect of self-care behavior interventions and involved adult patients (over 18 years of age) diagnosed with type 2 diabetes/non-insulin-dependent diabetes. The self-care management intervention was to use educational or behavioral strategies aimed to stimulate the performance of self-care to increase target behavior actions such as blood glucose monitoring, diet care and physical activity. The main focus of the assessment of the intervention's effectiveness on behavioral change was to be HbA1c as a marker of change. The studies were to include a control group with no intervention and to report measures and statistical data on the effect of the intervention on parameters specific to diabetes. The studies were included regardless of significant or non-significant findings reported. Studies were excluded if they did not clearly describe intervention techniques or were not published in English or Nordic language. Abstracts were not included because they generally lack sufficient information for evaluation. The selection procedure of the randomized controlled trials is illustrated in figure 1.

For the studies included in the analysis we categorized the form of self-care management intervention in two groups: 1) educational intervention and 2) behavioral psychosocial interventions. Techniques based on didactic-oriented intervention focusing on the knowledge acquisition, skills and information in order to improve diabetes self-management were categorized as education. Interventions were categorized as behavioral psychosocial if the intervention was based on cognitive, behavioral or motivational approaches, or if the study specified that the patients were receiving psychologically centered counseling involving relaxation, problem-solving, or motivational interviewing. Studies not explicitly labeling their intervention were included if they used one or more forms of intervention that could be coded into one of these two categories.

The mode of delivery was defined as individual or group session. The intervention could contain face-to-face contact, phone contact or both with a health-care provider. We considered the contact with health-care provider to be face-to-face if the patient was in personal contact with the intervention team at any time during the intervention. The intervention group was compared to a control group of usual care.
In the meta-analysis the outcome measure was long-term glycaemic control based on the percentage of glycated hemoglobin HbA1c. We applied HbA1c because it is a standardized measurement and a well established reference parameter used in diabetes treatment. HbA1c is directly associated with the risk of diabetic complications\textsuperscript{11,12,48}.

**Figure 1** Flowchart of the process of selected controlled trials through the analysis

3.1.3 Data Extraction and Internal Validity Assessment

The titles and abstracts of the studies identified by the search in the electronic databases and reference lists were independently examined by two of the authors. We included studies describing a controlled trial of a self-care management intervention in patients with type 2 diabetes. Two authors independently reread all full-text articles selected for further review. Differences over inclusion of studies were resolved through discussions and consensus\textsuperscript{28}. The list of included studies was completed 30th November 2007. In three of the studies included in the meta-analysis there were several intervention groups. For these three studies each intervention group in the study was compared to the control group and considered as an individual study. There were no cross-over trials or quasi-randomized trials that met all criteria for inclusion hence no study of this type was included in the analysis.
Key information from the included articles were independently extracted by two authors using a pre-specified data extraction form covering descriptive information of study sample, intervention and results. The following characteristics of the study sample were used to describe each study: country of origin, number of participants at baseline and follow-up, age, duration of diabetes, baseline glycaemic control, clinical subgroup, and type of treatment. Characteristics taken from the experimental intervention form were presented by type and duration of treatment, mode of delivery, specialty of healthcare provider, number of sessions and length of follow-up. Intervention intensity was defined by type of treatment, number of sessions and duration of treatment. All relevant results and statistical data to be used in the meta-analysis were extracted from the trials.

Internal validity was assessed using the criteria for Cochrane methodology for sources of selection and attrition bias of healthcare interventions. The possibility of selection bias was checked by inspection of the description of randomization procedure and allocation concealment. Attrition bias refers to systematic differences between the comparison-groups in the loss of participants from the study. Attrition bias was assessed by inspecting the rates of withdrawals and dropouts and checking the application of intention-to-treat analysis in each study. Since bias mentioned above can have significant effects on measured outcomes in intervention studies and thereby influence the results from the meta-analysis, we search for this information in the included articles.

3.1.4 Statistical analyses

The following information was extracted from the publications, if available: sample sizes at baseline and follow-up in each treatment group, mean and standard deviation at baseline and follow-up in each treatment group; mean and standard deviation of the individual differences between baseline and follow up; treatment effect, i.e. difference between the mean values of the individual differences together with standard error or confidence interval. Obvious misinterpretations of standard errors as standard deviations and vice versa were manually corrected. If the treatment effect was not explicitly given, it was computed from the available mean values. If the standard error of the treatment effect was not given, it was computed either from the confidence interval (a quarter of its length) or from the standard deviations of the individual differences in the two treatment groups, using the number of patients at follow up as sample size. If the standard deviations of the individual differences were not given, a conservative estimate based on the standard deviations at baseline and follow-up was used. If the standard deviations at baseline or follow-up were not given, the median standard deviation from all other studies was used. The meta-
analyses were based on a random effect model using Stata's meta command (version 9.2). We tested for heterogeneity by the chi-square test for heterogeneity. Potential publication bias was assessed by Begg's adjusted rank correlation test and Egger's test.

A univariate meta-regression was used to find potential factors associated with the treatment effect. The following subgroups were included in the regression-analysis: 1) type of intervention divided into behavioral psychosocial intervention or education, 2) sample size divided into $n \leq 99$ or $n > 99$, 3) year of publication divided into year $\leq 2004$ or year $> 2004$, 4) mean duration of diabetes divided into year $\leq 8.5$ or year $> 8.5$, 5) baseline glycated hemoglobin divided into HbA1c $\leq 8.5$ % or HbA1c $> 8.5$ %, 6) duration of intervention divided into month $\leq 9$ or month $> 9$, 7) follow-up period divided into month $\leq 12$ or month $> 12$, and age divided into year $\leq 60.5$ and year $> 60.5$. The out points of 2), 3), 4), 6) and 8) were chosen as the median among all studies. Mean HbA1c baseline values less than 8.5% is associated with only modest improvements or no significant improvements in glycaemic control following intervention$^{28,29}$. Therefore, mean HbA1c baseline values were divided into values equal to 8.5 % or less, or values above 8.5% in the subgroup analysis. Because we were also interested in the long-term effect of intervention on HbA1c, the dividing line in the follow-up period was set to 12 months. The meta-regression was based on Stata's metareg command.

### 3.2 Explorative study

#### 3.2.1 The phenomenological approach

The phenomenological approach in this thesis takes its starting point in the phenomenological thinking that one turns to things as they immediately present themselves to us, with the aim of letting the phenomenon show itself as it is given in immediate experience$^{50}$. Exploring the patients’ beliefs and feelings about the disease and its management gave us the opportunity to examine the significance of the intervention program on everyday life with diabetes. Using a phenomenological approach, we would get access to patients' perceptions of how life with diabetes is lived and handled. We perceived diabetes as a real phenomenon confirmed empirically by being present in the patients’ lives and by being experienced by patients in their life world. According to phenomenology, the world does not exist in detachment from its human interpretation$^{51}$; thus to manifest itself, the world needs to be experienced and conceptualized. The use of a phenomenological approach would allow us to discover and account for experiences and meanings in the human stream of consciousness$^{52}$. In this study the essence of phenomenology was to
discover what it is like to be living with diabetes which then constituted the fundamental question in the research. This implied for the researchers to have a desire to understand the phenomenon fully and to capture patients’ pre-reflective experiences as they lived it.

We accessed patients’ experience of daily living with diabetes through narrations from patients participating in focus groups. The focus on patients’ narrations would give the opportunity to see how patients create order in and give meaning to a life with diabetes. We viewed the conversation in the focus group interviews as comprising significant communicative details that have narrative features. The normative feature of the narratives should give access to the temporal dimension of the life of the patient with diabetes.

3.2.2 Data Collection

Data were collected during focus group interviews between May 2007 and May 2009. The interactive and synergistic nature of focus group interviews allowed us to explore patients' experiences with diabetes in a spontaneous and emotional way. Focus group interviews allowed access to a wide variety of ideas, views and experiences on self-management among patients with diabetes and insight into how a consensus was reached (or not) on issues relating to everyday life with diabetes. All participants in the focus group interviews had already participated in the four-day diabetes education program and thus several of the participants knew each other beforehand. Data collection from existing groupings in our case education groups gave us the opportunity to gain insight into the patients’ prior exchange of views on certain subjects.

To ensure that all patients had ample opportunity to express their own views and experiences, the focus groups comprised only three to five patients. Seven focus group interviews lasting 1-2 hours were conducted and recorded on tape. Three interviews were conducted immediately before the intervention (i.e. the five individual counseling sessions in the following year) and four were conducted just after the intervention. The interviews were held at a convenient location away from the patients’ homes and not directly connect to the premises where diabetes treatment took place. Data collection stopped when theoretical saturation was reached, i.e. when the data from the interviews began to be replicated. One of the authors moderated the interviews, and a co-moderator assisted during the interviews by taking notes and asking additional questions. The focus group interviews were guided by the three research questions shown in Table 2. The purpose of the research questions was to capture the lived experience as fully as possible with regard to patients’ experience of having diabetes. Throughout the interviews the participants were encouraged to be
particular about their experiences. The focus group interviews consisted of informal conversations which were affected by the interactive process between participants and between participants and researchers. The constitution of focus group interviews hereby implied that participants and researchers jointly produced the data.

Table 2 Example of questions guiding the interviews

<table>
<thead>
<tr>
<th>Research question</th>
<th>Interview question</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the lived experience of living with diabetes on a daily basis?</td>
<td>“Please tell me how you experience your daily life with diabetes.”</td>
</tr>
<tr>
<td></td>
<td>“How do you experience diabetes have affected your health?”</td>
</tr>
<tr>
<td></td>
<td>“Have you experienced any change in your daily conduct after you have been diagnosed with diabetes?”</td>
</tr>
<tr>
<td></td>
<td>“Please tell me of your relationship to your family, friends and colleagues. Do you experience any change after the diagnose?”</td>
</tr>
<tr>
<td>What is the lived experience of handling self-care activities before and after a motivational interviewing program?</td>
<td>“Please tell me what you do to take care of your diabetes.”</td>
</tr>
<tr>
<td></td>
<td>“What do you experience to be most important to you taking care of your diabetes?”</td>
</tr>
<tr>
<td></td>
<td>“Have you experienced to get help from family, friends and colleagues in any situation?”</td>
</tr>
<tr>
<td></td>
<td>“Have you engaged in any new activities following the motivational interviewing program?”</td>
</tr>
<tr>
<td></td>
<td>“What are your expectations of the motivational interviewing program?”</td>
</tr>
<tr>
<td></td>
<td>“Please tell me how you experienced the motivational interviewing program.”</td>
</tr>
<tr>
<td>What is the lived experience of everyday concerns about meeting requirements for certain health behaviors?</td>
<td>“Have you ever experienced not to be able to take care of your diabetes?”</td>
</tr>
<tr>
<td></td>
<td>“Have you ever experienced a conflict between what you wanted to do and what you thought you had to do to take of your diabetes?”</td>
</tr>
<tr>
<td></td>
<td>“What is good about having diabetes if you experience anything good?”</td>
</tr>
<tr>
<td></td>
<td>“Have you experienced any situation where you felt bad about your diabetes/self-care activities?”</td>
</tr>
</tbody>
</table>
3.2.3 Participants

Patients who were randomized to the one-year intervention program of five individual sessions based on Motivational Interviewing were invited to participate in the focus group interviews; consecutive patients were invited until a sufficient number of focus groups were conducted, i.e. when theoretical saturation was reached. Eight patients declined because of lack of time and two patients declined because of serious illness in the family. A total of 22 patients with diabetes participated in the focus group interviews. Five patients participated only in an interview before the intervention; nine participated only in an interview after the intervention and eight participated in interviews before and after the intervention (Table 3). All interviews were established to give a temporarily impression of the experiences with diabetes, diabetes self-management and treatment. All interviews were equally counted for. Twelve of the participants were women and ten were men. The age range was 30 to 72 years and the duration of diabetes ranged from six months to 5 years. The majority of the participants had diabetes type 2; only four had type 1. Approximately one-third of the patients were treated with insulin (with or without oral medication), one-third with oral medication only and one-third regulated diabetes through diet and exercise. Educational levels ranged from secondary school to university degree and connection to the labor market was varied, including retirement, disability pension, working full-time and working part-time work in a flexible job (for people with reduced ability to work). Fifteen patients were married or lived with a partner and seven lived alone. None of the patients came from an ethnic minority.

<table>
<thead>
<tr>
<th>Focus group before intervention</th>
<th>Focus group after intervention</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1</td>
<td></td>
<td>Laura, Annie, Jacob, Beth</td>
</tr>
<tr>
<td>No. 2</td>
<td></td>
<td>Carl, Jane, Paul, Peter</td>
</tr>
<tr>
<td>No. 3</td>
<td></td>
<td>Henry, Jan, Nanny, Kathy, Irene</td>
</tr>
<tr>
<td>No. 4</td>
<td></td>
<td>Jacob, Tina, Walter</td>
</tr>
<tr>
<td>No. 5</td>
<td></td>
<td>Paul, Mary, Peter, Hannah</td>
</tr>
<tr>
<td>No. 6</td>
<td></td>
<td>Nanny, Kathy, Irene, Winnie, Thomas</td>
</tr>
<tr>
<td>No. 7</td>
<td></td>
<td>Henry, James, Jenny, Clara, Jan</td>
</tr>
</tbody>
</table>

3.2.4 Data analysis

Data analysis was inspired by Giorgi’s phenomenological method. This method was used to examine the meanings expressed by participants in relation to managing diabetes in everyday life.
According to Giorgi, such analysis comprised a minimum of five basic steps: (a) collection of verbal data, (b) reading of the data, (c) dividing of data into parts, (d) organization of data from a disciplinary perspective and (e) synthesis of the data. The analytic process was not linear but could go back and forth between these steps.

The first stage of the analytic process comprised preparation of an interview guide containing broad and open-ended questions that would allow interview participants to express their viewpoint extensively; a word-by-word transcription was then made of information elicited during the interviews. In the second stage all the transcripts were read and reread to give a sense of the whole and to understand the meaning of the experiences from the participants’ standpoint; at this stage we did not try to thematize the data. In the third stage the first author divided the transcribed data material into what Giorgi calls “meaning units”; one of the other authors then confirmed these units. The task here was to separate the material into smaller parts by identifying themes that described the patients’ experiences of handling diabetes in everyday life. We ended up with a series of meaning units that were still expressed in the participants' own words. The fourth stage was a transformation of the participants’ everyday expressions into theoretical categories (Table 4). The meaning units were labeled with a code representing its content and then organized into theoretical categories using a standard word-processing program. The fifth and final stage comprised a synthesis of the themes identified from the interview material.

The narrative instrument. We were particularly interested to see whether the participants in the interview created a common consensus about being a diabetes patient. Therefore, in addition to the phenomenological method we examined the interactional framework within which the patients’ experiences were told. This was to understand how the meanings expressed by the patients were constructed in the interviews. The narratives in the interviews were often constructed from the many episodes spread throughout the interview told by the different participants and then condensed into a coherent story. The narratives were analyzed by looking at the structure inspired by Holstein and Gubrium’s description of extended stories. The structures of the narratives were broken down into interconnected components containing: (a) the preface that served to facilitate the story, (b) the continuations that allowed the story to continue and (c) the ending in which the point of the narrative emerged. The story was constructed on the basis of this condensation of the text and used as an abridgement after each theme.
### Table 4: Schematic example of step 3 and 4 in the phenomenological analysis process showing each of the three theoretical categories

<table>
<thead>
<tr>
<th>Step 3</th>
<th>Step 4</th>
<th>Codes</th>
<th>Theoretical categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meaning unit parts</strong></td>
<td><strong>Condensed meaning unit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thomas: “It’s difficult for me to eat six times a day because I drive around to customers throughout the day. Then I don’t get the right breaks.” Kathy: “Then you could have a small fruit bowl when you run around on the road.” Thomas: “My wife always makes sure that we have fruit with us when we go for a ride. But I forget it. I also forget to eat small snacks at home.”</td>
<td>Trying to get the diet regime into the daily living</td>
<td>Adapting self-managing behaviors</td>
<td>Becoming a self-regulating practitioner</td>
</tr>
<tr>
<td>Jacob: “You just have to do it. I try to follow the diet. And of course I hunger for Danish pastry. You can take one piece and then go back to the diet again the next day.” Tina: “But that is the problem. I just can’t stop with one piece of cake.” Jacob: “But you have to restrict yourself to one piece of cake.”</td>
<td>You have to following the diet required of the diabetes management</td>
<td>Getting control</td>
<td>Managing the rules of self-management</td>
</tr>
<tr>
<td>Peter: “I might be a little annoyed from time to time when my wife she will guide me in something. I'll find out myself. It’s like she gets overprotecting.” Jane: “Oh that’s nice. She just wants you to feel good. Look! That is what support is about.” Peter: “Yes. But it does still seem a little annoying for me anyway.” Carl: “I know how you feel. I've also had it sometimes with my wife. Sometimes she thinks she knows things better than me.” Jane: “She just wants you to feel good. But of course you have to be careful that your husband or wife doesn’t take over the lead.”</td>
<td>You have to be careful that the network do not take over the diabetes management</td>
<td>Network’s interference</td>
<td>Creating a supportive social network</td>
</tr>
</tbody>
</table>

### 3.3 Randomized controlled trial

#### 3.3.1 Research settings

This study was conducted at a diabetes clinic, located within a university hospital in Denmark with intake of patients from both urban and rural areas of the region. Patients can be referred by their general practitioner and other hospital departments to the diabetes clinic. At the clinic patients are offered ongoing individual counseling by dieticians, nurses or physicians and group education delivered by a multidisciplinary healthcare team over four days. The four-day diabetes education program include approximately eight to ten patients and focus on a range of themes such as diabetes...
treatment, prevention of diabetes-related complications, self-monitoring of blood glucose, diet, physical activity, alcohol use and issues regarding insurance. The teaching method is based on guided self-determination designed to guide patients and professionals in mutual problem solving\textsuperscript{61}.

3.3.2 Research subjects and design

To make sure that all participants included in the trial had the same basis of knowledge about diabetes and self-care requirements they were all recruited after participation in the group education program offered at the diabetes clinic. Patients were eligible if they had type 1 or type 2 diabetes mellitus, over 18 years of age and participated in the group education program offered at the diabetes clinic. Exclusion criteria included pregnancy, severe debilitating disease and cognitive deficit. Following written acceptance of the patients, these were randomized to a control group or intervention group. Randomization was done immediately after participation in the group education program. All outcome measures were assessed at randomization and one year after randomization in both groups (Figure 2).

Sequentially numbered, sealed, opaque envelopes were used to secure adequate allocation concealment. The randomization was performed in small blocks being the number of allocation within a block was the same for the two groups. Permuted blocks chosen randomly were used to eliminate deciphering. The person who generated the allocation scheme did not administer the allocation of the patients to the two groups and were not part of the research team.

The sample size was determined by a power calculation. With 352 patients, 176 in each group, the trial can detect a 0.4% difference in HbA1c. The power was set to 90%. This calculation
was based on a standard deviation of 1.15 in the HbA1c-value and a 5% two-sided significance level.

Medical treatment was not part of the intervention. All participants, irrespective of participation in the intervention group or control group, therefore underwent the same routine checkup at their general practitioner or outpatient clinic in charge of their diabetes care. This usually involves four visits a year at a physician. Biochemical tests and examinations are usually performed during the visits in accordance to national diabetes guidelines. Individual counseling and recommendations based on the results of the examinations, biochemical tests and their self-monitoring of blood glucose was received. Renewal of prescribed medication and test strips for blood glucose monitoring was also received at these checkups. As required patients can be referred to counseling in change of diet, smoking habit and alcohol use.

3.3.3 Research intervention

The theoretical approach of the intervention was based on the self-efficacy theory and motivation interviewing spirit. Our approach was based on Albert Bandura’s Self-efficacy theory of human intentional acts through their beliefs in their capability to perform a desired effect by their actions. The theory is based on the assumption that pulled by anticipated benefits people seek to gain control over events that affect their lives. Bandura’s refers to perceived self-efficacy as a person beliefs in own capability to organize and execute the courses of action required to produce given attainments. We considered perceived self-efficacy as one of several factors that might affect patients' behavior. Bandura emphasizes that "perceived self-efficacy operates within a broad network of sociostructural influences" (Bandura 1997, vii). This supports our assumption that conducting self-management activities in the everyday life patient are influenced by social structural factors as well as psychological factors.

Motivational interviewing was used as a method to facilitate the process in peoples’ self-regulation of motivation. The spirit of the method is characterized in identifying and mobilizing the client's intrinsic values and goals to stimulate behavior change, facilitating patient’s expression of both sides of the ambivalence, and respecting the patient’s autonomy and freedom of choice. Motivational interviewing is defined as a directive, patient-centered counseling style for eliciting behavior change by helping patients to explore and resolve ambivalence.

The one-year motivational interviewing program consisted of up to five individual counseling sessions lasting approximately 45 minutes and offered at one, three, six, nine, and twelve months. Each participant in the intervention group had a healthcare professional trained in motivational
interviewing assigned. The style of the interview was: 1) seeking to understand the person's frame of reference, 2) expressing acceptance and affirmation, 3) eliciting and selectively reinforcing the client's own self motivational statements expressions of problem recognition, concern, desire and intention to change, and ability to change, 4) monitoring the client's degree of readiness to change, and 5) affirming the client's freedom of choice and self-direction. Each session followed a semi-structured interview format of motivational interviewing specially developed for this intervention program. Subjects brought up during sessions were any problematic issues related to diabetes self-care experienced by the participants. The participants in the intervention group could be referred to an individual tailored counseling in changes of diet, physical activity, smoking habit and alcohol use as they required.

3.3.4 Education of the healthcare professionals prior to the intervention

Three diabetes specialist nurses, two dieticians, one physiotherapist and one psychologist were educated to carry out motivational interviewing. They were all coached by a MI-trainer from the Motivational Interviewing Network of Trainers in Nordic countries. The course content five day’s theoretical introduction to strategies in motivational interviewing, and critical dimensions of motivational interviewing: empathy and the motivational interviewing spirit. The course was followed by three practical coaching sessions every third month for eighteen month. The theoretical and practical part of the education included training in the key elements of motivational interviewing which are the patients-centered nature of eliciting change talk and exploring ambivalence about behavioral change while trying to examine discrepancies between the individual’s current behavior and core values or personal goals. The healthcare professionals were introduced to motivational interviewing method including reflective listening and acknowledgement to allow them to be able to clarify patient’s goals and concerns and elicit reasons for change in the patient’s own words. The method allowed the healthcare professionals to affirm self-confidence in ability to change, and support perceived importance of behavioral change in the patient. The role of the healthcare professionals was to coach and support the patient in discovering and developing his/her own resources for change and management at the patient’s request.

After the five days course the healthcare professionals were individually supervised by the MI-trainer in ten real patient situations for one year. The supervision included videotaping and evaluation inspired by Motivational Interviewing Treatment Integrity (MITI) coding system66. The MITI coding system is a validated tool to measure counselors’ competence in motivational interviewing method67 and comprises of two components; global ratings and behavior count. The
global ratings evaluate the overall judgment about motivational interviewing spirit performed by the counselor given on a five point Likert scale, where 1 is low competence and 5 is high competence. The behavior counts tally instances of particular counselor behavior and measures: 1) the percents of open question in proportion to all question asked, 2) the percents of complex reflection in proportion to all reflection made, 3) the ratio of total reflection to total question in the interview, and 4) the percents of MI-adherent behavior in proportion to the total behavior during the interview (Table 5 and Text box 1). Based on the supervision the healthcare professionals could improve their listening skills, their way of posing questions, problem-solving, goal-setting, and supporting patients in their behavioral changes.

### Table 5 Results of the MITI coding

<table>
<thead>
<tr>
<th>Behavior Count or Summary Score</th>
<th>Results</th>
<th>Competency in the practice of Motivational Interviewing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Clinical Ratings</td>
<td>Average of 4.7</td>
<td>High</td>
</tr>
<tr>
<td>Percent Open Questions</td>
<td>76 to 83 %</td>
<td>High</td>
</tr>
<tr>
<td>Percent Complex Reflections</td>
<td>36 to 42 %</td>
<td>High</td>
</tr>
<tr>
<td>Reflection to Question Ratio</td>
<td>1.8 to 0.8</td>
<td>Average to low</td>
</tr>
<tr>
<td>Percent MI-Adherent</td>
<td>80 to 100 %</td>
<td>High</td>
</tr>
</tbody>
</table>

### Text box 1 Example of MITI coding an interview

**Counselor:** “What have you already done to lose weight?” (Open question)  
**Patient:** “Right after the diabetes school I exercised three times a week, and I lost weight. But now I don’t seem to be able to exercise because I have so much to do. I teach after work, so it’s very hard for me to find time to exercise as well?” (Complex reflection)  
**Counselor:** “You need better planning of your time.” (Complex reflection)  
...  
**Counselor:** “I have some information about how you can control your blood glucose level, and I was wondering if maybe we could talk about it together?” (MI-adherent behavior)

### 3.3.5 Measurements

#### Laboratory measurements

One laboratory analyzed all the blood samples. Glycaemic control was assessed using HbA1c. HbA1c were measured by a high-performance liquid chromatography based ion exchanged procedure (Tosho Alc 2.2, Japan). The reference range was 4.3-6.3 %. Total cholesterol, HDL cholesterol, and triglyceride levels were measured in serum by enzymatic methods (Boehringer Mannheim GmbH Diagnostica, Mannheim, Germany). LDL cholesterol was calculated by Friedewald’s equation.

#### Questionnaires

Competence of diabetes self-management was assessed by validated questionnaires translated into a Danish version in accordance with recommendation. Problem Areas in Diabetes Scale (PAID) was used to measure diabetes-related distress reported by the participants. This twenty-item questionnaire assesses a wide range of feelings related to living with diabetes and the diabetes
treatment\textsuperscript{69,70}. Each item can be rated on a five-point Likert scale ranging from zero (“not a problem”) to four (“a serious problem”). Transforming PAID scores into a 0-100 scale all item scores are summed and multiplied by 1.25 which results in an overall PAID score with higher scores indicating greater emotional distress\textsuperscript{71,72}. High PAID scores are associated with low self-reported adherence\textsuperscript{70}.

The Perceived Competence for Diabetes Scale (PCDS) was used to measure competence at carrying out the diabetes treatment regime. This is five-item questionnaires that assess the degree to which participants feel confident about dealing with diabetes\textsuperscript{73,74}. Each item can be rated on a seven-point Likert scale ranging from one (“not true at all”) to seven (“very true”). The score on the PCS is calculated by averaging the responses on the five items. Minimum average score is one equaling lowest possible perceived competence in dealing with diabetes and maximum average score is seven equaling highest possible perceived competence in dealing with diabetes.

\textit{Clinical measurements}

Both height and weight were measured without shoes. Weight was measured without accessories, i.e., wallet, keys, mobile phone. Waist circumference was measured with a measuring tape directly on the individual’s skin. Restrictive garments and clothing were removed. The tape was placed at the uppermost border of the iliac crest horizontal to the floor. Measurement was made at the end of a normal expiration. Blood pressure was measured by the auscultatory method with use of a stethoscope and a sphygmomanometer. An inflatable cuff was placed around the upper left arm, at the same vertical height as the heart. Measurement was made in rest in a sitting position.

\textit{3.3.6 Statistical analysis}

For data analyses, the Statistical Package for the Social Sciences (SPSS, Version 18 Inc., Chicago, IL, USA) for Windows was used.

Intention to treat, where missing values were imputed with the last value carried forward method (LOCF), was used as was per protocol analyses. Data in this article are presented per protocol. When results of intention to treat analyses differed from those of the per protocol analyses it is presented in the text. Baseline characteristics were compared in the two study groups with use of chi-square tests for discontinuous variables and unpaired t-tests for continuous variables. Analyses of primary and secondary outcomes were performed with the use of paired t-test within group and unpaired t-test between groups (calculated on mean delta values of outcome variables). A two-tailed p-value with equal variances assumed < 0.05 was considered statistically significant.
Results are reported as means ± standard deviation (SD) or numbers N (%) with 95 % confidence intervals and p-values of the differences.

4. Research ethics
The study design was approved by the Regional Research Ethics Committee of Southern Denmark and the study was reported to the Danish Data Protection Agency. All patients were informed about the aim of the study and were included in the study after verbal and written consent. The study was performed in accordance with the Helsinki Declaration II. All patients have been anonymized in the study to avoid identification.

5. Summary of results

5.1 Paper I
We assessed the variations in the effectiveness of different self-care management interventions on glycaemic control indexed by glycated hemoglobin (HbA1c). Secondly, we examined the mediating effect of different study characteristics on the effect size, with specific focus on the difference between an educational intervention to the management of type 2 diabetes and a behavioral psychosocial intervention.

5.1.1 Results
We identified 4359 potential studies in the search strategy from which 187 full text articles were selected for detailed evaluation. Forty-seven randomized trials were eligible for the meta-analysis. Eighteen studies were classified as using behavioral psychosocial techniques as intervention method. Twenty-nine were classified as using educational techniques. The 47 studies yielded 7677 participants (sample sizes of 23 to 1973). Intervention ranged from 1 month to 8 years; follow-up ranged from 2 to 96 months.

The pooled mean difference in the decrease in HbA1c between patients assigned to self-care management intervention and those in the control group was 0.36% (95% CI 0.207 to 0.509) (Figure 1).
Two factors had significant effect on the effect size: sample size (effect size 0.42%, p=0.007) showed higher effects in small studies with sample size 99 or less compared to studies with sample size above 99 and follow-up period (effect size 0.49%, p=0.017) showed higher effects in studies with follow-up period 12 months or less compared to studies with follow-up period above 12 months.
months. For duration of intervention there was a non-significant 0.3% (p=0.077) larger reduction in HbA1c in studies with intervention duration of nine months or less compared to studies with intervention duration above nine months. There was only a small difference in the reduction in HbA1c between the subgroups defined by year of publication, mean duration of diabetes, mean HbA1c at baseline and age. These differences were not significant.

A comparison between psychologically centred techniques and educational techniques suggested a moderate, non-significant difference in effect size of about 0.26% (p=0.107) in favour for educational techniques. Sample size might be a confounding factor as when adjusting the effect of educational techniques versus behavioral psychosocial techniques for sample size there was a decrease in the difference in the reduction in HbA1c between the techniques. This might imply that the estimated advantage of educational techniques over behavioral psychosocial techniques partially could be explained by the fact that studies on educational techniques were more often based on small sample sizes.

5.1.2 Conclusions

Self-care management interventions have an effect. The results of the present study supports that this is especially true under conditions which imply a compact program with sessions closely grouped together. However, the effect may decrease over time. The benefits of promoting self-care management in patients with type 2 diabetes are reflected in glycaemic control and thereby hopefully also in morbidity and mortality. The role of intervention techniques seems to be of less importance, although our results indicate an advantage for educational techniques. The intervention form may have impact on the effectiveness and practicability in clinical practice.

5.2 Paper II

In this study, we explored how patients experienced their everyday life with diabetes. The aim was to describe the lived experience of patients living with diabetes following a one-year self-management intervention based on motivational interviewing. We placed particular focus on self-care activities and patients’ expectations and experiences of treatment.

5.2.1 Results

Mary (focus group 5): “Lilly [the assigned healthcare professional in the intervention program] has been really good to make me think about how I felt. This was really good for me. Also to make me face my problems and help me find out what has gone wrong. She supported me in telling the family how important it was to get them involved. Although it’s me who has diabetes and it’s my responsibility, we are a family and we have to stick together if we are to succeed.”
Data analysis based on a phenomenological method revealed three main themes concerning diabetes self-management: becoming a self-regulating practitioner, managing the rules of self-management and creating a supportive social network.

“Becoming a self-regulating practitioner” was about how patients handled the regimes of self-management in different daily situations and routines. Central to their management was daily consideration about how to adapt the recommended treatment regimen to other activities of everyday life, the focus here being blood glucose level. Diet, exercise and medication were instruments for achieving the goal of well-regulated blood glucose. Not all the participants believed that they could mobilize themselves to take care of their diabetes or get their network to support them in the effort to live in a life which takes account of diabetes. The inability to mobilize resources was often connected to the fact that patients had to deal with other problematic issues in their life. The counseling sessions in the intervention program were experienced as supportive in the process of mobilizing resources to handle the diabetes and to adopt an active role in diabetes management.

“Managing the rules of self-management” was about how patients used self-management to get control in their lives. The patients experienced a struggle of attaining a balance between following the recommendations for diabetes self-care and fulfilling their own needs. It appeared that patients negotiated the best way to manage their diabetes on a daily basis. All the patients in the study experienced the need to balance their lives while managing their diabetes; if they did something unhealthy they had to do something healthy as well. Handling diabetes in everyday life thus became subject to certain social rules that related to how diabetes was best managed. The rules of self-management were about adjusting one’s behavior to fit into different social contexts, while still being compatible with the treatment regimen. The patients found it important that their healthcare provider understood them in the struggle to do the right things. To handle the diabetes, the patients experienced that they had to be in control of their daily living.

“Creating a supportive social network” was about how the patients were able to get support from family, friends and colleagues on their own terms. Despite the fact that the patients in the study saw it as their own responsibility to take care of their diabetes, the lack of family support was seen as a barrier for patients to gain control of their daily routines of self-management. The patients used different strategies in developing a supportive network. Some patients made the network around them change behavior so that it was consistent with diabetes care. Other patients changed their own behavior to be consistent with diabetes care and sought the network to support and accept
this behavior. Common for all patients was that they tried to control the network to support them in being consistent with their own needs.

Narrative analysis revealed a divergence in patients’ self-perceived competence in handling diabetes. “Being a good diabetic” emerged as a powerful storyline in the narrative analysis of the focus group interviews. In the tightly constructed plot about being a good diabetic it became clear that those patients, who were successful in becoming a self-regulating practitioner, managing the rules of self-management and creating a supportive social network, were considered to be successful in the strive to be a good diabetics.

5.2.2 Conclusions

The findings from the current study indicate a need to involve patients in setting treatment objectives to ensure that the patient participates in a meaningful and appropriate treatment that can be transferred to various everyday situations. It is evident that people with diabetes have specific needs for support in the daily responsibility of managing the rules of conduct regarding diet, exercise, medication and blood glucose monitoring. Healthcare professionals should be aware of the individual’s needs of the patients and the difficulties that some vulnerable patients face in handling the responsibility of self-management. The patients experienced that the intervention based on motivational interviewing, which had an explorative and patient-centered approach, had helped them to mobilize their own resources to overcome problematic issues related to their diabetes care.

5.3 Paper III

In this study we examined the effect of a one-year intervention program based on motivational interviewing on competence of management and glycaemic control in patients diagnosed with type 1 or type 2 diabetes after attaining a group education program.

5.3.1 Results

In the period between December 2005 and June 2009 469 patients attended the diabetes education program in the diabetes clinic. One hundred and fifteen patients declined to participate in the trial and five patients did not meet the inclusions criteria. The distribution of gender was comparable in the deselected group and the eligible group of patients. The mean age in the deselected group was significantly higher than the age of those who participated in the trial (59.1 (±11.8) years vs. 56.4 (±12.1) years, p=0.040). The duration of diabetes was also significantly higher in the deselected group than in total among the participants (7.1 (±10.0) vs. 4.7 (±6.7), p=0.008). There was no
difference found between the deselected patients and the eligible patients with regard to weight, blood pressure, glycated hemoglobin and lipid profile.

349 eligible patients were randomized (92% retention rate) to either an intervention group (n=173) or usual care control group (n=176). We found no difference in characteristics of dropout subjects between the two groups, except the mean baseline HbA1c level, where the mean baseline HbA1c level was 7.3 % (±1.0) in the intervention group and 6.6 % (±0.7) in the control group (p=0.041). The baseline characteristics and health status of both groups were similar, except the mean triglyceride level, where there was a statistical significant difference, but not clinical significant difference (p=0.043).

Motivational interviewing did not have an effect on HbA1c level (Table 6). There was, however, a tendency of improvement in the HbA1c level (9.3% to 7.5%, n=23) among the patients in the intervention group with a mean baseline HbA1c value above 8%. The motivational interviewing group maintained PCDS scores (6.3 to 6.3 vs. 6.2 to 5.8, p=0.011), but no improvements was found in PAID scores (18.32 to 17.45 vs. 19.40 to 20.16, p=0.343) (table 6). There were no significant differences between the two study groups as regards to total cholesterol, LDL cholesterol, weight, waist circumference, systolic blood pressure or diastolic blood pressure at post-test (table 6).

Similar changes in medical treatment over time were found in the intervention and control group as regards insulin, oral hypoglycaemic agents (OHA), antihypertensive agents, cholesterol-lowering agents, anticoagulants and steroids.

5.3.2 Conclusions

Individual counseling based on motivational interviewing offered after a group education program might enhance patients’ perceived competence in dealing with diabetes. There was no effect found in diabetes-related distress or the cardiovascular risk profile such as HbA1c level, lipid profile, blood pressure or medication, and likewise there were no improvements in weight or waist circumference. Though, the intervention program based on motivational interviewing might have an effect on glycaemic control in patients with poor diabetes control.
Table 6 Changes in primary and secondary outcome measures over one year in intervention group and control group (per protocol analysis)

<table>
<thead>
<tr>
<th>Variables/group</th>
<th>Pretest</th>
<th>Post-test</th>
<th>Difference (post-test – pretest)</th>
<th>95 % CI within group</th>
<th>p-value</th>
<th>∆ mean between groups</th>
<th>95 % CI between groups</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>I (n=150)</td>
<td>6.98 (1.23)</td>
<td>6.86 (1.22)</td>
<td>-0.12 (1.05)</td>
<td>-0.29 to 0.05</td>
<td>0.161</td>
<td>-0.04</td>
<td>-0.26 to 0.17</td>
<td>0.675</td>
</tr>
<tr>
<td>C (n=161)</td>
<td>7.06 (1.09)</td>
<td>6.99 (1.09)</td>
<td>-0.07 (0.83)</td>
<td>-0.21 to 0.05</td>
<td>0.249</td>
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<tr>
<td>Total cholesterol (mmol/l)</td>
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<tr>
<td>I (n=148)</td>
<td>4.40 (1.04)</td>
<td>4.24 (0.92)</td>
<td>-0.15 (0.87)</td>
<td>-0.30 to -0.01</td>
<td>0.033</td>
<td>-0.02</td>
<td>-0.21 to 0.16</td>
<td>0.803</td>
</tr>
<tr>
<td>C (n=161)</td>
<td>(1.02)</td>
<td>(0.97)</td>
<td>-0.13 (0.68)</td>
<td>-0.25 to -0.01</td>
<td>0.040</td>
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<td>LDL cholesterol (mmol/l)</td>
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<tr>
<td>I (n=149)</td>
<td>2.31 (0.97)</td>
<td>2.16 (0.82)</td>
<td>-0.15 (0.86)</td>
<td>-0.29 to -0.01</td>
<td>0.031</td>
<td>-0.02</td>
<td>-0.18 to 0.16</td>
<td>0.861</td>
</tr>
<tr>
<td>C (n=160)</td>
<td>(2.32)</td>
<td>(2.19)</td>
<td>-0.14 (0.68)</td>
<td>-0.24 to -0.03</td>
<td>0.011</td>
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<tr>
<td>PAID</td>
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<tr>
<td>I (n=145)</td>
<td>18.32 (14.09)</td>
<td>17.45 (14.64)</td>
<td>-0.87 (14.20)</td>
<td>-3.20 to 1.47</td>
<td>0.464</td>
<td>1.63</td>
<td>-1.75 to 5.00</td>
<td>0.343</td>
</tr>
<tr>
<td>C (n=155)</td>
<td>19.40 (16.40)</td>
<td>20.16 (17.48)</td>
<td>0.76 (15.42)</td>
<td>-3.21 to 1.69</td>
<td>0.540</td>
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<tr>
<td>PCDS</td>
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<tr>
<td>I (n=145)</td>
<td>6.30 (1.05)</td>
<td>6.29 (1.12)</td>
<td>-0.015 (1.16)</td>
<td>-0.88 to 1.03</td>
<td>0.875</td>
<td>0.37</td>
<td>0.084 to 0.65</td>
<td>0.011</td>
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<tr>
<td>C (n=155)</td>
<td>6.19 (1.12)</td>
<td>5.81 (1.33)</td>
<td>-0.38 (1.31)</td>
<td>0.87 to 2.94</td>
<td>0.000</td>
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<tr>
<td>Weight (kg)</td>
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<tr>
<td>I (n=150)</td>
<td>89.03 (17.69)</td>
<td>89.20 (17.77)</td>
<td>0.17 (5.92)</td>
<td>-0.78 to 1.13</td>
<td>0.719</td>
<td>-0.56</td>
<td>-1.71 to 0.60</td>
<td>0.34</td>
</tr>
<tr>
<td>C (n=157)</td>
<td>89.68 (18.28)</td>
<td>90.41 (18.74)</td>
<td>0.73 (4.31)</td>
<td>0.05 to 1.41</td>
<td>0.036</td>
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<tr>
<td>Waist circumference (cm)</td>
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<tr>
<td>I (n=150)</td>
<td>102.72 (14.56)</td>
<td>103.21 (14.76)</td>
<td>0.49 (5.12)</td>
<td>-0.34 to 1.31</td>
<td>0.245</td>
<td>-0.30</td>
<td>-1.45 to 0.86</td>
<td>0.611</td>
</tr>
<tr>
<td>C (n=155)</td>
<td>101.97 (14.72)</td>
<td>102.76 (15.36)</td>
<td>0.79 (5.13)</td>
<td>-0.08 to 1.60</td>
<td>0.058</td>
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<td>Systolic BP (mmHg)</td>
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<tr>
<td>I (n=149)</td>
<td>132.57 (16.75)</td>
<td>135.44 (13.79)</td>
<td>2.87 (16.83)</td>
<td>0.15 to 5.60</td>
<td>0.039</td>
<td>3.61</td>
<td>-0.57 to 7.80</td>
<td>0.090</td>
</tr>
<tr>
<td>C (n=155)</td>
<td>132.66 (17.48)</td>
<td>131.92 (17.42)</td>
<td>0.74 (20.02)</td>
<td>-3.92 to 2.44</td>
<td>0.645</td>
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<tr>
<td>Diastolic BP (mmHg)</td>
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</tr>
<tr>
<td>I (n=149)</td>
<td>75.69 (10.49)</td>
<td>78.28 (8.78)</td>
<td>3.11 (10.55)</td>
<td>1.40 to 4.81</td>
<td>0.000</td>
<td>1.23</td>
<td>-1.14 to 3.57</td>
<td>0.309</td>
</tr>
<tr>
<td>C (n=155)</td>
<td>76.39 (9.91)</td>
<td>78.28 (8.78)</td>
<td>1.89 (10.30)</td>
<td>0.26 to 3.52</td>
<td>0.024</td>
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</tr>
</tbody>
</table>

Data are means (SD). Intervention group = I, Control group = C.

Analyses were performed with the use of paired t-test within group and unpaired t-test between groups (calculated on mean delta values of outcome variables).

Significant difference between pretest and post-test within group.

Significant difference between groups.

6. Discussion

6.1 Implication of self-management intervention and motivational interviewing

Several studies have found that self-management interventions are effective in improving short-term glycaemic control among patients with type 2 diabetes. In the present study, we found that in previous randomized control trials there was an overall modest but clinically relevant improvement in glycaemic control among patients with type 2 diabetes who received self-management intervention (0.36 %). This effect is not seen in patients with type 1 diabetes, but only little research has been done to investigate the effectiveness of self-management intervention among...
this patient group. Our results implied that in previous trials compact programs with sessions closely grouped together were most effective in improving glycaemic control, whereas type of regime seems to be of less importance in promoting self-care activities among patients with diabetes. The results from our randomized control trial did not correspond with the findings in our meta-analysis as no effect on glycaemic control was found among patients with diabetes after attaining an intervention program based on motivational interviewing. It could be argued that motivational interviewing has no effect in improving glycated hemoglobin, but factors like long duration of diabetes and low level of glycated hemoglobin at baseline might have had an influence on the results. The natural history of diabetes has to be considered here. Thus, beta-cell function gradually reduces over time, making the need for insulin treatment over time more likely. Therefore, the tendency of lower effect in our study patients with long duration of diabetes could be related to the natural history of diabetes. There was a tendency to higher effects in previous studies with high level of glycated hemoglobin at baseline. The results in our randomized control trial correspond with this. This is probably due to the fact that patient with low baseline potential might have little possibility of obtaining a high reduction in mean HbA1c. It could also be argued that our intervention program did not follow the patient in the intervention group intensively enough with sessions closely grouped together to achieve an effect on HbA1c as pointed out in our meta-analysis. A recently conducted randomized controlled trial evaluating a rehabilitation program in type 2 diabetes found a similar small effect on HbA1c that could be explained by the fact that the patient had to deal with different courses at the same time. This could very well be the case for some of the study patients in our study as they followed both the motivational interviewing sessions and tailored counseling in diet and physical activity. Essentially, motivational interviewing might not improve glycaemic control of patients who have a relatively lower HbA1c and longer duration of diabetes, especially when general practitioners and diabetologists see them regularly.

Only a small number of studies have examined the effect of self-management intervention including motivational interviewing on perception of self-care competence among patients with diabetes. There was a great variation of self-care measures among these studies and most of the studies measured self-care behavior concerning food choices, physical activity, medications, and symptom management. Assessment of self-care behavior in these studies relied on patient memory, and because no universally accepted measurement standards exist, assessment of self-care behaviors can be challenging and results between studies difficult to compare. Knight et al found that motivational interviewing increased the feeling of control among adolescents with type 1
Viner et al. also found that motivational interviewing increased self-reported self-efficacy among adolescents with type 1 diabetes\textsuperscript{122}, whereas Dale et al. found no effect of motivational interviewing on self-efficacy among adults with type 2 diabetes\textsuperscript{123}. Our study corresponds to the findings of King et al. and Viner et al. that motivational interviewing affected perceived competence in self-care, as we found that motivational interviewing maintained competence in dealing with diabetes among patients with type 1 and type 2 diabetes. We found no evidence, though, that motivational interviewing had effect on diabetes-related distress corresponding with the results of Dale et al.. This might indicate the need for further investigation of the effectiveness of motivational interviewing on perceived self-care competence. However, it is difficult to compare results of self-efficacy and self-competence between these studies because of the use of different assessment tools.

Another issue concerns the documentation of the use of motivational interviewing. None of the studies mentioned reported evaluation of the skills among the practitioners of motivational interviewing. The skills of motivational interviewing, including the use of reflective listening and adherence to MI-consistent behaviors cannot be adequately obtained through workshops alone\textsuperscript{124}. The workshop needs to be supported by subsequent individualized and tailored feedback and coaching over time with a trained coach (qualified according to MINT), based on the review of coded audiotapes of clinical consultations with consenting patients\textsuperscript{125}. To ensure that it was actually motivational interviewing that was evaluated in our trial we coded videotapes of clinical consultations with study patients inspired by Motivational Interviewing Treatment Integrity (MITI) Coding System. The coding showed that the healthcare professionals had a high competence in performing motivational interviewing. The effectiveness of motivational interviewing is not related to the counselor’s profession\textsuperscript{126}, but training and experience of motivational interviewing method have an influence on the effectiveness\textsuperscript{125}. In our study we used large resources to train the counselors in the motivational interviewing program to ensure their skills. It would be reasonable to speculate that implementing motivational interviewing into daily clinical work for healthcare professionals will be time-consuming. Therefore, further research in the implementation of motivational interviewing in clinical practice is recommended.

The appreciative approach in the intervention program might be an outcome mediator of importance on perceived competence in self-care among patients with diabetes. In our study we found that patients recognized the intervention’s explorative and acknowledging approach as supportive in handling diabetes in everyday life. Integrating diabetes self-care in the daily living
was, however, not always experienced as an easy task among the participants in the focus groups. This could be seen in the light of patient characteristics in the dropout group in our trial. Patients in the intervention group who dropped out during the intervention had significantly higher levels of HbA1c than those completing the intervention. This might indicate that some patients felt discomfort due to the scrutinizing nature of the intervention based on motivational interviewing that would get close to the person’s resistance to changing behavior and might unleash a feeling of failure in meeting the demands of change. In the focus groups some participants felt it was hard to live up to the demands of changing behavior in accordance with the diabetes regime. This might again indicate that the appreciative approach in the intervention program could be of importance in supporting patients in the daily diabetes care. This corresponds with the findings of the Moser et al. study and the Cooper et al. study. In the evaluation of a self-management intervention they found that support from the healthcare providers are a prerequisite for managing diabetes, and must address the individual’s unique life situation. Ingadottir and Halldorsdottir discussed the fluctuating and temporary nature of self-management behavior further. They argued that the essential structure of diabetes self-management is closely connected to the person’s conception of having diabetes. They found that within each person with diabetes there is both a sense of constraint and a sense of freedom related to handling diabetes. Therefore, adherence to the regimen for diabetes was reflected in this complexity of feelings along with fluctuating settings. The results of our study imply the need to go beyond the adherence thinking and to recognize self-management activities as an identity project. The patients in our study made sense of their identity through narratives about handling diabetes in everyday life. In the focus groups they compared their own ability to handle diabetes with that of others, and in the construction of a norm for appropriate management of diabetes they considered themselves as being either “good” or “poor” diabetics. The patients constructed their own sense of self on their ability to meet the challenges of self-management. Some patients found they were unable to control daily routines such as cooking and mealtimes. Well-regulated blood glucose was a benchmark for satisfactory handling of diabetes and both the individual and the surroundings were assigned the responsibility for failures and successes in the diabetes self-management. This could indicate that self-management is not just about being able to acquire skills but also about focusing on the patients’ own resources and trying to increase their beliefs in their ability to perform self-care activities. This might help patients to feel appreciated in relation to current problems in the daily routine of diabetes self-care. Furthermore, a
focus on what the patient believes to be appropriate and meaningful behavior related to daily diabetes care might improve the patient’s ability to perform self-management.

6.2 Perspectives on self-management demands

The retention rate was relatively high in our trial (92%). This could indicate that the participants in the trial were highly motivated with respect to willingness to focus on their self-care activities. In addition, it would be reasonable to speculate that perceived responsibility for taking care of diabetes might also be an issue here. The study participants experienced great responsibility in succeeding to live up to the diabetes regime. Our study touches a problematic issue in the treatment of diabetes. Patients with diabetes are expected to take responsibility and to participate autonomously in their own care, but this is not always compatible with patients’ needs. The patients in this study did not disclaim responsibility even when they felt that they could not live up to these expectations of self-regulation. It is conceivable that patients who considered themselves unable to mobilize themselves to take care of their diabetes will suffer under self-regulating demands. Thorne and Paterson stressed the tendency to ignore the needs of chronically ill patients for professional support and care. Others people’s expectations of competence and strength might be a heavy burden for some patients with diabetes. In the effort to promote self-care activities among patients with diabetes we therefore have to consider how these patients are approached. There may be psychologically and socially weak patients who simply do not fit into a self-care concept, requiring of patients that they participate actively in their own care, seek knowledge, administer medication, measure blood glucose, are aware of symptoms, have healthy lifestyle habits and engage in constructive cooperation with healthcare professionals. It is possible that if maintaining of a self-care concept that focuses solely on individual independence and self-management, patients will ultimately be let down. In our study the participants experienced that trustful and individual encounters with healthcare providers made them feel more prepared to meet the challenges of diabetes self-care. This could indicate that the relationship between patient and healthcare provider might be of particular importance in dealing with issues concerning self-management behavior. Thus, in research and clinical practice it might not be enough just to be explicit about the theoretical approach underpinning the counseling, but it is also necessary to be specific about the relationship between patient and healthcare provider.

In continuation of the above discussion about patients’ responsibility and autonomy with regard to their own care, the role of the social structures in the meaning construction of self-care could be scrutinized. The idea of the individual as a free and autonomous agent is being challenged
Self-management in diabetes care

in contemporary social theories of the individual’s relationship to society. The individual can be perceived as an object and target for specific strategies’ and procedures’ regulation\textsuperscript{129}. Hereby, the individual choices are controlled by specific social values and norms. Our conception of autonomy is expressed through the individual’s enterprising self, through different bodily practices, where the individual strives to achieve personal satisfaction in his/her earthly life by freedom to shape their lives through responsible choices\textsuperscript{130}. From this perspective, participants’ management of diabetes could be seen as controlled by the structures of society, where overall strategies regulate the individual’s choice towards a particular social order. In these approaches with a focus on the body as representation and body politics there is a disregard for the individual’s active role in the process of meaning and decision-making\textsuperscript{131}. The phenomenological approach, however, gives an understanding of the individual's social resistance and self-determination\textsuperscript{132}. On the basis of the above discussion about agent and structure, it could be argued that people with diabetes are to be regarded as individuals who both internalize and act in relation to social and health policies like diabetes self-care. It appears from our study that the self-care concepts of the individual responsibility for diabetes care were adopted by the participants. However, it was evident from the focus group interviews that the participants felt that being able to take care of diabetes in everyday life was not just about mobilizing resources to handle diabetes on their own, but much more about being able to mobilize resources to involve family, colleagues, and healthcare providers in the ongoing process towards a well-regulated diabetes.

6.3 Methodological reflections

The research process has been guided by methodological and theoretical reflections affecting the perspectives and empirical data that the thesis is based on. The strengths and limitations which might appear in the chosen approaches are discussed.

Meta-analysis

Only randomized controlled trials were included in the meta-analysis to increase comparability between studies. In addition to this study types other than randomized controlled trials rarely focused on glycated hemoglobin as an outcome. With regard to imparting evidence in the development of self-care behavior intervention in general, study types other than randomized controlled trials may also be important\textsuperscript{133}. Possible publication bias cannot be completely discounted in the meta-analysis. The statistical analysis gave no hint of publication bias, and we are not aware of any unpublished study fulfilling the criteria of our review. We did not search manually
in relevant journals to eliminate incomplete automatic databases. In general, it is a difficult task to ensure a complete ascertainment of unpublished research in educational and behavioral intervention, since a variety of disciplines is involved in this area. To reduce the limitation of database searches our search method for identification of studies followed the recommendation by McDonald et al.\textsuperscript{134}.

With regard to internal validity most studies included in the meta-analysis did not report on all potential sources of bias. Therefore, a validity rating as such has not been taken into account. To protect against unintended differences in intervention and control groups those providing and receiving care can be blinded\textsuperscript{49}. This is not possible in diabetes self-care intervention studies. Performance bias was therefore not used as a validity criterion. Detection bias was checked by inspection of the description of blinding procedure when it comes to persons responsible for assessing outcomes. To minimize the risk of bias these persons should be unaware of the assigned intervention. Glycated haemoglobin outcomes may not be that sensitive to detection bias, as the assessment procedure often includes external laboratories. Actually, very few studies reported on a blinding procedure.

In the meta-analysis two researchers read the same body of literature in order to generate a consensus of study characteristics and categorize the outcome variables\textsuperscript{135}. Ideally, reporting inter-rater reliability of study categories should be a part of the meta-analytic syntheses investigation\textsuperscript{136}. In our study we did not make a score of how much consensus there is in the ratings given by the two authors. In the comparison of the coding results there was now discrepancy with regard to categorizing interventions between the two authors, indicating accurate sample classifications. Thus, we cannot eliminate the inherent subjectivity to each author’s evaluation of study traits. In categorizing the interventions one of the pitfalls could also be that we depended on the accuracy of the study description.

**Explorative study**

Our access to patients' experience of the day to day living with diabetes was through what was narrated by patients in focus groups. This gave us the opportunity to get access to the temporal dimension of the life of the patients with diabetes\textsuperscript{137}. In this context, patients' representations of reality told through their narratives could be seen as being constructed in and through existing cultural assumptions about diabetes and self-management, which are sensitive to the situation in which they are constructed\textsuperscript{138}. In our study the phenomenological framework of understanding was
the focal point of data collection and analysis. This does not mean that we ignore the impact of social structures on diabetes patients’ actions and thoughts and that patients’ experience with diabetes might be related to the context in which they occur.

The use of focus group interview as data-gathering method meant that our only source of information was the patients’ reports of their lived experience with diabetes. Our results concerning experiences of everyday life with diabetes were thus an interpretation of the patients’ interpretation. An observational study exploring the social contexts and interactions that the patient enters into would have added further insights into everyday life with diabetes and allowed exploration of issues that patients did not construct discursively.

The phenomenological approach served to capture and describe how patients with diabetes oriented themselves to the lived experience of diabetes. The focus group discussions were found to be ideal in exploring how the self-managing patients with diabetes constructed their identity. The combination of these two approaches might have provided a greater understanding of patients' perceptions of how life with diabetes is lived and handled, given that focus groups stimulate the discussion and open up new perspectives. The consequence of the focus group setting was that the participants had time for reflection before adding their own perspectives. It is possible that accounts of reality formation are more likely to be stimulated and to be expressed in greater depth when shared in a group interview format. Group setting as data-gathering method could be a way to underpin the phenomenological research purpose.

The interactive and synergistic nature of the focus group setting did not prevent individual experiences from emerging, but there were some limitations. In a focus group interview there is not the possibility of examining all the individual patient’s individual perspectives in depth, and we had only limited insight into the perspectives of patients who felt unable to overcome problems in diabetes self-management. This issue was not pursued here because of the risk of sidetracking the group dynamics and violating the participants’ personal integrity. A purposive sampling to allow focus group interviews with patients who consider that they have problems with diabetes self-management could have been useful.

The fact that participants had been offered motivational interviewing when the interview took place might have had impact on the findings in the study. The participants, knowing that they would receive motivational interviewing, already might have new prospects and hopes for their future life with diabetes which could possibly have an impact on the experience told. Thus, in the intuitive
idea of the future the temporal dimension of the life of the patient with diabetes will be affected and might have an influence of the experience of life in the present\textsuperscript{142}.

In this study the essence of phenomenology was to discover the lived experience of diabetes, which required the researchers to be open\textsuperscript{53}. This openness could be affected by the background of the researcher. My background as a healthcare professional working with diabetes patient might affect my pre-understanding of what it is like to have diabetes. To address this issue I discussed my assumption with my supervisors and colleagues who were not in the field of diabetes and could thus question my assumption. Likewise, to ensure that we kept to the themes and variations that the participants expressed, we discussed amongst ourselves our impressions and interpretations during the analysis. Also, the study design allowed for repeated interviews with some of the same patients and groups, which reinforced the findings from the study because we were able to question our assumptions and pre-understandings over time. Another issue could be that because both the moderator and co-moderator in the focus group interview were healthcare professionals known to the patients, any critical perspectives on treatment might have been downplayed\textsuperscript{143}. However, patients mentioned the evaluation of the intervention spontaneously during the focus group discussions about handling diabetes in everyday life.

From the very beginning of the study the idea was to assemble focus groups to be followed through the intervention period. Because of dropouts it was not always possible to maintain the same group of people together, which meant that only a few focus groups could be followed over time. This might have affected the possibility of going into some themes in depth. In this context the focus group could have been combined with in-depth interview with some of the patients from the focus group.

\textit{The randomized controlled trial}

In our randomized controlled trial no improvements were found in the cardiovascular risk profile, whereas these improvements are often found in pharmacological studies\textsuperscript{11,12} with consequent improvements in mortality and morbidity. Research has therefore not been able to establish evidence on how medical treatment affects people’s beliefs in own competence in dealing with diabetes. We did not intervene in the medical treatment and it is therefore reasonable to assume that it was the intervention based on motivational interviewing that improved the patient’s perceived competence in diabetes. This might indicate that this kind of intervention adds another dimension to the diabetes care, compared with medical treatment. Therefore, the effectiveness of self-
management intervention given in addition to usual care might be best assessed with psychological rather than biochemical parameters in patients with a HbA1c level less than 8%. This is substantiated by a previous review that pointed out the difficulty in assessing the unique contribution of the diabetes patient education to diabetes outcomes\textsuperscript{144}. Another review recommended that the evaluation of diabetes patient education including self-management intervention is concentrated on the goal of optimal adjustment to living with diabetes as this kind of treatment is believed to play a discernable role to knowledge, self-determination, self-management and psychological adjustment\textsuperscript{145}.

PAID has shown to be responsive to change in perceived emotional distress in varying patient population\textsuperscript{146}. In our study we did not find that patients who received counseling based on motivational interviewing reduced their perceived emotional distress. However, there was a tendency that patients with poorly emotional distress had significant effect on PAID score after intervention, but the interpretation of how these changes in the PAID scores affect the patients’ quality of life remains unclear. The mean score of 18.32 at baseline in the intervention group is relatively low compared to the score of an typical unselected out-patient population group, which score in the mid 20s to 30s range\textsuperscript{72}. This might indicate that patient in the intervention group experienced less difficulties in the management of diabetes compared to diabetes patients in general.

The results from the PCDS questionnaire are difficult to translate for clinical practice. The instrument has not been developed directly to be used in clinical practice. Therefore, the interpretation of how changes in mean PCDS score have influence on patients’ diabetes self-management is not clear. Williams et al. found that an increase in perceived competence accounted for a significant decrease in glycated hemoglobin among patients with diabetes\textsuperscript{73}. Another issue of the PCDS questionnaire is the ceiling effect in data-gathering. The range of data that could be gathered by this particular instrument was constrained by inherent limits in the instrument's design. The ceiling effect occurred as a high proportion of subjects in the study had maximum scores in PCDS at baseline. This made discrimination among subjects among the top end of the scale impossible. Further, maximum scores at baseline made it impossible to detect any improvements in the intervention group. This means that the ceiling effect keeps the instrument from noting a measurement or estimate higher than some limit not related to the perceived competence in diabetes, but rather related to the design of the instrument. Ceiling effects limit the range of data reported by the instrument, reducing variability in the gathered data.
The power calculation showed that 352 patients were needed to show a 0.4% difference in HbA1c. Unfortunately several patients declined participation, which resulted in lower statistical power than planned. Except from perceived competence in diabetes we found no difference between the intervention and control group one year after baseline. The expected difference between the intervention group and control group was presumably set too high, taking the population into account. An insufficient sample size increases the risk of a type II error, and then a false acceptance of the null hypothesis. The intention to treat analysis did not differ from the per protocol analysis, indicating that the dropout rate was insignificant to the results, which diminishes the probability of an underestimation of the effectiveness of the intervention. The sample size calculation was only based on HbA1c and we cannot exclude the possibility that the study was underpowered to detect differences in other outcomes. We cannot totally exclude the risk of contamination bias which in this case could occur if patient in the control group changed their behaviors after interacting with patients in the intervention group or the healthcare professionals assigned to deliver the intervention also treated patients in the control group while coming to the diabetes clinic for routine care. Contamination bias might diminish the magnitude of the difference between the intervention and usual care and increases the risk of an underestimation of the effectiveness of the treatment. Although most of the patient entering this study went to their general practitioner for routine care which might minimize the risk of contamination bias, the use of a cluster design might have minimized the possibility of contamination bias even more\textsuperscript{147}. Furthermore, the Hawthorne effect could be an issue in relation to the effect measured\textsuperscript{148;149}. The study subjects might improve or modify an aspect of their behavior being experimentally measured simply in response to the fact that they are being studied and not in response to any particular experimental manipulation. Both participants in the intervention and control groups might have had a special focus on their self-care behavior when entering the trial.

Permuted block randomization with small blocks was conducted to ensure group balance at the end of the trial and to promote periodic balance in the sense that sequential patients are distributed equally between groups. This was important since it could not be ruled out that there might have been systematic differences between patients entering at different times during the study. However, this randomization procedure might lead to selection bias\textsuperscript{150;151}. The investigator was blinded from the randomization procedure itself to remedied selection bias. The study subjects and the investigator were not blinded to group assignment, which might have induced a bias favoring the intervention if patients and investigator expected a better effect of motivational
interviewing. In our study lack of blinding could have affected measurement of perceived competence, blood pressure, body weight and waist circumference but not glycaemic control and lipid profile. The response from the study subjects might be affected because they were aware of their treatment assignment, like responding more favorably when they received the new treatment if they were prejudiced in favor of the intervention. The unblinded investigator might unintentionally differentiate assessing outcomes in favor of intervention. In both cases, there was risk of bias that might increase the risk of overestimating the effectiveness of the intervention. Analysis of data was performed according to the predefined time points, patients and outcomes which reduced the risk of detection bias.

**Study participants**

The participants in this study are a selected group of patients with diabetes. The study populations comprised highly motivated patients who before entering the intervention participated in a group education program. Some of the patients had had diabetes for several years and had already successfully changed part of their lifestyle in accordance with the therapeutic regime of diabetes care. This might affect the generalizability of the results to all patients with diabetes. Our study population might represent the group of diabetes patients willing to change self-care behavior in a real-life setting. A strength of the study was that the study population had variation within the group with regard to demographic factors (e.g. gender, age, relation to labor market) and health-related factors (e.g. level of HbA1c, duration of diabetes, medical treatment), and we might assume that the results might be transferable to Danish patients with diabetes receiving motivational interviewing in another context. The results from the focus group indicated that the medical treatment and type of diabetes were important for the experience of the severity of diabetes. Thus insulin treatment and type 1 diabetes were experienced as a marker for diabetes being a fatal disease. It cannot be ruled out that this might have had an influence on how risk parameters were experienced and handled in this group of patients. This discussion is not elaborated further in the dissertation because it goes beyond the focal objective of the study. We found no clear pattern of how diabetes was managed according to gender or age in our material from the focus group. This might indicate that these factors did not have great influence of the experience of diabetes self-management.

Implementing a new approach in the diabetes treatment we have to consider who are most likely to benefit from this kind of intervention. Considering the group of patients who declined to participate in the trial it was evident that they were older and had had diabetes for a longer time than
those who participated in the trial. This could indicate that intensive interventions might be less attractive and manageable for the older population with diabetes. Furthermore, the patients in the intervention group who dropped out during the intervention had significantly higher levels of HbA1c than those completing the intervention. This could indicate that some patients felt discomfort due to the scrutinizing nature of the intervention based on motivational interviewing that would get close to the person’s resistance to changing behavior. It is of interest to find ways to support and motivate this patient groups as they might be at risk of developing diabetes-related distress symptoms.\textsuperscript{152}

7. Conclusions
The objectives of this study were examined through a meta-analysis, an explorative study and a randomized study. Based on the findings from the three sub-projects, we concluded:

1. Self-care behavior interventions have an effect on glycaemic control. Our results support the fact that this is especially true under conditions involving a compact program with sessions closely grouped together. However, the effect might vanish over time. The benefit from promoting self-care behavior in patients with type 2 diabetes is decisive in glycaemic control and thereby hopefully also in morbidity and mortality.

2. The role of intervention technique seems to be of less importance, although our results suspect an advantage for educational techniques.

3. The intervention form may have impact on the effectiveness and the current study indicates a need to involve patients in setting treatment objectives to ensure that the patient participates in a meaningful and appropriate treatment that can be transferred to various everyday situations. The patients experienced that the intervention based on motivational interviewing, which had an explorative and patient-centered approach, had helped them to mobilize their own resources to overcome problematic issues related to their diabetes care. Focus for self-management treatment ought to be the daily living with diabetes including social interactions.

4. Individual counseling based on motivational interviewing seemed to maintain patient’s perceived competence in dealing with diabetes. No effect was found in diabetes-related distress or the cardiovascular risk profile such as HbA1c level, lipid profile, blood pressure or medication, nor were any improvements in weight or waist circumference found.
8. Clinical implications

The findings of this study support the use of self-care behavior interventions in diabetes care. We recommend treatment provider to consider the intensity of the treatment and differentiated treatment when planning a self-management program as this might be a key to obtaining substantial effects.

It is evident that people with diabetes have specific needs for support in the daily responsibility of managing the rules of conduct regarding diet, exercise, medication and blood glucose monitoring. We therefore recommend treatment providers to be aware of the difficulties that some vulnerable patients face in handling the responsibility of self-management. A good understanding of how to meet the individual’s needs regarding care is necessary in the development of diabetes treatment strategies to ensure a sustainable treatment.

The present study found that motivational interviewing improved perceived competence in diabetes but not diabetes-related distress or any clinical outcomes in patients with diabetes. The lack of effect on HbA1c, lipid profile and other clinical outcomes such as weight and waist circumference might indicate that the patients in the intervention group did not change behavior towards a higher degree of diabetes self-care including healthy diet and more physical activity. Meanwhile, the improvements on patients’ cognition might take more time to achieve desirable behavioral changes in diabetes self-management. In this respect the improved cognition obtained by motivational interviewing might mediate clinical improvement in the long term. Therefore, when viewing an effect of motivational interviewing, it is important to keep in mind that motivational interviewing is based on making patients themselves aware of the potential for change in behavior and it will start a changing process for the patient that might result in improved health parameters over time126.

9. Perspectives and future research

Because of the wide variation of clinical sub-groups, intervention regimes and intervention providers in the studies included in the meta-analysis it was difficult to establish which type of regime was most effective, which sub-group of patients were most likely to benefit from the intervention regime, and to whom the intervention should be provided. Further research is needed to establish knowledge about these factors to be able to guide development of interventions that work.

We need to know whether self-care behavior changes can be maintained after completed treatment or permanent treatment is necessary in maintaining lifestyle changes in diabetes self-care. More and larger studies need to be conducted with a long follow-up period to establish knowledge
about intervention effect over time. Further, the present study did not answer the question about the long-term effect of motivational interviewing in diabetes care. As motivational interviewing seemed to start a changing process in patients, it indicates a need for long-term follow-up of the intervention program to establish full knowledge about the effect.

Equality in health services requires an individual assessment of each patient's resources, expectations and life situation to find the right treatment indicating that further research is needed to explore how treatment options can be differentiated to meet the diverse needs of the patient groups. Therefore, more qualitative studies focusing on specific needs for different patient groups could be of importance, and also study of the significance of the relationship between patients and treatment provider is recommended. It was evident from the focus group interviews that other actors than diabetes patients themselves were significant in the daily diabetes care. Therefore, it could be of interest to examine the importance of the development of network in this patient group and how this can be supported by healthcare professionals.

This study provided insight into the effect of a patient-centered approach. Implementing motivational interviewing as a new method in the diabetes care required a shift in the healthcare professionals’ role as well as practical training. Previous studies have shown that several barriers have to be overcome before a new method can be applied. To accommodate these barriers supervision and practical coaching sessions were held after the theoretical introduction to Motivational Interviewing. The supervision included videotaping and evaluation by the MITI coding system, both to facilitate the use of motivational interviewing and to ensure that the method was used correctly. With this in mind future research is recommended to focus on the implementing process of patient education and self-management intervention in clinical care. Though the motivational interviewing program was tested in a hospital setting, it might also be of interest to implement the concept in primary care as well. It is, therefore, recommendable to investigate how the concept could be integrated into the available treatment options offered to patients with diabetes in the municipal sector as well.

10. Summary
The objective of the present Ph.D. thesis was to study the importance of self-care management intervention in people diagnosed with diabetes. The thesis comprises three originals papers based on research work carried out from December 2005 to June 2010 at the Department of Endocrinology, Odense University Hospital, and consisted of a meta-analysis regarding the existing evidence on
self-management intervention in diabetes, a clinical randomized controlled trial regarding the effect of a self-management program and an explorative study regarding patients’ understanding and experience of diabetes self-management following the self-management program.

The aim of the meta-analysis was to assess the effectiveness of self-care behavioral interventions in improving glycaemic control in type 2 diabetes by analyzing the impact of different study characteristics on the effect size. The literature searched in 8 scientific databases up to November 2007 included original study articles of randomized controlled trials that evaluated a self-care behavioral intervention in adult patients diagnosed with type 2 diabetes. The 47 included studies yielded 7677 participants. The analysis showed a 0.36 % (95% CI 0.21 to 0.51) improvement in glycaemic control in people who received self-care behavior treatment. In the univariate meta-regression sample size (effect size 0.42 %, p=0.007) and follow-up period (effect size 0.49%, p=0.017) were identified to have significant effect on the effect size in favor of small studies and short follow-up. For type of intervention and duration of intervention there was a non-significant effect on effect size in favor of educational techniques and short intervention.

The aim of the explorative study was to explore how living with diabetes in everyday life is experienced following a self-management intervention program based on motivational interviewing. We conducted 7 focus group interviews, each comprising 3 to 5 participants diagnosed with type 1 or type 2 diabetes. Data analysis based on a phenomenological method revealed three main themes concerning diabetes self-management: 1) Becoming a self-regulating practitioner concerning how patients handled the regimes of self-management in different daily situations and routines, 2) Managing the rules of self-management concerning how patients used self-management to get control in their lives and 3) Creating a supportive social network concerning how the patients were able to get support from family, friends and colleagues on their own terms. A narrative analysis revealed a divergence in patients’ self-perceived competence in handling diabetes.

The aim of the randomized controlled trial was to study the effectiveness of a motivational interviewing intervention compared to usual care on changes in glycaemic control and competence of diabetes self-management in patients with diabetes mellitus. Adults with type 1 and type 2 diabetes mellitus who attended a four days group education program in a diabetes clinic at the department of Endocrinology were eligible. Exclusions criteria were pregnancy, severe debilitating disease and cognitive deficit. Randomization was generated by random permuted blocks, with allocation concealment by sequentially numbered, sealed, opaque envelopes. The intervention included up to five individual counseling sessions for one year based on motivational interviewing.
offered by a multidisciplinary team. 349 eligible patients were randomized (92% retention rate) to either an intervention group (n=173) or usual care control group (n=176). Motivational interviewing did not have an effect on HbA1c level post intervention. There was, however, a tendency of improvement in the HbA1c level (9.3% to 7.5%, n=23) among the patients in the intervention group with a mean baseline HbA1c value above 8%. No effect was found on lipid profile, blood pressure, medication, and weight or waist circumference. The motivational interviewing group maintained perceived competence for diabetes (PCDS scores; 6.3 to 6.3 vs. 6.2 to 5.8, p=0.011) post intervention, but no effect was found on problems areas in diabetes (PAID scores).

With this thesis we have shown that self-care behavior interventions have an effect on glycaemic control which is especially true under conditions which imply a compact program with sessions closely grouped together. However, the effect might vanish over time. We did not find evidence for the motivational interviewing program to improve glycaemic control, though patients with poor diabetes control might profit by the program. The motivational interviewing program enhanced perceived competence in self-management among patients with type 1 or type 2 diabetes mellitus. The study findings indicated that people with diabetes had specific needs for support in the daily responsibility of managing diet, exercise, medication and blood glucose monitoring. A meaningful treatment from the patient’s perspective would appear to be one that aims at overcoming problems that the patient experiences in self-management of diabetes. Further research is needed to establish knowledge about the long-term effect of interventions sustaining self-care activities in patients with diabetes. Future research is also recommended to focus on the implementing process of self-management intervention in clinical care.

11. Dansk resumé (summary in Danish)
Formålet med meta-analysen var at undersøge om behandlinger der understøtter egenomsorgsadfærd kan forbedre den glykæmiske kontrol hos personer med type 2-diabetes ved at analysere betydningen af forskellige studiekendetegn på effektstørrelsen. Litteratursøgningen omfattede otte videnskabelige databaser, hvor der søgtes i perioden op til november 2007. Søgningen inkluderede originale artikler af randomiserede kontrollerede forsøg, der vurderede effekten af behandlinger der understøtter egenomsorgsadfærd hos voksne patienter diagnosticeret med type 2 diabetes. De 47 inkluderede artikler omfattede 7677 deltagere. Analysen viste en 0,36% (95% CI 0,21 til 0,51) forbedring i den glykæmiske kontrol hos personer, der modtog behandling der understøtter egenomsorgsadfærd. I univariat meta-regressionen blev stikprovestørrelse (virkning størrelse 0,42%, p = 0,007) og follow-up periode (virkning størrelse 0,49%, p = 0,017) identificeret til at have væsentlig indvirkning på effektstørrelsen til fordel for små undersøgelser og kort follow-up. For interventionstype og interventionsvarighed blev der fundet en ikke-signifikant effekt på effektstørrelse til fordel for henholdsvis interventioner baseret på uddannelse og kort intervention.

Formålet med den eksplorative studie var at beskrive hvordan personer, der følger et behandlingsprogram baseret på motivationssamtalen, oplever livet med diabetes i hverdagen. Vi udførte 7 fokusgruppe interviews, der hver bestod af 3 til 5 deltagere diagnosticeret med type 1 eller type 2 diabetes. Dataanalysen baseret på en fænomenologisk metode afdækkede tre hovedtemaer vedrørende diabeteseegenomsorg: 1) At blive en selvregulerende praktiker handlede om hvordan patienter håndterede egenomsorgsregimet i forskellige daglige situationer og rutiner, 2) Håndtering af reglerne for egenomsorg handlede om hvordan patienter anvendte egenomsorg til at få kontrol over deres liv og 3) Oprettelse af et støttende socialt netværk handlede om hvordan patienterne var i stand til at få støtte fra familie, venner og kolleger på deres egne betingelser. En narrativ analyse viste en forskel i patienternes egen opfattelse af kompetence i håndtering af diabetes.

Formålet med det randomiserede kontrollerede forsøg var at undersøge effekten af et individuelt vejledningsprogram baseret på motivationssamtalen på den glykæmiske kontrol og oplevet diabeteskompetence hos patienter med diabetes mellitus. Voksne med type 1 og type 2 diabetes mellitus, der deltog i en fire dages gruppebaseret patientuddannelse på en diabetes klinik på Endokrinologisk afdeling, kunne deltagte. Eksklusionskriterier var graviditet, svær invaliderende sygdom og kognitive deficit. Randomiseringen blev genereret af tilfældige permuterede blokke, med skjult allokering ved sekventielt nummereret, lukkede, uigennemsegtige kuverter. Interventionen bestod af op til fem individuelle vejledende samtaler baseret på motivationssamtalen fordelt henover et år, tilbudt af et tværfagligt team. 349 valgbare patienter blev randomiseret (92%
retentions rate) til enten en intervention gruppe eller kontrolgruppen (n = 173), der modtog sædvanlig behandling (n = 176). Interventionen baseret på motivationssamtale havde ikke effekt på HbA1c niveau post interventionen. Der var dog en tendens til forbedring i HbA1c niveauet (9,3% til 7,5%, n = 23) blandt patienterne i interventionsgruppen med en gennemsnitlig baseline HbA1c værdi over 8%. Der blev ikke fundet effekt på lipidprofilen, blodtryk, medicin, vægt eller taljémål. Motivationssamtalerne vedligeholdt oplevet kompetence for diabetes (PCD scores; 6,3 til 6,3 versus 6,2 til 5,8, p = 0,011) post intervention, men der blev ikke fundet nogen signifikant forbedring i oplevet problemområder i diabetes (PAID scores).

Med denne afhandling har vi vist, at behandlinger der understøtter egenomsorgsadfærd har en effekt på den glykæmiske kontrol. Vores resultat viste, at dette især gjaldt under forhold med et kompakt program, hvor sessionerne placeres tæt sammen. Dog kan den virkning forsvinde over tid. Vi har ikke kunnet påvise at vejledning baseret på motivationssamtalen forbedrede glykæmisk kontrol, dog synes patienter med dårlig diabeteskontrol at have udbytte af vejledningen. Vejledningen baseret på motivationssamtalen forbedrede oplevet kompetence i egenomsorg hos patienter med type 1 eller type 2 diabetes mellitus. Undersøgelsens resultater viste, at mennesker med diabetes har særlige behov for støtte i det daglige ansvar for at håndtere kost, motion, medicin og blodskørmål. En meningsfuld behandling fra patientens perspektiv synes at være en, der sigter på at overvinde de problemer, patienten oplever i diabetes egenomsorgen. Yderligere forskning er nødvendig for at etablere viden om de langsigtede virkninger af interventioner der støtter egenomsorgsaktiviteter hos patienter med diabetes. Fremtidig forskning anbefales også at fokusere på implementeringsprocessen af behandling der understøtter egenomsorg i den kliniske praksis.
Reference List


Ref Type: Report


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(46) Richter B, Berger M. Randomized controlled trials remain fundamental to clinical decision making in Type II diabetes mellitus: a comment to the debate on randomized controlled trials (For debate) [corrected]. *Diabetologia* 2000; 43(2):254-258.


(51) Kvale S, Brinkmann S. Interviews. Learning the craft of qualitative research interviewing. 2nd ed. Los Angeles: SAGE; 2009.


(58) Kitzinger J. The methodology of Focus Groups: the importance of interaction between research participants. *Sociology of Health & Illness* 1994; 16(1):103-121.


(65) Miller WR, Rollnick S. Ten things that motivational interviewing is not. *Behav Cogn Psychother* 2009; 37(2):129-140.


Ref Type: Unpublished Work


(74) Zoffmann V. Guided self-determination: a life skills approach developed in difficult Type 1 diabetes: PhD Thesis [Department of Nursing Sciences, University of Aarhus; 2004]


(93) Gary TL, Bone LR, Hill MN, Levine DM, McGuire M, Saudek C et al. Randomized controlled trial of the effects of nurse case manager and community health worker


(119) Vadstrup ES. Aspects of the management of lifestyle intervention in type 2 diabetes mellitus [Faculty of Health Sciences, University of Copenhagen; 2010.


Ref Type: Hearing

Ref Type: Report


**Appendix**

**Paper I**

**Paper II**
Rosenbek Minet LK, Lønvig EM, Henrisksen JE, Wagner L. The Experience of Living With Diabetes Following a Self-Management Program Based on Motivational Interviewing. Qualitative Health Research 2010

**Paper III**
Rosenbek Minet LK, Wagner L, Lønvig EM, Henriksen JE. The effect of motivational interviewing intervention on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education program: a randomized controlled trial
Paper I
Review

Mediating the effect of self-care management intervention in type 2 diabetes: A meta-analysis of 47 randomised controlled trials

Lisbeth Minet, Sine Møller, Werner Vach, Lis Wagner, Jan Erik Henriksen

1. Introduction

According to King et al. [1], the prevalence of type 2 diabetes is of epidemic proportions and during the next decades the number of people affected by this chronic disease is estimated to increase further [1].

Although type 2 diabetes cannot be cured, the disease can be managed by non-pharmacological and pharmacological strategies, and increasing importance is given to the management of type 2 diabetes. Glycaemic control is an important factor in the management of type 2 diabetes, as a high degree of glycaemic control has proved to be effective in reducing diabetes-related complications [2] such as blindness, kidney damage, amputation of lower limbs, cardiovascular illnesses with a risk of early mortality [2,3].

Key to managing type 2 diabetes and maintaining a high degree of glycaemic control is adherence to the regime of daily treatment. However, many patients find themselves unable to follow the lifestyle recommended for patients with diabetes (which involves a healthy diet, physical exercise, no smoking, a low alcohol intake and in some cases glucose monitoring and medication), which makes them more prone to diabetes-related complications. This in turn involves a price paid for by the individual in terms of personal well-being, health and finances, which themselves translate into social costs of various kinds.

A patient’s inability to adhere to the treatment regime seems to be grounded in psychological and motivational rather than educational factors, as studies indicate that knowledge of the specific lifestyle guidelines is a necessary but not an adequate factor to facilitate the appropriate behavioural changes [4,5].

Therefore, a growing number of studies have been conducted to examine different types of self-care behaviour and psychological interventions and their effect on the management on type 2 diabetes. These studies show variations in relation to a range of factors such as the type of non-pharmacological intervention, the...
length of the intervention, and the subgroup (ethnicity, gender, age and HbA1c) of type 2 diabetes patients.

Previous systematic reviews and meta-analysis of educational and behavioural psychosocial interventions in type 2 diabetes have indicated modest improvements in glycaemic control [6-9]. One review showed that case management was more robust in improving glycaemic control compared to other quality improvement strategies for type 2 diabetes [9]. The previous studies were all comprehensive analyses of self-care interventions with an educational intervention or behavioural psychosocial interventions or both types of intervention, but none of them had systematically compared the effectiveness of an educational intervention compared to a behavioural psychosocial intervention.

The present meta-analysis assessed the variations in the effectiveness of different self-care management interventions on glycaemic control indexed by glycated haemoglobin (HbA1c).

The aim of this meta-analysis was to examine the mediating effect of different study characteristics on the effect size, with specific focus on the difference between an educational intervention to the management of type 2 diabetes and a behavioural psychosocial intervention. The studies included have therefore been divided into two subgroups: one group containing studies that provide patients with education only, and the other group containing studies that provide patients with an intervention containing behavioural and psychosocial elements.

2. Methods

2.1. Data sources and searches

We searched in the following electronic databases: MEDLINE (1952–2007), EMBASE (1980–2007), CINAHL (1982–2007), PsycINFO (1967–2007), Cochrane Library (1980–2007), SveMed+ (1977–2007), Bibliotek.dk (2007) and Web of Sciences (2007). Text word and controlled terms such as MeSH terms in Medline were applied. The following search terms were used: ‘Diabetes Mellitus’ was used to identify health condition. Since self-care treatment can be labelled with different terms [10] we used ‘self-care’, ‘education’, ‘self-management’, ‘empowerment’, ‘health behaviour’, ‘self-care behaviour’, ‘life style’, ‘health promotion’, ‘coping’, and ‘compliance’ to identify the intervention. Clinical trials or ‘intervention studies’ were used to identify studies of the appropriate design. The search was restricted to humans and adults (over 18 years of age). Although only studies published in English or Nordic language were included in the analysis, there was no language restriction in the search strategy.

The reference lists of all relevant studies were assessed and searched for additional studies. Likewise previously conducted meta-analyses on the effect of non-pharmacological intervention in patients with diabetes were reread in the search for additional studies. No attempts were made to identify unpublished studies.

2.2. Study selection

Our protocol was implemented with reference to the QUOROM guidelines [11]. Studies qualified for inclusion were randomised controlled trials because this study design generally supports high validity [12]. All studies included tested the effect of self-care behaviour interventions and involved adult patients (over 18 years of age) diagnosed with type 2 diabetes/non-insulin-dependent diabetes. The self-care management intervention was to use educational or behavioural strategies aimed to stimulate the performance of self-care to increase target behaviour actions such as blood glucose monitoring, diet care and physical activity. The main focus of the intervention was to be behavioural changes assessed through HbA1c changes as a marker of change. The studies were to include a control group with no intervention and to report measures and statistical data on the effect of the intervention on parameters specific to diabetes. The studies were included regardless of significant or non-significant findings reported [13].

Studies were excluded if they did not clearly describe intervention techniques or were not published in English or Nordic language. Abstracts were not included because they generally lack sufficient information for evaluation.

For the studies included in the analysis we categorised the form of self-care management intervention in two groups: (1) educational intervention and (2) behavioural psychosocial interventions. Techniques based on didactic-oriented intervention focusing on the knowledge acquisition, skills and information in order to improve diabetes self-management were categorised as education. Interventions were categorised as behavioural psychosocial if the intervention was based on cognitive, behavioural or motivational approaches, or if the study specified that the patients were receiving psychologically centred counselling involving relaxation, problem-solving, or motivational interviewing. Studies not explicitly labelling their intervention were included if they used one or more forms of intervention that could be coded into one of these two categories.

The mode of delivery was defined as individual or group session. If the intervention did not include any face-to-face contact with a health-care provider, this was noted. We considered the contact with health-care provider to be face-to-face if the patient was in personal contact with the intervention team at any time during the intervention. The intervention group was compared to a control group of usual care.

In the meta-analysis the outcome measure was long-term glycaemic control based on the percentage of glycated haemoglobin HbA1c. We applied HbA1c because it is a standardised measurement and a well established reference parameter used in diabetes treatment. HbA1c is directly associated with the risk of diabetic complications [2,14,15].

2.3. Data extraction and internal validity assessment

The titles and abstracts of the studies identified by the search in the electronic databases and reference lists were independently examined by two of the authors. We included studies describing a controlled trial of a self-care management intervention in patients with type 2 diabetes. In case of doubt the full original article was retrieved for rereading. Two authors independently reread all full-text articles selected for further review. Differences over inclusion of studies were resolved through discussions and consensus [6]. The list of included studies was completed 30th November 2007.

In three of the studies included in the meta-analysis there were several intervention groups. For these three studies each intervention group in the study was compared to the control group and considered as an individual study.

There were no cross-over trials or quasi-randomised trials that met all criteria for inclusion hence no study of this type was included in the analysis.

Key information from the included articles were independently extracted by two authors using a pre-specified data extraction form covering descriptive information of study sample, intervention and results. The following characteristics of the study sample were used to describe each study: country of origin, number of participants at baseline and follow-up, age, duration of diabetes, baseline glycaemic control, clinical subgroup, and type of treatment. Characteristics taken from the experimental intervention form were presented by type and duration of treatment, mode of delivery, speciality of health-care provider, number of sessions and length of follow-up. Intervention intensity was defined by type
Table 1
Summary of 47 randomised controlled trials evaluating self-care management programmes for patients with type 2 diabetes included in the analysis.

<table>
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<tr>
<th>Year, country and author</th>
<th>Number of participants recruited/at follow-up</th>
<th>Mean age (years)</th>
<th>Mean duration of diabetes (years)</th>
<th>Clinical subgroup (type of treatment)</th>
<th>Model and duration of intervention</th>
<th>Regimen in intervention and speciality of therapist</th>
<th>Follow-up (years or months)</th>
<th>Internal validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997, Australia, Samaras et al. [21]</td>
<td>26/not stated</td>
<td>60.5</td>
<td>Not stated</td>
<td>Older sedentary people (D,T,I)</td>
<td>Group b.psy.soc. for 6 months</td>
<td>6 group meetings followed by exercise group sessions by nurse educator, exercise physiologist, group facilitator and physician</td>
<td>12 months</td>
<td>No significant difference between groups at baseline characteristics except from weight where the control group are heavier</td>
</tr>
<tr>
<td>2002, USA, Miller et al. [22]</td>
<td>98/92</td>
<td>72.6</td>
<td>7.2</td>
<td>7.2 (0.1)/7.4 (0.1)</td>
<td>Group b.psy.soc. for 10 weeks</td>
<td>10 weekly group sessions by dietician</td>
<td>Not stated</td>
<td>Allocation concealment adequate. No drop from baseline to follow-up assessments. There are no significantly differences between the groups with respect to baseline metabolic parameters</td>
</tr>
<tr>
<td>2002a, USA, Keyserling et al. [23]</td>
<td>134/112</td>
<td>67</td>
<td>10.4</td>
<td>10.8 (not stated)/11.3 (not stated)</td>
<td>Individual and group counselling and individual b.psy.soc. for 12 months (categorised as b.psy.soc.)</td>
<td>4 individual counselling sessions, 3 group b.psy.soc. and 12 individual b.psy.soc. sessions by peer counsellor</td>
<td>12 months</td>
<td>Allocation concealment adequate. The differences between the comparison groups in attrition rate are 3%</td>
</tr>
<tr>
<td>2001, Denmark, Gaede et al. [24]</td>
<td>160/149</td>
<td>55.1</td>
<td>6.0</td>
<td>8.4 (1.5)/8.8 (1.7)</td>
<td>Individual and group b.psy.soc. for 3.8 years</td>
<td>Individual and group diet consultations, 5 group smoking cessation session, and 6 educational exercise consultations by multidisciplinary team</td>
<td>Not stated</td>
<td>No significant difference between groups at baseline characteristics All outcomes are analysed on the basis of the original treatment assignment</td>
</tr>
<tr>
<td>2003, Italy, Di Loreto et al. [25]</td>
<td>340/not stated</td>
<td>61.8</td>
<td>7.6</td>
<td>7.6 (0.1)/7.7 (0.1)</td>
<td>Individual b.psy.soc. for 2 years</td>
<td>1 counselling session recommending physical activity, phone call 1 month later and then every 3 months by physician</td>
<td>Not stated</td>
<td>There are no significantly differences between the groups with respect to baseline variables. Statistical analysis was carried out on an intention to treat basis</td>
</tr>
<tr>
<td>2003, USA, Toobert et al. [26]</td>
<td>279/not stated</td>
<td>8.5</td>
<td>7.43 (1.30)/7.40 (1.48)</td>
<td>Postmenopausal women (treatment not stated)</td>
<td>Group education and b.psy.soc. for 6 months (categorised as b.psy.soc.)</td>
<td>27 education and relaxation training sessions; speciality not stated</td>
<td>6 months</td>
<td>The differences between the comparison groups in attrition are 2%. Analyses of dropouts vs. those completing follow-up are conducted. An intention to treat analysis is conducted</td>
</tr>
<tr>
<td>2004, USA, Krein et al. [27]</td>
<td>246/209</td>
<td>61</td>
<td>11</td>
<td>9.3 (1.5)/9.2 (1.4)</td>
<td>Poorly controlled type 2 diabetes (D,T,I)</td>
<td>Individual b.psy.soc. for 18 months</td>
<td>Phone calls and face-to face visits (number not stated) by case nurse manager</td>
<td>Not stated</td>
</tr>
<tr>
<td>2004, UK, Kirk et al. [28]</td>
<td>70/59</td>
<td>57.6</td>
<td>Not stated</td>
<td>Inactive individuals (D,T,I)</td>
<td>Individual and group b.psy.soc. and phone calls for 12 months (categorised as b.psy.soc.)</td>
<td>2 exercise consultations, 4 support phone calls by research assistant</td>
<td>Not stated</td>
<td>Allocation concealment adequate. The differences between the comparison groups in attrition rate are 3% Analyses are based on intention to treat and with missing data removed</td>
</tr>
<tr>
<td>2005, UK, Steed et al. [29]</td>
<td>124/104</td>
<td>59.8</td>
<td>10.8</td>
<td>8.2 (1.3)/8.6 (1.8)</td>
<td>General (treatment N5)</td>
<td>Group b.psy.soc. for 3 months</td>
<td>6 b.psy.soc. sessions by diabetes specialist nurses and dieticians</td>
<td>3 months</td>
</tr>
<tr>
<td>Year, country and author</td>
<td>Number of participants recruited/at follow-up</td>
<td>Mean age (years)</td>
<td>Mean duration of diabetes (years)</td>
<td>Mean (SD) % HbA1c at baseline for all participants</td>
<td>Clinical subgroup (type of treatment)</td>
<td>Model and duration of intervention</td>
<td>Regimen in intervention and speciality of therapist</td>
<td>Follow-up (years or months)</td>
</tr>
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</tr>
<tr>
<td>2005, USA, Rosal et al. [30]</td>
<td>35/32</td>
<td>62.6</td>
<td>8.2</td>
<td>7.7 (1.2)/ 9.3 (1.8)</td>
<td>Low-income Spanish-speaking individuals (D,T,I)</td>
<td>Group and individual b.psy.soc. for 10 weeks</td>
<td>10 group b.psy.soc. and 11 individual b.psy.soc. sessions by diabetes nurse, nutritionist and assistant, 6–24 group sessions by certified dietitians and nutritionists, 3 computer-assisted motivational interviewing sessions by health professionals with master or BA degrees</td>
<td>6 months</td>
</tr>
<tr>
<td>2005, USA, Anderson et al. [31]</td>
<td>239</td>
<td>61</td>
<td>8.5</td>
<td>8.74 (2.13)/ 8.41 (2.22)</td>
<td>African Americans (treatment NS) General (treatment Not stated)</td>
<td>Group b.psy.soc. for 6 weeks</td>
<td>Individual b.psy.soc. for 8 weeks</td>
<td>12 months</td>
</tr>
<tr>
<td>2006, UK, Glasgow et al. [32]</td>
<td>217/197</td>
<td>61.0</td>
<td>NS</td>
<td>7.3 (1.5)/ 7.2 (1.3)</td>
<td></td>
<td></td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 4%. Analyses of dropouts vs. those completing follow-up are not conducted, but attrition was low</td>
<td>2 months</td>
</tr>
<tr>
<td>2006, USA, Gabbay et al. [33]</td>
<td>332/Not stated</td>
<td>64.5</td>
<td>9.5</td>
<td>7.4 (1.4)/ 7.36 (1.5)</td>
<td>General (D,T,I)</td>
<td>Individual b.psy.soc. for 12 months</td>
<td>Min. 1 visit every 4 months by nurse case manager</td>
<td>12 months</td>
</tr>
<tr>
<td>2007, USA, West et al. [34]</td>
<td>217/202</td>
<td>53</td>
<td>5</td>
<td>7.54 (1.4)/ 7.62 (1.4)</td>
<td>Women with BMI ≥ 30 kg/m² and HbA1c ≤ 7% (D,T)</td>
<td>Individual and group education for 18 months (categorised as b.psy.soc.)</td>
<td>12 months</td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 3%</td>
</tr>
<tr>
<td>2007, Japan, Shibayama et al. [35]</td>
<td>134/120</td>
<td>61.5</td>
<td>11.5</td>
<td>7.3 (0.8)/ 7.4 (0.7)</td>
<td>6.5% ≤ HbA1c ≤ 8.5% (D,T)</td>
<td>Individual b.psy.soc. for 12 months</td>
<td>12 months</td>
<td>Allocation concealment is adequate. There are no significantly differences between the groups with respect to baseline variables. Statistical analysis was carried out on an intention to treat basis</td>
</tr>
<tr>
<td>2007, Sweden, Adolffson et al. [36]</td>
<td>101/88</td>
<td>63.1</td>
<td>6.6</td>
<td>7.4 (1.0)/ 7.1 (0.8)</td>
<td>Age below 76 years, 6.5% ≤ HbA1c ≤ 10%, diabetes for more than 1 year (D,T)</td>
<td>Group b.psy.soc. for 6 weeks</td>
<td>6 b.psy.soc. sessions by multidisciplinary team and 17 individual counselling by education nurse</td>
<td>12 months</td>
</tr>
<tr>
<td>2007, Korea, Ko et al. [37]</td>
<td>437/308</td>
<td>53.7</td>
<td>6.1</td>
<td>9.4 (2.0)/ 9.2 (1.9)</td>
<td>Age below 75 years (D,T,I)</td>
<td>Group b.psy.soc. for 5 days and individual counselling for 4 years (categorised as b.psy.soc.)</td>
<td>17 individual counselling by education nurse</td>
<td>4 years</td>
</tr>
<tr>
<td>2007, Thailand, Wattana et al. [38]</td>
<td>157/147</td>
<td>56.8</td>
<td>6.2</td>
<td>8.08 (1.87)/ 8.09 (1.98)</td>
<td>Age above 35 years (D,T)</td>
<td>Group and individual b.psy.soc.; period not specified</td>
<td>5 group b.psy.soc. sessions and 2 individual b.psy.soc. sessions by nurse</td>
<td>24 weeks</td>
</tr>
<tr>
<td>1988, Germany, Kronsbein et al. [39]</td>
<td>127/99</td>
<td>64</td>
<td>7</td>
<td>7.1 (1.6)/ 6.5 (1.6)</td>
<td>General (D,T,I)</td>
<td>Group education for 1 month Individual and group education for 10 weeks</td>
<td>4 educational sessions by multidisciplinary team</td>
<td>12 months</td>
</tr>
<tr>
<td>1990, Canada, Estey et al. [40]</td>
<td>60/53</td>
<td>55.2</td>
<td>Not stated</td>
<td>6.3 (1.1)/ 6.1 (1.4)</td>
<td>General (D,T)</td>
<td>Group education for 1 month Individual and group education for 10 weeks</td>
<td>3 day education programme, 4 telephone calls, 1 home visit; speciality not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>1995, USA, Franz et al. [41]</td>
<td>203/179</td>
<td>56.4</td>
<td>Not stated</td>
<td>8.3 (1.8)/ 8.3 (1.9)</td>
<td></td>
<td>Individual education for 6 weeks</td>
<td>3 counselling sessions by dietician</td>
<td>6 months</td>
</tr>
<tr>
<td>1995, Austria, Pieber et al. [42]</td>
<td>107/94</td>
<td>64.7</td>
<td>7.2</td>
<td>8.57 (1.79)/ 8.77 (2.08)</td>
<td>Non-insulin treated</td>
<td>Individual education for 4 weeks</td>
<td>6–8 h by office staff and GPs</td>
<td>6 months</td>
</tr>
<tr>
<td>Year</td>
<td>Country</td>
<td>Study Design</td>
<td>Sample Size</td>
<td>Age</td>
<td>Diagnosed Diabetes</td>
<td>Intervention</td>
<td>Follow-Up</td>
<td>Attrition</td>
</tr>
<tr>
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<td>--------------------</td>
<td>--------------</td>
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<td>-----------</td>
</tr>
<tr>
<td>1996</td>
<td>Finland</td>
<td>Not stated</td>
<td>86/55</td>
<td>55-79</td>
<td>Overweight African Americans (D,T,I)</td>
<td>Group and individual education for 6 months</td>
<td>12 months</td>
<td>Not stated</td>
</tr>
<tr>
<td>1997</td>
<td>USA</td>
<td>Not stated</td>
<td>32/55</td>
<td>55-79</td>
<td>Overweight African Americans (D,T,I)</td>
<td>Individual education for 9 months</td>
<td>9 months</td>
<td>Not stated</td>
</tr>
<tr>
<td>1999</td>
<td>USA</td>
<td>Not stated</td>
<td>256/224</td>
<td>7.9</td>
<td>Mexican American (D,T,I)</td>
<td>Systemic group education for 4 years</td>
<td>Not stated</td>
<td>12 months</td>
</tr>
<tr>
<td>2002</td>
<td>Italy</td>
<td>Not stated</td>
<td>112/90</td>
<td>9.6</td>
<td>&lt;80 years, 1 year attendance at clinic (D,T,I)</td>
<td>Suboptimum glycaemic control (treatment not stated)</td>
<td>3 years</td>
<td>Not stated</td>
</tr>
<tr>
<td>2003</td>
<td>USA</td>
<td>Not stated</td>
<td>2205/1973</td>
<td>11.25</td>
<td>7.68 (1.28)/7.80 (1.42)</td>
<td>Individual education; period not specified</td>
<td>Not stated</td>
<td>24 months</td>
</tr>
<tr>
<td>2003a</td>
<td>USA</td>
<td>Not stated</td>
<td>72/59</td>
<td>9</td>
<td>8.8 (2.2)/8.5 (2.0)</td>
<td>Individual education for 2 years</td>
<td>Not stated</td>
<td>Allocation concealment is adequate</td>
</tr>
<tr>
<td>2003b</td>
<td>USA</td>
<td>Not stated</td>
<td>75/59</td>
<td>9</td>
<td>8.4 (2.0)/8.5 (2.0)</td>
<td>Individual education for 2 years</td>
<td>Not stated</td>
<td>Allocation concealment is adequate</td>
</tr>
<tr>
<td>2003c</td>
<td>USA</td>
<td>Not stated</td>
<td>70/59</td>
<td>9</td>
<td>8.6 (1.9)/8.5 (2.0)</td>
<td>Individual education for 2 years</td>
<td>Not stated</td>
<td>Allocation concealment is adequate</td>
</tr>
<tr>
<td>2003</td>
<td>Korea</td>
<td>Not stated</td>
<td>169/127</td>
<td>9.5 (0.3)/9.5 (0.3)</td>
<td>Suboptimum glycaemic control (treatment not stated)</td>
<td>Group and individual education for 44 weeks</td>
<td>Not stated</td>
<td>The differences between the comparison groups in attrition rate are 5%</td>
</tr>
<tr>
<td>2003</td>
<td>India</td>
<td>Not stated</td>
<td>50/38</td>
<td>13.4</td>
<td>8.8 (1.1)/8.3 (0.9)</td>
<td>Individual education (phone-delivered) for 3 months</td>
<td>12 months</td>
<td>Persons responsible for assign outcomes are unaware of the assigned intervention</td>
</tr>
<tr>
<td>2004</td>
<td>USA</td>
<td>Not stated</td>
<td>53/49</td>
<td>2.7</td>
<td>7.7 (1.0)/7.6 (1.0)</td>
<td>Individual education for 6 months</td>
<td>Not stated</td>
<td>The differences between the comparison groups in attrition rate are 6%</td>
</tr>
<tr>
<td>2004a</td>
<td>USA</td>
<td>Not stated</td>
<td>103/49</td>
<td>12.1</td>
<td>9.7 (3.1)/9.6 (2.9)</td>
<td>Individual group education for 12 months</td>
<td>Not stated</td>
<td>26 individual and group sessions by trained interventionist</td>
</tr>
<tr>
<td>2004b</td>
<td>USA</td>
<td>Not stated</td>
<td>95/59</td>
<td>10.6</td>
<td>10.2 (2.5)/9.6 (2.9)</td>
<td>Individual group education for 12 months</td>
<td>Not stated</td>
<td>26 individual and group sessions by trained interventionist</td>
</tr>
<tr>
<td>Year, country and author</td>
<td>Number of participants recruited/at follow-up</td>
<td>Mean (SD) % HbA1c at baseline for i/for c</td>
<td>Clinical subgroup (type of treatment)</td>
<td>Model and duration of intervention</td>
<td>Regimen in intervention and speciality of therapist</td>
<td>Follow-up (years or months)</td>
<td>Internal validity</td>
<td></td>
</tr>
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<td></td>
</tr>
<tr>
<td>2004, Sweden, Sarkadi and Rosenqvist [54]</td>
<td>77/64</td>
<td>6.44 (0.438) / 6.44 (0.375)</td>
<td>Recently diagnosed with diabetes (D,T,I)</td>
<td>Group education for 12 months</td>
<td>Number of sessions Not stated; by specially trained pharmacist and diabetes nurse specialist</td>
<td>24 months</td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 3%</td>
<td></td>
</tr>
<tr>
<td>2004, Netherland, Goudswaard et al. [55]</td>
<td>54/50</td>
<td>8.2 (1.1)/ 8.8 (1.5)</td>
<td>General (T)</td>
<td>Individual education for 6 months</td>
<td>6 education sessions by diabetes nurse</td>
<td>18 months</td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 6% Analyses are based on intention to treat, with the last value carried forward for missing data</td>
<td></td>
</tr>
<tr>
<td>2004, Israel, Maislos and Weisman [56]</td>
<td>82/63</td>
<td>11.6 (1.3)/ 11.1 (1.1)</td>
<td>HBA1C ≥ 10 (D,T,I)</td>
<td>Group education for 6 months</td>
<td>Weekly counselling sessions by diabetes nurse educator and dietician (average of visits not stated)</td>
<td>Not stated</td>
<td>Adherence to follow-up was significantly different between the two groups (17%)</td>
<td></td>
</tr>
<tr>
<td>2004, Hong Kong, Ko et al. [57]</td>
<td>180/178</td>
<td>8.6 (1.6)/ 8.4 (1.2)</td>
<td>Chinese, age 35–70, HbA1c ≥ 8–11 (D,T,I)</td>
<td>Individual education for 1 year Individual and group education for 12 months</td>
<td>5 individual education sessions by education nurse 6 individual sessions, 6 group sessions and brief monthly phone calls by dietician</td>
<td>12 months</td>
<td>Allocation concealment is adequate</td>
<td></td>
</tr>
<tr>
<td>2004, USA, Wolf et al. [58]</td>
<td>147/118</td>
<td>7.9 (1.6)/ 7.5 (1.5)</td>
<td>Obese individuals (treatment not stated)</td>
<td>Group education for 6 months</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Analysis done on an intention to treat basis</td>
<td></td>
</tr>
<tr>
<td>2005, USA, Skelly et al. [59]</td>
<td>47/43</td>
<td>9.19 (2.54)/ 9.00 (2.78)</td>
<td>African American women (T,I)</td>
<td>Individual education; period not specified Individual education for 12 months</td>
<td>4 education and counselling sessions by nurse 1.2 education and counselling sessions per year; speciality not stated</td>
<td>Not stated</td>
<td>Statistical analysis was carried out on an intention to treat basis</td>
<td></td>
</tr>
<tr>
<td>2005, Israel, Rachiman et al. [60]</td>
<td>141/110</td>
<td>9.5 (1.6)/ 9.6 (1.9)</td>
<td>Hypertension and hyperlipidaemia (D,T,I)</td>
<td>Individual education for 1 year Individual and group education for 12 months</td>
<td>Not stated</td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 2% Analysis done on an intention to treat basis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005, UK, Young et al. [61]</td>
<td>591/508</td>
<td>7.9 (5.2–15.1)/ 8.0 (4.8–14.9)</td>
<td>General (D,T,I)</td>
<td>Individual education via phone calls for 12 months</td>
<td>Counselling by “telecarers” and diabetes nurse (average number of calls not stated)</td>
<td>Not stated</td>
<td>Statistical analysis was carried out on an intention to treat basis</td>
<td></td>
</tr>
<tr>
<td>2007, USA, Cramer et al. [62]</td>
<td>67/not stated</td>
<td>Not stated</td>
<td>HbA1c ≥ 8.0% for the past 6 months</td>
<td>Individual and group education for 7 months</td>
<td>7 individual sessions and 1 group session by nurse case manager 3 individual and 6 group educational sessions and telephone counselling by multidisciplinary team</td>
<td>9 months</td>
<td>Statistical analysis was carried out on an intention to treat basis</td>
<td></td>
</tr>
<tr>
<td>2007, Korea, Song and Kim [63]</td>
<td>59/49</td>
<td>9.4 (1.8)/ 9.0 (1.2)</td>
<td>General (D,T)</td>
<td>Individual and group education for 12 weeks</td>
<td>Not stated</td>
<td>Allocation concealment is adequate. The differences between the comparison groups in attrition rate are 5% Statistical analysis was carried out on an intention to treat basis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Follow-up = baseline to last measured endpoint; i = intervention group; c = control group; D = diet; T = tablets; I = insulin; b.psy.soc. = behavioural psychosocial interventions.

* SE.
of treatment, number of sessions and duration of treatment. All relevant results and statistical data to be used in the meta-analysis were extracted from the trials.

Internal validity was assessed using the criteria for Cochrane methodology for sources of selection and attrition bias of healthcare interventions [16]. The possibility of selection bias was checked by inspection of the description of randomisation procedure and allocation concealment. Attrition bias refers to systematic differences between the comparison groups in the loss of participants from the study. Attrition bias was assessed by inspecting the rates of withdrawals and dropouts and checking the application of intention to treat analysis in each study. Since bias mentioned above can have significant effects on measured outcomes in intervention studies and thereby influence the results from the meta-analysis, a note was made in Table 1, if corresponding information was present in an article.

2.4. Statistical analysis

The following information was extracted from the publications, if available: sample sizes at baseline and follow-up in each treatment group, mean and standard deviation at baseline and follow-up in each treatment group; mean and standard deviation of the individual differences between baseline and follow-up; treatment effect, i.e. difference between the mean values of the individual differences together with standard error or confidence interval. Obvious misinterpretations of standard errors as standard deviations and vice versa were manually corrected. If the treatment effect was not explicitly given, it was computed from the available mean values. If the standard error of the treatment effect was not given, it was computed either from the confidence interval (a quarter of its length) or from the standard deviations of the individual differences in the two treatment groups, using the number of patients at follow-up as sample size. If the standard deviations of the individual differences were not given, a conservative estimate based on the standard deviations at baseline and follow-up was used. If the standard deviations at baseline or follow-up were not given, the median standard deviation from all other studies was used.

The meta-analyses were based on a random effect model using Stata's meta command (version 9.2). We tested for heterogeneity by the chi-square test for heterogeneity. Potential publication bias was assessed by Begg’s adjusted rank correlation test and Egger’s test.

A univariate meta-regression was used to find potential factors associated with the treatment effect. The following subgroups were included in the regression analysis: (1) type of intervention divided into behavioural psychosocial intervention or education, (2) sample size divided into n ≤99 or n > 99, (3) year of publication divided into year ≤2004 or year > 2004, (4) mean duration of diabetes divided into year ≤8.5 or year > 8.5, (5) baseline glycated haemoglobin divided into HbA1c ≤8.5% or HbA1c ≥8.5%, (6) duration of intervention divided into month ≤9 or month > 9, (7) follow-up period divided into month ≤12 or month > 12, and (8) age divided into year ≤60.5 and year > 60.5.

The out points of (2), (3), (4), (6) and (8) were chosen as the median among all studies. Mean HbA1c baseline values less than 8.5% is associated with only modest improvements or no significant improvements in glycaemic control following intervention [6,7]. Therefore, mean HbA1c baseline values were divided into values equal to 8.5% or less, or values above 8.5% in the subgroup analysis. Because we were also interested in the long-term effect of intervention on HbA1c, the dividing line in the follow-up period was set to 12 months.

The meta-regression was based on Stata’s metareg command.

3. Results

3.1. Included articles

We identified 4359 potential studies in the search strategy from which 187 full-text articles were selected for detailed evaluation. Out of 23 additional studies included from reading the reference lists we found that only two studies could be included in the meta-analysis. Forty-seven studies meeting all the inclusion criteria were included in the analysis. The flow diagram in Fig. 1 provides information about the number of studies identified, included, and excluded and reasons for exclusion.

A summary of the 47 studies included in the meta-analysis is listed in Table 1. Eighteen studies were classified as using behavioural psychosocial techniques as intervention method. Twenty-nine were classified as using educational techniques. The pooled mean age of participants in studies using behavioural psychosocial techniques was 60.7 years, and 59.3 years for studies using educational techniques.

3.2. Effectiveness of self-care management intervention

Using a random-effects model the pooled mean difference in the decrease in HbA1c between patients assigned to self-care management intervention and those in the control group was 0.36% (95% CI 0.207–0.509). This was statistically significant. The effect of interventions on glycated haemoglobin is shown in Fig. 2. The chi-square test for heterogeneity was significant (p < 0.001). The pooled estimate with a fixed-effects model was similar (0.30% (95% CI 0.237–0.367)). There was no evidence for publication bias in the funnel plot (not shown), in the Begg’s adjusted rank correlation test (p = 0.38), or the Egger’s test (p = 0.43).

3.3. Study characteristics associated with treatment effect

To identify potential factors which may influence the difference in effect sizes when analysing different intervention types we performed univariate meta-regressions and selected subgroup analyses. The results from the univariate meta-regression analysing potential factors for association with the treatment effect are shown in Table 2. In the regression analyses we compared the subgroups defined by a given potential factor. We found a significantly larger reduction in HbA1c in studies with sample size 99 or less compared to studies with sample size above 99 (effect size 0.42%, p = 0.007), and a significantly larger reduction in HbA1c in studies with follow-up period 12 months or less compared to studies with follow-up period above 12 months (effect size 0.49%, p = 0.017). The regression analyses showed a non-significant 0.26% (p = 0.107) larger reduction in HbA1c in studies using educational techniques compared to studies using behavioural psychosocial techniques, and a non-significant 0.3% (p = 0.077) larger reduction in HbA1c in studies with intervention duration of 9 months or less compared to studies with intervention duration above 9 months.

There was only a small difference in the reduction in HbA1c between the subgroups defined by year of publication, mean duration of diabetes, mean HbA1c at baseline and age. These differences were not significant.

In Table 2 we included all p-values from a meta-regression using each factor as a continuous variable. These p-values were similar to those based on dichotomizing each factor.

3.4. Comparison between behavioural psychosocial techniques and educational techniques

To further investigate the difference in effect in type of intervention we identified potential confounders influencing the
result by comparing the descriptive factors between behavioural psychosocial interventions and educational techniques (Table 3). We found the distribution in sample size and publication year differs most between the two groups, and could therefore be potential confounders. Only a small proportion (22%) of the studies using behavioural psychosocial techniques had a sample size of 99 or less compared to studies using educational techniques (55%). Seventeen percent of the studies using educational techniques had publication year after 2004 compared to a much larger proportion in the group of studies using behavioural psychosocial techniques (56%).

The distribution of duration of diabetes in the study population and mean HbA1c at baseline differed only a little between the two groups. There was no difference in distribution between the two groups when it came to intervention duration and follow-up period.

When we adjusted the effect of educational techniques versus behavioural psychosocial techniques (0.26%, \(p = 0.107\)) separately for any potential factor (shown in Table 4) there was an increase in the difference in the reduction in HbA1c between the techniques in favour of educational techniques except for sample size. The frequent increase by adjusting may indicate that confounding of the choice of educational or behavioural psychosocial techniques with other study factors may imply an underestimation of the difference between the two techniques. On the other hand the decrease when adjusting for sample size may imply that the estimated advantage of educational techniques over behavioural psychosocial techniques may be partially explained by the fact that studies on educational techniques are more often based on small sample sizes. Note, however, that none of the increased adjusted effects reach significance.

We made subgroup analyses to explore whether studies with a sample size of 99 or less, duration of intervention of 9 month or less, mean HbA1c at baseline above 8.5% or follow-up period of 12 months or less the difference in effect between studies testing behavioural psychosocial techniques and studies testing educational techniques was more pronounced than in the overall analysis. These four groups were selected because of the large average effect shown in the meta-regression, so that they offer a good opportunity to study the difference between the two types of intervention.

Assessing the effect of the type of intervention in the four groups we found the following differences in effect sizes between educational techniques versus behavioural psychosocial behavioural psychosocial techniques: (1) mean HbA1c at baseline 0.64% \((p = 0.054)\), (2) time of intervention 0.25% \((p = 0.305)\), (3) sample size 0.17% \((p = 0.552)\), and (4) follow-up period 0.29% \((p = 0.209)\).

4. Discussion and conclusion

4.1. Discussion

The results of this meta-analysis support that self-care management intervention improves glycaemic control in patients...
with type 2 diabetes. There was a 0.36% (95% CI 0.21–0.51) improvement in glycaemic control indexed by glycated haemoglobin in people who received self-care management treatment. The estimated 0.36% reduction in glycated haemoglobin in patients with type 2 diabetes was modest, but evidence suggests that such a difference is large enough to reduce the risk of development and progression of diabetic microvascular complications [14,17]. The improvement in glycaemic control found in this study is similar to the effect seen in previous studies analysing educational and behavioural interventions in type 2 diabetes [8,18].

There is significant heterogeneity among the studies with respect to effect sizes. This implies that there may be some factors, which need to be in place to ensure any effect or substantial effect of self-care interventions.

We could identify two factors with significant effect on the effect sizes: sample size and follow-up period. Analysis of the sample size ($p = 0.007$) showed higher effects in small studies. This may point to publication bias, but the formal tests on publication bias did not indicate this. Sample size seemed to be associated with intervention duration. There was a tendency that the smaller the study, the shorter intervention duration and the closer the sessions were grouped together. This may indicate that self-care management interventions may have a higher effect if the programme is compact with sessions closely grouped together. Follow-up period

![Fig. 2. The results of the single studies (effect estimate and 95% confidence interval). The studies are in chronological order. The dashed line indicates the estimate join effect based on a random effects model.](image-url)
(p = 0.017) showed higher effects in studies with short follow-up. This may indicate that the effect of self-care management interventions may decrease over time. For intervention duration (p = 0.077) we found a non-significant, but highly plausible tendency, showing shorter interventions to be more effective. This may again indicate that compact intervention programmes as given in the short interventions, allow participants to remember and better synthesize the information. In the meta-regression analysis mean duration of diabetes (p = 0.590) and mean HbA1c at baseline (p = 0.486) were not found to be highly predictive factors, but there are plausible tendencies: The tendency of higher effect in studies with longer intervention duration may have a better possibility to obtain a high reduction in mean HbA1c. There was indication of a trend over time in year of publication.

The univariate meta-regression suggests a moderate, non-significant difference in effect sizes of about 0.26% in favour for educational techniques. This effect may be partly explained by the fact that educational studies on average are smaller than behavioural psychosocial studies. Moreover, in none of the subgroups of studies with a high average effect of the intervention, we could demonstrate a substantial difference between behavioural psychosocial and educational techniques. As there was no difference in the distribution of studies with longer intervention between the two types of interventions the difference in effect sizes may lead to the assumption that behavioural psychosocial techniques are more sensitive to intervention intensity than educational techniques.

Table 3
The percentage distribution of descriptive factors in studies testing behavioural psychosocial techniques and studies testing educational techniques.

<table>
<thead>
<tr>
<th>Descriptive factors of the study</th>
<th>Type of intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b.psy.soc. techniques</td>
</tr>
<tr>
<td>Sample size &lt;99</td>
<td>22%</td>
</tr>
<tr>
<td>Year of publication year &lt;2004</td>
<td>44%</td>
</tr>
<tr>
<td>Duration of diabetes &lt;8.5 years</td>
<td>67%</td>
</tr>
<tr>
<td>Mean HbA1c at baseline &lt;8.5%</td>
<td>67%</td>
</tr>
<tr>
<td>Duration of intervention &lt;9 months</td>
<td>47%</td>
</tr>
<tr>
<td>Follow-up period &lt;12 months</td>
<td>85%</td>
</tr>
</tbody>
</table>

Table 4
The adjusted pooled mean difference in HbA1c between behavioural psychosocial techniques and educational techniques for potential factors.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Effect size (%)</th>
<th>CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>47</td>
<td>0.183</td>
<td>-0.121–0.488</td>
<td>0.239</td>
</tr>
<tr>
<td>Publisher year</td>
<td>47</td>
<td>0.284</td>
<td>-0.072–0.641</td>
<td>0.119</td>
</tr>
<tr>
<td>Mean duration of diabetes</td>
<td>35</td>
<td>0.347</td>
<td>-0.074–0.768</td>
<td>0.106</td>
</tr>
<tr>
<td>Mean HbA1c at baseline</td>
<td>46</td>
<td>0.231</td>
<td>-0.099–0.562</td>
<td>0.171</td>
</tr>
<tr>
<td>Duration of intervention</td>
<td>44</td>
<td>0.303</td>
<td>-0.022–0.628</td>
<td>0.068</td>
</tr>
<tr>
<td>Follow-up period</td>
<td>33</td>
<td>0.361</td>
<td>-0.001–0.723</td>
<td>0.051</td>
</tr>
</tbody>
</table>

ES = effect size.

* The pooled mean difference in the decrease in HbA1c between intervention and control group within a given subgroup.

** The pooled mean difference in HbA1c between the two subgroups within a given potential factor.

*** The p-value in the univariate regression where the variable is used as a continuous variable.

**** The logarithm of the variable was used in the analysis.
this meta-analysis of self-care intervention. Ismail et al. found a reduction of 0.76% in glycated haemoglobin in favour of psychological interventions [6]. The indication in the subgroup analysis that small studies, short follow-up period and short duration of intervention are associated with larger differences in effect sizes may to some extent explain the relatively larger reduction in glycated haemoglobin found in the meta-analysis by Ismail et al. testing psychological interventions. In their analysis they mainly included small studies with short follow-up period.

In the interpretation of the results of the present study intervention intensity was identified as a probable factor mediating the effect of intervention. Unfortunately, we were not able to investigate this factor directly. A clear characteristic of session intensity was difficult to establish due to a great variation in description between the studies included. From the material we could not deduce whether session intensity was defined as number of contacts or numbers of hours spend with the patient. Therefore, we did not include number of session in our univariate meta-regression. The significance of number of contact or length of a single contact to promote diabetes self-care could not be definitively determined in the analysis. However the number of sessions seemed to be associated with duration of treatment but not type of treatment. It seemed that treatments of a shorter duration had a larger number of sessions per month than treatments of a longer duration (3.0 sessions in average per month versus 0.8 sessions in average per month). This may support the assumption that there is an advantage to provide sessions closely grouped together.

The reference interval for HbA1c is not standardised and is likely to vary between the studies included. Such a variation was not to be established in the material because many of the studies included did not report on the reference interval. However, the potential variations in reference interval are levelled since we looked at differences in HbA1c. Therefore, we assumed that the differences calculated in the studies were comparable regardless of difference in the reference interval for HbA1c between studies and consequently the mean differences for each study could be pooled to get an overall estimate of all studies.

Only randomised controlled trials were included in this analysis to assure high validity. In addition to this study types other than randomised controlled trials rarely focused on glycated haemoglobin as an outcome. In respect to impart evidence in the development of self-care management interventions in general study types other than randomised controlled trials may also be important [19].

Possible publication bias cannot be completely discounted for. The statistical analysis did not indicate publication bias, and we are not aware of any unpublished study fulfilling the criteria of our review. We did not manually search in relevant journals to eliminate incomplete databases [20]. In general, it is a difficult task to assure a complete ascertainment of unpublished research in educational and behavioural psychosocial interventions since a variety of disciplines are involved in this area. To reduce the limitation of databases-search our search method for identification of studies followed the recommendation by McDonald et al. [20].

With regards to internal validity most studies included in the analysis did not report on all potential sources of bias. Therefore, a validity rating as such has not been taken into account. To protect against unintended differences in interventions and control groups those providing and receiving care can be blinded [16]. This is not possible in diabetes self-care intervention studies. Performance bias was therefore not used as a validity criterion. Detection bias was checked by inspection of the description of blinding procedure when it comes to persons responsible for assessing outcomes. To minimise risk of bias these persons should be unaware of the assigned intervention. Glycated haemoglobin outcomes may not be that sensitive to detection bias, as the assessment procedure often includes external laboratories. Actually, very few studies reported on a blinding procedure.

There is a wide variation of clinical subgroups, intervention regimes and intervention providers in the studies included in the meta-analysis. Therefore it is difficult to establish which type of regime is the most effective, which subgroup of patients most likely to benefit from the intervention regime and who should provide the intervention. Further research is needed to establish knowledge about these factors to be able to guide development of interventions that work.

4.2. Conclusion

Self-care management interventions have an effect. The results of the present study support that this is especially true under conditions which imply a compact programme with sessions closely grouped together. However, the effect may decrease over time. The benefits of promoting self-care management in patients with type 2 diabetes are reflected in glycaemic control and thereby hopefully also in morbidity and mortality. The role of intervention techniques seems to be of less importance, although our results indicate an advantage for educational techniques. The intervention form may have impact on the effectiveness and practicability in clinical practice.

4.3. Practice Implications

The findings of this meta-analysis support the use of self-care management interventions in diabetes care and suggest that further research is needed to establish the most effective regime. Further research is recommended on how intervention frequency and duration of intervention are influencing self-care management in patients with type 2 diabetes. Intensity of the treatment and differentiated treatment may be a key to obtain substantial effects. More and larger studies need to be conducted with a long follow-up period to establish knowledge about intervention effects over time. Investigation into whether self-care management changes can be maintained after completed treatment or permanent treatment is necessary in maintaining lifestyle changes in diabetes self-care is recommended.

Acknowledgements

Authors contributions: Minet had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Minet, Møller, Wagner and Henriksen.

Acquisition of data: Minet and Møller.

Analysis and interpretation of data: Minet, Møller, Vach, Wagner and Henriksen.

Drafting of the manuscript: Minet and Møller.

Critical revision of the manuscript for important intellectual concept: Minet, Vach, Wagner and Henriksen.

Statistical analysis: Vach.

Obtained funding: Minet.

Administrative, technical, or material support: Minet, Vach, Wagner and Henriksen.

Study supervision: Wagner and Henriksen.

Financial disclosures: None declared.

Funding: The study is funded by the Danish Association of Diabetes, TryggFonden, Odense University Hospital and the University of Southern Denmark.

Role of sponsors: None of the funding organizations or sponsors had any role in the design and conduct of the study, in the collection, management, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.
Conflict of interest: All authors report no actual or potential conflict of interest including no financial, personal or other relationships with other people or organizations within 3 years of beginning the submitted work that could inappropriately influence, or be perceived to influence, our work.

References


Paper II
The Experience of Living with Diabetes Following a Self-Management Program Based on Motivational Interviewing

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Abstract

Self-management is an important part of diabetes treatment, but the promotion of self-care activities is still a challenge. In this study, we explored how living with diabetes in everyday life is experienced following a self-management intervention program based on motivational interviewing. We conducted 7 focus group interviews, each comprising 3 to 5 participants diagnosed with type 1 or type 2 diabetes. Data analysis based on a phenomenological method revealed three main themes concerning diabetes self-management: becoming a self-regulating practitioner, managing the rules of self-management and creating a supportive social network. Narrative analysis revealed a divergence in patients’ self-perceived competence in handling diabetes. The study findings indicate that people with diabetes have specific needs for support in the daily responsibility of managing diet, exercise, medication and blood glucose monitoring. A meaningful treatment from the patient’s perspective would appear to be one that aims at overcoming problems that the patient experiences in self-management of diabetes.

Keywords

Diabetes; focus groups; illness and disease, experiences; motivation; narrative inquiry; phenomenology; research, qualitative; self-care; self-efficacy
The large amount of research in the self-management area testifies to the urgency this factor is given in diabetes treatment. Self-management of diabetes involves a number of considerations and choices that the patient with diabetes must take on a daily basis. It requires that patients are able to reconcile their resources, values and preferences with a therapeutic regimen of healthy diet, exercise, no smoking, low alcohol intake, glucose monitoring and, for some patients, medication (Funnell & Anderson, 2004). Knowledge of how self-management evolves in the lives of patients with diabetes is stressed to be essential in the organization of treatment approaches (Spenceley & Williams, 2006). This has led to increased focus on patient responsibility, as exemplified in attempts to encourage patients to be active participants in their diabetes treatment, thereby enabling them to control their diabetes (van Dam, van der Horst, van den Borne, Ryckman, & Crebolder, 2003). However, managing the daily care of diabetes seems to be a challenging task for many patients (Funnell & Anderson, 2004; Peyrot et al., 2005). A patient’s ability to be involved in the daily routine of diabetes care seems to be grounded in psychological and motivational factors as well as educational factors (Steed, Cooke, & Newman, 2003). The inability to conduct self-management activities and to assume responsibility for daily diabetes care is reflected in poor outcomes, which makes the patients more prone to diabetes-related complications such as blindness, kidney damage, amputation of lower limbs and cardiovascular illnesses. In research there has thus been a keen interest in identifying approaches that will strengthen the individual's belief in their own competence to handle their diabetes.

The findings of several meta-analysis of randomized controlled trials provide extensive evidence for the effectiveness of self-management interventions on diabetic control, but the long-term effects of such interventions are uncertain (Minet, Moller, Vach, Wagner, & Henriksen, 2010; Ismail, Winkley, & Rabe-Hesketh, 2004; Gary, Genkinger, Guallar, Peyrot, & Brancati,
2003; Norris, Engelgau, & Narayan, 2001). This could indicate a need for an examination of the role of the different elements in the interventions and how the intervention might relate to the problems experienced in the daily management of diabetes. We can examine the significance of a treatment on everyday life with diabetes by exploring people's beliefs and feelings about the disease and its management (Greenhalgh, 2002). By putting the patient experience at the centre, we can elucidate factors that affect the individual and then identify contexts that provide an understanding of diabetes self-management in general (Lawton, Peel, Parry, Araoz, & Douglas, 2005).

We know from previous qualitative research evaluating interventions to improve self-management among patients with diabetes that self-management activities consist of a complex and dynamic set of processes that are deeply embedded in the individual’s unique life situation (Moser, van der Bruggen, Widdershoven, & Spreeuwenberg, 2008). This research indicated that support from diabetes specialist nurses and family caregivers are a prerequisite for managing diabetes. A trial that evaluated patient education found that health care providers had to reward behaviors rather than physiological outcomes if patients’ self-management changes are to be encouraged and maintained (Cooper, Booth, & Gill, 2003). Cooper et al. argued that there is a lack of support for the self-monitoring practice in the health care system. There was some evidence that multiple lifestyle modifications are beneficial in promoting diabetes self-management (Malpass, Andrews, & Turner, 2009). Previous research also suggested that patient involvement (Adolfsson, Starrin, Smide, & Wikblad, 2008), cultural adaptation (Garvin, Cheadle, Chrisman, Chen, & Brunson, 2004), family involvement (Handron & Leggett-Frazier, 1994) and individualization (Ockleford, Shaw, Willars, & xon-Woods, 2008; Price, 1993) are important factors in the development of interventions seeking to increase self-management among people with diabe-
tes. Our study was a further step toward a broader understanding about how diabetes treatment can support the patient in dealing with diabetes in everyday life. The aim of this study was to explore and describe the lived experience of patients living with diabetes following a one-year self-management intervention based on motivational interviewing. We placed particular focus on self-care activities and patients’ expectations and experiences of treatment.

**Method**

**Setting**

This study was part of an ongoing research project exploring the self-efficacy of people with diabetes in a nurse-led intervention program based on motivational interviewing described by Miller and Rollnick (Miller & Rollnick, 1991). Our approach was derived from Albert Bandura's self-efficacy theory, where humans perform intentional acts through their belief in their capability to produce a desired effect through their actions (Bandura, 1997). The research project was a randomized controlled trial that involved 349 people diagnosed with diabetes type 1 or type 2 and examined the impact of an intervention program on glycaemic control and patient’s experiences regarding self-management competence as compared to usual care in the control group. All participants included in the trial received a four-day diabetes education program focusing on a range of themes such as diabetes treatment, prevention of diabetes-related complications, self-monitoring of blood glucose, diet, physical activity, alcohol use and issues regarding insurance and following this three-monthly visits to their physician. Just after the diabetes education program patients were randomized to either a control group or to the intervention group receiving five individual sessions in one year. Health care providers, educated in motivational interviewing, conducted the sessions. The goal of the intervention was to help patients to recognize and address problem areas in the self-management of diabetes. Motivational interviewing is a pa-
tient-centered directive clinical style for enhancing intrinsic motivation to change by exploring and resolving ambivalence (Miller & Rollnick, 2009). We believe this counseling style facilitates patients’ self-efficacy and participation in their own treatment. All patients in the intervention group were offered counseling in changes of diet, physical activity, smoking habit, and alcohol use. The health care provider referred the patient to tailored counseling sessions on the patient’s request.

**Data Collection**

Data were collected during focus group interviews between May 2007 and May 2009. The interactive and synergistic nature of focus group interviews allowed us to explore patients' experiences with diabetes in a spontaneous and emotional way (Kvale & Brinkmann, 2009). Focus group interviews allowed access to a wide variety of ideas, views and experiences on self-management among patients with diabetes (Bojlén, 2003) and insight into how a consensus was reached (or not) on issues relating to everyday life with diabetes (Morgan & Spanish, 1984). All participants in the focus group interviews had already participated in the four-day diabetes education program and thus several of the participants knew each other beforehand. Data collection from existing groupings, in our case education groups, gave us insight into the patients’ prior exchange of views on particular subjects (Kitzinger, 1994).

To ensure that all patients had ample opportunity to express their own views and experiences, the focus groups comprised only three to five patients (Morgan & Spanish, 1984). Seven focus group interviews lasting 1 to 2 hours were conducted and recorded on tape. Three interviews took place immediately before the intervention (i.e. the five individual counseling sessions in the following year) and 4 took place just after the intervention. The interviews were held at a convenient location away from the patients’ homes and not directly connect to the premises.
where diabetes treatment took place. Data collection stopped when theoretical saturation was reached (Agar, 1996), i.e. when the data from the interviews began to be replicated. One of the authors moderated the interviews, and a co-moderator assisted during the interviews by taking notes and asking additional questions.

The focus group interviews were guided by the three research questions: (a) What is the lived experience of living with diabetes on a daily basis, (b) What is the lived experience of handling self-care activities – both before and after a motivational interviewing program, and (c) What is the lived experience of everyday concerns about meeting requirements for certain health behaviors? This was to capture the lived experience as fully as possible with regard to patients’ everyday experiences with diabetes. The opening question was: “Please tell me how you experience your daily life with diabetes”. Throughout the interviews the participants were encouraged to be specific about their experiences. The constitution of focus group interviews implied that interviewees and interviewers jointly produced the data.

Participants

Patients who were randomized to the one-year intervention program of five individual sessions based on motivational interviewing were invited to participate in the focus group interviews; consecutive patients were invited until a sufficient number of focus groups were conducted, i.e. when theoretical saturation was reached. Eight patients declined because of lack of time and 2 patients declined because of serious illness in the family. A total of 22 patients with diabetes participated in the focus group interviews. Five patients participated only in an interview before the intervention; 9 participated only in an interview after the intervention and 8 participated in interviews before and after the intervention. All interviews were established to give a temporarily impression of the experiences with diabetes, diabetes self-management and treatment. All inter-
views were given equal weight in the analysis. Twelve of the participants were women and 10 were men. The age range was 30 to 72 years and the duration of diabetes ranged from 1 to 11 years. The majority of the participants had diabetes type 2; only four had type 1. Approximately one-third of the patients were treated with insulin (with or without oral medication), one-third with oral medication only and one-third regulated diabetes through diet and exercise. Educational levels ranged from secondary school to university degree and connection to the labor market was varied, including retirement, disability pension, working full-time and working part-time work in a flexible job (for people with reduced ability to work). Sixteen patients were married or lived with a partner and 6 lived alone. None of the patients came from an ethnic minority.

**Research ethics**

The study design was approved by the Regional Research Ethics Committee of Southern Denmark and the study was reported to the Danish Data Protection Agency. All patients were informed about the aim of the study and were included in the study after verbal and written consent. The study was performed in accordance with the Helsinki Declaration II. The patients have been anonymized in the manuscript to avoid identification.

**Data Analysis**

Data analysis was inspired by Giorgi’s phenomenological method. This method was used to examine the meanings expressed by participants in relation to managing diabetes in everyday life. According to Giorgi, such analysis comprised a minimum of five basic steps: (a) collection of verbal data, (b) reading of the data, (c) dividing of data into parts, (d) organization of data from a disciplinary perspective and (e) synthesis of the data (Giorgi, 1985; Giorgi, 1997). The analytic process was not linear but could go back and forth between these steps. The first stage of the analytic process comprised preparation of an interview guide containing broad and open-ended
questions that would allow interview participants to express their viewpoint extensively; a word-by-word transcription was then made of information elicited during the interviews. In the second stage all the transcripts were read and reread to give a sense of the whole and to understand the meaning of the experiences from the participants’ standpoint (Giorgi, 1997); at this stage we did not try to thematize the data. In the third stage the first author divided the transcribed data material into what Giorgi calls “meaning units” (Giorgi, 1985); one of the other authors then confirmed these units. The task here was to separate the material into smaller parts by identifying themes that described the patients’ experiences of handling diabetes in everyday life. We ended up with a series of meaning units that were still expressed in the participants’ own words. The fourth stage was a transformation of the participants’ everyday expressions into theoretical categories (Table 1). The meaning units were labeled with a code representing its content and then organized into theoretical categories using a standard word-processing program. The fifth and final stage comprised a synthesis of the themes identified from the interview material.

*The narrative instrument.* We were particularly interested to see whether the participants in the interview created a common consensus about being a diabetes patient. Therefore, in addition to the phenomenological method we examined the interactional framework within which the patients’ experiences were told (Bruner, 1991). This was to understand how the meanings expressed by the patients were constructed in the interviews (Holstein & Gubrium, 2000). The narratives in the interviews were often constructed from the many small episodes of discussions between the participants spread throughout the interview. These many episodes where then condensed into a coherent story. In our analysis of the narrative structure in the interviews, we were inspired by Holstein and Gubrium’s description of extended stories (Holstein & Gubrium, 2000). Therefore, the narratives were broken down into three interconnected components containing: (a)
the preface that served to facilitate the story, (b) the continuations that allowed the story to continue and (c) the ending in which the point of the narrative emerged. The story was constructed on the basis of this condensation of the text and used as an abridgement after each theme.

**Synthesis**

With the phenomenological method three main themes emerged as being important in understanding patients’ experiences of daily life with diabetes and experiences of individual counseling. These themes were: (a) becoming a self-regulating practitioner, (b) managing the rules of self-management and (c) creating a supportive social network.

**Becoming a self-regulating practitioner**

“Becoming a self-regulating practitioner” was about how patients handled the regimes of self-management in different daily situations and routines. The patients discussed practical approaches to gain control over the everyday realities of being diagnosed with diabetes. Central to their management was daily consideration about how to adapt the recommended treatment regimen to other activities of everyday life, the focus here being blood glucose level. Diet, exercise and medication were instruments for achieving the goal of well-regulated blood glucose.

In each focus group there were one or two patients who appeared unable to handle the challenges of managing diabetes in the everyday life. This was illustrated in a discussion between two participants in a focus group before the intervention. Jane, who had had diabetes for two years, was still experiencing difficulties in managing diabetes in her everyday life. Carl, who had had diabetes for one year experienced no difficulties:

Carl: What do you do to make your diet healthy?
Jane: Nothing because I’m never at home. I have a daughter and a grandson, who really need me. So they take all my time.

Carl: That’s no reason for not eating the right diet.

Jane: But it’s not at the right hour. And I do not make the dinner myself. I’m usually staying with my daughter.

Carl: What is the right time for you to eat?

Jane: I prefer to eat before seven o’clock. But dinner is not usually finished before nine o’clock. My daughter can’t manage to make dinner earlier. And when I go to bed ten o'clock – because when I’m eating so late my blood glucose gets too high.

Carl: I’m very sensitive about changing my meal time. Yesterday I went shopping and knew I wouldn’t eat dinner before eight o’clock. But my blood glucose was low as I usually eat about seven o’clock. So I had to eat something before I went shopping. I didn’t eat as much as I would normally do. I just ate a little bit. Then I could draw out the time until my proper meal. So, there you are!

Jane: Yes. I can see that.

Carl: I think that as a diabetic you have to look after yourself. It doesn’t seem that anyone else will do it for you.

Not all the participants believed that they could mobilize themselves to take care of their diabetes or get their network to support them in the effort to live in a life which takes account of diabetes. The inability to mobilize resources was often connected to the fact that patients had to deal with other problematic issues in their life. The patients who were inexperienced in handling their diabetes allowed other participants to give advice about daily diabetes care, usually in terms of their
own successful stories in meeting the challenges of diabetes self-management under various circumstances.

Adapting self-managing behaviors. When they were diagnosed with diabetes the patients had had to consider changes in their daily routines. Some patients experienced difficulties in adapting these changes into their daily life, whereas others had had to make only minimal changes. This was illustrated in a focus group after the intervention in a discussion between Paul and Mary about how they tried to comply with their therapeutic regimens. Paul and Mary both lived with their families. Mary talked about how the counseling sessions had helped her to face a specific problem she was experiencing at home:

Paul: Concerning the diet. I got everything under control. I eat fish, vegetables and lean meat. Actually it’s the same as before I got diabetes. So I didn’t have to change anything. And my family, who lives together with me, they want to eat the same as I do.

Mary: Well, with my family it is very different. They can eat anything and they don’t want lean meals. So my husband and I went to the counseling together, because I wanted them to consider my needs when they are cooking at home. I found that to me it was all about planning. Now I’m planning what to eat a whole week ahead. I find recipes for the whole week and make sure that the right foods are available at home like cauliflower and carrots. Then it’s easier to eat the right things. I write notes like: ‘Remember vegetables for Mum’.

The patients in the study strived to live in accordance with what they believed would help them maintain well-regulated diabetes. Handling diabetes was an immediate concern in the everyday life of the patients in the study, not least because of the risk of getting complications. The coun-
counseling sessions in the intervention program were experienced as supportive in the process of mobilizing resources to handle the diabetes and to adopt an active role in diabetes management.

**Managing the rules of self-management**

“Managing the rules of self-management” was about how patients used self-management to get control in their lives. In all the focus groups patients discussed the struggle of attaining a balance between following the recommendations for diabetes self-care and fulfilling their own needs. It appeared that patients negotiated the best way to manage their diabetes on a daily basis. The debate was about how the patients could take proper care of the diabetes in terms of maintaining a blood glucose as normal as possible while they fulfilled their own needs. It was important for all the patients in the focus groups to be able to take part in a normal life and to fit in.

**Getting a balance.** The patients experienced that proper conduct in diabetes care could interfere in how they wanted to live their life. This was illustrated in a discussion between three participants in a focus group before the intervention. Laura did not eat in accordance with what she thought was right to eat to take care of her diabetes and she had difficulty in losing weight. Annie and Jacob were both much more confident than Laura in handling everyday life with diabetes, and they considered their diabetes to be well-regulated:

Annie: Well, at first I had to adjust and find out what products we should buy and such things. It suited me just fine. We did not eat much fat before I got diabetes, but now I have sort of cut down on it again after all. So obviously, there might be a time in between where you would have liked a piece of cake without taking it. Then there are other times when you just take a piece of cake.

Laura: I would say that I eat cake whenever the others do, I just don’t take so much. It is
clear then—we were told by the nurses at the diabetes school that it was all right to take a
little piece of cake, you just had to do some exercise afterwards.

Jacob: You can do that. That would be all right.

Laura: I feel completely outside when the others are sitting with a piece of cake, and I
just sit and watch. So I end up eating a piece of cake as well.

Jacob: Yes, it is tiring. So it's easier just to be like the others for one day, and then tomor-
row I must return to my life again. Then I can’t go up to the bakery and buy a couple of
cinnamon sticks and fresh bread. I roughly have it under control.

All the patients in the study experienced the need to balance their lives while managing their
diabetes. Getting a balance was a give and take situation; if they did something unhealthy they
had to do something healthy as well. Handling diabetes in everyday life thus became subject to
certain social rules that related to how diabetes was best managed. The rules of self-management
were about adjusting one’s behavior to fit into different social contexts, while still being com-
patible with the treatment regimen. The patients found it important that their health care provider
understood them in the struggle to do the right things. This was illustrated in a focus group dis-
cussing how the counseling sessions had helped the patients to handle their diabetes through the
setting of goals:

Paul: Otherwise, you would really have something to fight against if you had some prob-
lems to be solved. It is somewhat disheartening if there is one on the other side who says:
‘Ah, you just take it easy. It doesn’t matter. You just wait and see – in three months you'll
look at it completely differently’. It's not a starting point for a conversation. You have to
be helped setting goals and be told that you are on the right track. And that you just can
carry on. At the next meeting new goals can be set.

Moderator: What about the rest of you?

Peter: Yes, I can feel I have lost weight and now I feel better.

Hannah: It’s the same here. I have looked after two young people who had not taken care of their diabetes. They died at the age of 30 years.

**Getting control.** To handle the diabetes, the patients experienced that they had to be in control of their daily living. The diet became central to the management of diabetes in terms of feeling in control. Even for those patients who used insulin the major concern was how to get the diet right. The patients in the study experienced that if they should take proper care of their diabetes, they had to live a life of moderation; they could not just give themselves away. The patients noted that their usual routines for diabetes self-care were often put to the test in different social contexts such as parties, at work or in relation to sports. This was illustrated in a focus group after the intervention discussing how festive times such as New Year disrupted daily routines:

Henry: I’d like a cup of Irish coffee with brown sugar on New Year’s Eve. But I can’t. So, at one of the session she said: ‘Who says you can’t do that? Just take your Irish coffee with brown sugar. You just have to pay the bill tomorrow. Then you can go for an extra walk’. It was Lilly. I think I spoke extremely well with Lilly. I have a friend who just got diabetes. And I say: ‘Do whatever you can to get to the diabetes school’.

James: Yes, it puts your mind at rest to go there.

Moderator: So it’s important to have a sense of security when you take care of your diabetes.

Henry: Yes.
Jenny: I feel more confident because I have no guilty conscience if I eat something. Then I know that I can do that.

Jan: Of course you have to think about what you eat. If I get a dessert or just something sweet, I get a little stomach ache.

Clara: I think the diabetes education gave us the information about what we should do. Then we got guidance in the counseling sessions about how to adopt that into everyday life.

Creating a supportive social network

“Creating a supportive social network” was about how the patients were able to get support from family, friends and colleagues on their own terms. Despite the fact that the patients in the study saw it as their own responsibility to take care of their diabetes, the lack of family support was seen as a barrier for patients to gain control of their daily routines of self-management. This was illustrated in a discussion between three participants in a focus group before the intervention.

Nanny experienced difficulties in mobilizing herself to lose weight and wanted her husband to support her. Henry and Kathy felt they got the support they needed to take care of their diabetes:

Nanny: I have to lose 20 kilos. Then the doctor would be really happy and so would I of course. But it’s very difficult. I have lost the first ten now, but I’m still missing 10. And I would like - it would mean a lot to me – it would be good for me to have someone to help me.

Henry: You should ideally be two as we are at my home. Take supper for instance. My wife she’s on low-calorie diet, so we actually have to eat the same thing. I think it’s easier when we are two.
Nanny: Yes.

Kathy: You have to be in it together.

Henry: Yes. You have to.

Nanny: You are very lucky. My husband should be replaced. He eats pastries and sweets and drinks soft drinks from morning to evening. And he puts it right in my face. ‘I just want to be good to you’, he says.

Henry: Yes, that’s not nice.

Kathy: My husband has stopped eating cake every evening because I have diabetes.

To lay down a strategy. The patients used different strategies in developing a supportive network. Some patients made the network around them change behavior so that it was consistent with diabetes care. Other patients changed their own behavior to be consistent with diabetes care and sought the network to support and accept this behavior. Common for all patients was that they tried to control the network to support them in being consistent with their own needs. The need for support depended on the situation. The discussion between two participants in a focus group after the intervention illustrated different strategies to involve the network:

Peter: The worst thing is to be invited out. You can’t expect the host to cook in accommodation with a diabetic diet. We then have to eat the things that are good for us and leave the rest.

Mary: I do not really agree with that.

Peter: I will not demand that they cook a diet I can eat.

Mary: No, no. But if it’s a couple of good friends who know us really well. Then I expect them to think of me.
Peter: Oh.

Mary: Yes, otherwise they are not real friends. I also take them into consideration when I’m cooking. I do not serve shrimp and shellfish for someone who has an allergy to them. Of course, I also sort out what I can eat. If you’re visiting someone who doesn’t know you well they can’t consider your needs. But if it’s some really good friends then they should consider me and ensure that there is the right food on the table.

Mary felt that the counseling sessions had helped her to make demands on her network to support her in handling the diabetes. She explained:

Mary: Lilly has been really good to make me think about how I felt. This was really good for me. Also to make me face my problems and help me find out what has gone wrong. She supported me in telling the family how important it was to get them involved. Although it’s me who has diabetes and it’s my responsibility, we are a family and we have to stick together if we are to succeed.

**Being a Good Diabetic**

“Being a good diabetic” emerged as a powerful storyline in the narrative analysis of the focus group interviews. In the tightly constructed plot about being a good diabetic it became clear that those patients, who were successful in becoming a self-regulating practitioner, managing the rules of self-management and creating a supportive social network, were considered to be successful in the strive to be a good diabetics. The patients in the focus groups who were able to tell successful stories about handling their diabetes became dominant in the process toward a consensus about how it was to have diabetes. This was illustrated in a focus group discussion be-
tween Carl, Peter and Jane about monitoring blood glucose in different daily contexts. As in the other focus groups, this storyline’s preface was often centered on problem areas in self-management. The preface was used to demarcate the conversational space for the patient to elaborate their positions:

Carl: Do you also measure your blood glucose frequently?
Jane: Yes. It goes up and down.
Carl: I just think I like to get my blood glucose inside the right range, as we should.
Jane: Yes.
Carl: And I actually think it’s exciting, a moment of tension inside me just before I measure it. Could I get it inside the right range? It’s really exciting. To see if everything fits together. Do you follow me?
Jane: Yes.
Carl: And then try to eat after the figures.
Jane: Yes, but it doesn’t work. It’s quite impossible. Because when I'm not at home, I can’t hit the figures.
Carl: Yes, but I'm also at work and have to make ends meet. Let me tell you, today the department celebrated some results.

Carl and Jane both clamed turns to talk, but it ended up with Carl positioning himself as the one continuing the story. Jane invited Carl to proceed. In the continuation phase Carl put the story into a context and gave the listener a hint of the story’s direction. Jane made appreciative utterances to encourage Carl to continue his story:
Jane: Yes.

Carl: And there was a hot dog stand. All the others started eating sausages. I never usually eat sausages. And then I thought: What do you do now!

Jane: Yes.

Carl: So I tried to calculate from my blood glucose level what I should do. You see, it was a problem and I had to figure out what was best for me to do. How I made the ends meet.

Jane: Yes, yes.

Carl: And I actually think this is exciting. And tonight when I get home I will know if I did the right thing.

Jane: Yes that's true.

[...]

Carl: This was from 11:30 to 13:30 o’clock. I usually eat around half past twelve. So the first hour I chose to sit and look at the others eating their sausages.

Peter: You didn’t.

Carl: Yes.

Jane: You did, really?

Carl: Yes. There were also soft drinks to get. So I got myself a drink the first hour.

Carl and Peter completed the story together. At the end, where the point emerges, Peter took up the position as leading storyteller. His story underlined the point that Carl made, even though the story took off in a different direction than Carl’s story. Carl was telling a successful story, whereas Peter was telling an unsuccessful story:
Peter: You have to admit it's hard sometimes. We just had a family get-together. And I had to sit and watch them eat all the good food. I must admit that I tried to control myself, but I got too much to eat. And next day I was unwell. I really was.

Carl: You had gotten too much to eat.

Peter: Yes, I had. And it also made my blood glucose - even if my blood glucose is not dramatically high compared to yours - it was nine. That is a lot in my case because it’s usually around six or seven.

They came to a consensus that as a diabetic they had to be upfront and control themselves, otherwise their blood glucose could get too high. They experienced that they had to be able to manage their diabetes in every different situation they got into. Handling diabetes in everyday life requires an effort of those who want to be good diabetics.

**Discussion**

For the patients in this current study, being able to undertake self-management of diabetes was closely connected to a sense of self and was an important element of everyday life with diabetes. The patients’ perception of their ability to perform self-management varied, but a common experience was that handling diabetes on a daily basis required resources and much consideration before acting. Diabetes self-management as a practice required patients to actively engage other people around them and the structural conditions in various contexts of their lives. Like other conditions in human life diabetes self-management has to be an integrated behavior that reproduces itself in different social contexts (Holzkamp, 1998). As a practice it did not happen spontaneously, but occurred only with the patient’s active involvement. An understanding of how patients acquire skills in self-management can be illustrated by looking at the relationship be-
between learning and the social interaction in which learning takes place (Lave & Wenger, 1991). From the perspective of Lave and Wenger (1991), patients do not learn about diabetes care through the acquisition of knowledge, but rather through their participation in the everyday life in which the diabetes self-care is conducted. Thus, the patient’s level of involvement in different life contexts and the social world in which the contexts was produced, was a decisive factor when patients gained skills in self-management. Balcou-Debussche and Debussche stressed that one of the challenges for self-management education interventions is to avoid abstraction away from the personal, familial and social realities of the patient if patients are going to benefit from self-care interventions (Balcou-Debussche & Debussche, 2009). The patients found themselves responsible for conducting diabetes self-management in different life situations, but the support from healthcare professionals in doing so was acknowledged.

In the current study the patient’s concerns about how to conduct self-management were part of the creation of the identity as a person with diabetes. The recognition of the imputability of action clarifies how considerations of moral norms guide a person to what he or she believes to be proper conduct (Ricoeur, 1992). The norms of diabetes control were applied in everyday life in relation to the person’s ability, preferences, social interactions and living conditions. Self-management was thus contextual, unlimited and changeable. Parallels can be drawn to other studies showing that health behavior is contextual and dynamic, and is about walking a fine line to live a good life. Beth Elverdam stressed the complexity of health behavior in families. She found that health was about making it work and was related to peoples’ own perception of conducting healthy behaviors (Elverdam, 2003). The current study’s findings were also compatible with Nyhlin’s study showing how patients with diabetes had to find a balance between the diabetes regime and the social world in which the patients interact with others (Nyhlin, 1991).
and Halldorsdottir discussed the fluctuating and temporary nature of self-management behavior further. They argued that the essential structure of diabetes self-management is closely connected to the person’s conception of having diabetes (Ingadottir & Halldorsdottir, 2008). They found that within each person with diabetes there is both a sense of constraint and a sense of freedom related to handling diabetes. Therefore, adherence to the regimen for diabetes was reflected in this complexity of feelings along with fluctuating settings. The results of our study imply the need to go beyond the adherence thinking and to recognize self-management activities as an identity project. The patients made sense of their identity through narratives about handling diabetes in everyday life. In the focus groups they compared their own ability to handle diabetes with that of others, and in the construction of a norm for appropriate management of diabetes they considered themselves as being either “good” or “poor” diabetics. The patients constructed their own sense of self on their ability to meet the challenges of self-management. Some patients found they were unable to control daily routines such as cooking and mealtimes. Well-regulated blood glucose was a benchmark for satisfactory handling of diabetes and both the individual and the surroundings were assigned the responsibility for failures and successes in the diabetes self-management. This could indicate that self-management is not just about being able to acquire skills but also about being able to mobilize one’s beliefs in one’s own ability to perform self-regulated practices to control diabetes (Bandura, 1997).

The social network played a role in the patient’s perception of themselves as a person with diabetes. Interference from family, colleagues and friends was experienced differently depending on personal preferences and the particular context. Some patients found they were unable to control the interference from the social network. Maunsbach found that the primary network produces a person’s personal and social identity and thus has a major bearing on the per-
son’s conducts and beliefs (Maunsbach, 1999). She pointed out that an involving and supportive network in everyday life leads to a more consistent and long-term adherence with a treatment regimen, especially with regard to dietary and exercise habits. This indicates that a person’s interaction with other people can modify self-management behavior. Performing self-management is not a one-dimensional, consistent process. On the contrary, in order for patients to self-manage diabetes various external demands from different areas of life must be integrated into a whole. Holzkamp discussed this active integration of the various demands from work, family, friendship and other events in a person’s life, where the individual seeks to prioritize own resources in relation to the requirements based on what is appropriate for maintaining daily life (Holzkamp, 1998).

The findings from this study indicated a problematic issue in the treatment of diabetes. Patients with diabetes are expected to take responsibility and to participate autonomously in their own care, but this is not always compatible with patients’ needs. The patients in this study did not disclaim responsibility even when they felt that they could not live up to these expectations of self-regulation. It is conceivable that patients who considered themselves as unable to mobilize themselves to take care of their diabetes will suffer under self-regulating demands. Thorne and Paterson stressed the tendency to ignore the needs of chronically ill patients for professional support and care (Thorne & Paterson, 1998). Others’ expectations of competence and strength can be a heavy burden for some patients with diabetes. The patients in this study recognized the intervention’s explorative and acknowledging approach as supportive in handling diabetes in everyday life. It could be that focusing on the patients’ own resources and trying to increase their beliefs in their ability to perform self-care activities might help patients to feel appreciated in relation to current problems in the daily routine of diabetes self-care. Furthermore, a focus on
what the patient believes to be appropriate and meaningful behavior related to daily diabetes care might improve patient’s ability to perform self-management.

The phenomenological approach served to capture and describe how patients with diabetes oriented themselves to the lived experience of diabetes. Empirical studies based on phenomenology should adopt an open attitude throughout the whole research process (Norlyk & Harder, 2010). In this study the phenomenological approach implied for the researchers to have a desire to understand the phenomenon fully and to capture patients’ pre-reflective experiences as they lived it. The focus group discussions were found to be ideal in exploring how the self-managing patients with diabetes constructed their identity. The combination of these two approaches might have provided a greater understanding of patients' perceptions of how life with diabetes is lived and handled, given that focus groups stimulate the discussion and open up new perspectives (Bradbury-Jones, Sambrook, & Irvine, 2009). The consequence of the focus group setting was that the participants had time for reflection before adding their own perspectives (Bradbury-Jones et al., 2009). The interactive and synergistic nature of the focus group setting did not prevent individual experiences from emerging, but there were some limitations. In a focus group interview there is not the possibility to examine all of the individual patient’s individual perspectives in depth, and we had only limited insight into the perspectives of patients who felt unable to overcome problems in diabetes self-management. This issue was not pursued here because of the risk of sidetracking the group dynamics and violating the participants’ personal integrity. A purposive sampling to allow focus group interviews with patients who consider they have problems with diabetes self-management would be useful.

It could be argued that because both the moderator and co-moderator were healthcare professionals known to the patients, any critical perspectives on treatment might have been
downplayed (Mishler, 1986). However, patients mentioned the evaluation of the intervention spontaneously during the focus group discussions about handling diabetes in everyday life. The use of a phenomenological method meant that our only source of information was the patients’ reports of their lived experience with diabetes. Our results concerning experiences of everyday life with diabetes were thus an interpretation of the patients’ interpretation. An observational study that explored the social contexts and interactions that the patient enters into would have added further insights into everyday life with diabetes, and allowed exploration of issues that patients did not construct discursively.

The study design allowed for repeated interviews with the same patients, which reinforced the findings from the study because we were able to question our assumptions and pre-understandings over time. To ensure that we kept to the themes and variations that the participants expressed, we discussed amongst ourselves our impressions and interpretations during the analysis. We analyzed the findings from the focus group interviews before and after the intervention together rather than separately in the text, while accepting that not all interviews provided information on all study questions.

**Conclusion**

The findings from the current study indicate a need to involve patients in setting treatment objectives to ensure that the patient participates in a meaningful and appropriate treatment that can be transferred to various everyday situations. The analysis focused on the lived experiences of patients living with diabetes in daily life. It is evident that people with diabetes have specific needs for support in the daily responsibility of managing the rules of conduct regarding diet, exercise, medication and blood glucose monitoring. Healthcare professionals should be aware of the difficulties that some vulnerable patients face in handling the responsibility of self-management. The
patients experienced that the intervention based on motivational interviewing, which had an explorative and patient-centered approach, had helped them to mobilize their own resources to overcome problematic issues related to their diabetes care. A good understanding of how to meet the individual’s needs regarding care is necessary in the development of diabetes treatment strategies to ensure a sustainable treatment. Further research is needed to explore how treatment options can be differentiated to meet the diverse needs of the patient group.

Acknowledgement

The authors thank the study patients for their participation and willingness to share their thoughts and life experiences. Thanks to Claire Gudex for language editing of the manuscript. Thanks also to Dorthe Nielsen for assistance with the focus group interviews, and to the team members Lene Sjöberg, Inge Kamp, Ewa Romanczuk, Iben Eggertsen, Trine Flemming Larsen, Gitte Kramer and Bettina Nielsen for their invaluable contributions throughout the study.

Declaration of Conflicting Interests

The authors declared no conflicts of interest with respect to authorship and/or publication of this article.

Funding

The author disclosed receipt of the following financial support for the research and/or authorship of this article: The National Board of Health, Funen County, Danish Association of Diabetes, Odense University Hospital, University of Southern Denmark and TRYG Fonden.
References


Kitzinger, J. (1994). The methodology of Focus Groups: the importance of interaction between research participants. *Sociology of Health & Illness*, 16(1), 103-121.


**Bios**

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Table 1. Schematic example of step 3 and 4 in the phenomenological analysis process

<table>
<thead>
<tr>
<th>Step 3</th>
<th>Step 4</th>
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<tbody>
<tr>
<td>Meaning unit parts</td>
<td>Condensed meaning unit</td>
</tr>
<tr>
<td>Thomas: It’s difficult for me to eat six times a day because I drive around to customers throughout the day. Then I don’t get the right breaks.</td>
<td>Trying to adopt the diet regime into daily living</td>
</tr>
<tr>
<td>Kathy: Then you could have a small fruit bowl when you drive around.</td>
<td>Adapting self-managing behaviors</td>
</tr>
<tr>
<td>Thomas: My wife always makes sure that we have fruit with us when we go for a ride. But I forget it. I also forget to eat small snacks at home.</td>
<td>Becoming a self-regulating practitioner</td>
</tr>
<tr>
<td>Jacob: You just have to do it. I try to follow the diet. And of course I hunger for Danish pastry. You can take one piece and then go back to the diet again the next day.</td>
<td>You have to follow the diet required by the diabetes management</td>
</tr>
<tr>
<td>Tina: But that is the problem. I can’t stop with just one piece of cake.</td>
<td>Getting control</td>
</tr>
<tr>
<td>Jacob: But you have to restrict yourself to one piece of cake.</td>
<td>Managing the rules of self-management</td>
</tr>
<tr>
<td>Peter: I get a little annoyed from time to time when my wife tries to guide me in something. I’ll find out myself. It’s like she gets overprotective.</td>
<td>You have to be careful that the network does not take over the diabetes management</td>
</tr>
<tr>
<td>Jane: Oh that’s nice. She just wants you to feel good. Look! That is what support is about.</td>
<td>Interference from the network</td>
</tr>
<tr>
<td>Peter: Yes. But it does still seem a little annoying for me anyway.</td>
<td>Creating a supportive social network</td>
</tr>
<tr>
<td>Carl: I know how you feel. I’ve also had it sometimes with my wife. Sometimes she thinks she knows things better than me.</td>
<td></td>
</tr>
<tr>
<td>Jane: She just wants you to feel good. But of course you have to be careful that your husband or wife doesn’t take over the lead.</td>
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Paper III
The effect of motivational interviewing intervention on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education program: a randomized controlled trial

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Words:
Abstract: 256
Main text: 3,967
Abstract

Objective Effectiveness of a motivational interviewing intervention compared to usual care on changes in glycaemic control and competence of diabetes self-management in patients with diabetes mellitus.

Methods 469 patients attended a four days group education program in a diabetes clinic at a university hospital in Denmark. Randomization was generated by random permuted blocks, with allocation concealment by sequentially numbered, sealed, opaque envelopes. The intervention included up to five individual counseling sessions for one year based on motivational interviewing offered by a multidisciplinary team. Adults with type 1 and type 2 diabetes mellitus who had no severe debilitating disease or cognitive deficit were eligible. Primary outcomes were HbA1c and competence of self-management (measured by PAID and PCDS scores) assessed at 0 and 12 months. Intention to treat and per protocol analyses were used.

Results 349 eligible patients were randomized (92% retention rate) to either an intervention group (n=173) or usual care control group (n=176). Motivational interviewing did not have an effect on HbA1c level (6.98 to 6.86 vs. 7.06 to 7.00, p=0.675) or PAID scores (18.32 to 17.45 vs. 19.40 to 20.16, p=0.343). Though, the motivational interviewing group maintained PCDS scores post intervention (6.3 to 6.3 vs. 6.2 to 5.8, p=0.011) Motivational interviewing did not have an effect on HbA1c level. There was, however, a tendency of improvement in the HbA1c level (9.3% to 7.5%, n=23) among the patients in the intervention group with a mean baseline HbA1c value above 8%.

Conclusion Motivational interviewing program might enhance perceived competence for diabetes among patients with type 1 or type 2 diabetes mellitus. Patients with poor diabetes control and high diabetes-related distress might profit most by the motivational interviewing program.

Trial registration Clinical Trials NCT00555854.

Funding The National Board of Health, Funen County, Danish Association of Diabetes, Odense University Hospital, University of Southern Denmark and TRYG Fonden.

Keywords Diabetes Mellitus, Self Care, Clinical Trial, Patient Education, Motivation.

Abbreviations

MI Motivational interviewing
MITI Motivational Interviewing Treatment Integrity Coding System
OHA Oral Hypoglycemic Agents
PAID Problem Areas in Diabetes Scale
PCDS Perceived Competence for Diabetes Scale
Introduction
The burden of diabetes is increasing worldwide. It has been calculated that, in 2030, the total number of subjects with diabetes mellitus will be 366 million (1). The increasing prevalence of the disease combined with the fact that the disease is associated with increased morbidity and mortality emphasize the importance of effective diabetes care.

The treatment of diabetes includes lowering blood glucose and the level of risk factors that damage blood vessels (2-4) which is reflected in a therapeutic regimen of a healthy diet, exercise, tobacco cessation, low alcohol intake, glucose monitoring and, for many patients, medication. Self-management of diabetes requires that patients are able to reconcile their resources and preferences with the therapeutic regimen of diabetes, which can be a challenging task for many patients (5;6).

The findings of several meta-analyses of randomized controlled trials provide extensive evidence for the effectiveness of self-management intervention on diabetic control (fasting blood glucose and glycated haemoglobin), but the long-term effects of such interventions are uncertain (7-11). Knowledge about the effectiveness of self-management intervention on other diabetes-related outcome measures including blood pressure, lipid profile, body weight, self-management skills, health behavior and psychosocial aspects is less clear (12-14).

Patient-centered approaches might be a key to improve clarification of patients’ concerns in consultation and hereby make the treatment goal more applicable to patients’ everyday life (15). The evidence of the effects of patient-centered methods on patients’ healthcare behaviors or health status is limited (15), but motivational interviewing defined by Rollnick and Miller is a patient-centered method that has successfully been used to elicit and sustain a person’s behavior changes in a number of health care areas (16). A recent review of motivational interviewing showed improvements in health behavior (e.g. diet and exercise) in patients with diabetes (17). Research has not yet been able to establish full consensus about the effect of motivational interviewing on glycaemic control in patient with diabetes (17-19). Previous reviews emphasize the need for studies of high methodological quality and adequate power and to explore the effect of motivational interviewing on glycaemic control in patient with diabetes. Only a few studies have explored the effect of motivational interviewing on psychosocial aspects in diabetes (20-22). These studies were small and varied in methodological quality. Additionally, further elaboration of the theoretical model underpinning the intervention program is needed (11;12).

With this study we explored the significance of supporting patients with diabetes to manage their diabetes in everyday life. The aim was to study the effect of a one-year intervention program based on motivational interviewing on glycaemic control and competence of management in patients diagnosed with type 1 or type 2 diabetes mellitus after attending a group education program. Our hypothesis was that a motivational intervention program would increase the patients beliefs in own capability to succeed in their diabetes care and would lead to increased self-care behavior in relation to diabetes, and hereby improve glycaemic control.

Method
Research settings
This study was conducted at a diabetes clinic, located within a university hospital in Denmark with intake of patients from both urban and rural areas of the region. Patients can be referred by their general practitioner or other hospital departments to the diabetes clinic. At the clinic patients are offered ongoing individual counseling by dieticians, nurses or physicians and group education delivered by a multidisciplinary healthcare team over four days. The four-day diabetes education program includes approximately eight to ten patients and focuses on a range of themes such as diabetes treatment, prevention of diabetes-related complications, self-monitoring of blood glucose, diet, physical activity, alcohol use and issues regarding insurance. The teaching method is based on
Research subjects and design

Patients were eligible if they had type 1 or type 2 diabetes mellitus, were over 18 years of age and had participated in the group education program offered at the diabetes clinic. Exclusion criteria included pregnancy, severe debilitating disease and cognitive deficit. Following written acceptance by the patients, they were randomized to either a control group or an intervention group. Randomization was done immediately after participation in the group education program. All outcome measures were assessed at randomization and one year after randomization in both groups. Randomization was generated by random permuted blocks, with allocation concealment by sequentially numbered, sealed, opaque envelopes. The person generating the allocation scheme did not administer the allocation of the patients to the two groups and was not part of the research team.

The sample size was determined by a power calculation. With 352 patients, 176 in each group, the trial can detect a 0.4% difference in HbA1c. The power was set to 90%. This calculation was based on a standard deviation of 1.15 in the HbA1c-value and a 5% two-sided significance level.

Medical treatment was not part of the intervention. All participants, irrespective of participation in the intervention group or the control group, therefore underwent the same routine check-up at their general practitioner or outpatient clinic in charge of their diabetes care. This usually involves four physician visits per year. Biochemical tests and examinations are usually performed during the visits in accordance with national diabetes guidelines. Individual counseling and recommendations based on the results of the examinations, biochemical tests and their self-monitoring of blood glucose are given. Renewal of prescribed medication and test strips for blood glucose monitoring are also given at these check-ups. As required patients can be referred to counseling in change of diet, smoking habit and alcohol use.

Research intervention

The theoretical approach of the intervention was based on the self-efficacy theory and motivation interviewing spirit. Perceived self-efficacy is defined as people's beliefs about their capabilities to produce designated levels of performance exercising influence over events that affect their lives (24). Motivational interviewing was used as a method to facilitate this process. Motivational interviewing is defined as a directive, patient-centered counseling style for eliciting behavior change by helping patients to explore and resolve ambivalence (25;26).

The one-year motivational interviewing program consisted of five individual counseling sessions lasting approximately 45 minutes and offered at one, three, six, nine, and twelve months. Each participant in the intervention group had a health care professional trained in motivational interviewing assigned. The style of the interview was: 1) seeking to understand the person's frame of reference, 2) expressing acceptance and affirmation, 3) eliciting and selectively reinforcing the client's own self-motivational statements of problem recognition, concern, desire and intention to change, and ability to change, 4) monitoring the client's degree of readiness to change, and 5) affirming the client's freedom of choice and self-direction. Each session followed a semi-structured interview format of motivational interviewing, especially developed for this intervention program. Subjects brought up during sessions were any problematic issues related to diabetes self-care experienced by the participants. The participants in the intervention group could be referred to individually tailored counseling in changes of diet, physical activity, smoking habit and alcohol use as they required.
Education of the health care professionals prior to the intervention

Three diabetes specialist nurses, two dieticians, one physiotherapist and one psychologist were educated to carry out motivational interviewing. They were all coached by a MI trainer from the Motivational Interviewing Network of Trainers in the Nordic countries. The course comprised a five-day theoretical introduction to strategies in motivational interviewing. The course was followed by three practical coaching sessions every three months for eighteen months. The theoretical and practical part of the education included training in the key elements of motivational interviewing which are the patients-centered nature of eliciting change talk and exploring ambivalence about behavioral change while trying to examine discrepancies between the individual’s current behavior and core values or personal goals. The healthcare professionals were introduced to the motivational interviewing method including reflective listening and acknowledgement to allow them to be able to clarify the patient’s goals and concerns and elicit reasons for change in the patient’s own words. The role of the healthcare professionals was to coach and support the patient in discovering and developing his/her own resources for change and management at the patient’s request.

After the five-day course the health care professionals were individually supervised by the MI trainer in ten real patient situations for one year. The supervision included videotaping and evaluation inspired by Motivational Interviewing Treatment Integrity (MITI) Coding System.

Measurements

Questionnaires

Competence of diabetes self-management was assessed by validated questionnaires translated into a Danish version in accordance with recommendation (23). Problem Areas in Diabetes Scale (PAID) was used to measure diabetes-related distress reported by the participants. This twenty-item questionnaire assesses a wide range of feelings related to living with diabetes and the diabetes treatment (27;28). Each item can be rated on a five-point Likert scale ranging from zero (“not a problem”) to four (“a serious problem”). Transforming PAID scores into a 0-100 scale all item scores are summed and multiplied by 1.25 which results in an overall PAID score with higher scores indicating greater emotional distress (29;30). High PAID scores are associated with low self-reported adherence (28). The Perceived Competence for Diabetes Scale (PCDS) was used to measure competence at carrying out the diabetes treatment regime. This is a five-item questionnaire assessing the degree to which participants feel confident about dealing with diabetes (31;32). Each item can be rated on a seven-point Likert scale ranging from one (“not true at all”) to seven (“very true”). The score on the PCDS is calculated by averaging the responses on the five items. Minimum average score is one equaling lowest possible perceived competence in dealing with diabetes and maximum average score is seven equaling highest possible perceived competence in dealing with diabetes.

Laboratory measurements

One laboratory analyzed all the blood samples. Glycaemic control was assessed using HbA1c. HbA1c was measured by a high-performance liquid chromatography-based ion exchanged procedure (Tosho Alc 2.2, Japan). The reference range was 4.3-6.3%. Total cholesterol, HDL cholesterol, and triglyceride levels were measured in serum by enzymatic methods (Boehringer Mannheim GmbH Diagnostica, Mannheim, Germany). LDL cholesterol was calculated by Friedewald’s equation (33).

Clinical measurements

Both height and weight were measured without shoes. Weight was measured without accessories, i.e. wallet, keys, mobile phone. Waist circumference was measured with a measuring tape directly
on the individual’s skin. Restrictive garments and clothing were removed. The tape was placed at the uppermost border of the iliac crest horizontal to the floor. Measurement was made at the end of a normal expiration. Blood pressure was measured by the auscultatory method with use of a stethoscope and a sphygmomanometer. An inflatable cuff was placed around the upper left arm, at the same vertical height as the heart. Measurement was made at rest in a sitting position.

**Statistical analysis**
For data analyses, the Statistical Package for the Social Sciences (SPSS, Version 18 Inc., Chicago, IL, USA) for Windows was used.

Intention to treat, where missing values were imputed with the last value carried forward method (LOCF), was used as was per protocol analyses. Data in this article are presented per protocol. When results of intention to treat analyses differed from those of the per protocol analyses it is presented in the text. Baseline characteristics were compared in the two study groups with use of chi-square tests for discontinuous variables and unpaired t-tests for continuous variables. Analyses of primary and secondary outcomes were performed with the use of paired t-test within group and unpaired t-test between groups (calculated on mean delta values of outcome variables). A two-tailed p-value with equal variances assumed < 0.05 was considered statistically significant. Results are reported as means ± standard deviation (SD) or numbers N (%) with 95% confidence intervals and p-values of the differences.

**Research ethics**
The study design was approved by the Regional Scientific Ethics Committee of Southern Denmark (project-ID: VF-20050131) and the study was reported to the Danish Data Protection Agency. All patients were informed about the aim of the study and were included in the study after verbal and written consent. The study was performed in accordance with the Helsinki Declaration. The protocol of the study was registered at ClinicalTrials.gov (No. NCT00555854).

**Results**

**Baseline data**
In the period between December 2005 and June 2009 469 patients attended the diabetes education program at the diabetes clinic. Some 115 patients declined to participate in the trial and five patients did not meet the inclusions criteria. The reason for decline was mainly lack of time or lack of energy to complete the trial. Of the 120 deselected patients, 62 were women and 56 were men. The distribution of gender was comparable in the deselected group and the eligible group of patients. The mean age in the deselected group was 59.1 (±11.8) years. This was significantly higher (p=0.040) than the age of those who participated in the trial, where the total mean age was 56.4 (±12.1) years. The duration of diabetes was 7.1 (±10.0) years in the deselected group and 4.7 (±6.7) years in total among the participants. This difference was significant (p=0.008). No difference was found between the deselected patients and the eligible patients with regard to weight, blood pressure, glycated haemoglobin and lipid profile.

Of the 349 eligible patients, 173 patients were randomized to the intervention group and 176 to the control group. During the one-year follow-up 28 participants (8%) dropped out of whom 17 had been allocated to the intervention group and 11 to the control group (Figure 1). We found no difference in characteristics of dropout subjects between the two groups, except for the mean baseline HbA1c level, which was 7.3% (±1.0) in the intervention group and 6.6% (±0.7) in the control group (p=0.041).
The baseline characteristics and health status of both groups were similar, except for the mean triglyceride level, where there was a statistically significant difference, but not a clinical significant difference (p=0.043) (Table 1).

**Intervention**

In the intervention group the average visits per patient were 4.6 with an average time of 34 minutes per session during the one-year intervention program. In the intervention group 85% completed the full intervention program with the five sessions. The last 15% in the intervention group had between 1 and 3 sessions.

In the intervention group 17% were referred to individual counseling in change of diet. The mean numbers of visit per patient were 2.0 (minimum 1 and maximum 5 visits). Some 25% in the intervention group were referred to an individually tailored physical activity program. The mean numbers of visits per patient were 5.7 (minimum was 1 visit and maximum was 50 visits). Of the patients who participated in dietary counseling and a physical activity program, 15% received both therapies. Seven percent in the intervention group participated in individual counseling on smoking cessation. The mean numbers of visits per patient were 4.9 (minimum 2 and maximum 10 visits). Finally, 3% of the patients in the intervention group were referred to individual counseling in change of alcohol use.

**One-year follow-up**

There were no significant differences between the two study groups with regard to mean level of HbA1c, total cholesterol and LDL cholesterol at post-test (Table 2). Also, no statistically differences were found in weight, waist circumference, systolic blood pressure or diastolic blood pressure between the intervention and control group at post-test (Table 2). The patients in the intervention group showed significantly higher levels of perceived competence in dealing with diabetes compared with the control group (p=0.011), but no difference in diabetes-related distress was found between the groups (p=0.343) (Table 2). The intention to treat analyses did not differ from per protocol analyses.

Similar changes in medical treatment over time were found in the intervention and control group as regards insulin, oral hypoglycaemic agents (OHA), antihypertensive agents, cholesterol-lowering agents, anticoagulants and steroids.

Post hoc analysis showed significant improvement in HbA1c level for baseline values above 8% in the intervention group (n=23), where the mean HbA1c level was 9.3% (±1.6) at baseline and 7.5 % (± 2.2) at 1-year follow-up (p≤0.001) (Figure 2a). A drop below 8% in HbA1c was not seen in the control group (n=31), though there was a change in HbA1c level from 8.9% (±1.2) at baseline to 8.3 (±1.2) at 1-year follow-up (p=0.011) (Figure 2b). Post hoc analysis also showed that patients in the intervention group with high PAID scores (above 40) improved the PAID scores from 51.9 to 27.0 (p≤0.001, n=30). The same improvements were not seen in the control group, where the patients with PAID scores above 40 change scores from 52.7 to 40.0 (p=0.009, n=30).

**Discussion**

The main finding of this one-year follow-up study was that patients with diabetes participating in a motivational interviewing program maintained their perceived competence in dealing with diabetes compared with a control group. We found no evidence that the intervention improved diabetes-related distress, glycaemic control or lipid profile in the intervention group compared with the control group. Patients in the intervention group did not significantly improve their glycaemic control, and the between-group difference in HbA1c was only 0.04%. There was a significant
improvement in lipid profile in both groups after one year, but no statistical difference between
groups.

Previous meta-analyses have revealed that self-management interventions in diabetes have
produced modest short-term improvements in glycaemic control. There was a tendency to non-
significant improvements in glycated haemoglobin in the included studies where the mean HbA1c
values were less than 8.5% at baseline (7;8;11;34). A tendency to lower effect on glycaemic control
was found in studies where the duration of diabetes was above 9 months (11). Our results
matches with these findings. Essentially, motivational interviewing might not improve
glycaemic control of patients who have such a relatively lower HbA1c and longer duration of
diabetes, especially when general practitioners or diabetologists see them regularly. In our study we
found a 1.8% improvement in the HbA1c level among the patients in the intervention group with a
mean baseline HbA1c value above 8%. This indicates that the intervention program based on
motivational interviewing might have an effect on glycaemic control in patients with poor diabetes
control. Inconsistency in previous reviews of the effect of motivational interviewing on glycaemic
control in patients with diabetes (17-19) might be explained by the variation in baseline HbA1c
between studies.

The lack of effect on HbA1c, lipid profile and other clinical outcomes such as weight and
waist circumference might indicate that the patients in the intervention group did not change
behavior towards a higher degree of diabetes self-care including healthy diet and more physical
activity. These findings are supported by the fact that we found no evidence that motivational
interviewing improved diabetes-related distress. Meanwhile, we found that motivational
interviewing maintained perceived competence for diabetes. It might take more time before these
improvements on patients’ cognition could be seen on desirable behavioral changes in diabetes self-
management. In this respect the improved cognition obtained by motivational interviewing might
mediate clinical improvement in the long term. Therefore, in order to see an effect of motivational
interviewing, it is important to keep in mind that motivational interviewing is based on making
patients themselves aware of the potential for change in behavior and starts a changing process for
the patient that might result in improved health parameters over time (35).

It appears from the mean PAID result at baseline that patients entering into the study had a
relatively low level of diabetes-related distress. This is similar to what is found in unselected out-
patient groups (29). The mean PAID score reduction of 0.87 (arbitrary unit) after one year in the
intervention group was small compared to the mean PAID score reductions found in other studies
evaluating diabetes intervention programs, where the change scores were between 6 and 20
(arbitrary unit) (29). The mean PAID scores at baseline in these studies were typically in the 40s.
The fact that the patients had participated in an education program before entering into the study
might be the reason for such relatively low level of diabetes-related distress at baseline which might
be reflected in the follow-up measurement. Our study indicated that those with high PAID scores
(above 40) might benefit most from the motivational interviewing program as the mean change
score in this group was 24.9. The same improvement was not found in the control group of those
with baseline mean score above 40 (mean change score was 12.7). This might indicate that the
intervention program based on motivational interviewing helped patients overcome problematic
issues in living with diabetes.

The mean PCDS results at baseline were close to maximum score in both the intervention and
the control group which might also be explained by the fact that the patient received education in
diabetes before entering the study. Patients in the intervention group maintained the high score in
perceived competence in dealing with diabetes at follow-up while there was a decrease in mean
PCDS score of 0.38 point in the control group. This might indicate that the intervention helped
patients feel more competent in managing their diabetes. The instrument has not been developed
directly to be used in clinical practice. Therefore, the interpretation of how changes in mean PCDS score have influence on patients’ diabetes self-management is not clear. Williams et al. found that an increase in perceived competence accounted for a significant decrease in glycated haemoglobin (32). An association between mean PCDS score and HbA1c level was not found in our study.

Implementing a new approach in diabetes treatment we have to consider who are most likely to benefit from this kind of intervention. Considering the group of patients who declined to participate in the trial, it was evident that they were older and had diabetes for a longer time than those who participated in the trial. This could indicate that intensive interventions might be less attractive and manageable for the older population with diabetes. Furthermore, the patients in the intervention group who dropped out during the intervention had significantly higher level of HbA1c than those completing the intervention. This could indicate that some patients had discomfort in the scrutinizing nature of the intervention based on motivational interviewing that would get close to the person’s resistance to change behavior.

This study provided insight into the effect of a patient-centered approach. Implementing motivational interviewing as a new method in diabetes care required a shift in the healthcare professionals’ role as well as practical training. Previous studies have shown that several barriers have to be overcome before a new method can be applied (36-38). To accommodate these barriers supervision and practical coaching sessions were held after the theoretical introduction to Motivational Interviewing. The supervision included videotaping and evaluation by the MITI coding system both to facilitate the use of motivational interviewing and to ensure that the method was used correctly in the intervention.

The power calculation showed that 352 patients were needed to show a 0.4% difference in HbA1c. Unfortunately, several patients declined participation, which resulted in lower statistical power than planned. Furthermore, we cannot totally exclude the risk of contamination bias which in this case could occur if patients in the control group changed their behaviors after interacting with patients in the intervention group, or if the healthcare professionals assigned to deliver the intervention also treated patients in the control group coming to the diabetes clinic for routine care. Contamination bias might diminish the magnitude of the difference between the intervention and usual care. Most of the patients entering this study, however, went to their general practitioner for routine care which might minimize the risk of contamination bias, but use of a cluster design might have minimized the possibility of contamination bias even more.

Conclusion
The motivational interviewing program maintained patients’ perceived competence in dealing with diabetes. No effect was found in diabetes-related distress or in the cardiovascular risk profile such as HbA1c level, lipid profile, blood pressure or medication, and similarly there were no improvements in weight or waist circumference. Motivational interviewing might start a changing process in a patient which indicates a need for long-term follow-up of the intervention program to establish full knowledge about the effect.
Acknowledgement
The authors thank the study patients for their participation in the study. Thanks to the team members Lene Sjöberg, Inge Kamp, Ewa Romanczuk, Iben Eggertsen, Trine Flemming Larsen, Gitte Kramer and Bettina Nielsen for their invaluable contributions to the study. Thanks to the staff at the Diabetes Clinic Department of Endocrinology for co-operation and assistance throughout the trial. Thanks also to Lise Stark for language editing of the manuscript.

Declaration of Conflicting Interests
The authors declared no conflicts of interest with respect to authorship and/or publication of this article.

References


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<th>Control (n=176)</th>
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<td>Cholesterol-lowering treatment</td>
<td>107 (61.8)</td>
<td>119 (67.6)</td>
<td>-</td>
</tr>
</tbody>
</table>

Data are means ± SD or N (%).

Middle school is between seventh and ninth grade. High school is ninth to twelfth grade.

aBaseline characteristics were compared in the two study groups with use of chi-square tests and unpaired t-tests.

bMost of the patients in this group were retired.

cSignificant difference between the two groups.
<table>
<thead>
<tr>
<th>Variables/group</th>
<th>Pretest</th>
<th>Post-test</th>
<th>Difference (post-test – pretest)</th>
<th>95 % CI within group</th>
<th>p-value</th>
<th>Δ mean between groups</th>
<th>95 % CI between groups</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Intervention (n=150)</td>
<td>6.98 (1.23)</td>
<td>6.86 (1.22)</td>
<td>- 0.12 (1.05) -0.29 to 0.05 0.161</td>
<td>-0.04</td>
<td>-0.26 to 0.17</td>
<td>0.675</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control (n=161)</td>
<td>7.06 (1.18)</td>
<td>6.99 (1.09)</td>
<td>- 0.07 (0.83) -0.21 to 0.05</td>
<td>0.249</td>
<td></td>
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<tr>
<td>Total cholesterol (mmol/l)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention (n=148)</td>
<td>4.40 (1.04)</td>
<td>4.24 (0.92)</td>
<td>- 0.15 (0.87) -0.30 to -0.01</td>
<td>0.033\textsuperscript{a}</td>
<td>-0.02</td>
<td>-0.21 to 0.16</td>
<td>0.803</td>
<td></td>
</tr>
<tr>
<td>Control (n=161)</td>
<td>4.57 (1.02)</td>
<td>4.44 (0.97)</td>
<td>- 0.13 (0.68) -0.25 to -0.01</td>
<td>0.040\textsuperscript{a}</td>
<td>-0.02</td>
<td>-0.18 to 0.16</td>
<td>0.861</td>
<td></td>
</tr>
<tr>
<td>LDL cholesterol (mmol/l)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Intervention (n=149)</td>
<td>2.31 (0.97)</td>
<td>2.16 (0.82)</td>
<td>- 0.15 (0.86) -0.29 to -0.01</td>
<td>0.031\textsuperscript{a}</td>
<td>-0.02</td>
<td>-0.18 to 0.16</td>
<td>0.861</td>
<td></td>
</tr>
<tr>
<td>Control (n=160)</td>
<td>2.32 (0.87)</td>
<td>2.19 (0.85)</td>
<td>- 0.14 (0.68) -0.24 to -0.03</td>
<td>0.011\textsuperscript{a}</td>
<td>-0.02</td>
<td>-0.18 to 0.16</td>
<td>0.861</td>
<td></td>
</tr>
<tr>
<td>Problem areas in diabetes (PAID)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention (n=145)</td>
<td>18.32 (14.09)</td>
<td>17.45 (14.64)</td>
<td>- 0.87 (14.20) -3.20 to 1.47</td>
<td>0.464</td>
<td>1.63</td>
<td>-1.75 to 5.00</td>
<td>0.343</td>
<td></td>
</tr>
<tr>
<td>Control (n=155)</td>
<td>19.40 (16.40)</td>
<td>20.16 (17.48)</td>
<td>0.76 (15.42) -3.21 to 1.69</td>
<td>0.540</td>
<td></td>
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<tr>
<td>Perceived competence for diabetes (PCDS)</td>
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<tr>
<td>Intervention (n=145)</td>
<td>6.30 (1.05)</td>
<td>6.29 (1.12)</td>
<td>- 0.015 (1.16) -0.88 to 1.03</td>
<td>0.875</td>
<td>0.37</td>
<td>0.084 to 0.65</td>
<td>0.011\textsuperscript{b}</td>
<td></td>
</tr>
<tr>
<td>Control (n=155)</td>
<td>6.19 (1.12)</td>
<td>5.81 (1.33)</td>
<td>- 0.38 (1.31) 0.87 to 2.94</td>
<td>0.000\textsuperscript{a}</td>
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<tr>
<td>Weight (kg)</td>
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</tr>
<tr>
<td>Intervention (n=150)</td>
<td>89.03 (17.69)</td>
<td>89.20 (17.77)</td>
<td>0.17 (5.92) -0.78 to 1.13</td>
<td>0.719</td>
<td>-0.56</td>
<td>-1.71 to 0.60</td>
<td>0.34</td>
<td></td>
</tr>
<tr>
<td>Control (n=157)</td>
<td>89.68 (18.28)</td>
<td>90.41 (18.74)</td>
<td>0.73 (4.31) 0.05 to 1.41</td>
<td>0.036\textsuperscript{a}</td>
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<tr>
<td>Waist circumference (cm)</td>
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<tr>
<td>Intervention (n=150)</td>
<td>102.72 (14.56)</td>
<td>103.21 (14.76)</td>
<td>0.49 (5.12) -0.34 to 1.31</td>
<td>0.245</td>
<td>-0.30</td>
<td>-1.45 to 0.86</td>
<td>0.611</td>
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</tr>
<tr>
<td>Control (n=155)</td>
<td>101.97 (14.72)</td>
<td>102.76 (15.36)</td>
<td>0.79 (5.13) -0.08 to 1.60</td>
<td>0.058</td>
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<tr>
<td>Systolic BP (mmHg)</td>
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</tr>
<tr>
<td>Intervention (n=149)</td>
<td>132.57 (16.75)</td>
<td>135.44 (13.79)</td>
<td>2.87 (16.83) 0.15 to 5.60</td>
<td>0.039\textsuperscript{a}</td>
<td>3.61</td>
<td>-0.57 to 7.80</td>
<td>0.090</td>
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</tr>
<tr>
<td>Control (n=155)</td>
<td>132.66 (17.48)</td>
<td>131.92 (17.42)</td>
<td>0.74 (20.02) -3.92 to 2.44</td>
<td>0.645</td>
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<tr>
<td>Diastolic BP (mmHg)</td>
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<td></td>
</tr>
<tr>
<td>Intervention (n=149)</td>
<td>75.69 (10.49)</td>
<td>78.80 (8.96)</td>
<td>3.11 (10.55) 1.40 to 4.81</td>
<td>0.000\textsuperscript{a}</td>
<td>1.23</td>
<td>-1.14 to 3.57</td>
<td>0.309</td>
<td></td>
</tr>
<tr>
<td>Control (n=155)</td>
<td>76.39 (9.91)</td>
<td>78.28 (8.70)</td>
<td>1.89 (10.30) 0.26 to 3.52</td>
<td>0.024\textsuperscript{a}</td>
<td></td>
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</tr>
</tbody>
</table>

Data are means (SD).
Analyses were performed with the use of paired t-test within group and unpaired t-test between groups (calculated on mean delta values of outcome variables).

aSignificant difference between pretest and post-test within group.

bSignificant difference between groups.
Figure 1 Flow diagram of inclusion of the study population

469 patients attended the diabetes education program in the diabetes clinic between December 2005 and June 2009.

- 115 Declined
  - 5 Did not meet the inclusions criteria

349 eligible patients

- 17 Dropouts due to
  - 7 During intervention
  - 3 Non-attendances
  - 2 Do not wish to participate
  - 1 Pregnancy
  - 2 Other critical disease
  - 2 Moving to another region

173 randomised to intervention group

176 randomised to control group

156 follow-up 1 year intervention group

165 follow-up 1 year control group

11 Dropouts due to

- 2 Non-attendances
- 7 Do not wish to participate
- 1 Deceased
- 1 Other critical disease

156 follow-up 1 year intervention group

165 follow-up 1 year control group
Figure 2a HbA1c level at baseline and at 1-year follow-up in the intervention group.

**HbA1c level at baseline and 1-year follow-up**

- **Gruppe: Intervention**

The scatter plot shows the distribution of HbA1c levels at baseline and follow-up for the intervention group. The data points are plotted according to their baseline HbA1c levels on the x-axis and follow-up HbA1c levels on the y-axis.
Figure 2b HbA1c level at baseline and at 1-year follow-up in the control group