

Lifestyle intervention in patients at risk of type 2 diabetes

The effects of two low-intensity interventions, how lifestyle intervention influences health related quality of life – and how the 13-item Sense of Coherence questionnaire can predict successful lifestyle change

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Scientific environment

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Abstract

Background: The global prevalence of type 2 diabetes (T2D) is rapidly increasing, linked to the epidemic of obesity and inactivity. There is substantial research evidence for prevention of T2D by lifestyle interventions in high-risk individuals. Less comprehensive lifestyle interventions, or population-based strategies, are needed for the more than half of Europeans at risk of T2D. Two low-intensity interventions in adult Norwegians at risk of T2D were tested in a randomised, controlled design.

Methods: Individuals at high risk of T2D were identified by general practitioners (GPs) using the seven-item “Finnish Diabetes Risk Score” (FINDRISC) and referred to the local hospital. A thorough first consultation with the study physician focused on delivering a simple, clear and true message about the importance of the individual’s own efforts regarding both T2D and general health. Participants were randomly assigned to an “individual physician group” (IG) or an “individual plus interdisciplinary group” (IIG) for an 18-month follow-up. Participants in the IG and IIG groups consulted the study physician every six months. In addition, the IIG group participated in an interdisciplinary group-based programme (≤ 10 participants, eight times (five hours per day)) over a period of three months. Outcome measures were changes in lifestyle according to established goals that have been shown to reduce incidence of T2D and to improve health. Furthermore, the influence of lifestyle changes on health-related quality of life (HRQOL) was assessed by Short Form 36 (SF-36), and the predictive ability for successful lifestyle change of the score of the Sense of Coherence (SOC) questionnaire at baseline was explored.

Findings: Two hundred and thirteen participants, 50% men, were included in the study, of whom 182 (85%) completed it. At baseline, their mean age was 46.5 years (SD 11 years), their mean BMI was 36.8 (SD 6), 90% were obese, 60% had an unhealthy diet, more than 50% had poor aerobic capacity, and 25% smoked daily. The participants at baseline reported clinically important lower HRQOL compared with the general Norwegian population. The 15% of subjects who dropped out

differed significantly at baseline from the completers, with an even higher frequency of unhealthy lifestyle characteristics, an even lower HRQOL, a younger age, and reported clinically significantly lower SOC scores.

From baseline to follow-up, there were no statistically significant additional effects or trends of group intervention on lifestyle change. Of all included participants, one in four achieved a clinically important weight loss, one in five achieved a clinically important improvement in aerobic capacity and one in eight reached both goals, regardless of group allocation. Reaching the two most important goals - i.e., a 5% weight loss and 10% improved aerobic capacity, was defined as a successful lifestyle change, was achieved by 26 participants and was best predicted by a high baseline SOC score. Of these 26 participants, one was in the lowest SOC tertile, four were in the medium tertile and 21 were in the highest tertile.

In the whole study population, no clinically important change in mean HRQOL scores was seen from baseline to follow-up. However, a moderate or large clinical improvement in HRQOL was achieved by one in three participants, best determined by a small weight loss combined with a small improvement in aerobic capacity.

Conclusions: Subjects referred from GPs for being at risk of T2D had surprisingly high BMI, reported a high prevalence of unhealthy lifestyle parameters and had markedly lower HRQOL than the general Norwegian population. Clinically important healthy lifestyle changes could be achieved with modest clinical efforts. A group intervention yielded no additional effects. Among the observed lifestyle changes, a small weight loss and a small improvement in aerobic capacity were best correlated with improved HRQOL. The baseline SOC score can predict a successful lifestyle change, and we recommend that health care professionals use this score to screen all patients on one occasion. The SOC score may increase the health care professionals' awareness of the patients' mastery levels and thereby improve the chances of important future health outcomes. It can assist them to achieve an advantageous categorizing of their patients, which can be important for the choice of further treatment for those patients.

List of publications

The thesis is based on the following papers.

Paper I

Nilsen V, Bakke PS, Gallefoss F. Effects of lifestyle intervention in persons at risk for type 2 diabetes mellitus—results from a randomised, controlled trial. *BMC Public Health* 2011;11:893–901

Paper II

Nilsen V, Bakke PS, Rohde G, Gallefoss F. Predictors of health-related quality of life changes after lifestyle intervention in persons at risk of type 2 diabetes mellitus. *Qual Life Res* 2014;23:2585–93

Paper III

Nilsen V, Bakke PS, Rohde G, Gallefoss F. Is sense of coherence a predictor of lifestyle changes in subjects at risk for type 2 diabetes? *Public Health* 2015;129:155–61

Abbreviations

BMI	body mass index
CAD	coronary artery disease
CI	confidence interval
CVD	cardio-vascular diseases
DBP	diastolic blood pressure
DPP	Diabetes Prevention Program (USA)
DPS	Diabetes Prevention Study (Finland)
FINDRISC	The Finnish Diabetes Risk Score
FHD	family history of diabetes
GP	general practitioner
HRQOL	health-related quality of life
IFG	impaired fasting glucose
IGM	impaired glucose metabolism
IGT	impaired glucose tolerance
ITT	intention to treat
MCS	mental component summary
NNT	number needed to treat
OGTT	oral glucose tolerance test
OR	odds ratio
PCS	physical component summary
QOL	quality of life
RCT	randomised controlled trial
SBP	systolic blood pressure
SD	standard deviation
SES	socio-economic status

SF-36 the Short Form 36 (questionnaire for HRQOL)

SOC sense of coherence

T2D type 2 diabetes

Contents

SCIENTIFIC ENVIRONMENT	2
ACKNOWLEDGEMENTS.....	3
ABSTRACT.....	5
LIST OF PUBLICATIONS.....	7
ABBREVIATIONS	8
CONTENTS	10
1. BACKGROUND.....	13
1.1 THE DIABETES EPIDEMIC	13
1.2 LIFESTYLE INTERVENTION EFFECTIVELY PREVENTS T2D	14
1.3 HEALTH-RELATED QUALITY OF LIFE.....	15
1.4 THE THEORY OF SALUTOGENESIS.....	16
1.5 THE LOCAL STORY BEFORE STARTING THE STUDY	17
2. AIMS OF THE THESIS	19
3. MATERIALS AND METHODS.....	20
3.1 STUDY POPULATION	20
3.2 THE FIRST CONSULTATION.....	20
3.3 DESIGN OF THE STUDY AND THE INTERVENTION AFTER THE FIRST CONSULTATION.....	23
3.4 ASSESSMENTS	24
3.4.1 <i>Demographic and clinical variables</i>	25
3.4.2 <i>Diet quality</i>	25
3.4.3 <i>Aerobic capacity</i>	26
3.4.4 <i>HRQOL</i>	26

3.4.5	<i>Mastery</i>	27
3.4.6	<i>Outcome measures</i>	28
3.5	STATISTICS.....	29
3.6	ETHICS	30
4.	SUMMARY OF RESULTS	31
4.1	BASELINE FINDINGS	31
4.2	FINDINGS FROM BASELINE TO FOLLOW-UP	34
4.2.1	<i>Article 1</i>	34
4.2.2	<i>Articles 2 and 3</i>	35
5.	DISCUSSION	38
5.1	METHODOLOGICAL CONSIDERATIONS	38
5.1.1	<i>Validity and study design</i>	38
5.1.2	<i>Internal validity</i>	38
5.1.3	<i>External validity</i>	40
5.1.4	<i>Reliability</i>	41
5.1.5	<i>Identifying subjects at risk</i>	42
5.1.6	<i>The unblinded study physician present for both study groups</i>	42
5.1.7	<i>Study strengths and limitations</i>	43
5.2	DISCUSSION OF SOME OF THE MAIN RESULTS.....	43
5.2.1	<i>Why was there no additional effect of group intervention?</i>	43
5.2.2	<i>Drop-outs</i>	45
5.2.3	<i>Socio-economic status</i>	46
5.2.4	<i>What can explain the improved HRQOL?</i>	48
5.2.5	<i>The predictability and future use of the SOC questionnaire</i>	50

6.	CONCLUSIONS.....	55
7.	PERSPECTIVES.....	56
8.	REFERENCES.....	60
9.	LIST OF ERRORS.....	69
10.	APPENDIX I-V.....	70

1. Background

1.1 The diabetes epidemic

The prevalence of diabetes, of which type 2 diabetes (T2D) accounts for around 90%, is increasing at an alarming rate worldwide, with an estimated doubling of the number of people with diabetes between the years 2000 and 2030 (1-3). This estimated increase will continue even if levels of obesity remain constant, which implies that this may be an underestimate of future diabetes given the increasing prevalence of obesity (1). More than half the European population will suffer from hyperglycemia or T2D during their lifetime (4). The onset of T2D is gradual, with most individuals progressing through a pre-diabetic high-risk state of hyperglycemia; either impaired fasting glucose (IFG, fasting plasma glucose 5.6 to 6.9 mmol/l) or impaired glucose tolerance (IGT, a 2 h plasma glucose 7.8 to 11.0 mmol/l) two hours after an oral load of 75 g dextrose (WHO definition). There is an increasing incidence of T2D from the lowest to the highest quartile of IFG (5, 6). Approximately 50% of people with IGT will progress to T2D within 10 years if untreated (7). Subjects with IGT have a higher risk of developing cardio-vascular diseases (CVD) compared with those with IFG (8). Life expectancy can be shortened by as much as 15 years by T2D, with up to 75% of patients dying of macro-vascular complications (3). This represents a huge public health problem. There is a genetic predisposition for T2D, with five to 10 times greater lifetime risk for people with a first-degree family member with T2D compared with a person with no family history (9). The likelihood of developing T2D is greater in certain ethnic groups, such as people of South Asian and African descent (10). However, T2D is essentially a lifestyle disease that is strongly linked to obesity and inactivity (11). The World Health Organization published its first Report on the Prevention of Diabetes Mellitus in 1994 (12).

Strongly related to this diabetic epidemic is physical inactivity, which is widespread in the population. It is estimated to account for 12% of all deaths in the USA and

considered to be one of the most crucial public health problems (13). Maximal oxygen uptake and exercise test duration represent the strongest predictors of mortality (13). This means that if a physician wants to measure one single property or value for patients to stratify them regarding their future health, properties like blood pressure and blood lipids are far less predictive than an exercise test.

1.2 Lifestyle intervention effectively prevents T2D

In the Finnish Diabetes Prevention Study (DPS), 523 overweight subjects with impaired glucose tolerance (IGT) were randomised to either a control or an intervention group (14). The aim of the study was to investigate whether T2D could be prevented by interventions that affect the lifestyles of subjects at high risk. In the intervention group, the subjects were given detailed advice about how to achieve the goals of the intervention; i.e., i) a reduction in weight of 5% or more, ii) a total intake of fat less than 30% of energy consumed, iii) an intake of saturated fat less than 10% of energy consumed, iv) an increase in fibre intake to at least 15 g per 1000 kcal and v) moderate exercise for at least 30 minutes per day. Furthermore, frequent ingestion of whole-grain products, vegetables, fruits, low-fat milk and meat products, soft margarines, and vegetable oils rich in monounsaturated fatty acids was recommended. The results from Finland after a mean duration of follow-up of 3.2 years were impressive, with a cumulative incidence of T2D of 11% (95% confidence interval (CI), 6%-15%) in the intervention group and 23% (95% CI, 17%-29%) in the control group. This means that the risk of diabetes was reduced by 58% in the intervention group and seemed to be strongly associated with changes in lifestyle. About one in three of those participants who did not achieve any of the goals had developed T2D by the one-year follow-up visit, whereas none of the subjects who reached four or five goals developed T2D, regardless of their randomisation group. Similar findings were published from the US for the Diabetes Prevention Program (DPP) one year later in 2002, where 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations were randomly assigned to placebo,

metformin (850 mg twice daily) or a lifestyle-modification programme with the goals of at least a 7% weight loss and at least 150 minutes of physical activity per week (15). The average follow-up was 2.8 years. The lifestyle intervention reduced the incidence of T2D by 58% (95% CI, 48%-66%), and metformin reduced it by 31% (95% CI, 17%-43%) compared with placebo. The lifestyle intervention was significantly more effective than metformin, with an estimated cumulative incidence of diabetes at three years of 29%, 22% and 14% in the placebo, metformin and lifestyle-intervention groups, respectively.

Both the DPS from Finland and the DPP from the US found a relative reduction in the incidence of T2D of 58% in subjects at high risk of diabetes. At baseline, mean body mass index (BMI) was 31 in Finland and 34 in the US. A very interesting, and in my opinion surprising, finding was the small weight loss associated with these results. The mean weight loss in the Finnish study was 3.5 kg in the intervention group and 0.9 kg in the control group, while in the US study the average weight loss was 0.1 kg, 2.1 kg, and 5.6 kg in the placebo, metformin and lifestyle-intervention groups, respectively (14, 15). A moderate weight loss combined with a moderate increase in physical activity was found to halve the incidence of T2D in high-risk subjects.

1.3 Health-related quality of life

Evaluation of morbidity and mortality is no longer sufficient to evaluate all aspects of an individual's life within the health context. Subjective patient-reported outcomes, such as quality of life (QOL) assessments, are often included in clinical studies as supplements to analysis of objective factors (16). A modest correlation between objective health measures and QOL has been shown (16). QOL can be divided into three levels: i) the individual's overall satisfaction with life, ii) several broad health domains, and iii) disease-specific domains (17). The concepts at each level are significantly integrated, and one level can impact on the others (16, 17). Health-related quality of life (HRQOL), i.e. level two, is the focus of this thesis. A variety of

illnesses and even symptoms of preclinical, undiagnosed diseases are captured by HRQOL (18). Aspects such as housing, financial status and environment are excluded, while the most common basic components of HRQOL are functional status, well-being and general health. Functional status reflects an individual's self-reported perception of his or her physical, psychological and social functioning (19).

As a physician, I have experienced statements from patients, colleagues and friends who say things like "quality of life for me is to smoke, relax and eat the food I want to eat". Could working with lifestyle change among subjects at risk of T2D decrease their HRQOL? Numerous studies have demonstrated that obese persons experience significant impairment of HRQOL as a result of their obesity, with greater impairment associated with greater degrees of obesity (19). Obese subjects not seeking treatment have the best HRQOL, those seeking conservative treatment have a more moderate HRQOL and those seeking surgery have the worst HRQOL (20, 21). A variety of treatments in obese persons undergoing weight loss have been shown to improve HRQOL (19, 22). Lifestyle interventions aimed at reducing cardio-vascular risk factors improve both quality of life and patient satisfaction (23). HRQOL is an important issue that is recommended to be included in weight management treatment and research (19, 24).

1.4 The theory of salutogenesis

As a reaction to the one-sided focus on pathogenesis in health research, Aron Antonovsky created the concept of salutogenesis (*salute*: of health, *genesis*: the origins) (25). He studied a group of individuals who stayed healthy despite experience of the concentration camps of the Second World War. The theory of salutogenesis represents a broad perspective on health; i.e., health is not a dichotomous variable but rather represents a continuum. The story of the individual, rather than the diagnosis or risk factors, is the focus. Use of potential or existing resistance resources and active adaptation is stressed as the ideal in treatment (25). Antonovsky was intrigued and raised the salutogenic question of why these

imprisoned people were able to stay healthy. He postulated that it was because of the way that they viewed their life, and three components emerged from his research: the ability of people to understand what happens around them (comprehensibility), the extent to which they were able to manage the situation on their own or with significant others in their network (manageability) and their ability to find meaning in the situation (meaningfulness). These three components formed the concept of sense of coherence (SOC). I questioned whether the SOC concept would influence the ability to make lifestyle changes in subjects at risk of T2D. Was it possible to identify at baseline subjects who are most likely to benefit from lifestyle intervention?

1.5 The local story before starting the study

My great interest in “lifestyle medicine” started early in my career but escalated when I read The Lyon Diet Heart Study (26). In this study, a Mediterranean-type diet was compared with a prudent Western-type diet in a randomized, single-blind design for patients who survived their first myocardial infarction. The results after 46 months were impressive. Subjects following the Mediterranean-style diet had a 50% to 70% lower risk of recurrent heart disease, despite a similar coronary risk factor profile (plasma lipids and lipoproteins, blood pressure, body mass index and smoking status). These findings illustrate that factors beyond lipids and lipoproteins, which have historically been our primary targets of intervention, have great potential. A dietary pattern that emphasizes fruits, vegetables, breads and cereals, fish and α -linolenic acid was thought to be responsible for the effects (27). In my opinion, two important consequences of this study were: i) patients had a great opportunity to influence their own treatment and ii) the message that “small, simple changes create great results” was established. This latter point was further highlighted in the DPS and DPP studies, where a mean weight loss of 3-5 kg combined with a moderate increase in physical activity more than halved the incidence of T2D in high-risk subjects. These three studies created the basis for the happy message that “small, simple changes create great results”. I clearly remember how these results inspired

me and how they convinced me to try to implement interventions for nutrition and physical activity as a part of the treatment in the hospital in which I worked. The clear statement of my boss, Pål Friis, on this was: “you have to make this a project and evaluate your results”. Without knowing the implications of what this meant, I started planning my project together with my supervisor Frode Gallefoss. Prevention of T2D was seen as an opportunity, because an alarming increase in the prevalence of T2D was expected in both industrialized and developing countries (28). The challenge as I saw it was to transfer the good results from the high-risk strategy prevention trials to population-based strategies. Comprehensive lifestyle interventions like DPS (seven face-to-face counselling sessions during the first year and every 3 months thereafter plus voluntary free-of-charge supervised exercise sessions in the gym) and DPP (16 face-to-face counselling sessions delivered over 24 weeks with monthly follow-up), have limited generalisability. Therefore, low-intensity lifestyle interventions in the real world had to be tested for their effectiveness.

My father was imprisoned in Buchenwald, one of Adolf Hitler’s concentration camps of the Second World War from January 1944 to March 1945. He survived with no visible physical injuries, and my experience is that this stay under horrendous conditions gave him perspectives that actually enriched his life. He said many times: “most problems I met later in life were small ones”. My curiosity about how mastery and coping could influence the experience of “a good life” was awakened.

The publication of the results from this study has been delayed partly because in 2005, Sørlandet Hospital gave me the assignment of establishing interdisciplinary treatment for patients with morbid obesity. This work has taken much of my time since then but has given me further experience in the field of working with lifestyle changes among obese patients. My own experience through these years is that the findings and the theme of this project have not “gone out of date”.

2. Aims of the thesis

The overall aim of this project was to assess the degree of lifestyle change in subjects at risk of T2D after lifestyle counselling at two different intensities.

Aims:

1. To assess, in a real-life setting by a randomised, controlled trial, the effects of a low-intensity individual lifestyle intervention by a physician versus the same physician intervention combined with an interdisciplinary, group-based approach (Paper I).
2. To assess the health-related quality of life (HRQOL) of subjects at risk of T2D undergoing lifestyle intervention and to find predictors for improved HRQOL (Paper II).
3. To determine whether the Sense of Coherence (SOC) questionnaire at baseline could predict the outcome of this lifestyle intervention programme (Paper III).

3. Materials and methods

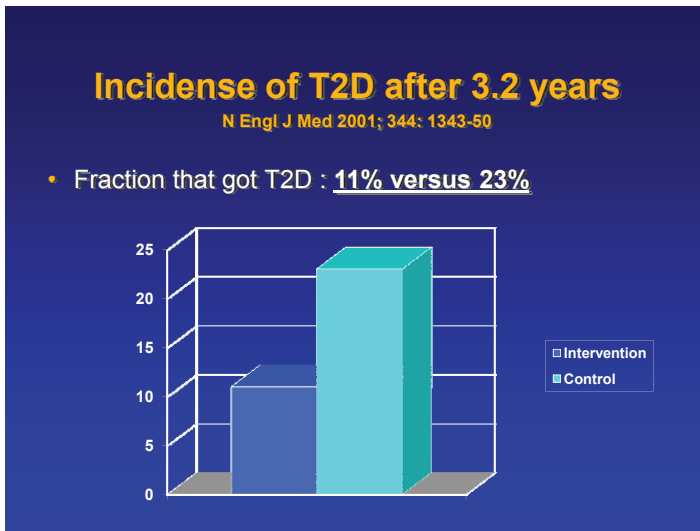
3.1 Study population

The seven-item “Finnish Diabetes Risk Score” (FINDRISC) was used to identify subjects at high risk of T2D. This score is a simple, fast, inexpensive and non-invasive tool for identifying subjects at high risk for T2D (29). It assesses waist circumference, body mass index (BMI), age, medication against high blood pressure, activity level, history of high blood glucose and daily consumption of vegetables/fruits. FINDRISC has been shown to be a good predictor of coronary artery disease (CAD), stroke and total mortality, which means that it has the ability to select subjects with multiple risks (30). The total score ranges between 0 and 20. A FINDRISC ≥ 9 is found to identify $> 70\%$ of new cases of drug-treated T2D within five years (29). However, the positive predictive value of a score ≥ 9 for T2D is low: 0.13 and 0.05 in two different cohorts (29). This means that in a cohort with a score ≥ 9 , most subjects will not develop T2D. However, subjects with a score ≥ 9 will still profit from a healthier lifestyle. Hence, all general practitioners (GPs) in the four nearest municipalities to the Sørlandet Hospital Kristiansand were each supplied with 10 FINDRISC-questionnaires by post and asked to use them for patients at risk of T2D. They were requested to refer individuals aged 18-64 with a FINDRISC ≥ 9 to the hospital.

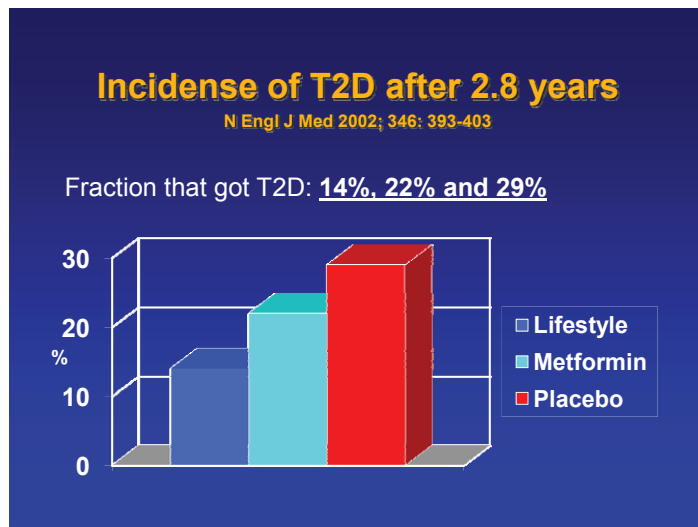
3.2 The first consultation

All referred subjects were assessed by the same physician—i.e. the writer of this thesis—in a clinical examination. It included a thorough discussion of their family history of diabetes and heart disease, as well as assessment of their tobacco and alcohol consumption. They were told that they were at risk of T2D and that scientific studies have shown that changes in lifestyle such as losing weight and increasing

physical activity can reduce this risk. They were told about the method used in the DPS. All subjects were then shown this Power Point diagram outlining the main results from the DPS.



We agreed that this finding might not be a surprising one because the intervention group received more help than the control group. However, I then asked them a question that in my experience “woke up” the subjects. I asked: “how many kg do you think the subjects in the intervention group had to lose to achieve these great results?” A common reply to that question was “20 kg”. This indicates that most subjects in this study, and maybe also in the community, believe that you have to make big lifestyle changes to achieve health effects. They were really surprised when I told them that the mean weight loss was 3.5 kg and that this mean weight loss was only 2.4 kg more than that in the control group. I thereafter “sold” them the message that “small, simple changes create great results”. This statement was followed by confirmation that comparable results were also found in another study from another country, then by showing this Power Point diagram of the main results from the DPP.



I told them that the mean weight loss in the lifestyle group was 5.6 kg, confirming that great health effects are achievable after moderate weight loss. I emphasized that in addition, the results of both studies were strongly dependent on a moderate increase in physical activity.

Finally, the following information, statements and advice were given:

1. The probability of T2D can be reduced by 50% with only small changes in lifestyle.

2. The same changes can considerably reduce the probability of heart disease.

3. The following advice was emphasized.

- Increase consumption of fruit and vegetables.
- Have at least 30 minutes of activity per day.
- Achieve at least 5% weight loss.
- Reduce the consumption of sugar and saturated fat.
- Use oil as the main source of fat.

-
- Consume cod-liver oil daily.

At the end of the consultation, participants were asked whether they wanted to participate in the study. Exclusion criteria were: a known diagnosis of diabetes mellitus, the presence of serious heart, lung, kidney or liver failure, serious psychiatric illness, substance abuse and lack of fluency in the Norwegian language. Written informed consent was obtained. Participants were randomly assigned to an “individual physician group” (IG) or an “individual plus interdisciplinary group” (IIG) by use of a closed-envelope method with unknown block sizes. All GPs received written information about inclusion, group allocation and aims, and the advice given.

3.3 Design of the study and the intervention after the first consultation

This was a randomised controlled trial (RCT) of which the results are presented in paper I. However, because there were no statistically significant differences or trends between intervention groups, the results in papers II and III are presented as a longitudinal cohort study with changes from start to follow-up. This was done to increase the readability of the work.

Participants in the IG group consulted the study physician at 6, 12 and 18 months after randomisation and otherwise received care from their GP as usual. The study physician used elements of motivational interviewing during these consultations, a well-known, scientifically tested method when counselling clients and considered to be a useful intervention strategy in the treatment of lifestyle problems and disease. A systematic review and meta-analysis of randomised controlled trials shows that motivational interviewing in a scientific setting outperforms traditional advice given during treatment of a broad range of behavioural problems and diseases (31). In addition to the intervention stated for the IG group above, the IIG group participated in a group-based programme (≤ 10 participants), one day (five hours per day) each

week for six weeks and a new gathering after 12 weeks. Issues of importance for the participations' success in lifestyle change were emphasized. The participants' level of knowledge and self-consciousness were improved, including information about how to avoid diabetes and CAD. The topics for these group sessions were research findings and factual information about nutrition and physical activity, habit change, ambivalence, action plans, risk situations, coping strategies, etc. The group intervention also included a variety of physical training, one hour for each group session day. The IIG programme was interdisciplinary with a dietician, a physiotherapist, an ergonomist, a nurse and a physician who all utilised motivational interviewing techniques. An individual 30-minute consultation with a nurse or ergonomist completed the intervention one month after the last group meeting.

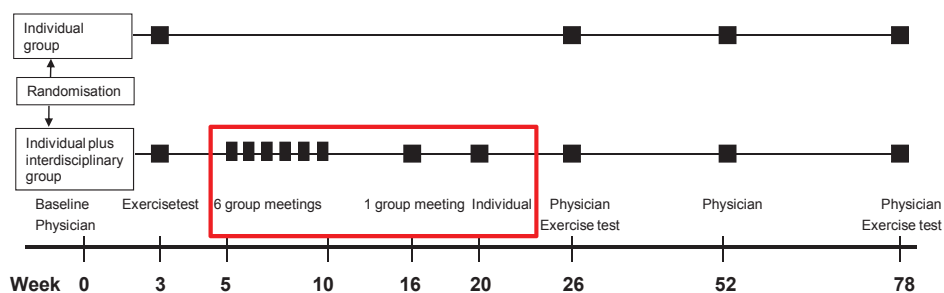


Figure 1: Overview of the study design with the additional intervention for the IIG shown in the red box.

3.4 Assessments

The following measurements were used in this thesis:

- Demographic and clinical characteristics
- The Smart Diet Score questionnaire to assess diet quality
- Physical test on a treadmill to assess aerobic capacity

-
- The Short Form 36 Health Survey (SF-36) to assess HRQOL
 - The SOC 13 item questionnaire to assess mastery

3.4.1 Demographic and clinical variables

The demographic variables included age, sex, education (in three categories: primary, secondary and high school/university, of which the two first are defined as “low education” and the last as “high education”), employment status (two categories: “at work” and “not at work” (disabled, sick leave, unemployed) and marital status (two categories: living alone and married/cohabiting). Smoking habits were classified as current smoker, occasional smoker and non-smoker. Heredity for T2D, overweight/obesity, CAD and cancer were classified as present if at least one first-degree relative had been diseased. Use of medication including anti-hypertensives, statins, acetyl salicylate, anti-depressants, anxiolytics, anti-diabetics and weight-reducing drugs were also assessed.

At every visit to the study physician, the following assessments were performed: fasting blood sample, systolic and diastolic blood pressure (SBP and DBP), waist circumference to the nearest cm at a level midway between the lowest rib and the iliac crest, height without shoes to the nearest cm (only first visit) and weight in indoor clothes to the nearest 100 g. Blood pressures were measured with an Omron M41 and weight with a Seca 771. An oral glucose tolerance test (OGTT), required to rule out diabetes and to identify patients with IGT, was not performed either prior to or during the study. Unlike the DPS and DPP, we did not use OGTT because my basic attitude was that subjects would profit from lifestyle changes irrespective of their OGTT outcome. Lifestyle changes to achieve improvements in general health were the main issue.

3.4.2 Diet quality

In nutritional research, the problem of how to measure habitual food intake in studies of obesity remains a challenge, with under-reporting being one of many problems

(32). We considered weight changes to be the best way to overcome the problem with under-reporting. We wanted to be able to recognize if the constituents of the usual diet of the subjects did change during the study, and for this purpose, we used the Smart Diet Score questionnaire. This is a simple self-administered questionnaire with 15 questions that provides a good estimate of dietary fat and fibre but is less accurate in terms of the intake of vegetables, fish and snacks (33). The final diet score ranges between 15 and 45 points, with a score between 15 and 29 points categorized as “unhealthy”, between 30 and 37 points as “somewhat unhealthy” and ≥ 38 points as a “healthy” (33). A question was added to the questionnaire to ascertain the number of days on which cod-liver oil was consumed during the previous week. Cod-liver oil is the one and only dietary supplement that is recommended for all citizens in Norway older than six weeks.

3.4.3 Aerobic capacity

A physical test on a treadmill was carried out during the first month after randomisation and repeated after six and 18 months to determine maximal aerobic capacity (VO₂max), utilising a modified Bruce protocol designed for people in poor physical condition (34). The results were categorized into six levels according to the normative data for VO₂max for sex and age: very poor, poor, fair, good, excellent and superior aerobic capacity (35). An increase in exercise capacity of 3.5 ml/kg/min (one metabolic equivalent (MET)) has been shown to be associated with a 12% improvement in survival in healthy men (36).

3.4.4 HRQOL

HRQOL was assessed at baseline and then at 6 and 18 months using the Medical Outcomes Survey, Short Form 36 (SF-36), version 1. This is a generic quality-of-life instrument that has been extensively tested nationally and internationally, and has satisfactory reliability and validity. The SF-36 has proven applicability to both healthy subjects and patients with medical conditions, thereby making it possible to

draw comparisons between patients and a general population (37, 38). Normative data from the general Norwegian population (n = 4,444) were used for comparison (39). The answers from the 36 items are coded into eight domains: four are interpreted as physical indicators (general health perception (GH), physical functioning (PF), role limitation physical (RP) and bodily pain (BP)) and four as mental health indicators (mental health (MH), social functioning (SF), vitality (VT) and role limitation emotional (RE)). The eight domains are transformed to a scale of 0-100, in which 0 is the worst possible and 100 is the best possible health state (37). Norwegian SF-36 norm data for the age group were used to aggregate the two summary scales from z-score transformations of the eight domains, a physical component summary (PCS) and a mental component summary (MCS) (38). These summary scales are standardized, to achieve a mean score of 50 and a standard deviation of 10 in the general population. Scores above 50 represent better functioning compared with the general population and vice versa. Changes (Δ values) in the eight domains and two summary scores were calculated by subtracting the baseline value from the follow-up value, i.e., a positive value implies an improvement, whereas a negative value implies a worsening of HRQOL.

3.4.5 Mastery

The instrument used to measure mastery at an individual level was the SOC 13 item questionnaire. SOC-13 has been shown to be reliable, valid, feasible and cross-culturally applicable, and the questionnaire examines Antonovsky's postulated properties for salutogenesis (40). Subjects were asked to indicate their level of agreement with each of the items on a seven-point scale (1 = never, 7 = always). The total score was summed and could range from 13 (low SOC) to 91 (high SOC), where a higher score indicated a stronger SOC or mastery. SOC was only measured at baseline because we wanted to explore its predictive value. Furthermore, mastery is known to be stable in the same person over short time intervals, although not as stable as Antonovsky assumed (40).

3.4.6 Outcome measures

Primary outcomes were changes in lifestyle according to established goals that have been shown to reduce incidence of T2D, to improve health and to improve cardiovascular risk profile. These were defined as:

- weight reduction $\geq 5\%$ (41, 42),
- reduction in waist circumference of ≥ 5 cm (43, 44), and
- improvement in exercise capacity of one MET (3.5 ml/kg/min) or a 10% improvement (36, 45).

In addition, two more “soft” outcomes regarding dietary changes were evaluated:

- consumption of cod-liver oil \geq five days per week (46, 47), and
- ≥ 4 point increase in Smart Diet Score. The outcome for this diet change is an arbitrary threshold that is not evidence based. It reflects an improvement in four of 15 areas of diet.

Of these outcome measures, weight reduction (correlates with waist circumference reduction) and improvement in exercise capacity were seen as better outcome measures than the dietary changes because they are objective in contrast to the less reliable questionnaire-based information on dietary changes.

One of the challenges of studying HRQOL is that improvements that are statistically significant nevertheless can be of little clinical relevance (48). Even though evaluating clinically significant HRQOL changes is a complex issue, clinically important changes were the primary outcomes (49). On a 100-point scale, mean score changes of 5–10 points were considered to be small, changes of 10–20 points were considered to be moderate and changes of > 20 points were considered to be large, as reported in previous publications (49, 50). Furthermore, regarding the summary scales (PCS and MCS), a 2–5 point change was considered to be small, a 5–8 point

change was considered to be moderate and a ≥ 8 point change was considered to be large, corresponding to effect sizes of 0.20–0.49, 0.50–0.79 and ≥ 0.80 (38, 49).

3.5 Statistics

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) versions 16 and 18.

The power calculation of study size was performed based on an estimated drop-out rate of 15%-20%, a spontaneous rate of achieving the lifestyle outcomes of about 20% and a difference between the intervention groups of at least 20%. This last assumption corresponds to a “number needed to treat” (NNT) of 5. On the basis of these assumptions, with a power $> 80\%$ ($\beta \leq 0.20$), a significance level α (p) ≤ 0.05 , and a two-sided test, the appropriate study size was calculated to be 200 participants, with 100 in each group.

Continuous variables were tested for normality, were compared using Student’s t-test and are presented as mean and standard deviation (SD) as the central tendency and dispersion measures, respectively. Pearson’s chi-square test was used to assess the differences between groups when variables were categorical, and the McNemar test was used when testing within-group changes from baseline to follow-up. A paired t-test was used for comparisons of quantitative data between baseline and follow-up at 18 months.

In paper II, simple linear regression analyses and multiple linear regression analyses (GLM procedure in SPSS) were applied to identify significant predictors for changes in HRQOL from baseline to follow-up, with adjustment for baseline HRQOL values in the multiple analyses. Independent variables in the multiple regression analyses were selected based on both clinical experience and findings from a study showing that socio-demographic variables (age, sex, living conditions and education) influence HRQOL (51). Furthermore, the relative importance of weight loss and improved fitness in the improvement in HRQOL, achieving the weight goal alone,

achieving the aerobic capacity goal alone and the two combined were tested in the multiple linear regression analyses. To strengthen the analyses for the combined lifestyle achievement, multiple logistic regression analyses were also performed using the same independent variables: these yielded odds ratios (ORs) indicating at least a small, clinically significant change in HRQOL as the dependent variable.

To produce a prognostic model of successful lifestyle change in paper III, a multivariable logistic regression analysis was conducted. Achievement of the combined objective clinically important lifestyle changes (both weight loss $\geq 5\%$ and increased fitness $\geq 10\%$) was set as the dependent variable, with the various demographic and clinical variables, the SF-36 summary scores and the SOC scores as explanatory variables. Enter, forward and backward methods were tested, and in the final adjusted model, the 'enter' method was used, including all of the independent variables in the model regardless of the level of significance obtained for each separate variable. Unadjusted multivariate logistic regression analyses were also performed for comparison, where the odds ratios (ORs) were used to describe the bivariate associations. Based on this multivariate logistic regression analysis, a receiver operating characteristic (ROC) curve was constructed, and the area under the curve (AUC) was used to assess the sensitivity and specificity of the combined predictors.

3.6 Ethics

This study was approved by the Regional Committee for Medical Research Ethics of southern Norway and was conducted according to the principles of the Declaration of Helsinki. All patients gave their written consent.

4. Summary of results

4.1 Baseline findings

From March 2004 to September 2005, the GPs referred 234 subjects at risk for T2D based on a FINDRISC ≥ 9 , of whom 213 (91%) were included in the study and 182 (85% of included) completed the study.

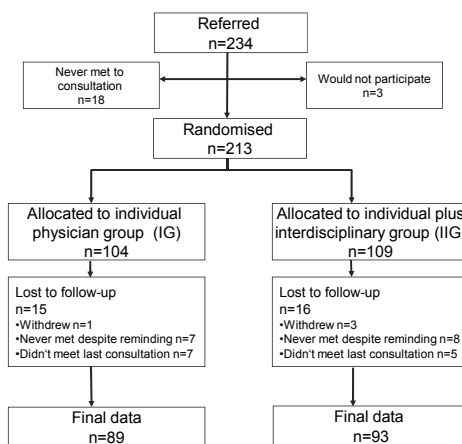


Figure 2: Flow of participants through the trial.

At baseline, the incidence of obesity was 90%, and the mean BMI was 36.8 (SD 6), considerably higher than those in the DPS and DPP studies. The participants reported clinically significantly lower HRQOL than did the general Norwegian population on all eight domains of the SF-36 and on the PCS and MCS summary scales. The reported HRQOL was comparable to that of patients undergoing bariatric surgery. Only small proportions of participants had good (or better) aerobic capacity or were eating a healthy diet. Randomisation seemed to be successful for all baseline variables except for BMI and the use of anti-hypertensive drugs: the IG group had significantly lower BMI and used significantly fewer anti-hypertensive drugs than the IIG group.

Table 1: Baseline characteristics of patients included in the study, stratified by randomisation status. Values are presented as means with standard deviation (SD) in parentheses, unless stated otherwise.

	IG n = 104	IIG n = 109
Age	45.9 (11)	47.0 (11)
Sex, male, %	53	47
Married or cohabiting, %	79	69
Basic education (%): Primary	15	16
Secondary	58	55
High school/university	27	29
Employed, %	64	61
Long term sick leave/disabled, %	30	33
Daily smoker, %	27	23
Weight measures		
• Weight, kg (SD)	111.5 (22)	113.0 (22)
• Body mass index (BMI), kg/m ²	35.9 (5.7) *	37.6 (6.2) *
• BMI > 30, %	87	93
• Waist circumference, cm	118 (14)	120 (15)
Fasting serum blood tests.		
• Glucose (mmol/l)	5.5 (0.8)	5.6 (0.8)
• HbA1c	5.7 (0.4)	5.6 (0.4)
• Total cholesterol (mmol/l)	5.5 (1.1)	5.3 (1.1)
• HDL-cholesterol (mmol/l)	1.18 (0.31)	1.25 (0.41)
• Triglycerides	1.9 (0.9)	1.8 (1.3)
Blood pressure mmHg		
• Systolic	144 (18)	144 (20)
• Diastolic	90 (11)	89 (11)
Aerobic capacity		
• O ₂ uptake ml/kg/min	27.6 (7.8)	26.1 (7.4)
• Poor or very poor aerobic capacity, %	57	53
• Good, excellent or superior aerobic capacity, %	26	23
Diet		
• Smart Diet score	29 (4)	29 (4)
• Healthy diet, %	2	1
• Somewhat unhealthy diet, %	38	39
• Unhealthy diet, %	61	60
• Days per week using cod-liver oil	1.7 (2.8)	1.7 (2.9)
• Cod-liver oil ≥ 5days a week, %	24	24
Heredity for: **		

• Type 2 diabetes, %	22	29
• Overweight or obesity, %	36	41
Medication		
• Anti-hypertensive, %	29 *	42 *
• Statins, %	16	20
• Acetyl salicylate, %	16	17
• Anti-depressants, %	11	6
• Anxiolytic, %	0	0
• For weight reduction, %	10	5
HRQOL		
• Bodily pain	63 (29)	56 (28)
• General health (GH)	59 (25)	56 (23)
• Physical function (PF)	76 (20)	74 (19)
• Physical role limitation (RP)	66 (40)	61 (41)
• Mental health	74 (20)	73 (17)
• Social function (SF)	79 (28)	79 (24)
• Vitality (VT)	48 (23)	46 (22)
• Emotional role limitation (RE)	74 (38)	78 (37)
HRQOL summary scores		
• Physical component summary (PCS)	43 (11)	40 (12)
• Mental component summary (MCS)	47 (14)	48 (12)
Sense of coherence		
• SOC score	63 (14)	63 (13)

* Inter-group differences with $p < 0.05$ based on chi-square test for categorical variables and independent sample t-test for quantitative data. ** Heredity: at least one first-degree relative with the disease.

The 15% of subjects who dropped out differed significantly at baseline from the completers. Drop-outs were 3.8 years younger (43.2 versus 47.0 years), and more often on anti-depressants (23% versus 6%), and had higher BMI (38.9 versus 36.4), lower aerobic capacity (24.1 versus 27.2), lower diet score (27.5 versus 29.0) and twice the frequency of both daily smoking (50% versus 21%) and long term sick leave or disability (57% versus 28%), (all p values < 0.05). Furthermore, they reported clinically important deficits in all HRQOL domains, and their SOC scores were dramatically lower (49 versus 66, ($p < 0.001$)).

Low education at baseline (primary and/or secondary education only), present in more than two-thirds of participants, was associated with a poorer diet (2.2 points

lower ($p < 0.001$)), lower aerobic capacity (4.6 ml/kg/min lower ($p < 0.001$)) and more than twice the frequency of daily smoking (30% versus 12%, $p = 0.006$) compared with those with high education.

4.2 Findings from baseline to follow-up

4.2.1 Article 1

The IIG group attended on average five (5.2) of the seven group meetings, and 94% attended the final, individual consultation. The attendance at the final treadmill test was 62% of all included; i.e., 72% of completers. There were no statistically significant differences in the main outcome measures between the two study groups (Figure 3).

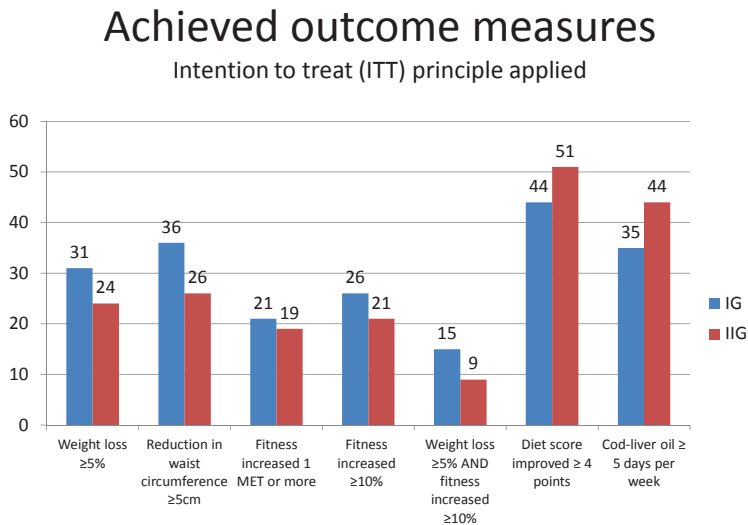


Figure 3: Success rate for the different outcome measures among all subjects included in the study, according to randomisation status.

When both intervention groups were pooled, the mean weight loss from baseline was modest: 1.9 kg (SD 5.6), 2.0 kg (SD 6.2) and 2.8 kg (SD 7.1), respectively, at 6-, 12-

and 18-month assessments; i.e., a mean weight loss of 2% (SD 6%) from the baseline to the follow-up. The mean increase in maximal aerobic capacity was 2.2 ml/kg/min (SD 3.8) and 2.3 ml/kg/min (SD 4.4), respectively, at 6- and 18-month assessments; i.e., a mean improvement in fitness of 9% (SD 25%) from the baseline to the follow-up. Most successful were the dietary changes, with nearly 50% making healthy dietary changes and a doubling in numbers of those using cod-liver oil at least 5 days per week. Of all included participants, about one in four achieved a clinically important weight loss, one in five achieved a clinically important improvement in aerobic capacity and one in eight reached both these goals.

4.2.2 Articles 2 and 3

When a successful, clinically significant lifestyle change was defined as both weight reduction $\geq 5\%$ and an improvement in exercise capacity of $\geq 10\%$ from baseline to follow-up, 26 participants could be defined as having been successful. This means a success rate of 12% of all included participants, 14% of completers and 20% of subjects with complete follow-up data. We found a statistically significant association between a successful lifestyle change and a low physical HRQOL at baseline, with an adjusted OR of 1.08 (95% CI 1.00-1.16) for each point decrease in the PCS score. However, the best predictor of success was a high total SOC score, with an adjusted odds ratio (OR) of 1.21 (95% CI = 1.11-1.32) for each additional SOC point. The distribution according to SOC tertiles among the 26 subjects who achieved success is shown in Figure 4.

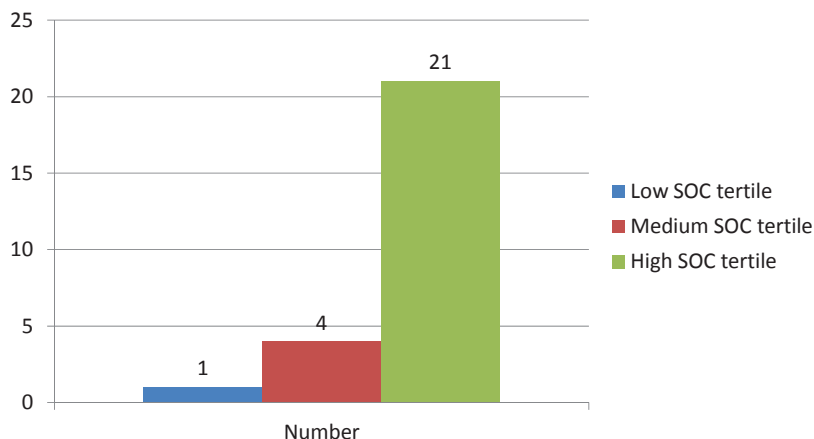


Figure 4: The 26 subjects who made successful lifestyle changes.

When comparing the success rate in the high SOC tertile group with the two other tertile groups combined, a highly significant difference was found ($p < 0.001$).

Among the participants with complete data, the proportions who succeeded were 3%, 8% and 44% in the low, medium and high SOC tertile groups, respectively. When the intention-to-treat principle (ITT) was applied, these proportions were 2%, 6% and 32%, respectively. On the basis of the data set from completers, the NNT to achieve one successful lifestyle change was 31, 13 and 2 in the low, medium and high SOC tertile groups, respectively. When applying the ITT principle, the corresponding NNTs were 67, 16 and 3.

The mean changes in all HRQOL scores were small and not of clinical importance. However, a moderate or large clinical improvement in HRQOL was achieved in one third of participants. The improvements in HRQOL were essentially achieved during the first 6 months and stabilised thereafter. Improved PCS was correlated with weight loss and improved fitness; i.e., 1.5 PCS points for every 5 kg lost and 3.4 points for every 5 ml of improvement in maximal aerobic capacity (ml O₂ uptake/kg/min). No significant correlations were identified for improved MCS. The best determinant for improved HRQOL was obtained using a composite measure for clinically significant

lifestyle change; i.e. both a weight reduction of at least 5% and an improvement in exercise capacity of at least 10%, which was associated with a clinically significant improvement in five of the eight SF-36 domains and in the PCS.

5. Discussion

5.1 Methodological considerations

5.1.1 Validity and study design

There is a need to consider the validity of the results. Validity is divided into internal validity (the validity of inferences drawn as they pertain to the subjects of the study) and external validity (the degree to which the results are applicable to other populations) (52). We used a randomised controlled trial (RCT) design, which is most appropriate for evaluating the efficacy of an intervention and also has favourable internal validity (53). However, because the results did not differ significantly between the two groups, most results are presented as a longitudinal cohort study with changes from baseline to follow-up. We believe that this increases the readability of the papers but realize that we have lost the benefits of the optimal design. Aspects of internal and external validity will now be discussed.

5.1.2 Internal validity

Internal validity is the extent to which we are able to say that no variables other than the intervention applied caused the result, i.e., it refers to the degree of control exerted over potential confounding variables to reduce alternative explanations for the effects of the treatment (54). Three major threats to internal validity are confounding variables, selection bias and information bias. In the field of study of lifestyle changes, we must admit that a number of external factors can influence the results; i.e., are confounding variables. Examples of such factors include advertising campaigns for different foods and confectionery, campaigns for health promotion, different neighbourhoods, which influence the ability for daily physical activity, participation in weight loss courses and support or opposition from close relatives. However, an RCT design should result in comparable study groups in terms of

measured and unmeasured variables other than the intervention itself (53), as shown for the measured values for the baseline characteristics (Table 1). In any case, the factors that influenced the results can be hard to define with certainty, although it is reasonable to assume that participation in this study was the cause. During an 18-month follow-up period, it is unusual to find a 2% mean weight loss and a 9% increase in maximal aerobic capacity in a group of people, even if 90% are obese and probably want to lose weight. In a population-based survey of obese men and women from Norway, the mean weight increase was 3.7 kg and 3.3 kg, respectively, during an 11-year follow-up (55). In non-obese individuals (overweight and normal weight), even higher weight gains were seen: about 4.3 kg in men and 5.0 kg in women.

A selection bias that is of special concern in this study is the “healthy volunteer bias”, a well-known phenomenon (56-58). This bias refers to the observation that subjects who volunteer to participate in a study tend to be healthier than non-volunteers. Thus, the study participants will not be representative of all subjects at high risk for T2D selected by the FINDRISC questionnaire, and most probably they will be more interested in, and motivated for, lifestyle changes. Self-selection bias, closely related to healthy volunteer bias, may also have occurred. Although self-referral was not allowed, we know that some participants who had heard about the study consulted their GP solely so that they could be referred, leading to some degree of self-selection. Furthermore, participant consent can lead to a bias known as the Hawthorne effect, which means that a temporary change in behaviour occurs when people know that they are being observed during a research study (53).

Information bias means misclassification of variables or outcomes. As information about diet was based on a “fast and simple to use” questionnaire related to “mean diet habits”, recall bias may have occurred. Most of the methods used to examine an individual’s diet are too complicated and time-consuming for routine clinical use (33). This was decisive in our choice of tool. However, we admit that the validity of our diet data is not very good and that they must be considered with great caution. For HRQOL assessments, the generic SF-36 questionnaire was chosen, which reflects

HRQOL that is determined by both weight and other factors, whereas an obesity-specific instrument predominantly reflects weight-related HRQOL (21). The SF-36 seemed to be sensitive to the differences between participants and average Norwegians, and between drop-outs and completers. Furthermore, the SF-36 seemed to be responsive to the observed changes in HRQOL during the period working with lifestyle change. Results from earlier studies, including Norwegian studies, indicate satisfactory reliability and validity of the SF-36 (37, 59). However, a more obesity-specific HRQOL questionnaire would have been more sensitive to weight change than the generic SF-36 (60).

The 13-item SOC questionnaire has been so extensively tested that it was claimed in a review that there is no need for further testing of the reliability and validity of this instrument (40). There are different points of view regarding the use of either the total sum score or the three subscales separately. Antonovsky's intention was to use the total score, and no general patterns have emerged regarding the importance of the three dimensions (40). In general, the SOC questions are regarded by most people as more personal than those in the other questionnaires used. Thus, there are chances of a Hawthorne effect combined with a bias because of expectations and emotions.

For weight and aerobic capacity and the changes in these two variables during the study, information bias should not be a major problem. However, there are many known confounding variables in exercise testing (method of instruction, frequency of verbal encouragement, number of observers in the room, music played or not) (54). All exercise tests in this study were conducted by two dedicated people. There are no specific reasons why information bias in this study should be especially troublesome.

5.1.3 External validity

External validity means the generalisability of the results; i.e., how applicable the results in the study are to populations outside the study population. The presence of selection bias will in most instances lead to biased data, as the participants will not well represent the entire target population. Poor external validity is the most frequent

criticism by clinicians of RCTs, with many trials recruiting less than 5% of the eligible subjects/patients in the community (61). Those who are eligible, but not recruited, differ from subjects recruited into RCTs in terms of age, sex, race, severity of disease, educational status, social class and place of residence (61). However, an inclusion rate of > 91% and a participation rate of > 98% should indicate good external validity for this study. It demonstrates that our method was well accepted and may be appropriate for less-selected populations at risk of T2D. However, generalisation of the results may represent an overestimate of the effects.

5.1.4 Reliability

Assessments of reliability determine whether a scale or measurement yields reproducible and consistent results. In our studies, the most widely used method, Cronbach's α , was used for this purpose (62). This is based on item-to-item correlations in multi-item scales and is often referred to as internal consistency (63). A Cronbach's α coefficient higher than 0.70 may be considered to be satisfactory, higher than 0.80 good and higher than 0.90 excellent. However, it is not recommended that the Cronbach's α coefficient should be much higher than 0.90 (63). None of the reliability results has been previously published.

In our study, Cronbach's α for the eight SF-36 domains ranged from 0.47 (social function) to 0.85 (mental health and vitality) for the entire study population at baseline. Only two domains had Cronbach's α values < 0.70; i.e., social function (0.47) and emotional role limitation (0.61). This may be explained by the fact that they are based on the fewest questions: two and three questions, respectively. Of the other six domains, two were in the "satisfactory" and four in the "good" range.

For the SOC questionnaire, Cronbach's α was close to excellent, 0.88. The Cronbach's α ranged from 0.70 to 0.92 in 127 studies using the 13-item SOC questionnaire (40). Hence, the SOC scale shows high internal consistency, our study included.

In contrast to this, it is not possible to determine the reliability of the diet measurements, because there are no multi-item constructs. Each question in the Smart Diet questionnaire is independent.

5.1.5 Identifying subjects at risk

The seven-item FINDRISC questionnaire used in this study has now been replaced by an eight-item questionnaire (not available at the start of the study), adding a question about family history of diabetes (FHD) and also adding the age category > 64 years. This represents an improvement. The FINDRISC is now found to be the best available non-invasive screening tool for identifying individuals at high risk of T2D and finding undetected T2D/IFG/IGT, and is also associated with future impairment of glucose tolerance and progression towards T2D (64-67). Adding the FHD item influences prediction for both sexes, but the effect appears to be stronger in men (68). However, the effectiveness of lifestyle intervention in reducing the risk of T2D in high-risk individuals is independent of familial risk (69).

5.1.6 The unblinded study physician present for both study groups

The fact that the study physician was not blinded to the randomisation status of the participants and also was involved with both study groups may have biased the results. This could be one of the major criticism of the design and may have reduced the opportunity to find the real effects of the interdisciplinary, group-based approach. A more accurate comparison between the two groups might have emerged from the use of two different physicians for the two study groups. However, by using the same physician, we were able to see the effect of the efforts of the other health care professionals. Practical reasons were the basis of our choice of a single-physician intervention.

A treatment response can be strongly influenced by the doctor-patient relationship and patient preferences (61). There is little doubt that the study physician was enthusiastic and had preferences for “lifestyle changes as medicine”, but he did not

have preferences regarding the two study groups. His influence on the outcome emerges as significant for the IG group, apart from the methodological considerations, and with no additional effects for the IIG group. Regarding patient preferences, nearly all participants expressed their wish to be included in the IIG group. Many subjects stated their disappointment at ending up in “the wrong group”. Some of these disappointed patients stated that “they would show that they could manage this alone”.

5.1.7 Study strengths and limitations

Participation of all referrals who wanted to participate, equal sex distribution and a longitudinal design with 18 months follow-up are obvious strengths. Furthermore, a participation rate > 98% and a drop-out rate of 15% show that the interventions applied were convenient and acceptable. Objective assessments of weight (no self-report) and physical fitness on a treadmill (no questionnaire) are obvious study strengths. Finally, this is an unselected sample of subjects at risk of T2D referred from GPs. It should be applicable in ordinary clinical settings.

The main limitations include a relatively short follow-up, low attendance at the final treadmill test, low validity of diet data and the unblinded study physician. In addition, the above-mentioned biases and confounding factors must be considered.

5.2 Discussion of some of the main results

5.2.1 Why was there no additional effect of group intervention?

A large number of RCTs during recent years have found a higher degree of change towards a healthier lifestyle if subjects in the intervention group were offered more help (70-80). Lack of such additional effects is also found in some studies (81-84). A new systematic review and meta-analysis found a mean weight loss in the intervention arms of 2.3 kg at 12 months of follow-up and concluded that the

interventions were effective, although wide variations in effectiveness were observed (85). However, these studies vary considerably in the intensity and duration of the intervention and the follow-up period, and may therefore not be comparable.

A meta-analysis indicated that dietary counselling interventions for obese or overweight subjects result in a modest weight loss of about 5 kg after one year, of which half is regained after 3 years (86). This corresponds with an RCT studying subjects with IGT, where during the first year of the study the intervention group experienced extensive beneficial effects on a multitude of measured cardio-metabolic variables, but at 5-year follow-up most of these effects had disappeared because of low adherence to the new lifestyle regimen (87). Contrary to this, our study found a mean weight loss of 1.9 kg at six months, which slowly increased during the study to 2.0 kg at 12 months and 2.8 kg at the 18-month follow-up. This may indicate that the lifestyle changes will persist for a longer period. The stabilisation of aerobic capacity between 6 and 18 months supports this assertion. As explained, my experience during the first consultation with most of the participants was that they were surprised and encouraged by the message from the two landmark studies, DPS and DPP. All participants took part in this consultation, and our IG group therefore differs from many of the RCT control groups listed above. Our belief is that for some people, *a simple, clear and true message about the importance of their own efforts* is enough. When they comprehend and see the magnitude of the effects of their own efforts, and in addition understand that only relatively modest lifestyle changes are required, then the internal motivation for making permanent lifestyle adjustments reaches the level required for actual shifts. This may in part explain why the additional group allocation did not influence the results.

In concordance with this interpretation are findings from a recent RCT of lifestyle interventions in primary care for participants with pre-diabetes or metabolic syndrome (88). The primary outcome was weight loss $\geq 7\%$, as in the DPP study. Participants were randomised to a coach-led group intervention, a self-directed DVD intervention or usual care for a 15 month follow-up. During a 3-month intensive

intervention phase, participants in the two intervention groups received a weekly session of the DPP lifestyle intervention curriculum, delivered face-to-face or via a home-based DVD. The usual care group was provided with no information about weight loss or weight-loss goals. During the maintenance phase, participants in both interventions received monthly lifestyle change coaching by email. The percentages of participants who achieved the weight-loss goal were 37.0% in the coach-led and 35.9% in the self-directed group, both highly significantly different from 14.4% in the usual care group. Both intervention groups received the same *simple, clear and true message about the importance of their own efforts*, and the same result was achieved with the use of a DVD as with personal coaching.

Because of considerations of generalisability, our study was planned with two low-intensity treatments. Thus, we were prepared not to find great changes but believed that there would be an additive effect of the interdisciplinary, group-based approach. However, the design of the study, with the study physician involved with both groups, may be an explanation for the lack of significant differences between the two study groups. In any case, we have achieved important lifestyle changes in these subjects with modest efforts and have acquired important experience ourselves regarding working with “lifestyle changes as an important medicine”.

5.2.2 Drop-outs: “Those who need it the most, understand it the least”.

In this study, drop-outs differed from completers by being younger, having unhealthier lifestyle characteristics and reporting significantly lower HRQOL and SOC scores. Our data are in agreement with two RCTs: the SLIM study (lifestyle intervention to prevent T2D among subjects with IGT) and an exercise intervention trial for patients with T2D, where low socio-economic status, low aerobic fitness and fatness were associated with drop-out (78, 89). Drop-out also appears to be associated with high levels of stress, low initial weight loss, secondary disease, lower number of obesity-related diseases and osteoarthritis in the elderly (90-94). Only one of these

studies found younger age as a predictor for drop-out (91), as in our study: age was not a predictor for drop-out in the other studies.

In a systematic review, no consistent predictors of drop-out were identified, but some general trends emerged (95). Drop-outs seemed to be younger and less educated, and to have less body satisfaction, poorer body image, lower physical activity level, poorer mental health, lower self-efficacy and lower social support (95). Another review from behavioural medicine treatments showed that psychological variables and severity of symptom variables were more predictive of drop-out than demographic variables (96). Consequently, the drop-outs need the treatment more than the completers, which concurs with our study. Less diseased patients are getting more treatment than more diseased ones. Social–psychological processes and the patient’s mental health are predictive of attrition, and a more comprehensive examination needs to be undertaken both prior to and during treatment to overcome this challenge (95). A better identification of subjects at risk for attrition will allow provision of the support they need to benefit from the treatment, or alternatively more suitable intervention options can be offered.

5.2.3 Socio-economic status

Risk factors for T2D, and actual T2D, are both inversely associated with socio-economic status (SES) and educational level (97, 98). In our study, no socio-economic variables other than educational level were measured. However, education is a robust indicator of SES (99). Not only T2D is inversely associated with SES: in countries at all levels of income, health and illness follow a social gradient: the lower the SES, the worse the health (100). This is referred to as *social inequalities in health*. Studies in developed countries have shown an increasing prevalence of smoking, physical inactivity, unhealthy diet and obesity with decreasing SES (97, 101-103). However, the role of these traditional risk factors as explanatory variables for SES differences in T2D and CVD has diminished (97, 104, 105). Health behaviours are not the main determinants for health inequalities (100). Factors in the

social or psychological environment could be potential explanations (97). Nonetheless, screening for diabetes and interventions to prevent diabetes should be addressed especially to people of lower SES (97). Reduction of obesity by promoting physical activity and healthy diet choice would be the most important and feasible target for reducing the excess T2D risk seen in groups of subjects with low SES (97). In our study, 72% of participants had low SES, indicated by lack of higher education. Although a low education was associated with a poorer diet, lower aerobic capacity and daily smoking, low educational background was no barrier for behavioural change. Considering the main outcome measures, there were no statistically significant differences in success between low- and high-educated participants (Figure 5, unpublished data).

Achieved outcome measures according to education level
Intention to treat (ITT) principle applied

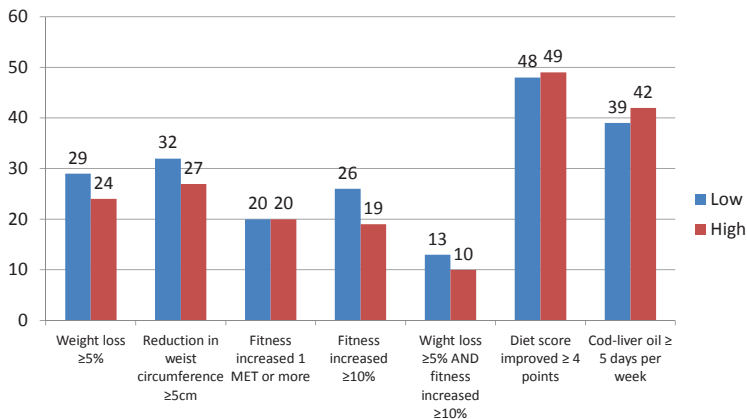


Figure 5: Success rate for the different outcome measures among all subjects included in the study, according to education level. “Low education” means primary or secondary school, whereas “high education” means high school or university. Similar results were obtained if the “low education group” consisted exclusively of primary school-educated participants.

Our findings are consistent with those of many studies. In the DPS study, the effectiveness of dietary and physical activity counselling was not influenced by educational attainment (106). In a moderate- to high-risk sample of 385 participants in the primary health care setting, enhancing self-efficacy and planning were similarly effective regardless of education level (99). Finally, in the Finnish national diabetes prevention programme, where high-risk individuals were effectively identified and a modest weight reduction of about 1 kg at one year was achieved, education level did not influence the result (107, 108). This is an encouraging finding. Although low SES is associated both with risk factors for T2D and with actual T2D, it does not influence the ability to achieve the desired lifestyle changes.

5.2.4 What can explain the improved HRQOL?

The mean difference for the eight HRQOL domains at baseline was 13 points higher for the general Norwegian population than for the study population, corresponding to a moderately significant clinical difference. In the DPP study, the mean score for the same eight domains was 15 points higher than in our study (109). This confirms how different the subjects included in our study were from both the general Norwegian population and the subjects at risk of T2D in the DPP study. As expected, all 10 baseline HRQOL variables were inversely correlated with the improvement in HRQOL: it is easier to improve HRQOL if it is bad than if it is good, and the motivation for change might be greater when HRQOL is low. This represents a possible “regression to the mean bias”; i.e., a change related to the baseline value (62).

A meta-analysis examining HRQOL in obese persons demonstrated that the SF-36 scores were apparently determined by factors other than weight, suggesting that these related more to emotional problems (21). However, a consistent finding in population-based studies examining the relationship between BMI and generic HRQOL is that increasing BMI is associated with impaired HRQOL, particularly for the physical aspects of quality of life (110-112). This was confirmed in our study

with an inverse, weak correlation between baseline values for BMI and PCS ($r = 0.24$) but no significant correlation for MCS. Similarly, a moderate inverse correlation was found for baseline aerobic capacity and PCS ($r = 0.59$) but none for MCS. Weak positive correlations were found between PCS and weight loss ($r = 0.24$) and PCS and improved fitness ($r = 0.34$), but none for MCS. These weak correlations mean that we cannot isolate the major factors that contributed to the changes in HRQOL, especially for the mental health domains.

A recent review of RCTs concluded that the relationship between weight loss and HRQOL is still poorly understood and that most likely weight loss does not lead to clinically improved HRQOL (113). However, another systematic review gives support for a consistently positive correlation between physical activity level and HRQOL in cross-sectional studies, with weaker support from RCT and cohort studies (114). Reverse causation may exist. Improved HRQOL may lead to increased physical activity, which again leads to weight loss. It is not possible to say “what comes first”. However, dose-dependent exercise-induced HRQOL improvements were found in an RCT including sedentary overweight/obese women, independent of weight change (115). This suggests a causal relationship and a direction: improved HRQOL is a result of increased exercise, not vice versa. Even an exercise dose of 74 min/week was associated with improvements in several HRQOL domains (115). This may demonstrate a great potential for the use of physical activity as “medicine”, not only as a tool for reduction of T2D, CVD or cancer – but also to improve HRQOL. Increase in physical activity is probably more important than weight loss for improvement of HRQOL.

Effects of long-term intensive lifestyle intervention on HRQOL and depressive symptoms in 5145 overweight/obese individuals with T2D were examined in the Look AHEAD trial (116). With a randomized controlled design and a median follow-up of 9.6 years, the effects of an intensive lifestyle intervention were compared with a control intervention of diabetes support and education. Participants in the intensive group met weekly for the first 6 months and three times per month for the next 6

months (combination of individual and group sessions the first year) and had monthly individual sessions in all subsequent years. The control group had three group sessions per year for the first 4 years, and one group session yearly thereafter. Improvements in fitness, cardio-vascular risk factors and weight loss were all better in the intensive group than in the control group; i.e. weight loss was 8.6% versus 0.7% and 6.0% versus 3.5% at 1 year and at study end, respectively (71). These changes and the extensive support that they achieved in the intensive group were accompanied by a mitigation of the age-related decline in physical HRQOL and protection from developing depression (116). Although the rate of cardio-vascular events was not reduced, these crucial health effects provide strong support for the importance of intensive lifestyle intervention in improving rather than impairing HRQOL and depressive symptoms (71, 116). Even though these findings apply to patients with T2D, we believe that they are relevant for subjects at risk of T2D and have significant public health implications.

5.2.5 The predictability and future use of the SOC questionnaire

A large number of recent studies have confirmed that high SOC scores are correlated with reduced atherosclerotic risk factors, healthier lifestyle behaviours, increased HRQOL, higher life satisfaction and lower HbA1c values (117-120).

SOC has been shown to be associated with health (121). With adjustment for SES and age, a low SOC score has been associated in previous studies with risk factors for T2D such as lower physical activity, unhealthy food choices and smoking (122, 123). Furthermore, adjusted for the above mentioned risk factors, SES and age, a low SOC score is still associated with T2D and all-cause mortality (123, 124). Hence, it seems that a low SOC score *per se* has a negative influence on several important health outcomes, independent of other known risk factors and SES.

During a mean follow-up of 8.3 years, a 20% reduced risk of all-cause mortality was seen among EPIC-Norfolk participants with a strong SOC, and lifestyle choices and SES explained only 23% of this reduction (124). Aetiological understanding of this

relationship requires further investigation. Is a high SOC score associated with other social and psychological profiles or other lifestyle factors that confer protection from T2D? Confounding of current emotional state with SOC may partly explain this gap, because SOC score and depressive symptoms were significantly correlated among a random sample of 25-64-year-old Finnish people (125). Hence, there seems to be an overlap between the measures of SOC and depressive symptoms. This is confirmed in our study, where the 8% of participants using anti-depressants at baseline had a statistically significantly lower mean SOC score compared with the rest: 53.1 (SD 11.4) versus 64.3 (SD 13.4), respectively ($p = 0.002$, unpublished data). A positive correlation between SOC score and baseline HRQOL data—i.e., for both PCS ($r = 0.21$, $p = 0.003$) and MCS ($r = 0.36$, $p < 0.001$) was verified (unpublished data). We believe that a better evaluation of psychological characteristics—for example by use of the Hospital Anxiety and Depression Scale (HADS) could have strengthened our study results. There are many indications of some psychological problems among our study participants, but we were not able to confirm these or to explore their possible consequences for the outcomes in the study.

This study showed that a low SOC score was associated with a lower ability to achieve the two desirable lifestyle changes of a weight loss of at least 5% and an increased aerobic capacity of at least 10%. To our knowledge, this is the first study to investigate whether SOC score influences the probability for successful lifestyle change among subjects at risk of T2D. We showed a strong predictive validity, with a robust statistically significant correlation ($p < 0.001$). However, no statistically significant associations between SOC score and diet change were found: in the adjusted model, the OR for successful diet improvement was 0.99 (95% CI 0.96-1.02, $p = 0.49$) and that for the “cod-liver oil goal” was 0.98 (95% CI 0.95-1.01, $p = 0.11$) (unpublished data). This weakens the results for predictability of SOC.

A high SOC score defines a way of thinking that enables people to identify and use the resources that are available to them (126). Antonovsky considered that SOC and social class would be related, and this was confirmed in the EPIC-Norfolk

participants where the proportion with strong SOC in the highest social class was twice that in the lowest (127). Contrary to this, we found no statistically significant differences in SOC score related to education level: mean SOC scores were 62.6 and 65.6 in the low- and high-educated groups, respectively ($p = 0.19$, unpublished data). Thus, there were no statistically significant differences according to education level regarding the proportions of participants in the SOC tertile groups.

However, we believe that the most interesting issue to discuss is how the SOC questionnaire could be utilised in the future. There is good evidence for the influence of SOC on health, lifestyle, morbidity and mortality –, and our study can add its predictability regarding the ability for lifestyle change. One interpretation of our results could be that among subjects in the population with a high SOC score, just *a simple, clear and true message about the importance of their own modest efforts* is enough to achieve important lifestyle changes. The NNT to attain one successful lifestyle change in the high SOC tertile group was only 2, and only 3 if the intention to treat (ITT) principle was applied. This is so effective that decision makers perhaps could consider promoting this message on television and in newspapers, repeatedly and over time. At a population level, this might give important results and might be highly cost-effective, although it would not affect those who need it the most.

Another crucial interpretation of our study and the knowledge about the importance of SOC for health is that GPs should consider to starting to screen their patients with this simple, 13-item SOC questionnaire. Although Antonovsky's assumption about the stability of SOC has been refuted by several authors, SOC seems to be comparatively stable over time (40); hence, a SOC assessment on one occasion is suitable for all practical purposes. We believe that using the SOC questionnaire to screen every patient would be a progression of great value for health care professionals. It is simple to use and may have great impact. The GPs' increased awareness of the level of mastery and coherence among their patients may also, through experience, make the GPs more able to develop and choose a better psychological approach when lifestyle change is of major importance. This again

may lead to new empirical approaches for patients with low and high SOC scores that could be tested scientifically.

Dividing the total SOC score into groups of low, medium and high SOC scores was not recommended by Antonovsky (40). However, a number of studies report such divisions, although no consensus for the defined cut-offs between the groups exists (40). Examples of divisions are shown in Table 2 together with the range of SOC scores in the tertiles from our study (unpublished data).

	Low SOC score	Medium SOC score	High SOC score
Harri M. (128)	<64	64-72	>72
Hedov et al. (129)	<61	61-74	>74
Ibrahim et al. (130)	<56	56-65	>65
Mendel et al. (131)	<62	62-75	>75
Our study	<58	58-71	>71

Table 2: Cut-off values for SOC scores in various studies.

Thus, the cut-offs found in our study agree well with those used in other studies. We believe that this type of SOC categorization can be of importance in the decision-making and patient approach for GPs or other health care professionals. It may represent crucial knowledge for increasing the professionals' awareness of the patients' mastery levels and future health possibilities. However, we agree that it is not clear at which level SOC no longer predicts the movement towards a healthy end (40). Still, it will help health care professionals to handle their patients better: some patients will have a high probability of benefiting from simple advice, whereas other patients need a more thorough examination of social and psychological issues before effective approaches and information can be utilised. A high SOC score might indicate that simple and strong messages are adequate for the purposes of a lifestyle change and that extra information and follow-up, such as we used in the IIG group, have no additional effects. Resources should rather be used on examination of social and psychological issues in selected patients based on low SOC scores. These might

be time-consuming investigations; yet, they are mandatory for developing an adjusted approach for many patients.

It is a major challenge to develop more appropriate, motivational approaches for subjects/patients with low SOC scores. Treatments must be more differentiated, and possible underlying problems and challenges must be explored. The continuation of therapy that suits best those who need it the least will increase social inequalities in health—the exact opposite of what we want to achieve. Furthermore, it is demotivating for health care professionals to engage in treatments where the NNT is 67, which was the case in the low SOC tertile group when the ITT principle was applied. This means “one success in every 67 patients treated”. Furthermore, for the 66 patients who do not succeed, this is not a good experience, because it can be increasingly detrimental for their self-image and their self-confidence. Hence, greater efforts and new approaches need to be directed towards subjects/patients with low SOC scores to close the gap in social inequalities in health. A prerequisite for this is to start screening all adult individuals with the SOC questionnaire on one occasion in their life. We will argue that it is better for a health care professional to be aware of a patient’s SOC score than not to be. The validity of this statement will hopefully be further discussed in oncoming research, and until then, our opinions should be applied with caution and wisdom.

6. Conclusions

This randomised, controlled study and cohort study testing the ability of two low-intensity interventions to induce lifestyle change in subjects at risk of T2D showed in an 18-month follow-up that:

1. referred subjects from GPs at risk of T2D having a high prevalence of unhealthy lifestyle parameters, markedly reduced HRQOL and surprisingly high BMI;
2. clinically important lifestyle changes can be achieved with modest clinical efforts but with no additional effects of a group-based multidisciplinary intervention;
3. clinically important lifestyle changes with moderate weight loss and moderate improvement of exercise capacity are associated with clinically and statistically significant improvements in HRQOL, particularly for the physical aspects of quality of life; and
4. individuals who are most likely to benefit from a lifestyle intervention can be identified by use of their SOC score at baseline.

7. Perspectives

Although Europeans have a moderate to low prevalence of diabetes compared with most other ethnic groups worldwide, more than half of them will suffer from hyperglycemia and T2D during their lifetime (4). At present, less than half of the European countries have adopted a National Diabetes Prevention Plan based on a proposal from The International Diabetes Federation (108). The world's first large-scale nationwide diabetes prevention programme in Finland effectively identified high-risk individuals and induced in them a modest weight reduction (107). At the population level, approximately 30% of the population were aware of the diabetes prevention programme, and 25% reported changes in health habits (108). This is one way to go. Awareness of an increased risk for T2D in healthy Americans is associated with implementing healthy lifestyle behaviours (132). However, increased awareness is not enough. For most people, goals such as those in this study will not be achieved simply by informing them and leaving them to make personal choices. Factors like the availability of different foods and the accessibility of environments for active ways of life are beyond people's direct personal control. In general, environmental changes accompanied by economic and social changes can essentially explain the epidemic of obesity, T2D and inactivity. Sugary drinks are more likely to be consumed excessively when they are cheap and well promoted and vending machines are placed within schools (133). Protection of public health, which is the sum of every individual's health, is not just a responsibility of people themselves. Successful prevention strategies rely on cooperative actions from policymakers and decision-takers in civil society, industry, health and other professions (133). If all sectors of society work together towards the same public health goals at local, national and international levels, the goals are more likely to be achieved and sustained (133). The conditions in which people live and die are shaped by political, social and economic forces (100). Concerted actions like those that have improved traffic safety and water quality and reduced smoking must be implemented. The interplay between environmental, social and economic factors that determine patterns

of production and consumption of food and drink and of patterns of physical activity and thus body composition, at local, national and global levels, is illustrated in Figure 6.

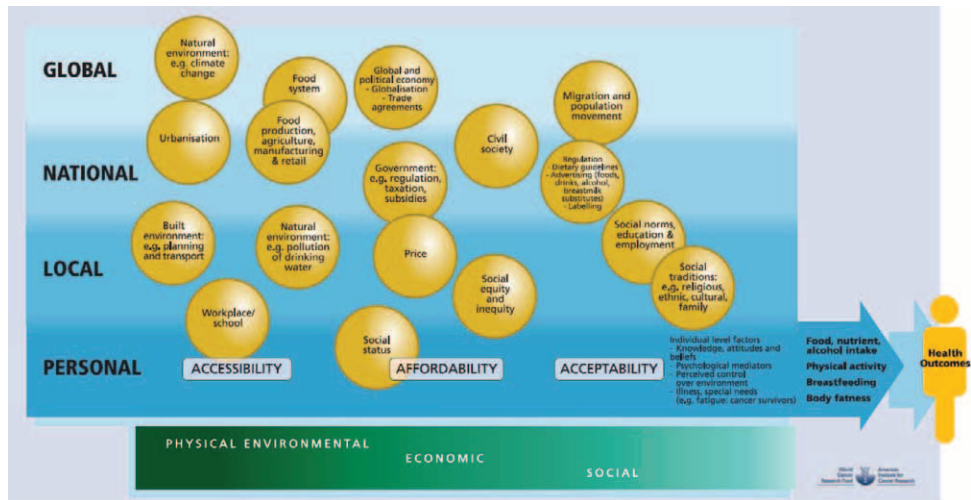


Figure 6: Factors that affect the risk of T2D and other chronic diseases (CVD, obesity and cancer). Reproduced from (133).

Lifestyles that reduce the risk of T2D also reduce the risk of CVD, obesity and some types of cancers (134). For the prevention of all these chronic diseases, the dietary recommendations are more or less the same (134). Fortunately, you do not have to live/eat in one way if you want to reduce your risk for heart disease – and in a totally different way if you want to reduce your risk for T2D or breast cancer. My experience is that most people are not aware of the great potential for prevention of common diseases that applies to T2D and especially to cancer. Consumption of appropriate diets, regular sustained physical activity and maintenance of healthy body weight can prevent about one-third of cases of the commonest cancers in higher-income countries (133). Two excellent examples are that 43% of all cases of colorectal cancer and 42% of all cases of breast cancer should be prevented by adhering to relatively modest lifestyle habits (133). The challenge is how to make healthy living, which now is very infrequent, widespread in the community.

Based on four simple lifestyle factors, among 23 153 healthy Germans aged 35-65 years from the general population, only 9% lived healthily (135). These factors were healthy diet, physical activity > 3.5 h/week, BMI < 30 and not smoking. Participants with all four factors at baseline had a 78% lower risk of developing a chronic disease than participants without one healthy factor; the reduction in risk was 93% for diabetes, 81% for myocardial infarction, 50% for stroke and 36% for cancer. In another prospective cohort study of 4886 randomly selected British adults with a mean age 44 (SD 16) at baseline, only 8% lived healthily according to four comparable lifestyle factors (136). These factors were healthy alcohol consumption, physical activity > 2 h/week, fruit and vegetable intake ≥ 3 times/day and not smoking. During a mean follow-up period of 20 years, all-cause mortality was 8% for the 8% of individuals with all four healthy lifestyle factors present. With only a single factor missing (26% of participants), the observed mortality was 18%; i.e., it more than doubled. The mortality rate rose slowly for each removed factor, ending at 29% for the 6% of individuals with no healthy lifestyle factors present; i.e., it more than tripled. Although these are both observational studies, and we cannot be certain about causality, they represent valid observations of the importance of having these four factors present. Although there are probably many confounding factors, this should not obscure the seriousness of these important observations. Even though the interpretation of causality in observational studies may be inappropriate, no one can question the observation itself: these factors are associated with observed, serious health consequences.

To summarize, there is great potential for prevention of the common chronic diseases that are widespread in many populations. Political willingness and courage are required if we really intend to prevent a substantial proportion of the disease burden. This study shows that some subjects, regardless of SES, can manage to make clinically important lifestyle changes with minimal effort from a physician. These changes were associated with great improvements in HRQOL. However, environmental changes will have a much greater impact and furthermore will reduce the social inequalities in health. Use of the SOC questionnaire as a screening

instrument on one occasion is recommended. It provides useful health information about people/patients that should be utilised by health care professionals.

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9. List of errors

The following error has been found in the thesis:

Paper II: page 3, Results, paragraph 2. “The mean weight loss and mean increase in maximal aerobic capacity from the baseline to the follow-up were 2% (SD, 6) and 9% (not 12%) (SD, 25), respectively.

10. Appendix I-V

Appendix number	Norwegian title	English title
Appendix I	Informasjonsbrev og henvisningskriv til fastlegene	Information letter and referral letter to GPs
Appendix II	Smart Diet kostspørreskjema	Smart Diet questionnaire
Appendix III	SF-36 spørreskjema	SF-36 questionnaire
Appendix IV	SOC-13 spørreskjema	SOC-13 questionnaire
Appendix V	Artikkel I-III	Paper I-III

Appendix I



Forebygging av type 2 diabetes

Kjære kollega

Vi vet i dag at type 2 diabetes (DM2) kan forebygges med økt fysisk aktivitet, kostomlegging og vekttap i størrelsesorden 3-5kg. Utfordringen for den enkelte og for oss som leger er å få til varige endringer på disse feltene. SSHF Kristiansand vil prøve ut et nytt, tverrfaglig behandlingstilbud som vil rette seg mot personer som har økt risiko for å utvikle DM2. Vi vet ikke om tilbudet vil ha effekt sammenlignet med vanlig oppfølging hos fastlegen. Vi legger derfor opp til en randomisert studie der halvparten av personene blir tilbakeført til sin fastlege (kontrollgruppe), mens den andre halvparten blir fulgt ved sykehuset (intervensjonsgruppe). Hver pasient vil bli fulgt i 1,5 år.

Vi ønsker at du bruker scoringssystemet ”**Diabetes risikoscore**” (se vedlagt artikkel Diabetes Care, mars 2003) for å finne personer med økt risiko for DM2. Følgende elementer inngår i risikoscoren:

Alder	45-54 år	2
	55-64 år	3
BMI	25-30	1
	> 30	3
Livomkrets	94-102 cm for menn, 80-88 cm for kvinner	3
	> 102 cm for menn, > 88 cm for kvinner	4
Bruk av blodtrykksmedisin		2
Høyt blodsukker nevnt av helsepersonell en eller flere ganger		5
Aktivitet	< 4 timer pr. uke	2
Ikke daglig inntak av frukt / grønnsaker		1
POENGSUM		

< 9 poeng lav diabetesrisiko
9-12 poeng moderat diabetesrisiko
>12 poeng svært høy diabetesrisiko

NB: Ytterligere økt risiko hvis nær(e) slektning(er) har DM2.

Ved å sette en grense på minst 9 poeng vil vi ”fange opp” ca. 80% av alle i befolkningen som kommer til å utvikle DM2 i løpet av neste 10-årsperiode. **Vi ønsker derfor å få henvist personer i alderen 20-64 år, som har minst 9 poeng i ovenfornevnte ”Diabetes risikoscore” til vår poliklinikk.** Før randomisering vil alle få en klinisk gjennomgang inkludert:

- Konkrete råd om hva den enkelte kan gjøre for å redusere risikoen for DM2
- Forespørsel om deltakelse i studien

Pasienter med diabetes kan ikke inkluderes, men **personer med nedsatt glukosetoleranse er godt egnet**. Eksklusjonskriterier forøvrig er alvorlig grunnlidelse, alvorlig psykiatrisk sykdom eller rusproblem. De må dessuten beherske norsk språk. Etter konsultasjonen får du som fastlege tilbakemelding på hvilken gruppe hver enkelt person har havnet i.

Vi håper på godt samarbeid og ber om at vedlagte henvisning brukes, 10 eksemplarer vedlegges. (vanlig henvisningsnotat ikke nødvendig, men viktig med fullt navn, fødselsdato og adresse)

Vennlig hilsen

ass.lege Vegard Nilsen
Medisinsk poliklinikk SSHF Kristiansand,
Serviceboks 416, 4604 Kristiansand



Prevention of type 2 diabetes

Dear college

Today we know that type 2 diabetes (T2D) can be prevented by increasing physical activity, a change in diet and by losing 3-5kilograms in weight. The challenge for patients and physicians is to create lasting change. SSHF Kristiansand is planning to test a new, multidisciplinary treatment for those at risk of T2D. We don't know whether this treatment will be effective, compared to normal care provided by GP, therefore we are organizing a randomized study in which half of the subjects will be referred back to their GP, (the control group) and the other half will receive hospital-based treatment (the intervention group). Each patient will be followed up for 1.5 years.

We want you to use the scoring system **"Diabetes risk score"** (see attached article Diabetes Care, March 2003) to find subjects at risk of T2D. The following items are included in the risk score:

Age	45-54 years	2
	55-64 years	3
BMI	25-30	1
	> 30	3
Waist circumference	94-102 cm for men, 80-88 cm for women	3
	> 102 cm for men, > 88 cm for women	4
Use of medication to treat high blood pressure		2
Elevated blood glucose recorded on one or more occasions by a health-care professional		5
Activity	< 4 hours per week	2
No daily intake of fruit / vegetables		1
SCORE		

< 9 points low risk of diabetes
9-12 points moderate risk of diabetes
>12 points very high risk of diabetes

NB: Even higher risk if close relatives have T2D.

By setting a limit of at least 9 points we will "catch" about 80% of all those in the population who develop T2D over the next 10 years. **We would like to accept subjects within the age range 20-64 years who score at least 9 points in the above mentioned "Diabetes risk score" to our hospital.** Before randomisation all will get a clinical examination included:

- Specific advice giving regarding what each individual can do to reduce the risk of T2D
- They will be asked for participation in the study

Patients with diabetes cannot be included, however, **subjects with impaired glucose tolerance are well suited.** Exclusion criteria include serious illness, serious psychiatric illness or substance abuse. Subjects must also be competent in spoken/written Norwegian. As a GP, after the consultation you will receive feedback about the treatment group to which each subject was allocated.

We look forward to your cooperation with this study, and ask that you use the attached referral forms (10 copies attached). (a normal referral letter is not required; however the full name, birthdate and address of subjects must be included)

Sincerely
ass.physician Vegard Nilsen
Medical department SSHF Kristiansand,
Servicebox 416, 4604 Kristiansand

HENVISNING ”Diabetes risikoscore” ≥ 9

Pasient:

Sett ring rundt der du mener personen scorer poeng og summer:

Alder	45-54 år	2
	55-64 år	3
BMI	25-30	1
	> 30	3
Livomkrets	94-102 cm for menn, 80-88 cm for kvinner	3
	> 102 cm for menn, > 88 cm for kvinner	4
Bruk av blodtrykksmedisin		2
Høyt blodsukker nevnt av helsepersonell en eller flere ganger		5
Aktivitet	< 4 timer pr. uke	2
Ikke daglig inntak av frukt / grønnsaker		1
POENGSUM		

< 9 poeng lav diabetesrisiko

9-12 poeng moderat diabetesrisiko, ca. 50% av alle som får DM2 scorer dette

>12 poeng svært høy diabetesrisiko

Diabetes i nær familie Ja Nei

Røyker: Ja Nei

Ønsker endring av livsstil: Ja Nei

Siste totalkolesterolverdi HDL-kolesterol

Coronarsykdom: Ja Nei

Medikamenter: statin Ja Nei

ASA Ja Nei

B-blokker Ja Nei

ACE-hemmer Ja Nei

Andre Ja Nei hvis ja, type:

Hilsen lege: Dato:

Sendes: Medisinsk poliklinikk, SSHF Kristiansand, Serviceboks 416, 4604 Kristiansand
MERK konvolutten: **prosjekt diabetesforebygging eller bruk tilsendte adresselapper**

REFERRAL "Diabetes risk score" ≥ 9

Patient:

Circle where you think the person are scoring points and sum up:

Age	45-54 years	2
	55-64 years	3
BMI	25-30	1
	> 30	3
Waist circumference	94-102 cm for men, 80-88 cm for women	3
	> 102 cm for men, > 88 cm for women	4
Use of medication to treat high blood pressure		2
Elevated blood glucose recorded on one or more occasions by a health-care professional		5
Activity	< 4 hours per week	2
No daily intake of fruit / vegetables		1
SCORE		

< 9 points low risk of diabetes
 9-12 points moderate risk of diabetes, which is the score achieved by approx. 50% of those developing T2D
 >12 points very high risk of diabetes

Family history of diabetes Yes No

Smoking: Yes No

Desire to change lifestyle: Yes No

Most recent total cholesterol value HDL-cholesterol

Coronary artery disease Yes No

Medication: statins Yes No

 ASA Yes No

 β-blockers Yes No

 ACE-inhibitor Yes No

 Other Yes No if yes, type:

Physician completing: Date:.....

Send to: Medical department, SSHF Kristiansand, Servicebox 416, 4604 Kristiansand NOTE the envelope: **diabetes prevention project or use attached address labels**

Appendix II

15 spørsmål om ditt kosthold

Copyright: Lipidklinikken®, Rikshospitalet.

Du får 15 spørsmål om ditt kosthold.

Les spørsmålene og de angitte svarmulighetene nøye!

Navn:

Fødselsdag:

Dato for besvarelsen:.....

**Sett kryss ved det svaret som passer best med gjennomsnittet av dine spisevaner.
Gi kun ett svar til hvert spørsmål.**

1. Melk (sur/søt)

Hvilken type bruker du oftest? *Som drikk, på gryn, grøt, dessert, i kaffe/te.*

Helmelk • Kulturmilk • Kefir • Kaffemelk 5% fett

Lettmelk • Cultura • Biola (syret lettmelk) • Ekstra Lett melk

Skummet melk • Skummet kultur melk • Biola bærdrick (0,1% fett)

Bruker kun opptil 1 liter i uken, eller drikker ikke melk

2. Fløte, rømme og lignende

Hvilken type bruker du oftest? *I matlaging, i kaker, i kaffe, i te, som dressing o.l.*

Kremfløte • Pisket krem • Crème Fraiche • Seterrømme

Kaffefløte • Matfløte • Vikingmelk • Rømmekolle • Lettrømme.....

Bruker fløte eller rømme én gang eller sjeldnere i uken

3. Brød, knekkebrød og andre kornprodukter

Hvilken type spiser du oftest?

Fine kornprodukter:

Vanlig kneipp • finbrød • fint hjemmebakket brød • loff • fine rundstykker • baguetter • riskaker • puffet ris • cornflakes • havrenøtter • frokostkorn (med sjokolade, honning, sukker o.l.)

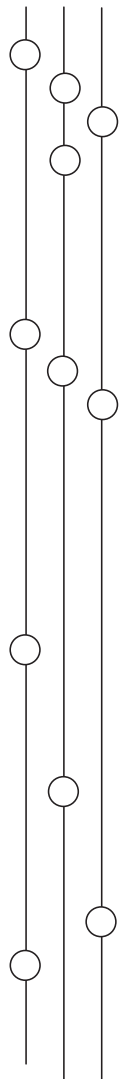
Mellomgrove kornprodukter:

Kneipp (Bakers og grovt sammalt) • helkornbrød • hjemmebakket brød med 50-70% sammalt • rugbrød (fint og grovt) • Norsk fjellbrød • Mesterbrød • grove rundstykker (industrielt) • lyst knekkebrød • kornblanding med frukt/nøtter/frø • Kellogs K

Grove kornprodukter:

grovbrød (kjøpt, hjemmebakket) • klibrød • grovt hjemmebakket brød (med mer enn 70% sammalt) • fullkornbrød • havrebrød • skonrokk • mørkt knekkebrød • pumpeknittel • havregryn • havregrot • grove kornblandinger (4-korn, Allbran)

Spiser mindre enn ett brødmåltid eller kornmåltid daglig



Name:
Birthdate:
Date answering:.....

15 questions about your diet

Copyright: Lipidklinikken®, Rikshospitalet.

This questionnaire contains 15 questions about your diet

Read thoroughly through the questions and answer options!

**Tick off the reply that best fits your normal eating habits.
Use only one reply for each question.**

1. Milk (sour/sweet)

What kind do you usually drink/use? *To drink, in porridge, desserts, coffee/tea.*

- Whole milk • Thick/sour milk • Milk Kefir • Coffee milk 5% fat
- Low-fat milk • Low-fat sour-milk • Biola
- Semi-skimmed milk • Sour semi-skimmed milk • Biola with berries (0.1% fat)
- Less than 1 litre per week or no milk.....

2. Cream, sour-cream or similar

What kind do you usually eat? *As part of food preparation, cakes, coffee, tea, as dressing etc.*

- Cream, • Whipped cream, • Crème Fraiche •
- 10% fat cream • Buttermilk pudding • 20% fat sour cream
- Use cream or sour cream once or less per week

3. Bread, crisp bread and cereals

What kind do you usually eat?

Non coarse-products:

- White bread • Bread containing minimal whole grain • Homemade white bread • white rolls • baguettes • rice cakes • puffed rice • cornflakes • puffed oats • cereals (containing chocolate, honey, sugar etc..) ...

Medium-coarse-products:

- Homemade bread (50-70% wholemeal) • rye bread (white and coarse) • coarse rolls (industry baked) • light crisp bread • cereals containing fruit/nuts/seed • Kellogs K

Coarse products:

- Whole grain bread • bran bread • coarse homemade bread (containing more than 70% whole-grain) • oat bread • rusks • dark crisp bread • pumpernickel • rolled oats • oatmeal porridge • coarse cereals (4-grain, Allbran)

- Eat bread and cereals less than once daily

Three vertical lines for marking answers. The first line has circles at the top, middle, and bottom. The second line has circles at the top, middle, and bottom. The third line has circles at the top, middle, and bottom.

4. Smør, margarin på brødmaten

Hvilken type bruker du oftest?

Meierismør • Tine smør (mykere) • Tine setersmør • Smøregod • Bremyk • Brelett • Melange margarin • Per margarin • Soft flora stekemargarin (kube) • Soya stekemargarin (kube) • Soft margarin uten salt og melk • Letta

Soft Flora (beger) • Soft Light • Soya margarin (beger) • Soya lett margarin • Oliven margarin • Olivero • Solsikke margarin

Vita • Vita lett • Omega

Braker vanligvis ikke smør eller margarin på brødmaten

5. Ost på brødmaten, i matlaging og på pizza o.l.

Hvilken type bruker du oftest?

Hvitost (F45) • Nøkkelost (F45) • Gudbrandsdalsost (G35) • Ekte geitost • Fløtemysost • Edamer • Gråddost • "Dessert oster" • Smørbare fete oster (H50 og fetere) • Mozzarella (mer enn 20% fett) • Feta ost (mer enn 20% fett) • Revet pizza-/pastaost • Taffelost • Burgerost • Snøfrisk, smørbar geitost • Parmesan

Lettere hvitost • Lettere nøkkelost • Lettere fløtemysost • Lettere Gudbrandsdalsost • Smørbare oster (16% fett) • Mozzarella (16% fett) • Fetaost (20% fett) • Prim med vaniljesmak

Cottage cheese • Gamalost • Pultost • Mager mysost • Prim • Mager prim • Smørbar magerost

Braker ost to ganger eller sjeldnere i uken, eller bruker aldri ost

6. Kjøttpålegg

Hvilken type bruker du oftest?

Leverpostei • Salami • Lett salami/spesialsalami • Servelat • Fårepølse • Falukorv • Fleskepølse • Morrpølse • Reinsdyrpølse • Stabburpølse • Sylte • Lammerull

Lett/mager leverpostei • Lett servelat • Delikat ovnsbakt postei

Bankekjøtt • Kalkunpålegg • Kyllingpålegg • 3% servelat (Det Sunne Kjøkken) • 3% leverpostei (Det Sunne Kjøkken) • Kalverull • Okserull • Skinke kokt/røkt • Hamburgerrygg • Annet rent rødt og hvitt kjøtt uten fett

Braker ikke kjøttpålegg ukentlig eller bruker aldri kjøttpålegg

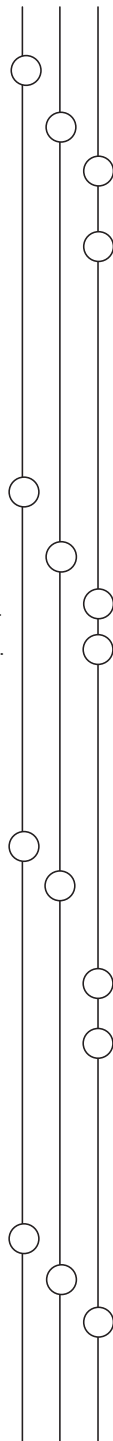
7. Fiskepålegg

Hvor ofte har du fiskepålegg på brødmaten? *Laks • makrell • sild • sardiner • brisling • tunfisk • reker • krabbe • crab-sticks • fiskepudding • fiskekaker • Havbris etc.*

På inntil 1 brødslike i uken, eller aldri

På 2 til 4 brødslike i uken

På 5 eller flere brødslike i uken



4. Butter, margarine on the bread

Which kind do you usually eat?

- Dairy butter • Different butter blends • Different types of soya-based hard margarines •
One light version of butter blend • margarine without salt and milk
- Softer margarine types, based on soya-, olive- or sunflower oil (containing either 80% or 40% fat).....
- Very soft Margarines based on reapseed and sunflower oil (containing either 80% or 40% fat)
- Do not usually use butter or margarine on bread

5. Cheese on bread, used in cooking, in pizza etc.

What kind do you usually eat?

- White cheese • Gouda • Edam • Brown cheese • Cumin cheese • Different regular cream cheeses
“Dessert cheeses” • Mozzarella (more than 20% fat) • Feta (more than 20% fat) • Grated cheese
for pizza /pasta • Cheese for burgers • Parmesan
- Lower-fat white cheese • Lower-fat cumin cheese • Lower-fat brown cheese • Different light cream
cheeses (16% fat) • Mozzarella (16% fat) • Feta (20% fat)
- Cottage cheese • Aged cheese • Soft cheese • Very low-fat brown cheese • Very low-fat cream
cheeses
- Use cheese twice per week or less, or do not use cheese.....

6. Meat on bread

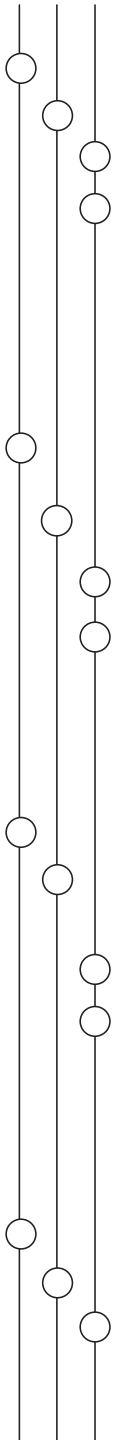
What kind do you usually eat?

- Liverpaste • Salami • Low-fat salami/ very low-fat salami • Bologna • Smoked mutton sausage
• High fat sausage • Cured sausage • Lamb, meat roll for sandwiches.....
- Low-fat liver pâté • Low-fat bologna saveloy • Pâté based on plant seed oils
-
- Roastbeef • Turkey • Chicken • 3% bologna • 3% liver pâté • Veal meat roll • Beef meat roll
Ham • Other pprocessed (low-fat) red and white meat
- Meat on bread less than once per week.....
- .

7. Fish on bread

How often do you have fish on your bread?

- Salmon • mackerel • herring • sardines • cod • tuna • shrimp • crab • crabsticks • etc.*
- Up to 1 slice of bread per week or none
- 2 to 4 slices of bread per week
- 5 or more slices of bread per week



8. Majonespålegg

Hvor ofte har du majonespålegg på brødmaten? *Rekesalat • krabbesalat • frokostsalat • italiensk salat I.*

På inntil 1 brødslike i uken, eller aldri

På 2 til 7 brødslike i uken

På 8 eller flere brødslike i uken

9. Kjøtt til middag

Hvilken type bruker du oftest?

Også medregnet kjøtt i sammensatte retter som pizza, lasagne, pastaretter, gryteretter, lapskaus, taco og lignende og bacon til frokost

Grillpølse • Wienerpølse • Kjøttpølse • Knakkpølse • Nakkekoteletter med fettrand • Lammekoteletter • Medisterfarse • Medisterpølse • Medisterdeig • Medisterkake • Wienerschnitzel • Fenalår • Bacon med fettrand • Flesk • Grillben • Fårekjøtt • Pinnekjøtt • Ribbe • And • Gås

Kjøttdeig • Kjøttkaker • Kjøttpudding • Kjøpte karbonader • Hamburger • Kebabkjøtt • Lettpølse • Kyllingpølse • Kamkoteletter med fettrand • Nakkekoteletter uten fettrand • Kylling med skinn • Høne med skinn • Kalkun med skinn • Blodpudding • Bayonneskinke med fettrand • Hamburgerrygg med fettrand

Kjøtt uten synlig fett • Karbonadedeig • Biff • Stek uten fettrand • Bogskinke • Kamkoteletter uten fettrand • Pølse med 3% fett (Det Sunne Kjøkken) • Kjøttpudding med 3% fett (Det Sunne Kjøkken) • Viltkjøtt • Kalv • Lam indrefilet • Høne uten skinn • Kylling uten skinn • Kalkun uten skinn

Spiser ikke kjøtt ukentlig, eller aldri

.

10. Fisk til middag

Hvor mange ganger i uken spiser du fisk, fiskemat og/eller fiskeretter?

Inntil en gang i uken eller aldri

2 til 3 ganger i uken

4 eller flere ganger i uken

.

11. Fett i matlaging

Hvilken type fett bruker du oftest? *I matlaging: steking, baking, i saus.*

Meierismør • Tine smør (mykere) • Tine setersmør • Bremyk • Smøregod • Melange margarin (kube) • Per margarin (kube) • Soft Flora stekemargarin (kube) • Soya stekemargarin (kube)

Soft Flora (beger) • Soya margarin, (beger) • Solsikke margarin • Oliven margarin • Olivero

Olje • Flytende margarin • Vita • Omega

Bruker vanligvis ikke fett i matlagingen

8. Mayonnaise products

How often do you use mayonnaise on your bread? *Shrimp salad • crab salad • Italian salad.*

- Up to 1 slice of bread per week or none
- 2 to 7 slices of bread per week
- 8 or more slices of bread per week

9. Meat as a main dish

Which type do you use most often?

Also includes meat in mixed dishes such as pizza, lasagne, pasta dishes, casseroles, stew, tacos and bacon with breakfast

- Different kinds of sausages • Chops (fat on) • Ground pork / high-fat pork sausages
• Wiener schnitzel • Bacon • Spare ribs • Duck • Goose
- Minced beef • Meat rissoles • Meatloaf • Bought hamburgers • Hamburger • Kebab
Low-fat sausage • Chicken sausage • Comb chops with fat • Neck chops without fat
• Chicken with skin • Hen with skin • Turkey with skin • Black pudding • Bayonne ham with fat.....
- Meat without visible fat • Extra lean minced beef (4% fat) • Steak • Ham without fat • Comb chops
without fat • Sausages with 3% fat • Meatloaf with 3% fat • Veal • Hen without skin • Chicken without skin
• Turkey without skin
- No week per meat, or no never eat meat

10. Fish as a main dish

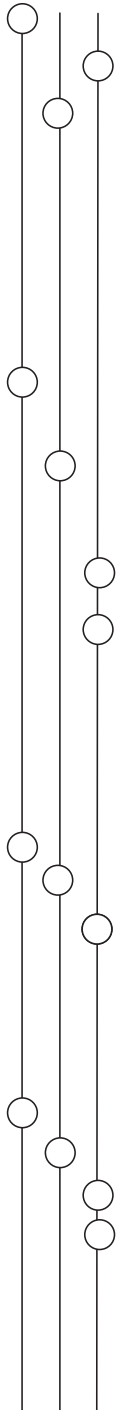
How often do you have fish or fish products as a main dish per week?

- Up to once per week or never
- 2 to 3 times per week
- 4 or more times per week

11. Fat sources in food preparation

What kind of fat do you most often use in the cooking? *In cooking: frying, baking, in sauces*

- Dairy butter • A mixture of dairy butter and margarine • Various types of soya-based hard
margarines
- Soya-, olive oil- or sunflower oil-based soft margarines
- Oils • Liquid margarine
- Usually no butter or margarine in food preparation



12. Grønnsaker

Hvor mange porsjoner grønnsaker, kokte og/eller rå, inkludert poteter, spiser du daglig?

1 porsjon = 150 g: 2 dl grønnsakblanding, 3 dl blandet salat, 2 gulrøtter, 2 poteter o.l.

0 til 1 daglig
2 daglig
3 eller flere

13. Frukt, bær, juice

Hvor mange porsjoner spiser/drikker du daglig?

1 porsjon = 150 g: 1 appelsin, 1 eple, 20 druer, 2 dl bær, 1,5 dl juice o.l.

0 til 1 daglig
2 daglig
3 eller flere daglig

14. Sukker

Hvor ofte spiser/drikker du dette?

1 brødslike med honning, syltetøy, prim, brunost, sjokoladepålegg eller annet søtt pålegg; 1 dl sukkret saft, brus, juice eller nektar; 5 sukkerbiter; ½ spiseskje sukker

0 til 2 ganger daglig
3 til 4 ganger daglig
5 eller flere ganger daglig

15. Godteri, sjokolade, snacks, kaker, fet kjeks, iskrem

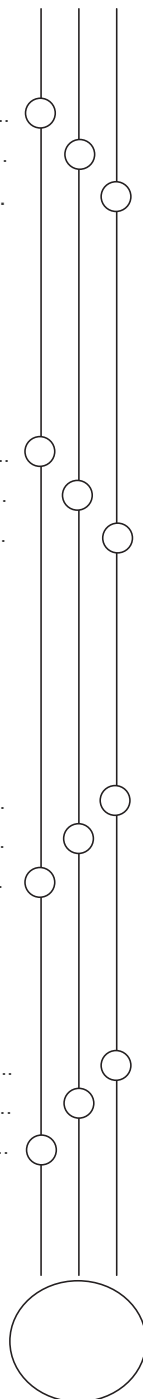
Hvor ofte spiser du dette?

1 gang i uken eller sjeldnere
2 til 3 ganger i uken
4 eller flere ganger i uken

Antall dager siste uke som du har tatt tran, trankapsler eller omega3-tilskudd:

0 1 2 3 4 5 6 7

ANTALL POENG:.....



12. Vegetables

How many servings of vegetables, boiled and/or raw, potatoes included, do you eat per day?

1 serving = 150 g: 2 dl mixed vegetables, 3 dl mixed salad, 2 carrots, 2 potatoes etc..

- 0 to 1 daily
- 2 daily
- 3 or more

13. Fruit, berries and juice

How many servings do you eat/drink per day?

1 serving = 150 g: 1 orange, 1 apple, 20 grapes, 2 dl berries, 1,5 dl juice etc.

- 0 to 1 daily
- 2 daily
- 3 or more daily

14. Sugar

How often do you eat/drink the following?

1 slice of bread with honey, jam, brown cheese, chocolate or other sweet/sugary spread;

1 dl sugar sweetened juice or soda; 5 cubes of sugar; ½ tablespoon of sugar

- 0 to 2 daily
- 3 to 4 daily
- 5 or more daily

15. Sweets, chocolate, snacks, cakes, fat cookies, ice cream

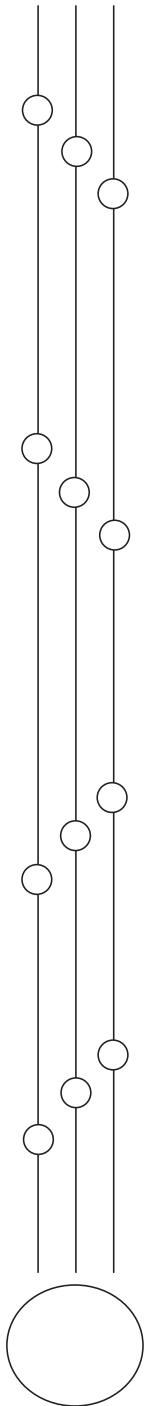
How often do you eat this?

- Once a week or less
- 2 to 3 times per week
- 4 times or more per week

**Number of days last week you took cod liver oil /capsules /
or Omega-3 supplements:**

0 1 2 3 4 5 6 7

NUMBER OF POINTS:



Appendix III

III

Noen spørsmål om helse og livet

I denne delen av undersøkelsen spør vi om hvordan du ser på helse og livet ditt. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre de daglige gjøremålene dine.

1. Stort sett, vil du si at din helse er?

Utmerket

Meget god

God

Nokså god

Dårlig

2. Sammenlignet med for ETT år siden, hvordan vil du si at din helse stort sett er nå?

Mye bedre

Litt bedre

Omtrent den samme

Litt dårligere

Mye dårligere

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

AKTIVITETER

Anstrengende aktiviteter, som å løpe, løfte tunge gjenstander, delta i anstrengende idrett.

Ja,
begrenser
meg myeJa,
begrenser
meg littNei,
begrenser
meg ikke i
det hele tatt

Moderate aktiviteter, som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid.

Løfte eller bære en handlekurv.

Gå opp trapper flere etasjer.

Gå opp trapper en etasje.

Bøye deg eller sitte på huk.

Gå mer enn to kilometer.

Gå noen hundre meter.

Gå hundre meter.

Vaske deg eller kle på deg.

Some questions about health and life

In this part of the survey we ask about how you assess your health and your life. This information will help us to understand how you experience life and in which degree you are able to perform activities of daily living.

1. In general, would you say your health is?

Excellent

Very good

Good

Fair

Poor

2. Compared to one year ago, how would you rate your health in general now?

Much
betterSomewhat
better

About the same

Somewhat
worse

Much worse

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities now? If so, how much

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderat activities, sucs as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lifting or carrying groceries.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bending or kneeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk more than two kilometers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk some hundred meters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk hundred meters.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bathing or dressing yourself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	Ja	Nei
Du har måttet redusere tiden du har brukt på arbeid eller på andre gjøremål.	<input type="checkbox"/>	<input type="checkbox"/>
Du har utrettet mindre enn du hadde ønsket.	<input type="checkbox"/>	<input type="checkbox"/>
Du har vært hindret i å utføre visse typer arbeid eller gjøremål.	<input type="checkbox"/>	<input type="checkbox"/>
Du har hatt problemer med å gjennomføre arbeidet eller andre gjøremål (f.eks. fordi det krevde ekstra anstrengelser).	<input type="checkbox"/>	<input type="checkbox"/>

5. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som f. eks. å være deprimert eller engstelig)?

	Ja	Nei
Du har måttet redusere tiden du har brukt på arbeid eller på andre gjøremål.	<input type="checkbox"/>	<input type="checkbox"/>
Du har utrettet mindre enn du hadde ønsket.	<input type="checkbox"/>	<input type="checkbox"/>
Du har utført arbeidet eller andre gjøremål mindre grundig enn vanlig.	<input type="checkbox"/>	<input type="checkbox"/>

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene?

Ingen	Meget svake	Svake	Moderate	Sterke	Meget sterke
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt	Litt	En del	Mye	Svært mye
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down the amount of time you spent on work or other activities.	<input type="checkbox"/>	<input type="checkbox"/>
Accomplished less than you would like.	<input type="checkbox"/>	<input type="checkbox"/>
Were limited in the kind of work or other activities.	<input type="checkbox"/>	<input type="checkbox"/>
Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down the amount of time you spent on work or other activities.	<input type="checkbox"/>	<input type="checkbox"/>
Accomplished less than you would like.	<input type="checkbox"/>	<input type="checkbox"/>
Didn't do work or other activities as carefully as usual.	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

Not at all	Slightly	Moderately	Quit a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	Nesten hele tiden	Mye av tiden	Endel av tiden	Litt av tiden	Ikke i det hele tatt
Følt deg full av tiltakslyst?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg veldig nervøs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vært så langt nede at ingenting har kunnet muntre deg opp?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg rolig og harmonisk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hatt mye overskudd?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg nedfor og trist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg sliten?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg glad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Følt deg trett?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger osv)?

Hele tiden	Nesten hele tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Hvor RIKTIG eller GAL er hver av de følgende påstander for deg?

	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
Det virker som om jeg blir lettere syk enn andre.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jeg er like frisk som de fleste jeg kjenner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jeg tror at helsen min vil forverres.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jeg har utmerket helse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks you:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of pep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been a very nervous person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt downhearted and blue?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you feel worn out??	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been a happy person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?

All of the time	Most of the time	Some of the	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am as healthy as anybody I know.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I expect my health to get worse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My health is excellent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix IV

SOC-13 spørreskjema

Nedenfor er det spørsmål om hvordan du har det nå og hvordan du har hatt det tidligere i livet. Vi vet at noen av disse spørsmålene kan oppfattes som svært personlige, men ber deg likevel å svare på dem. Du svarer ved å krysse av i den av rutene som du mener passer best i ditt tilfelle. Dersom du, for eksempel i spørsmål 1, ganske ofte går med en følelse av at du ikke helt bryr deg om hva som hender rundt omkring deg, kunne du sette krysset slik:

Svært sjelden eller aldri

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-------------------------------------	--------------------------	--------------------------

Svært ofte

1. Har du følelsen av at du egentlig ikke bryr deg om hva som foregår rundt deg?

Svært sjelden eller aldri

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Svært ofte

2. Har det hendt at du ble overrasket over oppførselen til personer som du trodde du kjente godt?

Har aldri hendt

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Har ofte hendt

3. Har det hendt at personer som du hadde regnet med, skuffet deg?

Har aldri hendt

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Har ofte hendt

4. Hittil har livet ditt:

Helt savnet mål og mening

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Gjennomgående hatt mål og mening

5. Føler du deg urettferdig behandlet?

Har aldri hendt

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Har ofte hendt

6. Har du noen ganger følelsen av at du er i en ukjent situasjon og ikke vet hva du skal gjøre?

Svært ofte

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Svært sjelden eller aldri

7. Å gjøre de tingene du gjør hver dag, er:

En kilde til glede

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

En kilde til smerte

og dyp tilfredsstillelse

og kjedsomhet

8. Har du svært motstridende tanker og følelser?

Svært ofte

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Svært sjelden eller aldri

9. Hender det at du har følelser inne i deg som du helst ikke vil føle?

Svært ofte

--	--	--	--	--	--	--	--

Svært sjelden eller aldri

10. Mange mennesker - selv de med sterk selvfølelse - føler seg iblant som en "ulykkesfugl". Hvor ofte har du kjent det slik?

Aldri

--	--	--	--	--	--	--	--

Svært ofte

11. Når et eller annet har hendt, har du da vanligvis oppdaget at:

Du overvurderte eller
undervurderte dets betydning

--	--	--	--	--	--	--	--

Du så saken i sin rette
proporsjon

12. Hvor ofte føler du at det ikke er noen mening i det du gjør i ditt daglige liv?

Svært ofte

--	--	--	--	--	--	--	--

Svært sjelden eller aldri

13. Hvor ofte har du følelser som du ikke er sikker på at du kan holde under kontroll?

Svært ofte

--	--	--	--	--	--	--	--

Svært sjelden eller aldri

9. Does it happen that you have feelings inside you would rather not feel?

Very often

--	--	--	--	--	--	--	--

Very seldom or never

10. Many people – even those with a strong character – sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?

Never

--	--	--	--	--	--	--	--

Very often

11. When something happened, have you generally found that:

You overestimated or underestimated its importance

--	--	--	--	--	--	--	--

You saw things in the right proportion

12. How often do you have the feeling that there's little meaning in the things you do in your daily life?

Very often

--	--	--	--	--	--	--	--

Very seldom or never

13. How often do you have feelings that you're not sure you can keep under control?

Very often

--	--	--	--	--	--	--	--

Very seldom or never

Appendix V

Paper I

RESEARCH ARTICLE

Open Access

Effects of lifestyle intervention in persons at risk for type 2 diabetes mellitus - results from a randomised, controlled trial

Vegard Nilsen^{1*}, Per S Bakke² and Frode Gallefoss³

Abstract

Background: Lifestyle change is probably the most important single action to prevent type 2 diabetes mellitus. The purpose of this study was to assess the effects of a low-intensity individual lifestyle intervention by a physician and compare this to the same physician intervention combined with an interdisciplinary, group-based approach in a real-life setting.

Methods: The "Finnish Diabetes Risk score" (FINDRISC) was used by GPs to identify individuals at high risk. A randomised, controlled design and an 18 month follow-up was used to assess the effect of individual lifestyle counselling by a physician (individual physician group, (IG)) every six months, with emphasis on diet and exercise, and compare this to the same individual lifestyle counselling combined with a group-based interdisciplinary program (individual and interdisciplinary group, (IIG)) provided over 16 weeks. Primary outcomes were changes in lifestyle indicated by weight reduction $\geq 5\%$, improvement in exercise capacity as assessed by VO_2 max and diet improvements according to the Smart Diet Score (SDS).

Results: 213 participants (104 in the IG and 109 in the IIG group, 50% women), with a mean age of 46 and mean body mass index 37, were included (inclusion rate $> 91\%$) of whom 182 returned at follow-up (drop-out rate 15%). There were no significant differences in changes in lifestyle behaviours between the two groups. At baseline 57% (IG) and 53% (IIG) of participants had poor aerobic capacity and after intervention 35% and 33%, respectively, improved their aerobic capacity at least one metabolic equivalent. Unhealthy diets according to SDS were common in both groups at baseline, 61% (IG) and 60% (IIG), but uncommon at follow-up, 17% and 10%, respectively. At least 5% weight loss was achieved by 35% (IG) and 28% (IIG). In the combined IG and IIG group, at least one primary outcome was achieved by 93% while all primary outcomes were achieved by 6%. Most successful was the 78% reduction in the proportion of participants with unhealthy diet (almost 50% absolute reduction).

Conclusion: It is possible to achieve important lifestyle changes in persons at risk for type 2 diabetes with modest clinical efforts. Group intervention yields no additional effects. The design of the study, with high inclusion and low dropout rates, should make the results applicable to ordinary clinical settings.

Trial registration: ClinicalTrials.gov: NCT00202748

Keywords: type 2 diabetes mellitus, prevention, lifestyle, obesity

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Background

The incidence of type 2 diabetes mellitus is increasing worldwide. Both genetic predisposition and behavioural and environmental risk factors are needed to develop type 2 diabetes [1]. Recent epidemiologic research suggests that the increased incidence of type 2 diabetes is largely due to changes in lifestyle factors such as diet and physical activity [2]. Lifestyle modification in high risk individuals has been proven effective in reducing type 2 diabetes [3];[4], more effective than drug treatment [4] and with sustained reduction in diabetes incidence [5,6]. Cochrane reviews summarize that exercise combined with diet can decrease the incidence of type 2 diabetes in high risk individuals, but that additional research is needed to reveal the best type of diet [7,8]. According to the International Diabetes Federation, up to 80% of type 2 diabetes is preventable by adopting a healthy diet and increasing physical activity. Even small weight losses combined with about 30 minutes of activity per day, are in many instances enough to prevent or at least postpone the disease [3,4]. One kg of weight lost is associated with a 16% reduction in diabetes risk [9].

Meta-analysis indicate that dietary counselling interventions for persons with obesity or overweight produce modest weight losses that diminish over time [10]. Compared with diet alone, diet in combination with exercise gives a 20% greater initial and sustained weight loss after one year [11]. Successful weight loss studies are usually conducted in tightly randomised, controlled trials (RCTs) with low inclusion rates and low external validity and applicability to clinical practice (Efficacy studies; "Can it work?") [12]. Effectiveness studies ("Does it work?") are usually studies with looser study designs (often simple audits or before-after designs), high inclusion rates, and brief feasible interventions, with focus on the ability to maintain the intervention as standard practice [12]. Patients included in such studies are more often in alignment with patients met in common clinical settings. There is an unmet need to develop practical, sustainable and low-intensity interventions for the large number of people at risk for type 2 diabetes [13]. In this trial, individual lifestyle counselling by a physician, with emphasis on diet and exercise, was provided for individuals at risk of type 2 diabetes. The effects of this intervention, alone or combined with an additional group-based interdisciplinary program over 16 weeks, was assessed in a randomised, controlled design with an 18 month follow-up.

Methods

Subjects and study design

The "Finnish Diabetes Risk score" (FINDRISC) was used to identify individuals at high risk for type 2

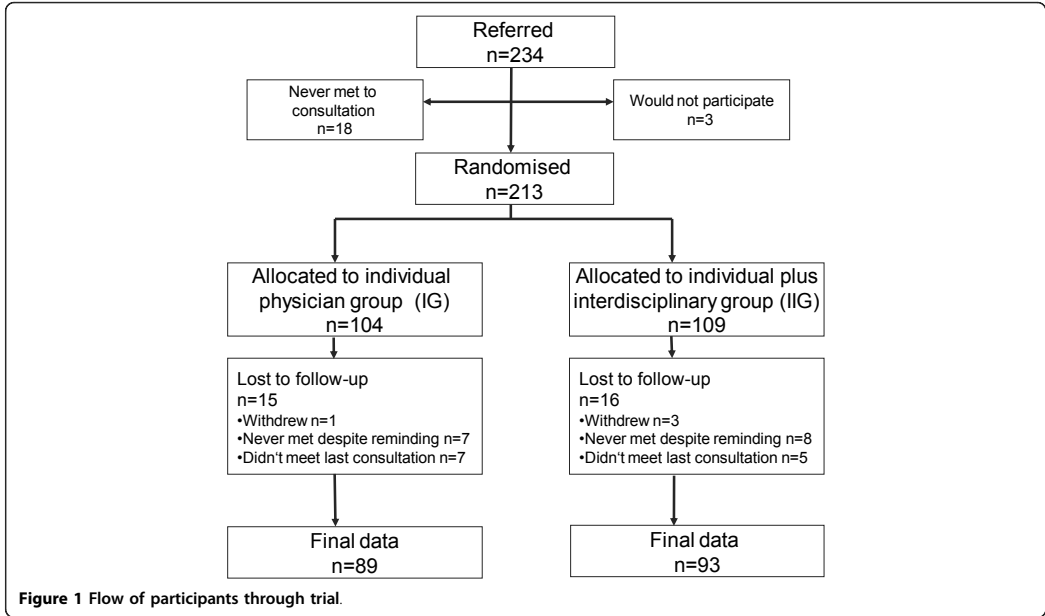
diabetes, assessing waist circumference, body mass index (BMI), age, medication against high blood pressure, activity, history of high blood glucose and daily consumption of vegetables/fruits. FINDRISC is found to be a simple and feasible tool, i.e. fast, non-invasive, reliable and at the start of this trial, the best available tool for use in clinical practice (14;15). It is also a good predictor of coronary artery disease (CAD), stroke and total mortality [16]. The total score ranges between 0-20. A FINDRISC-score ≥ 9 is found to identify > 70% of new cases of drug treated type 2 diabetes within five years [14]. Hence, all general practitioners (GPs) in the four nearest municipalities to the hospital were each supplied with ten FINDRISC-questionnaires by post, asked to use them on patients at risk for type 2 diabetes. They were requested to refer individuals aged 18-64 with a FINDRISC-score ≥ 9 to the hospital. The Regional Committee for Medical Research Ethics of southern Norway approved the study.

All referred individuals were assessed by the same physician in a clinical examination. A thorough conversation about family history of diabetes and heart disease was carried out, as well as tobacco and alcohol consumption assessments. Finally, the following information, statements and advices were given:

1. the probability of type 2 diabetes can be reduced by 50% with only small changes in lifestyle and weight
2. the same changes can reduce the probability for heart disease considerably
3. The following were emphasized:

- to increase the consumption of fruit and vegetables
- to get at least 30 minutes of activity pr. day
- to achieve at least 5% loss of weight
- to reduce the consumption of sugar and saturated fat
- to use oil as the main source of fat
- to consume cod-liver oil daily

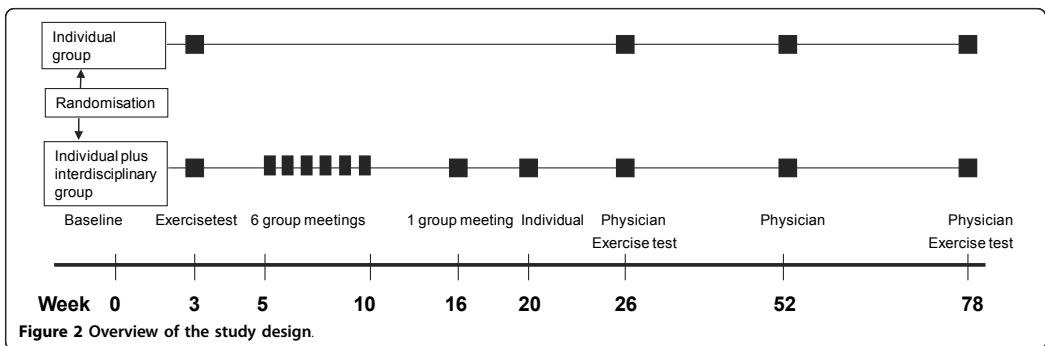
At the end of the consultation, participants were asked if they wanted to participate in the study. Exclusion criteria were: a diagnosis of diabetes mellitus, the presence of serious heart, lung, kidney or liver failure, serious psychiatric illness, substance abuse and not mastering the Norwegian language. A written informed consent was signed. They were randomly assigned to an "individual physician group" (IG) or an "individual plus interdisciplinary group" (IIG) by use of closed envelope method with unknown block sizes. All GPs received written information about inclusion, group allocation and aims and advices given. Flow of participants through the trial is shown in Figure 1.



Participants in the IG group consulted the study physician at six, twelve and eighteen months after randomisation and otherwise received care from their GP as usual. The study physician used elements of motivational interviewing during these consultations.

In addition, the IIG group participated in a group-based program (\leq ten participants), one day (five hours per day) each week for six weeks and a new gathering after twelve weeks. A systematic review of their situation was given, with emphasis on how to avoid diabetes and CAD, by increasing the level of knowledge and self-consciousness (Figure 2). The topics for these group sessions were research findings

and factual information about nutrition and physical activity, habit change, action plans, risk situations, coping strategies, etc. The group intervention also included a variety of physical training. The IIG program was interdisciplinary (dietician, physiotherapist, ergonomist, nurse and physician). Motivational interviewing techniques were utilised. This is a well-known, scientifically-tested method-, which outperforms traditional advice given in the treatment of a broad range of behavioural problems and diseases [17]. An individual 30-minutes consultation with a nurse or ergonomist completed the intervention one month after the last group meeting.



Assessments

At every visit to the study physician, the following assessments were performed: fasting blood sample, systolic and diastolic blood pressure (SBP and DBP) according to recommended standards [18], waist circumference at a level midway between the lowest rib and the iliac crest to the nearest cm, height without shoes to the nearest cm (only first visit) and weight in indoor clothes to the nearest 100 g. Blood pressures were measured by an Omron M41 and weight with a Seca 771. An oral glucose tolerance test (OGTT), required to rule out diabetes and to identify patients with impaired glucose tolerance (IGT), was not performed prior to nor during the study. These pragmatic inclusion criteria fits well with the aim of the study to test the effects of step one life style intervention in a group at risk for diabetes. The Smart Diet Score questionnaire was used; a fast, simple and validated tool for food assessment resulting in a diet score which ranges between 15 and 45 points [19]. A diet score between 15-29 points is categorised as "unhealthy", 30-37 points as "somewhat unhealthy" and ≥ 38 points as a "healthy" diet. A question was added to the questionnaire to ascertain the number of days with cod-liver oil consumption during the last week.

A physical test on a treadmill was carried out during the first month after randomisation and repeated after six and eighteen months, to determine maximal aerobic capacity (VO₂max), utilising a modified Bruce protocol designed for people in poor physical condition [20]. The results were categorised into six levels according to normative data for VO₂max for gender and age: very poor, poor, fair, good, excellent and superior aerobic capacity [21]. An increase in exercise capacity of 3,5 ml/kg per minute (one metabolic equivalent (MET)) is shown to be associated with a 12 percent improvement in survival [22].

Definition of end points

Primary outcomes were changes in lifestyle according to established goals that have been shown to reduce incidence of type 2 diabetes, improve health and to improve cardiovascular risk profile. These were defined as:

- weight reduction $\geq 5\%$ [23]
- reduction in waist circumference of ≥ 5 cm [24]
- improvement in exercise capacity of one MET [22]
- consumption of cod-liver oil \geq five days per week [25]
- ≥ 4 point increase in Smart Diet Score. The outcome for this diet change is an arbitrary threshold which is not evidence based. It reflects an improvement in four out of 15 areas of diet

Statistical analyses

Sample size was based upon a decision that a difference between groups in all main outcomes of $> 20\%$ was clinically important. Therefore, number needed to treat (NNT) = five, to experience one extra person with a favourable main outcome with the additional group session approach. The spontaneous rate of achieving the primary outcomes was estimated to be approximately 20%. The dropout rate was estimated to 15-20%. On the basis of these assumptions, with a power $> 80\%$ ($\beta \leq 0.20$), a significance level $\alpha \leq 0.05$, and a two-sided test, the appropriate study size was calculated to be 200 participants, with 100 in each group. Statistical package for Social Sciences 16 (SPSS Inc. Chicago, USA) was employed for statistical analyses. The χ^2 test was used to assess the differences between groups when variables were categorical and McNemar test when testing within-group changes from baseline to follow-up. The independent sample t-test was used to assess differences in means between study groups for continuous variables with normal distribution. Paired t-test was used for (within-group) comparisons of quantitative data between baseline and follow-up at 18 months.

Results

65 GPs out of about 90 referred 234 individuals from March 2004 to September 2005. 216 turned up for consultation (Figure 1). 213 participants were randomised (inclusion rate $> 91\%$) of whom 182 completed the study ($> 85\%$). Mean (standard deviation = SD) FIN-DRISC score was 12,0 (2,7) for the IG-group and 12,3 (2,8) for the IIG-group. 173 answered the diet questionnaire at the end of study (95% of completers). 201 performed the treadmill test at baseline (94% of included), 168 after six months and 131 (72% of completers) at the end of the study. The dropout rate from baseline to end of study was comparable in the IG- and the IIG group (15%), and comparable between genders. The drop-outs, as compared with completers, were 3,8 years younger (43,2 versus 47,0), more often on antidepressants (23% versus 6%), had higher BMI (38,9 versus 36,4), lower aerobic capacity (24,1 versus 27,2), lower diet score (27,5 versus 29,0) and doubled frequency of both daily smoking (50% versus 21%) and long term sick leave or disability (57% versus 28%), (all p values < 0.05). Participants in the IIG group attended on average five (5,2) of the seven group meetings, and 94% attended the final, individual consultation and assessment.

Randomisation seemed successful for all baseline variables except for BMI. Participants in the IG group had significantly lower BMI than persons in the IIG group (Table 1). 90% of participants were obese (BMI > 30). Weight reducing drugs (orlistat or sibutramin) were used by 10% in the IG-group and 5% in the IIG-group at baseline ($p =$

0,15), at follow-up they were used by 4% in the IG-group and by 5% in the IIG-group ($p = 0,79$). None were using metformin or glitazones. Anti-hypertensive drugs were used among 36% of all at baseline and 37% at follow-up. The percentage of subjects with hypertension (defined by systolic blood pressure ≥ 140 mmHg and/or diastolic pressure ≥ 90 mmHg [26] or use of anti-hypertensive drugs) was 71% in the IG-group and 76% in the IIG-group ($p = 0,25$) at baseline, and 79% and 82% ($p = 0,40$), respectively, at follow-up. Hypertension were seen more often among subjects using anti-hypertensive drugs compared to subject not using it at baseline, i.e. 75% versus 59%, respectively ($p = 0,02$), but at follow-up this difference was not significant, 76% versus 65% respectively ($p = 0,13$).

Poor or very poor aerobic capacity was found in 55% of all participants, and was twice as frequent among men (75%) as among women (36%), ($p < 0,001$). Aerobic capacity at baseline was weakly, inversely correlated with BMI ($r^2 = 0,22$, $p < 0,001$). An unhealthy diet was found in 60% of all participants, and more frequently among daily smokers (76%) compared with the occasional- and non-smokers (55%), ($p = 0,008$). More than two-thirds had lower education (primary or secondary education only). For individuals with primary and/or secondary education only, mean diet score was 2,2 points lower ($p < 0,001$), mean aerobic capacity 4,6 ml/kg/min. lower ($p < 0,001$) and the frequency of daily smoking more than doubled (30% versus 12%, $p = 0,006$), compared to those with higher education.

From baseline to follow-up there were no significant, additional effects of group intervention (Tables 1 and 2). Thus, the forthcoming results are presented as before-after differences for all participants combined. At least one primary outcome (Table 2) was achieved by 93% while all primary outcomes were achieved by 6%, indicating an important change in lifestyle. Most successful was the 78% reduction in the proportion of participants with unhealthy diet (almost 50% absolute reduction, Figure 3). The number of individuals consuming cod-liver oil ≥ 5 days per week increased by 25% and was thereby doubled. There was a mean increase in maximal aerobic capacity of 9% which was evident after six months and thereafter stable. One third of participants improved their aerobic capacity to an extent which is known to improve health (1 MET). Mean weight loss from baseline was modest: 1,9 kg (SD 5,6), 2,0 kg (SD 6,2) and 2,8 kg (SD 7,1) respectively, at 6, 12 and 18 months assessments, with no gender differences. One-third had a weight reduction $\geq 5\%$ (mean 9,4% (SD 4,0)), one third had a weight reduction less than 5% (mean 2,1% (SD 1,4)) and the last third gained weight (mean 4,0% (SD 3,8)). From baseline to follow-up there were no change in the proportion of participants with plasma glucose \geq

7,0 mmol/l (6%), IFG (15%) or normoglycemia (79%), and no between group differences.

Discussion

This study confirms that changes in lifestyle are possible in individuals at risk for type 2 diabetes, with modest clinical effort. This applies to both genders regardless of educational status. Almost half of participants abandoned their unhealthy diet, one third obtained a health-improving weight loss and one third improved their fitness by one MET. Adding interdisciplinary group-based counselling to the individual physician-based intervention, gave no additional effects.

Limitations of the study must be considered. First, dietary intake was assessed by self-report and may present a source of recall bias. General underreporting compounded with food-specific underreporting is frequent and may increase with increasing BMI [27,28]. Second, 28% of completers failed to perform the treadmill test, which weakens the results for change in fitness. We can consider the worst case scenario i.e. that all who did not attend the last test and all who dropped out did not improve their aerobic capacity. The success rate would then fall from 33 to 20% if success is defined as improvement of VO_{2max} of 1 MET. However, we contend that compliance with treadmill testing for almost three fourths of completers in such an unselected study population is a high standard result. Third, the study-physician (first author) was not blinded to the randomisation status of the participants. This may have biased the results. Fourth, dropouts differed from participants who completed testing by being younger and having poorer lifestyle parameters. Hence, withdrawal in this study does not occur at random, but is more common among individuals who are dissatisfied with their life style [10]. It is a paradox, and a major healthcare challenge, that those who have greatest need for a change in lifestyle are also those who are most likely to discontinue an intervention. Fifth, the generalisability of the findings in this study could be limited by self-selection bias or healthy volunteer bias. Thus, extrapolating these results to the general population may overestimate the effects. However, the results should be valid for patients at risk for diabetes according to the FINDRISC questionnaire.

A major strength of this study is the low drop-out rate compared with other weight loss studies. A meta analysis of 121 pharmaceutical randomised controlled trials with weight loss or weight gain prevention as major end points, found a drop-out rate of 37% at one year [29]. Studies including behaviour modification among overweight and obese out-patients report drop-out rates after one and two years of 53-77% [30,31]. The aim of this study was to evaluate a practical and low-intensity

Table 1 Baseline characteristics of 213 included subjects and changes in selected clinical and metabolic variables from baseline to follow-up at 18 months among 182 completers of the study.

	Individual physician group (IG) n = 104			Individual plus interdisciplinary group (IIG) n = 109			All n = 213			
	Baseline			Baseline			Baseline			
Age	45,9 (11)			47,0 (11)			46,5 (11)			
Gender, men, %	53			47			50			
Married or cohabiting, %	79			69			74			
High school or university, %	27			29			28			
Employed, %	64			61			62			
BMI	35,9 (6)			37,6 (6)			36,8 (6)			
	Baseline	Follow-up	P value	Baseline	Follow-up	P value	Baseline	Follow-up	Δ-value	P value
	n = 89			n = 93			n = 182			
Weight, kg	111,7 (22)	108,7 (23)	< 0,001*	110,5 (22)	108,0 (20)	0,001*	111,1(22)	108,3 (21)	2,8	< 0,001*
BMI, kg/m ²	35,8 (6)	34,8 (6)	< 0,001*	37,0 (6)	36,2 (6)	< 0,001*	36,4 (6)	35,5 (6)	0,9	< 0,001*
Waist circumference, cm	119 (14)	115 (15)	< 0,001*	118 (15)	116 (14)	< 0,001*	118 (14)	115 (14)	3	< 0,001*
Aerobic capacity, ml/kg/min ²	27,4 (8)	29,8 (8)	< 0,001*	26,4 (8)	28,7 (7)	< 0,001*	26,9 (8)	29,2 (7)	2,3	< 0,001*
Heart rate at end of exercise test ²	159 (22)	163 (21)	0,009*	159 (19)	161 (21)	0,17*	159 (20)	162 (21)	3	0,004*
SBP, mmHg	144 (18)	147 (19)	0,09*	144 (20)	143 (19)	0,84*	144 (19)	145 (19)	1	0,37*
DBP, mmHg	90 (11)	91 (10)	0,42*	88 (10)	91 (11)	0,03*	89 (11)	91 (11)	2	0,04*
Fasting plasma glucose, mmol/l	5,5(0,8)	5,6(0,7)	0,69*	5,6(0,8)	5,8(1,2)	0,06*	5,6(0,8)	5,7(1,0)	0,1	0,08*
HbA1c, %	5,6 (0,4)	5,6 (0,5)	0,11*	5,6 (0,4)	5,6 (0,5)	0,91*	5,6 (0,4)	5,6 (0,5)	0	0,29*
Total cholesterol, mmol/l	5,5 (1,1)	5,3 (1,0)	0,09*	5,4 (1,1)	5,2 (1,1)	0,07*	5,4 (1,1)	5,3 (1,0)	0,1	0,01*
HDL cholesterol, mmol/l	1,18 (0,3)	1,23 (0,3)	0,006*	1,28 (0,4)	1,25 (0,4)	0,17*	1,23 (0,4)	1,24 (0,3)	0,01	0,40*
Triglycerides, mmol/l	1,9 (1,0)	1,6 (0,7)	< 0,001*	1,8 (1,4)	1,5 (0,8)	0,01*	1,9 (1,2)	1,5 (0,7)	0,4	< 0,001*
Diet score, mean	29 (4)	33 (4)	< 0,001*	29 (4)	34 (3)	< 0,001*	29 (4)	34 (4)	5	< 0,001*
Healthy diet, % of all	2	16	0,007#	1	20	< 0,001#	2	18	16	< 0,001#
Unhealthy diet, % of all	60	17	< 0,001#	56	10	< 0,001#	58	13	45	< 0,001#
Daily smoking, %	21	17	0,22#	18	18	1,0#	20	17	3	0,34#
Days/week using cod liver oil	1,8 (3)	3,4 (3)	< 0,001*	1,8 (3)	4,1 (3)	< 0,001*	1,8 (3)	3,7 (3)	1,9	< 0,001*
Cod liver oil ≥ 5 days per week	25	43	0,02#	26	54	< 0,001#	25	49	24	< 0,001#

Values are means with standard deviations in parenthesis, unless stated otherwise.

¹Inter-group differences with p < 0.05 based on Chi-Square test for categorical variables and independent sample t-test for quantitative data

*paired sample t test # McNemar test

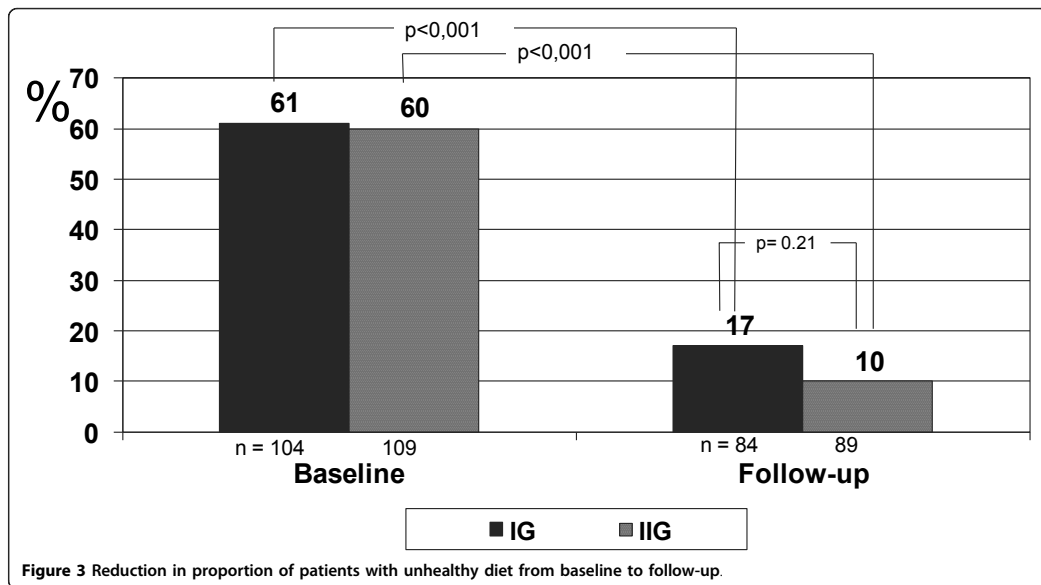
² N = 63 & n = 66 in the IG and IIG group, respectively

Δ-value displays the actual difference between baseline and follow-up

Table 2 Success in achieving primary outcomes by 18 months according to treatment group by proportions (%).

Primary outcome	Individual physician group (IG) n = 89	Individual and interdisciplinary group (IIG) n = 93	P value*	All n = 182
1. Weight reduction ≥ 5%	36	28	0,25	32
2. Waist circumference reduction ≥ 5 cm	42	30	0,11	36
3. Improved diet score ≥ 4 points	55	63	0,28	59
4. Cod-liver oil at least 5 days a week	43	54	0,15	49
Exercise test from baseline to follow-up	n = 63	n = 64		
1. Improved exercise test ≥ 1MET	35	33	0,80	34

* The χ^2 test



intervention with high external validity. An inclusion rate of > 91% of those referred and a participation rate of > 98% among those who turned up for consultation, no excluded individuals and a drop-out rate < 15%, is in accordance with this aim and increases the general applicability of the study results to common clinical settings. Low education was associated with a poorer diet, lower aerobic capacity and smoking, as found in other studies and reviews [32,33]. These factors and their interactions are possible confounders. These associations were not tested in an interaction term, since such results cannot be utilized in any clinically meaningful way. However, education level did not affect the success with respect to primary outcome achievements.

An unexpected finding was the much higher prevalence of poor or very poor aerobic capacity for gender and age at baseline among males compared with females. Some of the difference can be explained by a lower heart rate among males at the end of the first exercise test. This finding may reflect lower motivation and maximal effort, but may also be influenced by a trend toward more common use of beta blockers among men than women (25% versus 15%, $p = 0,08$). However, at the final test, both use of beta blockers and maximal heart rate was comparative between genders (20% versus 19%, $p = 0,84$). Further, the lower aerobic capacity observed in males was not explained by higher BMI. Indeed, BMI in males tended to be lower than in the female group (36,1 versus 37,4, $p = 0,10$). Therefore given that neither beta blocker use nor BMI differences

explain the lower aerobic capacity observed in this group of obese males, we do not have a clear explanation for the difference observed between genders. We note that FINDRISC has a better ability to detect men than women with low aerobic capacity. As far as we know, no one before has previously described the aerobic capacity in individuals screened by FINDRISC.

The short duration and low intensity intervention may explain the absence of additive effect for the group-based, interdisciplinary approach. Svetkey et al found a 8,5 kg initial weight loss in 1032 overweight or obese adults with hypertension/dyslipidemia after six months with 20 group-based meetings, but gradually this weight loss was reduced over the next 30 months to 3,5 kg [34]. Although statistically significant, there was little difference in final weight loss with regard to whether they after the first six months were randomised to monthly personal contact, free use of internet technology or self-directed control. Modest weight loss is nonetheless clinically important since there is a preferential loss of the more pathogenic visceral adipose tissue (VAT) compared with subcutaneous abdominal adipose tissue (SAT) with modest weight loss [35]. A Cochrane review of long-term non-pharmacological weight loss interventions for adults with pre-diabetes, found weight loss of 2,8 kg and 2,6 kg, respectively, after one and two years, which is comparable with the weight loss in this study [36]. Further, the weight loss in this study is even more clinically important if this result is compared with the natural concomitant weight gain found in population-based surveys [37,38].

The effects on glucose metabolism and lipids were modest. Despite the favourable lifestyle changes achieved, no difference was observed in the fasting plasma glucose and HbA1c values, or the proportion of subjects with impaired fasting glucose, within the 18-month study duration. Subgroup analyses including participants with both $\geq 5\%$ weight reduction and improved aerobic capacity ≥ 1 MET ($n = 24$) showed statistically significant ($p < 0.05$) changes from baseline to follow-up; a HbA1c reduction from 5,8 to 5,5%, drop in triglyceride levels from 2,0 to 1,3 mmol/l and in total cholesterol from 5,5 to 5,0 mmol/l. Blood pressure was not improved, in fact there was an increase in diastolic blood pressure in the IIG group. The prevalence of hypertension was very high, and higher among users of antihypertensive medications. Subgroup analyses including the same 24 participants from above with both $\geq 5\%$ weight reduction and improved aerobic capacity ≥ 1 MET, showed systolic/diastolic blood pressure reduction of 7/4 mmHg which significantly differed compared to a rise of 3/3 mmHg in the rest of the participants. Favourable metabolic improvements were achieved among subjects who significantly changed their lifestyle, not among the others. Use of anti-hypertensive or lipid lowering drugs did not change during the study.

Is there a lack of knowledge with regard to what persons at risk of type 2 diabetes should do to avoid type-2 diabetes? The "Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes" (SHIELD) demonstrates appropriate knowledge and healthy attitudes in individuals with or at risk for type 2 diabetes [39]. Despite this, only 28% of individuals at high risk for diabetes were exercising regularly and only 14% were following a prescribed diet. Patient empowerment has been advocated as an approach to improve this gap between patient knowledge and behaviour [39], which is comparable to the principles of Motivational Interviewing (MI) used in our study. Although different "dosages" of MI were performed in the IG and IIG groups, both groups were approached with MI, which may partly explain the lack of differences between intervention groups.

Previously published clinical trials show impressive results with relative risk reductions for type 2 diabetes of 58% for individuals with impaired glucose tolerance (IGT) [3,4]. Despite this, the World Health Organization estimates that the number of diabetes deaths will double between 2005 and 2030. In many European countries and in the US, adult obesity has reached epidemic proportions with a prevalence of approximately 34% [38,40], coupled with a 34% prevalence of overweight [38]. Strategies to prevent weight gain on a population level are poorly understood [41] and there remains a lack of evidence for an effective intervention to prevent

obesity [42]. To stop the epidemic, collaboration between academic, governmental, industrial and health care sectors is needed [43]. This implies that elements such as food supply, the availability of sweets, transport policy, advertising, labelling and prices have to be evaluated. Until governmental implementation of effective strategies to reduce the invasion of the metabolic syndrome is assured, an individual approach as shown in this study can be utilised with modest clinical efforts and clinically important results.

Conclusion

FINDRISC identifies subjects with high frequency of unhealthy lifestyle parameters. It is possible to accomplish important lifestyle changes in these subjects with modest efforts to prevent or delay development of type 2 diabetes or cardiovascular disease. Group intervention yields no additional effects. The results should be applicable to ordinary clinical settings.

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Authors' contributions

In this study all authors participated in the design and coordination of the study. VN conducted literature review, did all the clinical work and is the main author. FG helped to draft the manuscript and provided advice on data analysis. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Paper II

II

Predictors of health-related quality of life changes after lifestyle intervention in persons at risk of type 2 diabetes mellitus

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Gudrun Rohde · Frode Gallefoss

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Abstract

Purpose To assess health-related quality of life (HRQOL) of subjects at risk of type 2 diabetes undergoing lifestyle intervention, and predictors for improved HRQOL.

Methods The Finnish Diabetes Risk Score was used by general practitioners to identify individuals at risk. Low-intensity interventions with an 18-month follow-up were employed. HRQOL was assessed using the SF-36 at baseline and compared with results from a general Norwegian population survey and further at 6 and 18 months. Simple and multiple linear regression analyses were applied to identify predictors of changes in HRQOL of clinical importance.

Results Two hundred and thirteen participants (50 % women; mean age: 46 years, mean body mass index: 37) were included: 182 returned for 18-month follow-up, of whom 172 completed the HRQOL questionnaire. HRQOL was reduced with clinical significance compared with general Norwegians. The mean changes in HRQOL from the baseline to the follow-up were not of clinical importance. However, one out of three individuals achieved a moderate or large clinical improvement in HRQOL. The best determinant for improved HRQOL was obtained for a composite, clinically significant lifestyle change, i.e. both a weight reduction of at least 5 % and an improvement in exercise capacity of at least 10 %, which was associated

with an improvement in five out of the eight SF-36 domains.

Conclusion Subjects at risk of type 2 diabetes report a clinically important reduction in HRQOL compared with general Norwegians. The best predictor of improved HRQOL was a small weight loss combined with a small improvement in aerobic capacity.

Keywords Quality of life · Type 2 diabetes mellitus · Prevention · Lifestyle · Obesity

Introduction

Lifestyle modification in subjects at high risk of type 2 diabetes mellitus (DM) has been proven effective in reducing the incidence of type 2 DM [1–3]. Two systematic reviews that assessed the effects of lifestyle changes on the prevention of type 2 DM showed that no studies reported data on health-related quality of life (HRQOL) [4, 5]. The negative consequences of both type 2 DM and obesity on HRQOL have been well documented [6–8]. Significant HRQOL improvements have been observed after weight loss in obese individuals undergoing a variety of treatments [7, 9], although a systematic review of randomised trials reported inconsistent results [10]. The relative importance of weight loss versus improved fitness regarding the improvement in HRQOL via lifestyle modification is unclear. Among women, weight loss seems to be the main contributor to improved HRQOL, whereas increased fitness yielded disappointing effects [11]. In the Diabetes Prevention Program, all facets of the significant improvement in HRQOL observed were correlated primarily with weight loss [12].

The aim of this study was to assess HRQOL in an unselected group of subjects at risk of type 2 DM

Trial registration ClinicalTrials.gov: NCT00202748.

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undergoing lifestyle treatment and to identify predictors of clinically important HRQOL improvements. Low-intensity interventions with high applicability in ordinary clinical practice were chosen.

Methods

Subjects and study design

Individuals at high risk of type 2 DM were identified by general practitioners (GPs) using the seven-item “Finnish Diabetes Risk Score” (FINDRISC) [13]. FINDRISC is based on traditional risk factors for diabetes, such as body mass index (BMI), waist circumference, inactivity and age. Copies of the FINDRISC questionnaire were sent by post to approximately 90 GPs in the four municipalities located nearest to the hospital. Individuals aged 18–64 years with a FINDRISC score ≥ 9 , which implies a moderate-to-high risk of type 2 DM, were invited to participate in the study. Study inclusion was performed from March 2004 to September 2005, with an 18-month follow-up period. After signing written informed consent, participants were allocated randomly to an “individual physician group” (IG) or an “individual physician plus interdisciplinary group” (IIG). Individual physician interventions in both groups were delivered at baseline and at 6, 12 and 18 months. Subjects in the IIG participated in an additional 18 h group-based, interdisciplinary programme administered over 16 weeks. Since no statistically significant differences between intervention groups were found regarding change in lifestyle or change in HRQOL, the results are presented as a cohort study for all participants combined [14]. Details regarding recruitment methods, FINDRISC, exclusion criteria, the intervention programme and categorisation of aerobic capacity and diet have been thoroughly explained previously [14]. The study was approved by the Regional Committee for Medical Research Ethics of southern Norway.

Assessments

Socio-demographic features, height without shoes, weight in indoor clothes and the results of a modified Bruce protocol on a treadmill for subjects with low aerobic capacity were recorded at baseline and again after 6 and 18 months, yielding maximal oxygen uptake reported as mL/kg/min. A weight reduction $\geq 5\%$ and an improvement in exercise capacity of $\geq 10\%$ from the baseline to the follow-up were used as criteria for a clinically significant lifestyle change [14]. HRQOL was assessed at the baseline, 6 and 18 months using the Medical Outcomes Survey, Short Form 36 (SF-36), version 1. This is a generic instrument

that has been extensively tested nationally and internationally and has satisfactory reliability and validity. The SF-36 has proven to be applicable to both healthy subjects and patients with medical conditions, thereby rendering it possible to draw comparisons between patients and the general population [15, 16]. Normative data from the general Norwegian population ($n = 4,444$) were used for comparison [17]. The answers to the 36 items are coded into eight domains; four are interpreted as physical indicators (general health perception (GH), physical functioning (PF), role limitation physical (RP) and bodily pain (BP)) and four are interpreted as mental health indicators (mental health (MH), social functioning (SF), vitality (VT) and role limitation emotional (RE)). The eight domains are transformed to a scale of 0 to 100, in which 100 is the best possible and 0 the worst possible health state [15]. Norwegian SF-36 norm data for the age-group were used to aggregate the two summary scales from z -score transformations of the eight domains, a physical component summary (PCS) and a mental component summary (MCS) [16]. These summary scales are standardised, to achieve a mean score of 50 and a standard deviation of 10 in the general population. Scores above 50 represent better functioning compared with the general population and vice versa.

Definition of end-points

One of the challenges of studying HRQOL is that improvements that are statistically significant can, nevertheless, be of little clinical relevance [18]. The primary outcomes of this paper were clinically important changes in HRQOL. On a 100-point scale, mean score changes of 5–10 points were interpreted as small, changes of 10–20 points were considered moderate and changes of >20 points were considered large clinical changes [19, 20]. Regarding the summary scales (PCS and MCS), a 2–5 point change was interpreted as small, a 5–8 point change was considered moderate and a ≥ 8 point change was considered large, corresponding to effect sizes of 0.20–0.49, 0.50–0.79 and ≥ 0.80 [16, 20]. Changes (Δ values) in the eight domains and two summary scores were calculated by subtracting the baseline value from the follow-up value, i.e. a positive value implies an improvement, whereas a negative value implies a worsening of HRQOL.

Statistical analyses

Statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS), version 18.0. Differences in means between groups were assessed using an independent samples t test for continuous variables with normal distribution, and the χ^2 test was used for categorical

variables. Mean differences between the study group and normative data were assessed using the *t* test. Paired sample *t* test was used to detect changes in HRQOL data over time.

Simple linear regression analyses and multiple linear regression analyses (GLM procedure in SPSS) were applied to identify significant predictors of changes in HRQOL from baseline to follow-up for the eight domains and the two summary scales, with adjustment for baseline HRQOL values in the multiple analyses. Independent variables in the multiple regression analyses were selected based on both clinical experience and findings from a previous study that showed that socio-demographic variables (age, sex, living conditions and education) influence HRQOL [21]. Further, regarding the uncertainty about the relative importance of weight loss versus improved fitness regarding the improvement in HRQOL, the weight goal alone, the aerobic capacity goal alone and the two combined were tested in the multiple linear regression analyses. To strengthen the analyses for the combined lifestyle achievement, multiple logistic regression analyses were also performed using the same independent variables; these yielded the odds ratios (ORs) for at least a small, clinically significant change in HRQOL as the dependent variable. Confidence intervals (CIs) were reported at the 95 % level. The level of significance was set at $p \leq 0.05$.

Results

Sixty-five of the ~90 GPs who received the FINDRISC questionnaires referred at least one subject from March 2004 to September 2005. Out of the 234 eligible subjects at risk, all 213 individuals who wanted to participate were included in the study (Fig. 1). Of the 213 randomised subjects, 212 completed the SF-36 questionnaire at baseline and 172 (81 % of the randomised individuals) of the 182 subjects who attended the follow-up assessment completed the final SF-36 questionnaire. Unhealthy lifestyle parameters were prevalent: The mean BMI was 37, 90 % of subjects had a BMI >30, three out of five had an unhealthy diet, more than 50 % had poor aerobic capacity, and every fourth participant smoked daily (Table 1). Compared with the general Norwegian population, the population at risk of type 2 DM reported at baseline both statistically significant and clinically important deficits in HRQOL for all eight domains of the SF-36 and for the summary scores (Table 2), with the greatest disparities observed for the physical domains. The 15 % of subjects who dropped out reported clinically important deficits in HRQOL scores at baseline than did the completers of the study (Table 2).

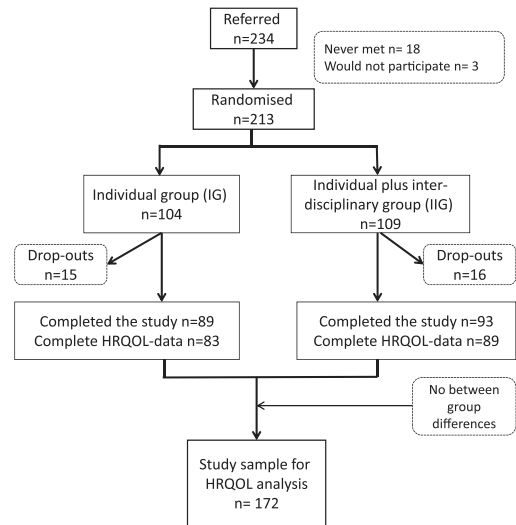


Fig. 1 Flow diagram of participant selection throughout the trial

Table 1 Baseline characteristics. Values are means with standard deviation (SD) or percentage

	All n = 213
Socio-demographic data	
Age	46.5 (11)
Gender, men (%)	50
Married or cohabiting, %	74
High school/university, %	28
Employed, %	62
Long-term sick leave/disabled, %	32
Daily smoker, %	25
Weight measures	
Weight, kg	112.2 (22)
Body mass index, kg/m ²	36.8 (6.0)
Waist circumference, cm	119 (14)
Diet	
Healthy diet, %	1
Somewhat unhealthy diet, %	39
Unhealthy diet, %	60
Aerobic capacity, ml/kg/min (n = 201)	26.8 (7.6)
Good, excellent or superior aerobic capacity, %	25
Poor or very poor aerobic capacity, %	55

The mean weight loss and mean increase in maximal aerobic capacity from the baseline to the follow-up were 2 % (SD, 6) and 12 % (SD, 25), respectively. Correspondingly, the mean changes in all HRQOL scores were

Table 2 Baseline values for HRQOL (SF-36) in the study population, from the general Norwegian population and from completers versus dropouts of the study

SF-36 domain*	All <i>n</i> = 212	Norm # <i>n</i> = 4,444	Completers <i>n</i> = 182	Dropouts <i>n</i> = 30
Bodily pain (BP)	60 (29)	75 (25)***	62 (28)	46 (31)**
General health (GH)	58 (24)	77 (21)***	60 (24)	42 (22)***
Physical function (PF)	75 (20)	90 (17)***	77 (19)	63 (21)**
Physical role limitation (RP)	64 (41)	82 (34)***	66 (40)	49 (42)*
Mental health (MH)	74 (18)	80 (15)***	76 (17)	64 (23)**
Social function (SF)	79 (26)	87 (20)***	81 (24)	65 (31)**
Vitality (VT)	47 (23)	61 (20)***	49 (22)	37 (23)**
Emotional role limitation (RE)	76 (37)	87 (29)***	79 (36)	55 (41)**
Physical component summary (PCS)	41 (12)	50 (10)***	42 (12)	36 (11)*
Mental component summary (MCS)	47 (13)	50 (10)***	48 (12)	41 (15)*

Data are presented as means (SD). Norm # normative data from the general Norwegian population aged 18–64 years. Independent samples *t* test between the whole study population (All) and Norm # and Completers and dropouts

* $p < 0.05$, ** $p < 0.01$ and *** $p < 0.001$

Table 3 Δ values from the baseline to the follow-up for HRQOL (SF-36) shown for all subjects and for those achieving and not achieving two main lifestyle change goals (weight reduction $\geq 5\%$ and improved aerobic capacity $\geq 10\%$)

SF-36 domain*	All <i>n</i> = 172	Not achieving both goals <i>n</i> = 96	Achieving both goals <i>n</i> = 26
Bodily pain (BP)	0 (25)	-2 (22)	13 (29)*
General health (GH)	4 (18)	2 (17)	14 (16)**
Physical function (PF)	5 (16)	5 (13)	17 (15)***
Physical role limitation (RP)	0 (40)	1 (37)	15 (42)
Mental health (MH)	2 (18)	2 (16)	7 (16)
Social function (SF)	3 (25)	0 (21)	14 (24)**
Vitality (VT)	5 (22)	3 (22)	17 (16)**
Emotional role limitation (RE)	3 (39)	6 (30)	3 (38)
Physical component summary (PCS)	2 (9)	1 (8)	8 (9)***
Mental component summary (MCS)	1 (13)	1 (11)	4 (11)

Data are presented as means with standard deviations in parenthesis. *p* values based on an independent samples *t* test performed between those achieving and not achieving the lifestyle change (* $p < 0.05$, ** $p < 0.01$ and *** $p < 0.001$)

small and not of clinical importance (Table 3, 4). However, a moderate or large clinical improvement in HRQOL was achieved in about one out of three participants, with the highest proportions found for general health (42 %) and vitality (41 %), the lowest for emotional role limitation (18 %) and the two summary scales in the middle with PCS (32 %) and MCS (31 %). The improvements in HRQOL

were basically achieved during the first 6 months and thereafter stabilised (Table 4).

A simple linear regression analysis uncovered that improved PCS was correlated with weight loss and improved fitness, respectively, i.e. 1.5 points for every 5 kg lost and 3.4 points for every 5 mL/kg/min improvement in maximal aerobic capacity. No significant correlations were identified for improved MCS.

In a multiple linear regression analysis, using HRQOL score as the dependent variable revealed that a weight reduction $\geq 5\%$ alone was associated with improvement in one physical domain (GH with $B = 7.6$ (2.4–12.9)), one mental domain (VT with $B = 8.4$ (2.3–14.5)) and one summary scale (PCS with $B = 2.9$ (0.2–5.6)). In the same model, an improvement in exercise capacity $\geq 10\%$ alone was correlated with improvement in only one physical domain (BP with $B = 8.9$ (0.8–17.1)) and one summary scale (PCS with $B = 3.5$ (0.6–6.5)). Further, this model demonstrated that the best predictor of improved HRQOL was a clinically significant lifestyle change defined as both a weight reduction $\geq 5\%$ and an improvement in exercise capacity $\geq 10\%$ from the baseline to the follow-up (Table 5). This combined lifestyle change was associated with improvement in three of four physical domains (not RP), two out of four mental components (VT and SF) and one of the two summary scales (PCS) of the SF-36 questionnaire (Table 5). The achievement of this composite lifestyle change was correlated with a large effect on PCS score compared with individuals who did not achieve it, with an unadjusted improvement on PCS of 7.8 (3.4–10.7) and an adjusted improvement of 6.4 (2.9–9.8) (Fig. 2; Table 5).

Table 4 Mean HRQOL values (SF-36) from baseline and 6 months to 6 and 18-month follow-up, respectively

SF-36 domain*	Baseline <i>n</i> = 166	6 months <i>n</i> = 166	6 months <i>n</i> = 150	18 months <i>n</i> = 150	Baseline <i>n</i> = 172	18 months <i>n</i> = 172
Bodily pain (BP)	62 (27)	62 (27)	63 (27)	62 (29)	62 (28)	62 (30)
General health (GH)	60 (23)	64 (23)*	64 (23)	64 (23)	59 (24)	64 (23)**
Physical function (PF)	78 (18)	80 (18)**	81 (17)	82 (17)	76 (19)	81 (18)***
Physical role limitation (RP)	65 (40)	71 (38)*	73 (37)	65 (40)**	65 (40)	65 (41)
Mental health (MH)	76 (17)	77 (17)	78 (16)	77 (18)	76 (17)	78 (17)
Social function (SF)	81 (25)	84 (23)	84 (22)	83 (23)	80 (25)	83 (23)
Vitality (VT)	49 (21)	53 (22)*	53 (22)	52 (24)	48 (22)	53 (23)**
Emotional role limitation (RE)	79 (36)	84 (31)	85 (30)	81 (35)	79 (36)	81 (34)
Physical component summary (PCS)	42 (11)	44 (11)*	44 (11)	44 (11)	42 (12)	44 (12)*
Mental component summary (MCS)	48 (13)	50 (12)	50 (12)	49 (14)	48 (13)	50 (13)

Paired sample *t* test. Data are presented as means with standard deviations in parentheses. Values marked with bold indicate statistical significance (* *p* < 0.05, ** *p* < 0.01 and *** *p* < 0.001)

Based on a multiple logistic regression model, the adjusted ORs for small clinically significant improvements in HRQOL for achievers of the composite lifestyle change versus non-achievers were statistically significant for three physical domains (GH, PF and BP), but none of the mental domains or the summary scales. The OR was highest for GH (7.0 (2.2–21.8)) and quite similar for PF (3.9 (1.2–13.3)) and BP (4.0 (1.4–12.1)).

Discussion

This study showed that subjects at risk of type 2 DM had markedly lower HRQOL than did the general Norwegian population on all eight domains of the SF-36 and on the PCS and MCS summary scales. However, HRQOL improvement in clinical importance was accomplished by a moderate lifestyle change achieved with modest clinical efforts.

The limitations of the study must be considered

First, dropouts differed from completers of the study, reporting significant decrements in HRQOL at the baseline. Thus, individuals who were most dissatisfied with their lives and who were in most need of a lifestyle change unfortunately seemed to dropout of the study. This observation coincided with results from a large meta-analysis and the experiences of many health care providers: “Those who need it the most, understand it the least”, which represents a major healthcare challenge [22].

Second, HRQOL was assessed using a generic instrument, not a disease-specific one. An obesity-specific instrument may have better sensitivity to detect changes than a generic one. The generic SF-36 was chosen since we only included subjects at risk of a disease. A mean BMI of 37 was a surprising finding in this study. Conversely, one

of the major advantages of a generic questionnaire is the possibility to draw comparisons between the study group and the general population and between a variety of medical conditions [6].

Third, the results of this study may be biased by a clustering bias of GPs referring the patients to the study or a selection bias through the participants’ willingness to participate. However, we are not, the way the study was designed, able to correct for these biases. Further, the attendance rate at the final fitness test weakens the study results assessing predictors, also due to a possibility of selection bias, i.e. those who achieve lifestyle changes turn up for the final assessment to a larger extent than those who do not.

Fourth, regarding the applicability of the results, the effects may have been overestimated because of a healthy volunteer bias: Volunteers are fitter and healthier than non-volunteers [23, 24]. On the other hand, as shown in Table 5, baseline values for all ten variables from the SF-36 questionnaire are inversely correlated with improvements in the same variables, i.e. HRQOL seems easier to improve if baseline values are low compared to high, thereby supporting the general tendency of the “regression to the mean” bias. This may support a tendency towards underestimation of the effects if those with even lower HRQOL had participated in the study. However, we are not able to exploit these potential biases thoroughly.

Finally, a follow-up time of 18 months does not automatically imply that the effects achieved are sustainable. It is common knowledge in lifestyle interventions weight loss studies that results diminish overtime [22]. We have no further follow-up assessment data.

The strengths of this study were as follows: First, the simple selection of eligible patients by GPs using the FINDRISC questionnaire. Second, an inclusion rate >91 %, a participation rate >98 %, the absence of excluded subjects and a dropout rate ≤15 % are all robust

Table 5 Predictors of improvement in health-related quality of life (SF-36) in a multiple linear regression analyses with adjusted regression coefficients (adj B)

	Bodily pain (BP) Adj B (95 % CI)	P	General health (GH) Adj B (95 % CI)	P	Physical function (PF) Adj B (95 % CI)	P	Physical role (RP) lim. Adj B (95 % CI)	P	Mental health (MH) Adj B (95 % CI)	P
Demographics										
Male	5.2 (-2.5–12.9)	0.19	0.5 (-5.3–6.3)	0.86	-0.4 (-4.4–3.7)	0.85	4.6 (-7.0–16.2)	0.43	2.3 (-3.0–7.7)	0.39
High education	5.0 (-3.5–13.5)	0.24	0.7 (-5.7–7.2)	0.82	0.7 (-3.7–5.2)	0.75	-7.4 (-20.2–5.3)	0.25	-4.8 (-10.6–1.1)	0.11
Working at baseline	7.9 (-1.0–16.8)	0.08	3.9 (-2.6–10.5)	0.24	5.1 (0.4–9.8)	0.03	24.3 (10.5–38.2)	0.001	0.7 (-5.2–6.6)	0.82
Living together	1.3 (-7.7–10.3)	0.78	-2.8 (-9.5–4.0)	0.42	0.6 (-4.2–5.5)	0.80	-2.2 (-15.8–11.4)	0.75	0.4 (-5.8–6.6)	0.91
Age*	0.1 (-0.3–0.5)	0.57	0.1 (-0.2–0.4)	0.61	0.0 (-0.2–0.2)	0.76	0.2 (-0.4–0.8)	0.45	0.1 (-0.2–0.3)	0.65
IIG group	0.1 (-7.8–8.0)	0.57	0.7 (-5.1–6.6)	0.81	-0.2 (-4.3–3.9)	0.93	-4.7 (-16.4–7.1)	0.43	-2.6 (-8.0–2.7)	0.33
Improved weight and fitness**	15.4 (5.7–25.1)	0.002	12.7 (5.4–19.9)	0.001	8.9 (3.8–14.0)	0.001	12.1 (-2.4–26.6)	0.10	5.6 (-1.1–12.2)	0.10
Adjustment for baseline value***	-0.4 (-0.5–0.2)	<0.001	-0.3 (-0.5–0.2)	<0.001	-0.5 (-0.6–0.3)	<0.001	-0.6 (-0.8–0.4)	<0.001	-0.5 (-0.7–0.3)	<0.001
R ² adjusted	22.3 %		19.1 %		39.1 %		32.2 %		20.6 %	
	Social function (SF) Adj B (95 % CI)	P	Vitality (VT) Adj B (95 % CI)	P	Emot. role (RE) lim. Adj B (95 % CI)	P	Phys. comp. sum. (PCS) Adj B (95 % CI)	P	Ment. comp. sum. (MCS) Adj B (95 % CI)	P
Demographics										
Male	1.7 (-5.0–8.5)	0.61	3.0 (-4.0–10.0)	0.40	3.0 (-7.0–12.9)	0.56	1.1 (-1.6–3.8)	0.44	0.7 (-3.3–4.7)	0.74
High education	-5.5 (-12.9–1.9)	0.15	-2.5 (-10.1–5.1)	0.52	-3.2 (-14.0–7.6)	0.56	0.8 (-2.2–3.7)	0.62	-2.9 (-7.2–1.5)	0.19
Working at baseline	8.1 (0.6–15.5)	0.04	5.6 (-2.1–13.4)	0.15	-4.6 (-15.5–6.3)	0.41	4.3 (1.1–7.5)	0.009	-1.1 (-5.4–3.2)	0.61
Living together	3.3 (-4.5–11.2)	0.40	-1.5 (-9.5–6.5)	0.71	-4.7 (-16.2–6.7)	0.41	-0.8 (-3.7–2.2)	0.62	-0.1 (-4.6–4.5)	0.98
Age*	0.3 (-0.1–0.6)	0.13	0.0 (-0.3–0.4)	0.88	-0.1 (-0.6–0.4)	0.70	0.0 (-0.1–0.2)	0.48	0.0 (-0.2–0.2)	0.94
IIG group	-2.4 (-9.2–4.4)	0.49	-5.8 (-12.7–1.1)	0.10	-4.6 (-14.6–5.4)	0.36	0.2 (-2.6–3.0)	0.89	-2.7 (-6.7–1.3)	0.18
Improved weight and fitness**	11.3 (2.9–19.7)	0.01	11.3 (2.8–19.9)	0.01	-1.3 (-13.6–11.1)	0.84	6.4 (2.9–9.8)	<0.001	2.2 (-2.7–7.1)	0.38
Adjustment for baseline value***	-0.5 (-0.7–0.4)	<0.001	-0.4 (-0.6–0.3)	<0.001	-0.5 (-0.7–0.4)	<0.001	-0.4 (-0.5–0.3)	<0.001	-0.4 (-0.6–0.2)	<0.001
R ² adjusted	31.5 %		22.2 %		31.6 %		28.7 %		15.6 %	

Regression analyses of demographics, clinical characteristics and baseline values for the eight domains for HRQOL and the two summary scales. Each independent variable was compared with its "opposite", i.e. females with males, low with high education, no work with work, etc. *p* values marked with bold indicate statistical significance. R² represents how well the model explains the dependent variable. * Age in years. ** Both a weight reduction ≥5 % and an improvement in exercise capacity of ≥10 % from the baseline. *** Influence of the baseline value of each domain on the delta value

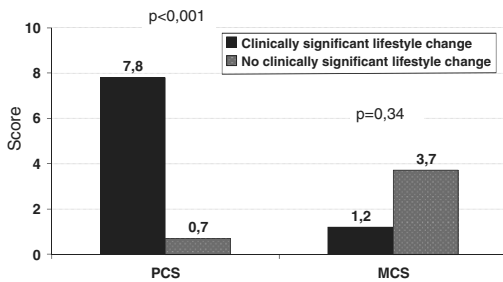


Fig. 2 Changes in PCS and MCS scores associated with achieving or not achieving the combined lifestyle change (weight reduction ≥ 5 % and improvement in exercise capacity ≥ 10 % from the baseline to the follow-up) based on independent *t* tests

characteristics for this clinical study [14]. The general applicability of these results to common clinical settings should thus be good.

As 90 % of the study population was obese, and obesity is related to a lower HRQOL [6], the finding of reduced HRQOL in this study was as expected; however, the magnitude of the difference compared with the general Norwegian population was surprising. Two large meta-analyses have shown that, among obese persons, those not seeking treatment have the best HRQOL, those seeking conservative treatment have a more moderate HRQOL and those seeking surgery have the worst HRQOL [25, 26]. It is surprising that the subjects in this study, who were not seeking treatment for obesity, but were assessed to be at risk of type 2 DM through a questionnaire survey, reported an HRQOL that was as low as that of subjects undergoing bariatric surgery [26]. Decreased HRQOL in subjects at risk of type 2 DM is not a new finding [27, 28]. However, in contrast to findings from Finland, where subjects at risk reported lower general health and increased bodily pain compared with the general Finnish population, all eight dimensions of the SF-36 were significantly lower in our study [28]. This can be explained by the much higher prevalence of obesity in the present study (90 %) compared with the study from Finland (31 %). Chittleborough et al. studied HRQOL along the diabetes continuum in Australia and found a significantly lower score for bodily pain exclusively (i.e. increased pain) among those with impaired fasting glucose compared with those with normal glucose levels, whereas those with diabetes scored significantly lower on all dimensions, with the exception of mental health [27].

The relative importance of weight loss versus improved fitness regarding the improvement in HRQOL in this study showed an improvement of 1.5 PCS points for every 5 kg lost and 3.4 points for every 5 mL of improvement in maximal aerobic capacity (mL of O₂ uptake/kg/min). No

correlations between changes in body weight or fitness and MCS were found. Correspondingly, improvements in only two of the eight and one of the eight domains of the SF-36 were associated with weight loss or fitness improvement alone, respectively. However, the combination of both weight reduction and improved fitness was most highly correlated with improved HRQOL. Five out of the eight domains of the SF-36 were significantly improved in subjects who made a clinically significant lifestyle change (Table 5). Nevertheless, the correlation observed for Δ PCS was very weak, with an adjusted R^2 of 0.287, which means that only 28.7 % of the variation observed can be explained by this lifestyle change. In other words, most of the variation in Δ PCS could not be explained by the variables identified in this study. However, the study showed that subjects who attained clinically significant lifestyle changes exhibited an improved HRQOL. The greatest impact was found for physical HRQOL domains of functioning, which was in accordance with the results of other studies [6]. Subjects who exhibited an improvement in both weight and fitness may experience a new way of living when approximating their motivational goals. Our experience is that those who achieve both weight reduction and improved fitness often become very dedicated to their changes in lifestyle, in a way that is very similar to that adopted by those who want to quit smoking or alcohol abuse. Achieving their goals after such large motivational changes can then lead to a considerable improvement in reported HRQOL.

A large meta-analysis has shown that an obesity-specific HRQOL instrument reflected weight-related QOL with much better sensitivity than did the SF-36, and found that factors other than weight change were crucial for HRQOL changes [26]. The finding of a much lower HRQOL in the subjects included in this study compared with the general population based on the generic instrument SF-36 may be due to more emotional and complex problems in life, for which weight loss is not the “simple” solution. Obesity is a major public health problem, as a risk factor for a variety of illnesses and as having a devastating impact on HRQOL. This study confirmed the negative consequences of obesity on HRQOL. It also confirmed that even small changes in lifestyle may enhance HRQOL significantly, and that most subjects at risk of type 2 DM are obese, which are all in accordance with the findings of other reviews [6, 7]. Many health care professionals argue that, regarding obesity, for which a cure is unlikely, one of the most important health outcomes that warrants evaluation and improvement is quality of life [7]. We believe that lifestyle changes at a moderate level, as exemplified by a modest increase in physical activity and a small weight loss, will be the most important elements in

improving HRQOL for subjects at risk of type 2 DM. Improvement in HRQOL should, perhaps, be the main goal at the start of treatment, as this may increase the chances for further therapeutic success. In the future, preventive programmes including weight control and exercise should be established for the large proportion of subjects at risk of type 2 diabetes. An individual approach, such as that shown in this study, can be used with modest clinical efforts while yielding clinically important results.

Conclusions

In summary, this study of subjects at risk of type 2 DM showed that HRQOL was markedly reduced in this population. A clinically important improvement in HRQOL was clearly correlated with the achievement of a composite lifestyle change (weight reduction and improved aerobic capacity). However, correlation is not causation. But this association may indicate that important HRQOL improvements can be achieved by small improvements in lifestyle changes in subjects at risk of type 2 diabetes.

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Conflict of interest The authors declare that they have no conflict of interests.

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Paper III

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Original Research

Is sense of coherence a predictor of lifestyle changes in subjects at risk for type 2 diabetes?

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ABSTRACT

Objective: To determine whether the sense of coherence (SOC) could predict the outcome of an 18-month lifestyle intervention program for subjects at risk of type 2 diabetes.

Methods: Subjects at high risk of type 2 diabetes mellitus were recruited to a low-intensity lifestyle intervention program by their general practitioners. Weight reduction $\geq 5\%$ and improvement in exercise capacity of $\geq 10\%$ from baseline to follow-up indicated a clinically significant lifestyle change. SOC was measured using the 13-item SOC questionnaire.

Results: The study involved 213 subjects with a mean body mass index of 37 (SD ± 6). Complete follow-up data were obtained for 131 (62%). Twenty-six participants had clinically significant lifestyle changes. There was a 21% increase in the odds of a clinically significant lifestyle change for each point increase in the baseline SOC score (odds ratio = 1.21; confidence interval = 1.11–1.32). The success rate was 14 times higher in the highest SOC score tertile group compared with the lowest.

Conclusion: High SOC scores were good predictors of successful lifestyle change in subjects at risk of type 2 diabetes. SOC-13 can be used in daily practice to increase clinical awareness on the impact of mastery on the outcome of life-style intervention programs.

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Introduction

The prevalence of type 2 diabetes is increasing worldwide. Changes in lifestyle factors such as diet and physical activity are suggested to be the main reasons for this increase.¹ The

effective reduction of type 2 diabetes is possible if subjects at high risk make lifestyle modifications,^{2,3} although sustained lifestyle change such as that needed to avoid type 2 diabetes may be difficult to achieve.⁴ Thus, it is a challenge for subjects at risk to achieve desirable, permanent lifestyle changes. Moreover, it is difficult for clinicians to identify the subjects

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who are most likely to profit from a lifestyle modification program, thereby improving cost-effectiveness. Many studies have found that a positive health outcome can be predicted using the Sense of Coherence (SOC) questionnaire.^{5–8} The present study examined whether this simple assessment of the personality trait of mastery can be used as a tool to estimate the likelihood that subjects will achieve successful lifestyle changes.

The salutogenic theory, which focuses on predictors of positive health outcomes, was introduced in the 1970s by Antonovsky, who was interested in stress theory. Based on a study of healthy survivors from concentration camps in the Second World War, he postulated three important properties that allowed them to remain healthy despite their experiences: a) the ability to understand what happens, b) the ability to manage the situation alone or through significant others and c) the ability to find meaning in the situation. According to this theory, the ability to use your own resources is more important than the resources themselves.^{9,10} This ability is referred to as the SOC, which can be defined as a way of viewing life or mastery.^{9,10} The concept of SOC was shown to have the capacity to predict future health outcomes.⁹ Thus, the aim of the present study was to determine whether SOC at baseline could predict the outcomes of a low-intensity lifestyle intervention programme for subjects at risk of type 2 diabetes, and to assess the predictability of other simple demographic factors.

Methods

Subjects and study design

The study sample comprised subjects at high risk of type 2 diabetes mellitus who were referred to the local hospital by their general practitioner (GP). The 'Finnish Diabetes Risk score' was used by GPs to select subjects based on traditional risk factors for type 2 diabetes, such as the body mass index (BMI), waist circumference, inactivity and age.¹¹ The study operated from March 2004 to September 2005 and there was an 18-month follow-up period. This study was part of a randomized controlled trial, where one group received personal advice and another group received personal advice plus group sessions. There were no important outcome differences between these two treatment groups, as described previously,¹² so the results were combined for all participants for the purpose of this study. Written informed consent was obtained. The details of the recruitment methods, the intervention program and the main results have been published previously.¹² The study was approved by the Regional Committee for Medical Research Ethics of Southern Norway.

Assessments

Body weight and the results of a physical test on a treadmill, using a modified Bruce protocol for subjects in poor physical condition,¹³ were determined at baseline and at follow-up. Based on normative data for the maximal aerobic capacity (VO_2 max) with respect to gender and age, the subjects were classified into six levels, i.e., very poor, poor, fair, good,

excellent and superior aerobic capacity.¹⁴ A clinically significant lifestyle change was characterized as a weight reduction of $\geq 5\%$ and an improvement in the VO_2 max of $\geq 10\%$ from baseline to follow-up.¹² The health-related quality of life (HRQOL) was assessed at baseline and follow-up using the Medical Outcomes Survey Short Form 36 (SF-36), and the results were used to calculate a physical component summary (PCS) and a mental component summary (MCS). The SF-36 is used internationally as a generic measure of self-reported HRQOL.¹⁵ The scores for PCS and MCS range from 0 (worst possible) to 100 (best possible health state), where the results are standardized to fit a mean score of 50 to the general population.^{15,16} Changes in the PCS and MCS scores of 2–5 points are defined as small clinically significant changes, whereas changes of 5–8 and ≥ 8 are defined as moderate and large clinically important changes, respectively.¹⁷ The instrument used to measure mastery at an individual level was the SOC questionnaire. The two most widely used versions of the SOC questionnaire are the original version with 29 items and a shorter version with 13 items.⁹ The correlation between SOC-29 and SOC-13 is good ($r = 0.96$)¹⁸, so the short version was used in the present study. According to Antonovsky's three postulated properties, the questionnaire examines three sub-dimensions: meaningfulness, comprehensibility and manageability.^{9,19} SOC-13 was shown to be reliable, valid, feasible and cross-culturally applicable.⁹ Subjects were asked to indicate their level of agreement with each of the items on a seven-point scale (1 = never, 7 = always). The total score was summed, which could range from 13 (low SOC) to 91 (high SOC), where a higher score indicated a stronger SOC or mastery. Many studies have shown that the SOC changes with time, but Antonovsky assumed that it would stabilize in early adulthood with marginal subsequent fluctuations.^{9,20–22} The aim of the present study was to explore baseline predictors, so SOC was only measured at baseline.

Definition of end points

The primary outcome of this study was to evaluate the objective predictors for a successful, clinically significant lifestyle change, which were defined as weight reduction $\geq 5\%$ and an improvement in the exercise capacity of $\geq 10\%$ from baseline to follow-up.¹²

Statistical analyses

The statistical analyses were performed with the Statistical Package for Social Sciences version 18.0 (SPSS) using descriptive analyses of the baseline characteristics. Clinically significant lifestyle changes, the SF-36 PCS and MCS scores and their changes were computed, as well as the baseline SOC scores. To produce a prognostic model of successful lifestyle change, a multivariable logistic regression analysis was conducted using the combined objective clinically important lifestyle change as the dependent variable with the various demographic and clinical variables, the SF-36 scores and the SOC scores as explanatory variables. To use SOC as an explanatory variable, the results for each single question were analyzed separately, each of the three scores for the sub-dimensions (meaningfulness, comprehensibility and

manageability) and the total SOC score. Different methods were tested (enter, forward and backward) and the final adjusted model was obtained using the 'enter' method of logistic regression analysis by including all of the independent variables in the model, regardless of the level of significance obtained for each separate variable. Unadjusted multivariate logistic regression analyses were also performed for comparison, where the odds ratios (ORs) were used to describe the bivariate associations. Based on the multivariate logistic regression analysis, a receiver operating characteristic (ROC) curve was constructed and the area under the curve (AUC) was used to assess the sensitivity and specificity of the combined predictors. Theoretically, the AUC ranges from 0 to 1, with 1 as a perfect test, implying 100% sensitivity and specificity, and 0.5 as the worst possible value (no better than a random guess).^{23,24} Furthermore, based on the absolute rates of successful lifestyle change, the numbers needed to treat (NNT) were calculated to achieve one successful lifestyle change (1/absolute ratio of success), which has the advantage that it yields both the statistical significance and the clinical effort needed to achieve an important clinical outcome. These calculations were also performed based on the intention to treat (ITT) principle, assuming that all drop-outs and those with incomplete data did not achieve the combined life style change. This avoids any bias caused by omitting these participants from the main analyses. All of the confidence intervals (CI) were set at 95% and the level of significance was set at $\alpha \leq 0.05$.

Results

The authors randomly allocated 213 subjects to the study, of whom 182 (85%) completed the study and 131 (62%) provided complete data in terms of their change in weight and aerobic capacity (VO_2 max). The mean BMI was 37 (SD \pm 6), 90% of participants were obese (BMI > 30) and more than half of the

participants had a poor aerobic capacity at baseline (Table 1). The SOC score ranged from 27 to 89 with a mean score of 63 (SD \pm 14). There were no significant differences in the SOC score with respect to gender, home relations or educational categories, but the scores were significantly lower for daily smokers (60 (SD \pm 14)), subjects who were not working (58 (SD \pm 15)) and the subjects who dropped out of the study (49 (SD \pm 8)) compared with their counterparts. Objective combined lifestyle changes, i.e., a clinically significant weight reduction and an improved exercise capacity, were achieved by 26 subjects.

According to the multivariate logistic regression analyses, very similar clinical and statistical results were given by the different methods, i.e., enter, forward and backward. Using the enter method of logistic regression analysis, i.e., including all of the independent variables in the model the best predictor of success was a high total SOC score. In this model the total SOC score was clearly associated with the combined lifestyle change, with an adjusted OR for a clinically significant lifestyle change of 1.21 (CI = 1.11–1.32) for each additional SOC point (Table 2). This correlation differed little in the unadjusted model (1.17 (1.09–1.24)). A ten point higher SOC score was correlated with an OR for successful lifestyle change of 6.7 (2.8–16.1). Neither any single question nor any of the three sub-dimensions (meaningfulness, comprehensibility and manageability) in the SOC questionnaire was associated with successful lifestyle change. There was also a statistically significant association between a successful lifestyle change and a decreased physical HRQOL (lower PCS) according to SF-36 (Table 2), which yielded an adjusted OR of 1.08 (1.00–1.16) for each point decrease in the PCS score.

After dividing the subjects in this study into tertiles according to their SOC scores, the lowest tertile had a mean (SD) SOC score of 47.8 (7.5), the medium tertile had a score of 64.7 (4.0) and the highest tertile had a score of 78.0 (4.9). The proportions who dropped out from the final aerobic test and provided incomplete data were 53%, 23% and 26% in the low,

Table 1 – Baseline characteristics of the subjects included in the study. The values are means with standard deviations in parentheses or percentages.

	n = 213
Demographics	
Age (years)	46.5 (11)
Female (%)	50
Living alone (%)	26
High school or university education (%)	28
Sick leave or disabled (%)	32
Poor or very poor aerobic capacity (%)	55
SF-36 HRQOL	
PCS ^a	41 (12)
MCS ^b	47 (13)
Clinical characteristics	
Body mass index (BMI) (kg/m ²)	36.8 (6.0)
Aerobic capacity (ml/kg/min ²)	26.8 (7.6)
Sense of coherence (SOC, n = 197)	
SOC-score ^c	63.4 (13.6)

^a Physical component summary.
^b Mental component summary.
^c Sense of coherence score.

Table 2 – Odds ratios for successful lifestyle change assessed using multivariate logistic regression analysis.

	OR (95% CI)	p
Demographics		
Age (per year)	1.00 (0.93–1.08)	0.94
Female	2.94 (0.86–10.00)	0.09
Living alone	1.97 (0.47–8.26)	0.35
Higher education	0.53 (0.12–2.32)	0.40
SF-36 HRQOL		
PCS ^a (per point)	0.93 (0.86–1.00)	0.05
MCS ^b (per point)	0.94 (0.88–1.01)	0.08
Clinical characteristics		
Body mass index (kg/m ²)	1.13 (0.99–1.29)	0.07
Aerobic capacity (ml/kg/min ²)	1.14 (0.98–1.31)	0.09
Sense of coherence (SOC)		
SOC-score ^c (per point)	1.21 (1.11–1.32)	<0.001
SOC-score ^c (per 10 points)	6.73 (2.84–16.06)	<0.001

OR: adjusted odds ratios, 95% CI: 95% confidence interval and P-values. Bold values indicate statistically significant differences.
^a Physical component summary.
^b Mental component summary.
^c Sense of coherence score.

medium and high SOC tertile groups, respectively. Among the 26 subjects who achieved success, one was in the lowest SOC tertile, four in the medium tertile and 21 in the highest tertile. Thus, among the participants with complete data, the proportions who succeeded were 3%, 8% and 44% in the low, medium and high SOC tertile groups, respectively (Fig. 1). The corresponding results when the intention to treat principle was used were 2%, 6% and 32%, respectively (Fig. 1, Table 3). No participants with a SOC score <45 achieved a clinically significant lifestyle change. Thus, the NNT to achieve one successful lifestyle change among those who completed the trial as planned differed greatly according to the SOC tertiles, i.e., the NNTs were 31, 13, and 2 in the low, medium and high SOC tertile groups, respectively (Fig. 2). With the ITT principle applied, the NNT figures were of course higher, and especially for the low tertile group.

Discussion

The present study showed that a high level of mastery, which was assessed using the SOC questionnaire, was associated with an increased likelihood of successful lifestyle change for subjects at risk of type 2 diabetes, and vice versa.

The limitations of this study must also be considered. The results may have been weakened by the dropout rate of 15% and complete follow-up data were only obtained from 62% of the participants. This problem is highlighted further by the fact that the baseline characteristics of the completers and dropouts differed significantly,¹² thereby suggesting a possibility of attrition bias.²⁵ However, many studies of exercise testing obtained follow-up data from less than two-thirds of the randomized participants,²⁶⁻²⁸ and the statistically significant correlations connected to the SOC scores, i.e., the main message of this paper, were especially robust ($P < 0.001$).

In this study, the possibility of using the SOC score was tested to predict a successful lifestyle change, i.e., its predictive validity. The authors found that the predictive validity was acceptable and the frequency of drop-out in the low SOC tertile, was double that in the medium and high SOC tertiles. Divergent results have been reported previously, but a number of studies have found that a high SOC score can predict positive health outcomes, e.g., among survivors of a ferry

Table 3 – Rate of clinically significant lifestyle change (reduced weight and increased aerobic capacity) relative to the sense of coherence (SOC) score (n = 131).

	n	Success rate %	n	Success rate % ITT ^a
SOC ≥ 30	130	20.0	196	13.3
SOC ≥ 40	128	20.3	186	14.0
SOC ≥ 50	115	21.7	161	15.5
SOC ≥ 60	93	26.9	121	20.7
SOC ≥ 70	55	41.8	72	31.9
SOC ≥ 80	19	57.9	23	47.8

^a Intention to treat principle used for n = 197 based on the SOC score at baseline.

disaster, patients with chronic lower back pain, patients receiving surgery for morbid obesity and unemployed subjects with somatic disorders undergoing vocational rehabilitation.⁵⁻⁸ However, a systematic review concluded that the SOC questionnaire should not be recommended as a screening instrument due to inadequate definition of appropriate cut-off levels, i.e. it is not clear where SOC no longer protects the movement towards the healthy end.⁹ There is also a risk of negative health effects if one stigmatizes people in groups regarding their SOC. Instead, it has been suggested that the SOC concept could be implemented as a systematic orientation and perspective in the daily activities of the professionals.⁹ SOC seems a suitable tool for increasing the professionals' awareness of the individual mastery levels. This awareness will promote the professionals' and researchers' ability to develop and assess sensible future intervention programs for those with low mastery. When the NNT was 2-3 in the present study for subjects in the high SOC tertile, a cost-effective intervention is certainly indicated. When the NNT was 31 for subjects in the low SOC tertile, another approach with a better likelihood of success would be more appropriate. However, such programs adapted for patients with low mastery have not been developed yet. But an increased clinical awareness of patients with low mastery through SOC evaluation may increase the likelihood that such programs can be developed. Thus, the suggestion is that SOC could be used for screening to increase clinical awareness on those with low mastery, but until further research has answered

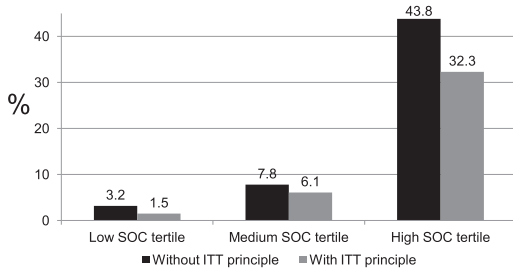


Fig. 1 – Success rate for different sense of coherence (SOC) tertiles at follow-up, with or without the intention to treat principle (ITT).

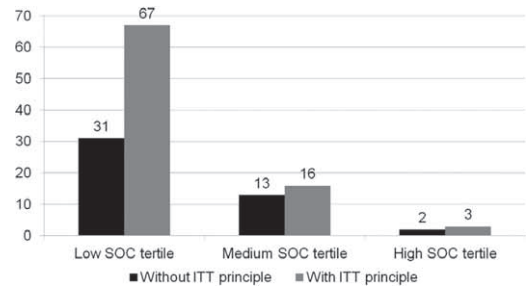


Fig. 2 – Numbers needed to treat to achieve one successful lifestyle change. SOC: sense of coherence; ITT: intention to treat.

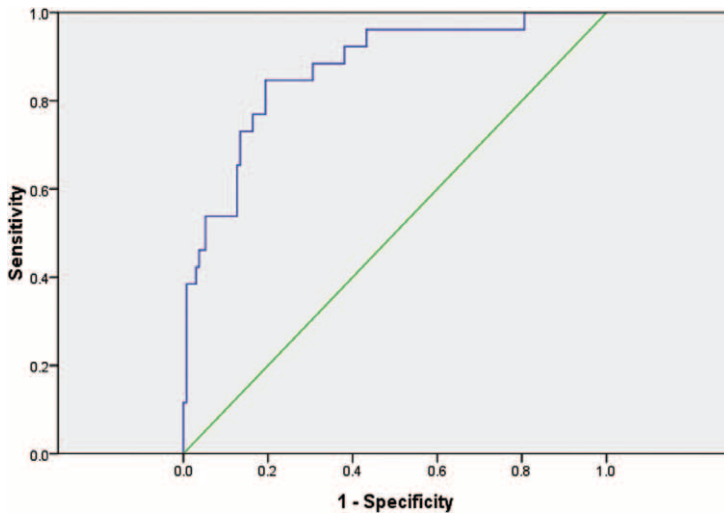


Fig. 3 – Receiver operating characteristic curve for the variables used in the logistic regression analysis to test the predicted probability of successful lifestyle change. The area under the curve is 0.87 (95% confidence interval = 0.80–0.95).

these questions, not for the selection to current intervention programs.

In general, predictors of weight loss and weight maintenance have been reported to be weak in previous studies. These predictors are often heterogeneous and most regression models explain no more than 25–30% of the variance in weight loss.²⁹ Factors such as self-esteem, motivation, dietary behaviors and exercise may be important correlates of success, but the magnitude of the variance they explain appears to be small and it can be highly variable between different groups.²⁹ The use of SOC may, when future research has answered important questions, make it easier to exclude subjects who will not benefit from a specific lifestyle change program, thereby improving cost-effectiveness and guiding the subjects towards more suitable interventions. The ROC curve analysis assessed the accuracy of the model's ability to separate positive cases from negative cases, and the AUC of 0.87 (0.80–0.95) was acceptable (Fig. 3). The AUC of 0.84 (0.75–0.93) for SOC in the univariate model implies an 84% higher probability of successful lifestyle change for a participant with a high SOC score vs a participant with a low SOC score. This type of knowledge may appear clinically important for the allocation of future health care resources.

The present study showed that low mastery, which was assessed based on the SOC score, was associated with a lower ability to achieve desirable lifestyle changes in subjects at risk of type 2 diabetes. A low SOC score has also been associated with an increased risk of myocardial infarction, type 2 diabetes, lower physical activity, unhealthy food choices and all-cause mortality.^{30–35} Kouvonen et al. found that both unhealthy lifestyle choices and a stress-inducing tendency/inadequate coping system could explain the association between low SOC and type 2 diabetes.³⁰ Thus, low mastery *per se* may be considered a major health problem that is associated with an unhealthy lifestyle, difficulty making lifestyle

changes, and, ultimately, it is linked directly with morbidity and mortality.

An interesting and widely discussed topic related to SOC, is its stability. According to Antonovsky, SOC stabilizes in early adulthood with marginal subsequent fluctuations.⁹ However, even Antonovsky believed that the SOC may be mutable, so it may be considered more as a 'dispositional orientation' than a personality trait.⁹ It is now well documented that SOC tends to increase with age and it can be changed markedly by dramatic life events (weakened by negative life experiences and strengthened by positive experiences) or via therapeutic interventions.^{9,36–38} This provides hope for subjects with low SOC scores because positive life experiences, interventions and age appear to increase the SOC score. In study, however, the mean SOC score was not higher for subjects aged ≥ 46 years compared with those below this age.

In addition to the SOC score, a decreased physical HRQOL (low PCS) was correlated with an increased likelihood of desirable lifestyle changes. Subjects with a lower PCS score may feel more uncomfortable and more physically impaired, and both conditions may motivate them to make lifestyle changes. A high level of internal motivation is required if an individual is to improve their health.^{39,40}

'Lifestyle diseases' are now a well-known concept and a huge number of conditions should be treated at least partly with lifestyle changes. In the present study, 90% of the subjects were obese and many had tried numerous different therapies with disappointing results. Thus, it is crucial not to guide them towards a new disappointment, which would be detrimental for their self-image and their self-confidence. This may also be demotivating for health professionals. Treating a high number of patients where only a few achieve the desired results is not a cost-effective allocation of scarce resources. Thus, a baseline assessment with SOC is recommended, mainly to improve awareness of the participants

with a very low likelihood of a positive health outcome, for whom more appropriate, motivational approaches may be developed. These suggestions should be tested in future research.

Author statements

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Ethical approval

Ethical approval was obtained from the Regional Committee for Medical Ethics of Southern Norway.

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Competing interests

The authors declare that they have no competing interests.

Authors' contributions

VN and FG participated in the design and coordination of the study. VN performed a literature review, did all the clinical work and was the main author of the manuscript. FG and GR helped draft the manuscript and provided advice on data analyses. All authors read and approved the final manuscript.

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