Motivating cardiac rehabilitation patients to maintain lifestyle changes

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Appendices

Errata

`Despise no man and consider nothing impossible,

for there is no man who does not have his hour

and there is no thing that does not have its place´

The Talmud

2 List of publications

I.   Mildestvedt T, Meland E. Examining the 'Matthew Effect' on the motivation and ability to make lifestyle changes in 217 heart rehabilitation patients. Scand J Public Health 2007; 35: 140-147.

II.   Mildestvedt T, Meland E, Eide GE. No difference in lifestyle changes by adding individual counselling to group-based rehabilitation RCT among coronary heart disease patients. Scand J Public Health 2007; 35: 591-598.

III.   Mildestvedt T, Meland E, Eide GE. How important are individual counselling, expectancy beliefs and autonomy for the maintenance of exercise after cardiac rehabilitation? Scand J Public Health 2008; 36: 832-840.

IV.   Mildestvedt T, Meland E, Folmo S, Eide GE, Williams G. Cognitive behaviour modification and autonomy support in heart rehabilitation - is personal choice beneficial? Submitted 2008

`Confidence is what you have before you understand the problem´

Woody Allen

3   Abbreviations

ADI   Anxiety Depression Irritability

BMI   Body Mass Index

CABG   Coronary Artery Bypass Graft Surgery

CAD   Coronary Artery Disease

CET   Cognitive Evaluation Theory

CR   Cardiac Rehabilitation

CT   Cognitive Therapy

CVD   Cardiovascular Disease

GE   General Expectancy

GI   Glycemic Index

HCCQ   Health Care Climate Questionnaire

INT   Intervention Group

MI   Myocardial Infarction

MI   Motivational Interviewing

PCI   Percutaneous Coronary Intervention

PES   Positive Expectation Score

RCT   Randomised Controlled Trial

REH   Standard rehabilitation

SCT   Social Cognitive Theory

SDT   Self-Determination Theory

SES   Socioeconomic Status

SPSS   Statistical Package for the Social Sciences

TSRQ   Treatment Self-Regulation Questionnaire

`I have learned to use the word 'impossible' with the greatest caution´

Wernher von Braun

4   Summary

Background

In Western societies, the single greatest opportunity to improve health and reduce premature death lies in personal behaviour. Personal behaviour is, however, embedded in social contexts. Therefore, we may question whether behavioural interventions are ethically justifiable. Those who are socioeconomically disadvantaged and people with emotional problems have a poorer prognosis for cardiovascular disease. Cardiac rehabilitation aims at improving lifestyle, but lifestyle changes are hard to achieve and even harder to maintain. Moreover, we want to develop interventions that do not leave some groups, and especially the disadvantaged, behind. Research is required to present and evaluate new and improved interventions. It is as important to describe why an intervention works (or does not work) as to present its efficacy. In this thesis, we wanted to present a newly developed intervention aimed at improving and maintaining lifestyle changes in a cardiac rehabilitation setting. We also wanted to explore whether lifestyle changes were harder to achieve among the socioeconomically disadvantaged and people with emotional problems. The intervention was based on elements from social cognitive theory and self-determination theory.

Aims

The main aim was to evaluate whether the intervention was superior to standard cardiac rehabilitation. We also examined important predictors derived from our theoretical basis. In a separate analysis, we wanted to analyse the effect of providing personal choice. The first paper examines how socioeconomic factors, disease severity and risk status affect the ability of individuals to make dietary and exercise improvements after heart disease. We also wanted to evaluate whether unfavourable lifestyle outcomes among disadvantaged people were mediated by motivational problems.

Methods

This is a randomised controlled trial and a longitudinal study of predictor variables in a four-week heart rehabilitation setting with two years of follow-up. During a two-year period starting in August 2000, 217 patients were recruited and randomised to either intervention or standard, multifaceted cardiac rehabilitation. At 24 months, 41 patients were lost to follow up, leaving 176 patients eligible for two-year analysis. The intervention was based on a cognitive theory and autonomy support from self-determination theory. It aimed at helping the patient to prioritise between different lifestyle achievements during two individual counselling sessions. They also received a telephone follow-up at six and 24 months, focusing on their prioritised goals. Their level of exercise, smoking and present dietary habits were measured

on inclusion and after six and 24 months. Different motivational factors and emotional distress were measured at baseline. Their predictive power was tested in the three dietary and exercise outcomes. Motivational factors were measured by task-specific self-efficacy questionnaires, General Expectancy and Treatment Self-Regulation Questionnaire. An Anxiety-Depression-Irritability questionnaire measured emotional status, while household income was chosen as the socioeconomic status predictor. Autonomy support was measured by the Health Care Climate Questionnaire.

Results

We found no statistically significant between-group differences. Both groups showed an improvement in their dietary and exercise measures. Self-efficacy predicted an increased frequency of eating fish dinners, more daily units of fruit and vegetables and increased physical capacity. Autonomous motivation was significantly associated with a lower saturated fat diet, exercise and exercise intensity. General expectancy was a significant predictor of increased exercise and physical capacity. Controlled motivation hampered improvement in physical capacity. Autonomous self-regulation was lowest among smokers and female participants. Participants with high scores for emotional distress predicted lower motivation for all the measures. We found no association between socioeconomic status (household income) and the ability to achieve lifestyle changes. Current smoking status predicted lower ability to obtain lifestyle changes on all measures. Emotional distress was related to lower ability to increase physical activity at six months but not at 24-month follow-up. The mediating effects of motivational factors were insignificant.

Conclusion

We found no effect of adding autonomy supportive, individual counselling to group-based interventions. Enhancing choice in a cardiac rehabilitation setting is not sufficient if the goal is to stimulate long-term lifestyle changes. Based on longitudinal documentation, this cardiac rehabilitation programme possibly improves long-term maintenance of dietary changes and exercise measures. Maintenance of these lifestyle achievements is related to autonomous motivation and self-efficacy. The results of this study do not support the suspicion that preventive efforts accentuate the socioeconomic differences in cardiovascular health. We need to target our rehabilitation efforts at special groups like smokers and the emotionally distressed.

5   General introduction

Lifestyle improvements are hard to achieve but even harder to maintain. Relapse to unhealthy habits remains the norm, regardless of the lifestyle behaviour in question [1]. If lifestyle changes are to give positive health outcomes they need to be sustained for a long time. We lack firm knowledge about how to make efficient interventions, and have even more unanswered questions regarding maintenance of lifestyle changes [2]. We wanted to perform a study to seek more evidence on how to achieve long-term maintenance of lifestyle changes in cardiac patients.

In recent decades, heart rehabilitation programmes have focused on the patients' psychosocial situation as well as their physical capacities [3, 4]. Different psychological interventions for coronary heart disease have been tried out with limited and conflicting results so far [5]. We know that there is a great potential for helping people to improve and adopt more heart-protective lifestyles [6]. When it comes to health-related outcomes, human behaviour is the largest source of variance [7]. But what are the factors that determine human behaviour? Current theoretical approaches offer competing explanations. We found an opportunity to address these issues in a cardiac rehabilitation setting.

The study population was chosen from a cardiac rehabilitation centre outside Bergen, Krokeide Rehabilitation Centre. They have developed their programme over the last two decades and wanted to evaluate an intervention developed at the centre. This intervention built upon recent advances in health psychology.

In this thesis, three of the four papers evaluate the efficacy of the intervention. The first paper addresses the question of whether lifestyle intervention is ethically justifiable. Some evidence points to an 'inverse care law': the people who are most in need of health care do not receive it. This can also be described as the 'Matthew effect'. The first paper deals with the question of whether such an effect is evident in cardiac rehabilitation.

In this introduction, you will find a short presentation of the epidemiology of cardiovascular disease (CVD) in Norway, a summary of the most important risk factors, a presentation of the development of cardiac rehabilitation services with up-to-date research evidence on the effects and a comprehensive presentation of theory. When looking for efficient interventions, we must, of course, identify the risk factors that we can modify by achievable changes. Much is known about important risk factors for CVD, and also about where important improvements can be achieved through efficient interventions [8]. A vast number of cardiovascular risk-reduction programmes has been evaluated [2, 9]. Despite this

knowledge, recent research has not led to major changes in the understanding of how we should promote cardiovascular risk reduction. Patients largely know what they should do, but still find it difficult to change and maintain a behaviour that will lessen their burden of disease. Evidence from both primary prevention and secondary prevention shows this [10, 11]. To understand more of the mechanisms we need to have theory-based interventions [1]. The methodological quality of many of the studies evaluating non-pharmacological treatments is often low and this needs to be improved [9]. We need interventions that achieve long-term changes of lifestyles and also help the patient to follow the medical treatment recommended in secondary prevention [12]. The theoretical basis for the intervention presented in this thesis is presented in chapter eight. The following chapters are presenting some epidemiology of CVD, risk factors of CVD and also a presentation of cardiac rehabilitation services.

6   Epidemiology of cardiovascular diseases in Norway

The problem of CVD worldwide is one of great concern to patients and health care agencies alike. Circulatory diseases, including strokes and myocardial infarction (MI) are the number one death cause worldwide, with approximately 30% of the annual total (WHO 1997). In Norway as in other developed countries, the incidence of fatal cardiovascular disease has dropped dramatically since the 1980s. In 2006, approximately 14,650 people died from cardiovascular diseases and about the same number of people experienced a non-fatal MI. As seen in Figure 1, the number of deaths from heart diseases among males aged 45 to 64 has fallen by 3/4 during the last 30 years. Since 2003, the decline has stabilised, and the difference between males and females is currently three to fourfold.

The impressive improvement among males is explained by different theories. Both improved preventive efforts and improvement in treatment and secondary preventions are important factors explaining the falling death rates from CVD. It has been estimated that 2/5 of the decline comes from secondary preventive efforts such as better medical treatment and improved lifestyles. Three-fifths is due to improvements in primary preventive settings [13]. Most deaths now occur among the oldest members of the population. People suffer their first infarction later in life than 20 years ago. Other important explanations are the decline in the prevalence of smokers combined with a 0.8 mmol/l decline in serum cholesterol. Dietary changes account for most of the decline in cholesterol levels [14]. Smoking cessation interventions have successfully led to a decrease in daily smokers among Norwegians (aged 16-74), from 33% in 1998 to 22% in 2007. The most important changes may be due to

interventions on the population level. Health care providers are still encouraged to invite smokers to individual smoking cessation programmes. Smoking cessation is an important goal for comprehensive cardiac rehabilitation, and health care providers hope for similar success in other behaviour domains [7].
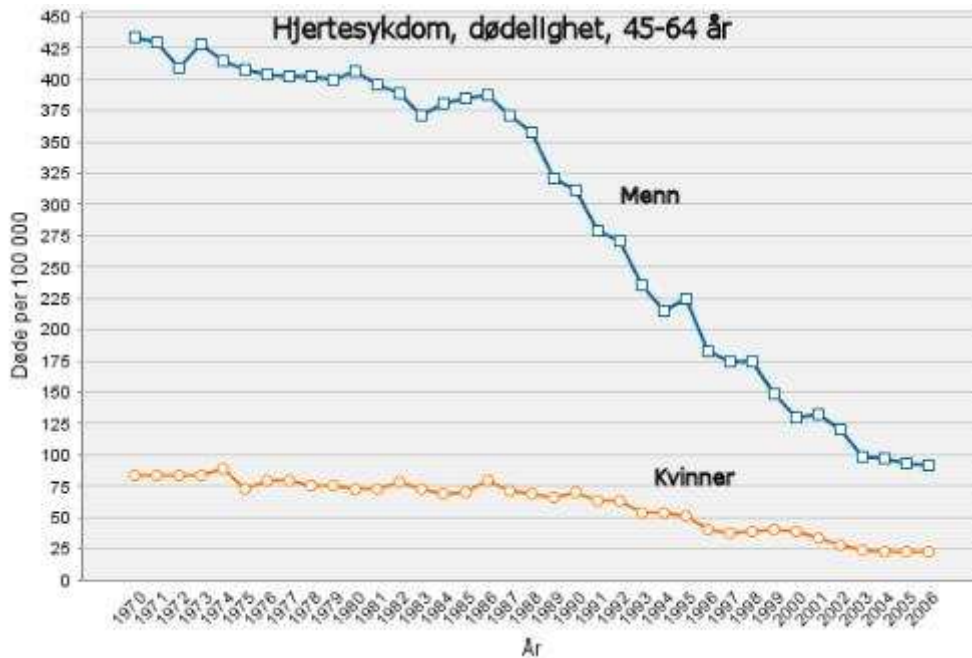
Figure 1 National health institute in Norway website 2008

7   The most important risk factors for cardiovascular diseases

When assessing individual risk, it is important to evaluate the sum of risk factors in order to decide what treatment to offer. An individual risk assessment is especially recommended in primary preventive settings [15], but this is also the basis for treatment decisions in secondary prevention and cardiac rehabilitation [16]. Age, gender, type 1 diabetes and a family history of cardiac disease are risk factors that we cannot modify. The most important modifiable risk factors are psychosocial factors, smoking, diet, hypertension, lipid profile, type 2 diabetes, abdominal obesity, being physically inactive and not taking recommended medication. Among possible modifiable risk factors, these nine factors were found to be responsible for some 90% of MI in the general population [8].

Multifactorial intervention studies typically try to facilitate changes in these risk factors. Different assessment tools have been developed based on Framingham data, European

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SCORE data and also on Scandinavian data in order to help the clinician to make a total evaluation of coronary risk [17, 18]. Interventions have been evaluated in both primary and secondary prevention. Strong evidence has not been produced that a multifactor approach is more efficient than interventions focusing on more limited lifestyle achievements. This applies to both primary prevention and secondary prevention of CVD [19, 20]. Researchers have recently discussed whether the clinician should consider more risk factors than the established ones. Including more risk factors has not led to important information in addition to the standard risk factors [21].

7.1 Smoking

Current and former smoking is responsible for approximately 1/3 of CVD [8]. Iestra et al combined two meta-analyses and found the effect of smoking cessation in coronary artery diseased (CAD) patients to be 35% [22]. These are all cohort studies and RCT data on this issue does not add to this knowledge. A larger randomized controlled trial on smoking will not be performed because the harmful effects of smoking are well established.

7.2 Exercise

Habitual physical activity decrease mortality and morbidity in both a primary and secondary preventive setting [23, 24]. The magnitude of this relationship is uncertain, being based on observational data. The effect of habitual physical activity on all-cause mortality among CAD patients has been estimated to be approximately 25% [22]. The absence of regular physical activity accounted for some 12% of MI in a large case-control study [8]. The impact on mortality is considered to be in line with what we see in relation to risk factors such as smoking, elevated lipid levels and overweight. Being inactive seems to affect health and mortality on the same level as being a smoker [25]. The magnitude of the benefit experienced by women is similar to that seen in men [26]. We observe an inverse linear dose-response relationship between volume of physical activity and all-cause mortality [27]. A Cochrane report found that exercise-based cardiac rehabilitation reduced total mortality by 27%, but it found no evidence of a decrease in non-fatal myocardial infarction [20].These findings were mainly based on observational data on white, middle-aged men.

7.3 Diet

According to the observational INTERHEART study, a daily consumption of fruit and vegetables protects against MI with an odds ratio of 0.7 (0.6-0.8), compared with those who

do not consume fruit and vegetables daily [8]. Interventions to improve diets have been reported with great discrepancies in the effect size. A systematic review found that a combination of dietary changes was associated with a possible reduction of 45% in all-cause mortality [22]. The Mediterranean diet has been evaluated in several randomised controlled trials. The strongest positive effect was found in the Lyon Diet Heart study in which 605 post-MI patients achieved a 68% decrease in cardiac death and non-fatal MI. The patients were followed for 46 months, and the diet was still closely followed by the experimental patients four years after the intervention [28]. The GISSI-Prevenzione trial is the largest randomised, controlled trial to examine the benefits of oil supplements [29]. They followed 11,234 post-MI subjects for 42 months and found a 20% decrease in mortality, a 30% reduction in CV deaths and a 46% reduction in sudden deaths. Life-saving diet after myocardial infarction includes [30, 31]:

- increased omega-3 fat intake from oily fish or rapeseed oil

- reduced saturated fats and total or partial replacement by unsaturated fats

- an increase in fruit, vegetables, nuts and whole grains

We have substantial data on what diet to recommend but it is difficult to implement the recommendations. Dietary advice on CVD prevention is complex. We find an abundance of both scientific and popular information on different diets to improve health and quality of life. Discrepancies in dietary advice lead to confusion and lack of compliance among those with coronary disease as well as the general population [32]. The increasing problem of obesity in Western countries may force us to add a decrease in carbohydrates, especially refined and high-GI carbohydrates, to the list of important dietary changes. (The glycemic index, or GI, ranks the impact of carbohydrate rich food on blood glucose level after digestion). It should be replaced by whole grains and fibre-rich products. This is also in line with the Mediterranean diet, the diet that was recommended in the Krokeide Rehabilitation study.

Moderate alcohol consumption has been reported as resulting in a small but potentially important 20% mortality reduction in CAD patients compared with those who do not drink [22], but there are no randomised controlled data to confirm this association [33]. Possible confounders in this data could be that some non-drinkers do not drink because of other health problems or because the use of medication may prevent them from being able to drink. Another perspective is the fact that increasing from a moderate to a high intake of alcohol leads to deterioration in a number of health parameters, including an increase in coronary risk. We should therefore be cautious about advising an increase in alcohol consumption among

coronary patients and keep in mind that some may develop unhealthy drinking patterns motivated by this advice [33].

7.4 Different stressors: Socioeconomic and psychosocial factors

In the general population, we often hear that stress is an important risk factor for myocardial infarction, but is this true? Stress is difficult to define and measure in a standardised way. There are different instruments, and it is difficult to evaluate the overall association between possible stressful factors and cardiovascular disease. The concept of stress encompasses several factors, including external factors such as stressful life events, financial problems, and job stress. Internal factors include different psychological problems and personality styles [34]. We find increasing evidence for psychosocial factors as an independent factor for CVD [4, 35]. For instance, hostility has been demonstrated to be associated with increased CVD risk, but risk estimates are modest [36]. Clinical depression and depressive symptoms increase CVD risk, with an effect size comparable to active or passive smoking, respectively [34]. Stressors associated with increased risk of CVD disease are often referred to as socioeconomic and psychosocial factors. Low socioeconomic status defined as having a low income, low education, living in a poor residential area or holding a low status job is related to all-cause and cardiovascular mortality. Low social support and the relationship to CVD risk has been reported to be mediated by both lifestyle and psycho-physiological stress responses due to the stress of social isolation [34].

Like other stressors, psychosocial factors also probably influence CVD, both through direct influence on disease mechanisms and indirectly by changing people's capacity to maintain heart-protective lifestyles [37, 38]. These indirect effects on lifestyles are difficult to measure since it takes a long time from adapting a heart-protective lifestyle until effects can be measured. In a 2005 review article, Rozanski et al. proposed six factors linking psychosocial risk factors and cardiac practice (Fig. 2). These are all important reasons why we need to take psychosocial factors into account in secondary preventive programmes [37].

May trigger acute cardiac events

Forms a barrier to medical interventions

Significant risk factor

Psychosocial stress

Linked to behavioural and cardiovascular risk factors

Commonly masquerades as cardiac symptoms

Highly prevalent
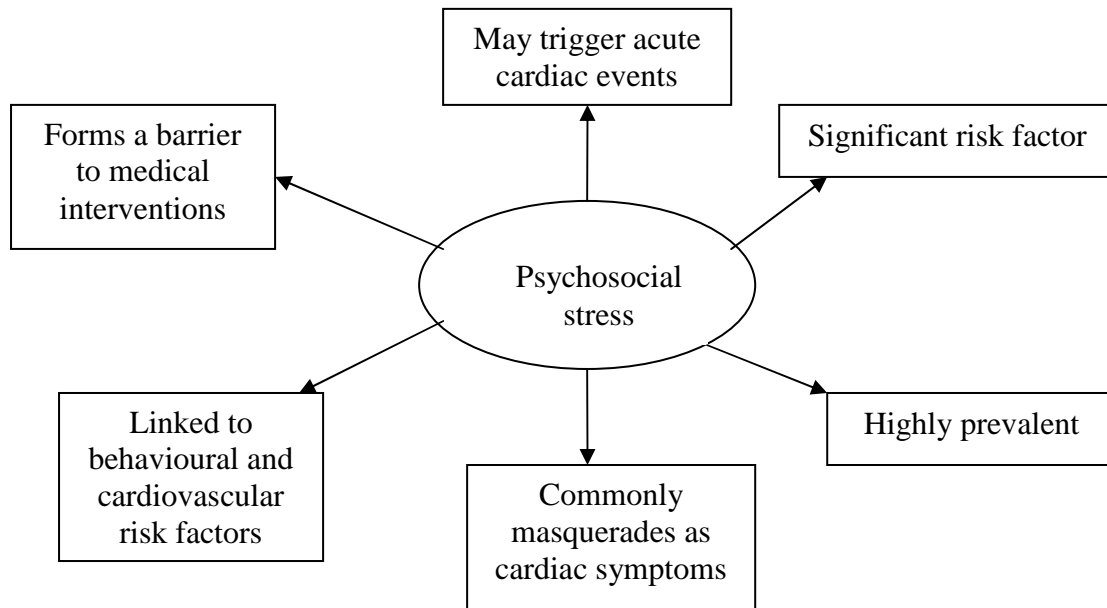
Figure 2 Psychosocial stress and cardiac practice

In an evaluation of 11,119 cases of myocardial infarction (MI), stress was assessed by asking questions about stress at home, work, and financial or major stressful life events. In this study, the proportion of all cases attributable to psychosocial risk factors – the population attributable risk (PAR) – was calculated to be 33% (adjusted for other risk factors) [39]. These retrospective, observational data suggested that interventions on high-risk individuals should be aimed at improving psychosocial stressors. To provide efficient psychosocial interventions, we need to identify those most in need of a specialised programme. Many reports have found that only a small proportion of eligible patients attend cardiac rehabilitation, and the selection process is not standardised [40]. In the absence of formal screening, health care providers are not capable of recognising depression in patients who have recently experienced MI [41].

Different psychosocial interventions to improve mortality and morbidity in cardiac practice have been presented with zero or positive results [5, 37]. A 2004 Cochrane report on psychological interventions for coronary heart disease reported a prevalence of poor quality studies and considerable heterogeneity between trials [5]. Positive effects have been in the range of a 20-40% reduction in mortality [3, 42]. It was a great disappointment when the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomised Trial study failed to demonstrate any effect on mortality after following 2,481 MI patients for 29 months. They provided cognitive behaviour therapy in 11 individual sessions for six months.

In addition, those who needed it also received group-based therapy and SSRI treatment. Medical treatment was given if the participant was clinically depressed. Only a modest effect was found on depression and perceived social support, and they found no effect on the medical endpoint of death and non-fatal MI [43]. Despite some negative results from larger intervention studies on CVD, psychosocial interventions are still an important component in heart rehabilitation programmes [34, 44].

Psychosocial risk factors tend to cluster in the same individuals and groups. Unhealthy lifestyles are more frequent among the poor, the less educated, those with psychological diseases and those who are socially isolated [35, 45]. The social gradient in current smoking behaviour has recently been evaluated in a Norwegian setting, and the authors recommend specifically tailored measures for lower socioeconomic groups [46]. Interventions to improve unhealthy lifestyles have been criticised for increasing the gap between underprivileged and the socioeconomically well-off [47].

Behavioural cardiology is an emerging field of clinical practice that attempts to improve patient adherence to behavioural interventions, [37].

8   Cardiac rehabilitation services

8.1   History, development and core components

Cardiac rehabilitation (CR) is characterised by comprehensive, long-term programmes involving medical evaluation, prescribed exercise, cardiac risk factor modification, education and counselling for patients who have suffered an MI, undergone cardiac surgery or are suffering from heart failure or angina pectoris. It aims at limiting the adverse physiologic and psychological effects of cardiac illness, control cardiac symptoms, reduce the risk of sudden death and reinfarction and enhance the patient's psychological and vocational status [48].

Cardiac rehabilitation has developed since the 1960s, and exercise was the primary component of these programmes. Cardiologists had to admit that the standard treatment of bed rest for six weeks following an MI was actually harmful, leading to unwanted deaths and also to increased disability. The first bold physicians started out in America by letting the patients sit upright for long periods of the day, demonstrating better survival in the 'early activity' group. The focus on physical activity has been developed into the recent strategy of increasing physical activity leading to vigorous interval training even among patients with

congestive heart failure [49, 50]. A combination of endurance and resistance training seems to be very promising [51].

Multifactor cardiac rehabilitation programmes developed since the mid-1970s focus on patient information, psychosocial support, return to work and increasing focus on medications to reduce CVD risk factors. The exercise part of these programmes has been extensively evaluated and it has proven to be beneficial [20]. It is recommended that modern CR should be multidisciplinary and multifaceted. It aims to provide optimal settings for secondary prevention interventions. The rationale for this is that the multidisciplinary setting makes it possible to intervene on a wider spectre of the different risk factors associated with CVD [16, 44]. Still, comprehensive CR has not been definitively proven to be more efficient in relation to hard endpoints than exercise alone [52].

Cardiac rehabilitation can be divided into three different phases: Phase I: Inpatient CR during hospitalisation following an index CAD event such as MI or acute coronary syndrome. Phase II: Early outpatient ambulatory phase IIa CR services, generally starting within the first six months after a CAD event. A more intensive IIb phase is also sometimes offered in inpatient rehabilitation settings. Phase III consists of long-term follow-up in community-based services. Patients are thus transferred to different levels of health care after a cardiac event. Lack of continuity and differences in emphasis on the provision of cardiac rehabilitation services in the different phases further increase difficulties in evaluating the efficiency of different programmes. In addition, it has not yet been established whether the rehabilitation services should be offered as an inpatient service or home-based rehabilitation.

8.2   Timing, frequency and duration

How soon should the patient attend rehabilitation after discharge from hospital, how often and for how many weeks? Several reports conclude that the optimal mix of components, frequency and duration of programmes has yet to be proven [6, 53]. Recommended strategies for risk factor reduction include frequent follow-up, intensive diet changes, individual and group exercise, coaching, group meetings, education in lifestyle modification and behavioural change, and formal cardiac rehabilitation programmes [54]. These strategies are time-consuming and difficult to implement in health services under pressure with respect to resources.

The European Heart Association claims that 8-12 weeks is considered adequate to cover the core components of CR and that those shorter programmes are not proven in the

literature [16]. Again, we face the challenge that the interventions and the outcomes are diverse and a specific 'dose' of rehabilitation is hard to prescribe.

8.3   Target population, referral, and adherence

All patients hospitalised with a primary diagnosis of ischemic heart disease are recommended to be referred to an early outpatient CR programme [55]. A controversial issue is whether it is justifiable to spend resources on referring all patients to a standardised rehabilitation programme. Many patients seem to be able to deal fairly well with the physical and mental challenges that accompany cardiac disease. If they receive high quality information and follow-up during the first months after an event, some 60-70% these patients could maintain a high-quality life without ever attending a multifaceted cardiac rehabilitation programme [13]. Offering standard rehabilitation to the most severely diseased and those experiencing the deepest psychological distress may also be inefficient. A recent review evaluated home-based versus hospital-based cardiac rehabilitation and stated that home-based cardiac rehabilitation was not inferior to hospital-based rehabilitation for low to moderate-risk patients [56].

Low levels of participation in cardiac rehabilitation services have been described in American, European and Australian settings [11, 57]. Determinants of referral to cardiac rehabilitation have been addressed in a recent systematic review evaluating 30,333 North American coronary artery disease patients [58]. The mean referral rate in this group was approximately 34%. Attendance after referral was less than 50%, which meant that as few as 15% of the patients eligible for cardiac rehabilitation actually attended CR. We lack detailed information about the situation in Norway but suspect it to be similar.

The physician's endorsement of the programme was reported as the most important predictor of whether or not the patients were referred [59]. Sociodemographic factors such as older age, female, being unmarried and lower income have been associated with lower referral rates. Females are under-represented in cardiac rehabilitation, both due to a lower referral rate but also because they attend less frequently. In the UK, approximately 15% of attendees are women, although they account for one third of cardiac patients. Similar patterns are shown among racial minorities [11, 59]. Of the cardiac diseases, uncomplicated MI is the most likely diagnosis to be referred to CR. Moreover, receiving more specialised interventions such as coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) leads to more referrals than receiving only medical interventions. The accessibility of the rehabilitation centre has been reported to be an important determinant of attendance [58]. So

far, we do not have much information from interventions that would help to improve uptake and adherence to CR, and further evaluations of methods are required [11].

In conclusion, low referral, less than 50% attendance by those referred and substantial dropout rates means that there are big challenges in comparing rehabilitation populations from different settings. This greatly compromises the external validity of cardiac rehabilitation studies in general. We have most information about low-risk, white male, post-MI patients. Patients` reasons for not taking up or adhering to cardiac rehabilitation have been reported to be multifactorial and very individual [56]. This calls for an individual approach to the selection of which programme to offer each individual patient with cardiac disease.

8.4   Effects of cardiac rehabilitation

The great diversity in different research reports makes it difficult to state an accurate effect of rehabilitation services. As presented, individual components of comprehensive CR have proven to be efficacious, and it is assumed that these effects are also present in a comprehensive setting. Comprehensive cardiac rehabilitation is difficult to evaluate because multiple interventions make it difficult to compare programmes [6]. Exercise programmes have been proven to be beneficial, but what is the additional effect of adding other components? So far, psychosocial interventions alone have had difficulty proving a reduction in CV mortality and morbidity [60]. Most studies report effects on improved QoL and life satisfaction but effect sizes have been modest and conflicting. Interventions may need to be of longer duration or greater intensity [60, 61]. Such interventions are thus expensive and time-consuming, and we still need more research in order to find out whether such interventions are cost-efficient.

A 2001 Cochrane database systematic review evaluated the effect of exercise, alone and as a part of comprehensive CR. Total cardiac mortality decreased by 31% in the exercise-only group and by 26% in the comprehensive rehabilitation group. No effect was demonstrated on the recurrence of non-fatal myocardial infarction. This report could not conclude whether comprehensive cardiac rehabilitation was more efficient than exercise-based CR alone [20]. The data were mainly based on middle-aged, white men. Other reports also question whether multifaceted rehabilitation programmes are superior to exercise alone [52].

8.4.1 Economic evaluations

Few studies have tried to provide substantial information about cost-effectiveness. In a 2005 study of CR activities in European Union member states, 454 phase II CR services were invited to provide information on costs. Of the 57% who responded, half provided no information on costs and the rest gave insufficient information to draw any conclusions. Individual programmes are difficult to compare and their cost-effectiveness is equally variable [62].

One of the economic evaluations most referred to is a randomised controlled study by Oldridge et al from 1993. They found that post-MI patients in the hospital-based rehabilitation group incurred lower total health costs. They also reported a gain in quality-adjusted life-years over 12 months [63]. Hospital-based rehabilitation versus home-based cardiac rehabilitation in a UK setting found both health gains and total health care costs to be similar [62]. Separating patients with different needs could be important in order to increase cost-efficiency. Low-risk patients could profit through early return to work without any formal rehabilitation [64]. The cost-effectiveness of supervised cardiac rehabilitation compared with usual care in myocardial infarction and heart failure has been evaluated, but there is still insufficient good quality evidence to draw any conclusions and further well-designed trials are required [65].

8.5 Krokeide rehabilitation centre

The study was conducted in a cardiac rehabilitation centre outside Bergen. Krokeide rehabilitation centre is beautifully situated by the sea some 20 km outside Bergen city centre. They have performed cardiac rehabilitation for 20 years, focusing on a multifactor rehabilitation programme in Phase IIb. They are owned by LHL - the Norwegian Heart and Lung Patient Organisation. This is a nationwide Norwegian interest organisation for people with heart and lung disease. At Krokeide, they have highly skilled and experienced staff. There is a physiotherapist, psychologist, doctor, nurse and social worker among the regular staff. They all work together in a team with the aim of increasing the total welfare of patients with cardiac disease.

The staff at Krokeide has found it important to regularly evaluate the rehabilitation work performed at Krokeide. Return to work among patients attending rehabilitation from 1996 to 1998 was evaluated in a report from 1999 [66]. They found self-evaluated health to be a strong predictor of return to work. Three quarters of the participants had returned to work part-time or full-time one year after the rehabilitation. Low income, low self-efficacy and

emotional problems predicted whether the patient became occupationally disabled during two-year follow-up. Another report based on preliminary data from this project found that negative emotional level predicted lower achievement of lifestyle goals [67]. Emotional problems were found among approximately 20% of the participants on admission. This is in line with previous reports [68]. This group was at greater risk of relapse and may have profited from further intervention and follow-up.

The designer of the intervention, clinical psychologist Svein Folmo, has presented the intervention project in two unpublished manuscripts [69, 70].

Pictures from Krokeide Rehabilitation Centre: Left overview, right exercise group

9   Theoretical basis for lifestyle changes

`To succed, one cannot afford to be a realist´

Albert Bandura

9.1   Introduction

We need to search for the most promising theoretical basis to promote the maintenance of health behaviour change in preventive cardiology. The theoretical basis and design of interventional studies is quite varied [12]. So far, it has been difficult to find useful meta-analyses to compare effects of interventions. Most studies on lifestyle changes provide evidence that the interventions increase the intention to change lifestyle. Transition to action is much harder to predict and the maintenance of achievements is even more difficult. Cognitive theories explain up to 50% of the variance of intentions but only 10-20% of the variance in health actions (p.88) [71]**.** The psychological processes underlying behaviour change initiation and maintenance are proposed to be different [72]. When it comes to lifestyle changes among CVD patients, the maintenance of achievements is a more clinically relevant outcome.

In this section, I will present the theoretical basis for the present research. The first paper in this thesis addressed the issue of whether lifestyle interventions are ethically justifiable. We evaluated whether social inequalities in this study group were an important factor in lifestyle changes. The Matthew effect and inverse care law are presented. The main theories supporting the intervention are the Self-Determination Theory (SDT) [73] and Social Cognitive Theory (SCT) [74].

Prominent researchers have called for interventions that integrate different theories [75, 76]. Plentiful research has been carried out on incentives as instruments for predicting lifestyle changes. But incentives can only predict lifestyle outcomes to a minor degree [75, 77]. Interventions that improve long-term maintenance of lifestyle change are called for, interventions that are theory-based and applicable by the practitioner. SCT as presented by Bandura in his self-efficacy theory is one of the most applied theories in health behaviour research [78]. He claims that people regulate themselves in an interrelationship between cognitions, emotions and the social environment [79]. The primacy of this self-regulation in health promotion is addressed by Bandura in a recent review article [76]. The assessment as well as the stimulation of autonomous self-regulation is emphasised.

There are numerous theories that attempt to explain human behaviour, with varying and often limited success [71]. SDT proposes that autonomous self-regulation is an essential predictor of maintained lifestyle changes. SDT is an upcoming theory with increasing utility in health research. In addition, SDT is said to provide the theoretical background for an extensively applied clinical method, motivational interviewing [80, 81]. Similarities between self-efficacy and autonomous self-regulation have already been presented [82]. The psychological processes underlying cardiac rehabilitation on the basis of SCT and SDT has recently been discussed in a cardiac rehabilitation setting evaluating intentions, planning and the maintenance of exercise [72]. In the next section, I will present the theories applied in this thesis in more detail.

9.1.1 Inequality and cardiovascular health

In the first paper, we address the ethical considerations relating to lifestyle interventions. Already some 2000 years ago, the apostle Matthew expressed the tendency for the rich to stay rich and the poor to stay poor: 'Whoever has will be given more, and he will have an abundance. Whoever does not have, even what he has will be taken from him.' (Matthew 13:12 NEV).

Social inequality has been proven to be an important causal factor explaining variation in cardiovascular morbidity and mortality [35, 83]. Emotional distress and various psychosocial factors have both neurohormonal and psychoimmunological effects that seem to be important in the pathogenesis of cardiovascular disease [38]. However, the major hypothesis concerning why social inequality leads to increased CVD is the uneven distribution of the classical risk factors [53]. This has led to a discussion of whether lifestyle advice is ethically justifiable [47]. However, Hart [84] maintains that the observed social inequalities are strong arguments for proactive care and lifestyle counselling. He formulated 'the inverse care law', stating that 'the availability of good health care tends to vary inversely with the need for it in the population served' [85].

Many researchers have addressed this law in cardiac services and primary healthcare settings [86]. However, the research evidence does not provide unequivocal support for this law, and it may be the use of services rather than access to them that is the problem [87]. The Matthew Effect relates to the inverse care law in describing how disadvantaged groups seem to deteriorate in different areas of life compared with those in better positions. The effect was originally described for academic achievements, but was later introduced in healthcare research [88].

9.2 Self-determination in lifestyle change

I will shortly present an overview of the self-determination theory (SDT). The theory is extensively presented in a handbook of self-determination [89]. The first section is a brief presentation of the historical basis for SDT; section two presents the theory, and the last section is a presentation of medical research based on the SDT.

9.2.1 The development of theories

Self-determination theory has its historical roots in the classical Aristotelian view of human development according to which we are born with an active tendency towards psychological growth and integration. We seek challenges and discover new perspectives, all of which provide us with experiences that, with integration, lead to a coherent sense of self. To the degree that an individual attains this sense of self, he or she can act according to it and be true to it. This is to act autonomously [89].

In both psychodynamic and humanistic theories, we find the general view of an active, integrated individual with the potential to act autonomously. Psychoanalytic theorists posit that behaviour has both conscious and unconscious components. Humanistic psychologists postulate a tendency to develop new skills: self-actualisation [90]. In humanistic psychology, the focus is not only on what the person is but also on what he or she has the potential to become. The experiencing person is of primary interest. Meaningfulness must precede objectivity, and the ultimate value is placed on the dignity of the person [91]. Similarly, in many cognitive theories, we find that development is characterised by an integrative tendency of new experiences. We seek challenges and new experiences, and they give rise to new patterns of thinking. These patterns of thinking are reorganised and brought into coherence with other cognitive structures [92].

In opposition to the assumption that an inner force drives people, we find the operant behaviourist position that maintains that our development has no inherent direction. We are products of our environment [93]. From 1950-1970, hundreds of research reports on human behaviour stated that extrinsic reward can control behaviour. SDT research demonstrated that such changes were only maintained as long as the rewards or punishments were present.

We note how the trends in psychological theory have changed during the last decades and that the patient-practitioner relationship has changed accordingly. The relationship has shifted from a paternalistic to a humanistic relationship in which the patient is a more equal partner. A practitioner will act differently depending on whether he or she believes that

patients have an inherent tendency towards growth and integration or focus on how to shape and control their behaviour.

9.3   The essence of self-determination theory

The basic components of self-determination theory have evolved over three decades from four mini-theories, namely cognitive evaluation theory, organismic integration theory, causality orientation theory and basic need theory. They all contribute to the wholeness of self-determination theory, and I will give a brief presentation of each of the theories. To prevent the readers from losing their overview of SDT, I will first summarise the theory as a whole.

SDT is a general theory of motivation and personality. It states that we all have a basic need to feel autonomous, competent and connected to others. If these needs are met, people will tend to internalize new behaviours in an autonomous manner. People have different tendencies to act autonomously, depending on their personalities and general causality orientation. People's orientation towards the social world can be autonomous, controlled or impersonal. These different orientations are relatively stable inner resources and they are all present to some extent in each individual. Motivation for behaviour will have both autonomous (intrinsic) and controlled (extrinsic) elements. According to SDT, a new behaviour that is internalised in an autonomous manner leads to longer maintenance than when the source of motivation is control. An example of this is when a former smoker describes personal, inner reasons for quitting as being more important than the pressure from a health care provider or important others. It is when the smoker finds the reasons for quitting to be autonomous that he or she is more likely to succeed. Intervention studies have shown that it is possible to increase autonomous reasons for lifestyle changes by [94]:

- Acknowledging people's feelings and perspective so that they feel understood.
- Using an interpersonal style that emphasises choice and minimises control. Limiting controlling language.
- Seeking different possible choices, but not too numerous and complex.
- Providing a meaningful rationale for why a proposed behaviour is being recommended. Giving relevant information.

9.3.1 Cognitive evaluation theory

This theory describes the effects of social context on people's intrinsic motivation. Research on the effect of rewards has contributed greatly to the development of the theory. Most people have received rewards for their performance, starting from early childhood, through school

and study. This pattern continues when they receive their first salary. CET explains how different types of rewards affect intrinsic motivation [95]. Deci and Ryan maintain that there are two primary cognitive processes that affect intrinsic motivation, namely perceived locus of causality and perceived competence. DeCharms first described the issue of perceived locus of causality in 1968 [96]. According to DeCharms, a person's understanding of the initiation and regulation of behaviour can be either intrinsic or extrinsic. SDT continued to develop this thinking.

When considering an event or action, people will often interpret the causes of behaviour or events. For instance, in the case of rewards, they can be interpreted as controllers of behaviour or as indicators of our competence. In the latter case, they can promote autonomous motivation even though a reward more often increases controlled motivation. The cognitive evaluation of a reward determines the effect it has on motivation. A possible disadvantage of rewards is that, if a person behaves in a certain manner in order to be rewarded, the probability of repeating the behaviour decreases once the reward is removed.

9.3.2 Organismic integration theory (OIT)

In SDT, people are naturally seeking challenges and new experiences, and they integrate them into their personality [73, 97]. We are inherently motivated to internalise the regulation of uninteresting though important activities [98]. We actually work to transform external regulation into self-regulation, becoming more integrated as we do so. This process of internalisation is a continuum. The more fully a regulation is internalised, the more it becomes part of the integrated self and the more it is the basis for self-determined behaviour.

Motivation type	Amotivated		Extrinsic motivation			Intrinsic motivation
Regulation	Non-regulation	External regulation	Introjected integration	Identified Regulation	Integrated Regulation	Intrinsic regulation
Quality of behaviour	Non-self-determined	──────────────────────────────────→				Self-determined
Example of statements from	I don't care	I am forced	I should do it for you	I want to do it for my health	I like to do it to feel well	I like the activity because it is fun!

Fig 3 The process of internalisation and integration

Successful integration of new activities or attitudes depends on whether the person feels autonomous, competent and related to the administrators of new activities. People must grasp a personal meaning by engaging in the activities, and this is most likely to occur when they feel a sense of volition and freedom from external demands.

Lifestyle changes are often a matter of necessity. They are necessary in order to improve health prospects. People may feel a strong external pressure to change their lifestyle habits. It is rare to be totally without intrinsic arguments for changing unhealthy habits even if there is external pressure for the behaviour change. In order to facilitate internalisation, the provider of support must emphasise the most autonomous arguments for changing lifestyle. This can take place when the facilitator offers an accepting relationship, acknowledges people's feelings, offers choices and offers a rationale for changing lifestyle and for the choices offered.

9.3.3 Causality orientation theory

This theory describes the relatively stable individual differences in people's motivation orientation towards the social world. It is more likely that a person with a general orientation towards acting autonomously will do so in different areas of life than a person whose general orientation is towards acting in a controlled manner. However, it is still possible to be autonomous in certain areas of life and continue to feel a great deal of pressure and control in other areas of life. In a similar manner as in OIT, the personality is described on a continuous scale between controlled and autonomous [99].

9.3.4 Need theory

Needs are thought to be universal. To qualify as a need, a motivating force must have a direct relation to well-being. Needs are satisfied in different ways, depending on factors like age, gender and culture. They might have different ways of finding satisfaction. Needs at one level must be satisfied to achieve the next level of needs.

Abraham Maslow (1908-1970) was an important needs theorist known for his contribution to humanistic psychology. Maslow´s hierarchy of needs is a theory that postulates that humans are motivated by satisfying their basic needs and then trying to satisfy other human needs. These are biological needs, safety and security, love and belongingness, self-esteem and self-actualisation.

In self-determination theory, we recognise three important needs that, when covered, will support healthy functioning. They are referred to in SDT as basic psychological needs. The need for competence, relatedness and autonomy provide the basis for categorising aspects of the environment as supporting versus impeding integrated and healthy functioning. A healthy person will seek these needs and strive to have them satisfied. *Competence* concerns the degree to which they feel able to achieve their goals and desired outcomes. *Relatedness* is defined as the extent to which they feel connected to others in a warm, positive, interpersonal manner. *Autonomy* is defined as the degree to which individuals feel volitional and responsible for the initiation of their behaviour. This is considered to be the most important need for providing self-determination.

Competence, relatedness and autonomy are all included in Maslow's theory, in which relatedness has its parallel in love and belongingness, competence is what we seek when striving for esteem and self-actualisation, and increased autonomy is a process involved in self-actualisation. Need theory in SDT is thus more occupied with certain aspects of former need theories.

Autonomy is not the same as independence, where the patient is left alone with his or her problems. Patients often need advice and support from their physician or providers. Autonomy is supported when the basic needs are met. The question is rather how we can provide a climate for development that supports the feeling of autonomy, competence and relatedness. The clinical technique of motivational interviewing (MI) may provide SDT researchers with new insights on how to apply SDT`s theoretical concept of autonomy support and how to develop SDT in different practices [81]. Both in MI and SDT, the motivation to change is elicited from the client and should not be imposed by the provider. They both rely on identifying and mobilising the client's intrinsic values and goals to stimulate behaviour change. The therapeutic relationship is a partnership based on client autonomy. Interventions based on these principles are client-centred, yet directive, with the goal of facilitating behaviour change. MI was first described by William Miller, who worked at Hjellestad in the 1980s [100]**.** Together with Rollnick, Miller developed their experiences with patients into a coherent theory and provided a description of the clinical procedure [101]. Their intervention strategy is useful in the treatment of different lifestyle areas and has been used in a number of intervention studies [102, 103].

SDT has also been integrated with social cognitive theories, where self-efficacy and autonomous self-regulation are regarded as complementary factors that both affect adherence.

Self-efficacy from SCT and the basic need for perceiving competence are related structures [82].

9.4 Self-determination theory applied to lifestyle change in experimental studies

Some controlled trials have tested the efficacy of SDT interventions in different health-related areas. Empirical support for and limitations of this research have recently been reviewed [104]. In brief, when patients experience autonomy, competence and relatedness, they have better mental health, greater quality of life and better health-related outcomes, such as reduced smoking, more physical activity, improved adherence to prescribed medication, improved glycemic control (for patients with diabetes) and greater intake of fruit and vegetables. Clinical controlled trials in the medical field comparing autonomy-enhancing counselling with other methods of counselling are still few, and results do not clearly support the claim that interventions based on this motivational style are superior to other methods.

Most of the randomised controlled studies identified are related to smoking cessation. Interventions concerning physical activity and dental hygiene are other research areas [105, 106]. A promising intervention study compared 120 primary care patients in Canada. This study aimed to increase physical activity during a three-month period. Intensive, autonomy-supportive counselling over three months significantly improved self-reported physical activity compared with three minutes of counselling in the control group [106]. Williams et al. conducted a randomised controlled trial on smoking cessation on 239 patients recruited from 27 physicians [107]. The participants received information in accordance with an established smoking cessation programme either in an autonomy-supportive style or in a controlling style. After 30 months, the quitting rates were no better in the autonomy-supported group, but the participants' autonomous reasons for quitting were enforced. An earlier study of intrinsic motivation among adolescents has shown better results for the smoking cessation outcome [108]. In a later study of 1,006 adult smokers Williams et al. found a causal role of autonomy support in the internalisation of autonomous motivation and perceived competence, and smoking cessation was supported [94]. An evaluation of financial incentives compared with personalised feedback showed that continuous abstinence, defined as seven-days' abstinence at both the three-and 12-month follow-ups, was twice as good in the feedback group [109].

Although SDT is not unambiguously supported by controlled comparisons in clinical trials, the theory is strongly supported by observational evidence in the clinical setting. The results of a motivation questionnaire given to 98 persons attending an eight-week outpatient

alcohol-treatment programme indicated that internalised motivation predicted attendance and involvement [110]. Controlled motivation also predicted attendance. People low on autonomous motivation attended poorly and were not very engaged in the treatment. In a review of 32 studies of brief interventions for problem drinkers, Bien et al. found that giving non-judgemental feedback, providing choice, encouraging patients to take responsibility and being empathic were the most important elements of successful interventions [111].

Another observational study followed extremely obese patients for two years. Initially, they were given a liquid-only diet for three months [112]. In this weight-loss programme, autonomous reasons for participating in the programme were associated with better attendance and a greater reduction in BMI.

In a diabetes study, 128 diabetes patients were followed for 12 months, with HbA1c measures and questionnaires exploring their degree of autonomous support and motivation [113]. This study supported the following relationship between autonomy support and lifestyle change measured with HbA1c (Figure 4):

| Perception of provider's autonomy support | → | Change in autonomous motivation | → | Change in perceived competence | → | Change in glucose control (HbA1c) |
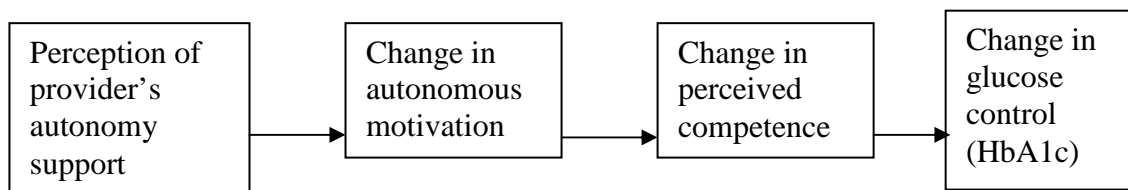
This relationship was further explored in a longitudinal study by Williams et al. [114]. They found that autonomy support from the health care provider improved glycemic control among type 2 diabetics by improving perceived competence and autonomous motivation in patients. There was no direct link between perceived autonomy support and change in glycemic control. Both autonomous regulation and perceived competence were statistically significantly related to change in glycemic control. The study showed that perceived competence was a mediator between autonomous motivation and glucose control. We may therefore claim, as mentioned in the introduction, that self-efficacy and SCT, on the one hand, and autonomous regulation and SDT, on the other, are complementary in human motivation for lifestyle change [82]. We find a similar model with perceived competence being associated with successful outcomes for smoking abstinence, diet and medical adherence as an outcome [115, 116].

In conclusion, we maintain that both experimental evidence and observational evidence support the relevance of autonomy-supportive counselling and autonomous regulation in human behaviour.

9.5 Social cognitive theories

Cognitive Therapy (CT) and Social Cognitive Theory (SCT) are both valuable approaches to understanding behaviour and psychological functioning among heart patients. They are also important as the theoretical basis for the intervention in the present study. The self-efficacy questionnaire was developed from SCT. The basic concepts of CT and SCT have often been applied to explain how patients' cognitive elements and social environment influence behaviour change such as exercise, dietary change and emotional adaptation [78, 117].

The social-cognitive approach was developed during the 1970s' on the basis of operant behaviourism, but it departs from behaviourism by recognising cognition and internal events as important factors in a reciprocal system. In the 1970s, behavioural modification techniques and cognitive therapy techniques became more integrated into cognitive therapy. The American psychiatrist Aaron Beck developed and described cognitive therapy based on the notion that the client's cognition was the key to efficient therapy [92]. Today CT is often used interchangeably with cognitive behaviour therapy since CT always has included some behaviour components. Nonetheless, Beck's particular approach should be referred to as CT.

9.5.1 Social Cognitive Theory

In opposition to a traditional trait and psychoanalytic emphasis on internal dispositions in controlling human behaviour, in its attempt to explain behaviour, SCT emphasises how people interact with the environment. Albert Bandura characterizes this interaction with the concept of reciprocal determinism [79].

In comprehensive cardiac rehabilitation, dietary change, exercise change, improving from psychological discomfort and abstaining from tobacco use are important factors influencing the patient's prognosis after heart disease. According to SCT, the likelihood that a patient will succeed in achieving these goals is determined by whether he or she recognises the goals as being important and achievable. Bandura emphasises that strengthening of competence is most important when facilitating behaviour change. Therapeutic change is not dependent on the elimination of emotional distress, but on the strengthening of coping and feeling of competence [78].

Self-efficacy is the belief that one is capable of performing the behaviour required to produce a desired outcome. Self-efficacy consists of two separate components: efficacy expectation and outcome expectation [78]. Efficacy expectation refers to individuals' belief that they posses the necessary competence and resources to master the behaviour in question. Outcome expectation refers to the beliefs that certain behaviour will produce the reward or reinforcement that the individual wants.
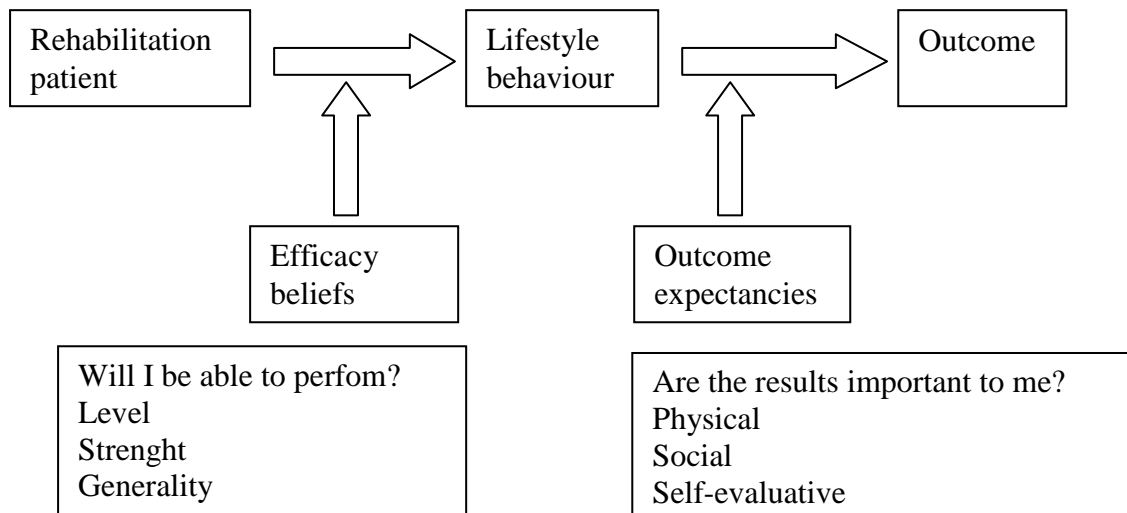
Figure 5 Self-efficacy beliefs and typical thoughts in a rehabilitation setting

According to Bandura, measurements of self-efficacy should be specific, contain varying levels of difficulty and allow for registration of the degree of confidence a person has that a given behaviour will be attainable [78].

Self-efficacy can be developed from four main sources: personal experience, vicarious experience, verbal persuasion and emotional arousal. Personal experience of success will be an incentive to reproducing behaviour, and defeat may hinder an individual in the process of achieving a goal and may increase the probability of avoidance. Secondly, vicarious experience allows the individual to improve self-efficacy when observing others. Seeing someone perform a threatening or difficult task with a positive outcome may enhance belief in self-efficacy, especially if this observation is repeated. A third source of self-efficacy is verbal persuasion**.** Encouragement and support from others can also provide support for coping effectively. Finally, emotional arousal in stressful situations can lead to a perception of low efficacy [78].

It is argued that the concept of general expectancy is a central common core of personality dispositions related to achievement areas [118]. In the achievement motivation theory, a success-oriented person has a general expectancy that engaging in achievement activities will lead to success, whereas a failure-oriented person will think the opposite [119]. General expectancy measures optimism concerning the disease and future prospects. The relationship between general self-efficacy and task-specific self-efficacy has been discussed [120].

The rehabilitation programme at Krokeide aims at facilitating self-efficacy in relation to increased physical activity by various reinforcements. Group-based exercise may provide personal experience of coping, observation of others who manage exercise, motivation from information from the leaders and a positive psychosocial environment that provides emotional support and well-being during the performance. Mæland confirms the hypothesis that group-based heart rehabilitation may influence self-efficacy positively by vicarious conditioning through reinforcement and encouragement from instructors and participants [13].

Critics claim that concept of self-efficacy is theoretically obvious and unnecessary to use for research. Of course you are more likely to perform if you believe you can do it than if you do not [71].

9.5.2 Cognitive Therapy

Cognitive psychotherapy is an active, directive, time-limited, structured approach used to treat a variety of psychiatric disorders, such as depression and anxiety [92]. The principles of CT have been implemented in the treatment of different groups of patients, for instance heart rehabilitation groups [121] and patients with somatoform diseases [122]. Originally, it was developed to serve as a therapy that not only cured, but also prevented relapse into depression [92]. It is based on the theoretical assumption that an individual's affect and behaviour is largely determined by the way a person structures his or her world. Cognitions are based on attitudes or assumptions stored in the person's mind and developed from previous experiences, and are activated in specific situations or states of mind, which, in turn, influence our emotions, behaviour and physiological activation [117]. CT aims to change dysfunctional patterns of thought or beliefs. Some of these thoughts are rooted in our core belief systems and are the source of negative automatic thoughts. Beck described these thoughts as stable and underlying beliefs, which are partly created by the individual's childhood experiences [92]. In short intervention programmes, such as heart rehabilitation programmes, specific situational beliefs are the focus of investigation and change.

CT emphasises that control of intense feelings may be achieved by changing one's ideas or thoughts [92]. CT supports Bandura's Reciprocal Interaction Model, in which a person's behaviour influences other people, whose actions in turn influence the individual [78]. On the individual level, affect, behaviour and cognition are elements in a reciprocal system [117]. The non-qualitative difference between psychopathology and normal functioning is also an important basis for the cognitive approach is also [117].

As with psychoanalytic approaches to therapy, the goal of cognitive therapy is to relieve emotional distress and other symptoms of disease. CT focuses on the future by exploring the person's misinterpretations, self-defeating behaviour and dysfunctional attitudes and assumptions. Nevertheless, Aaron Beck emphasises the importance of the therapist being sensitive to unpleasant emotions and being an empathic therapist who creates 'a good working alliance' [92]. CT has proved to be useful not only in psychiatric clinical settings, but also in the field of lifestyle change [121], cardiac rehabilitation [123] and chronic diseases [124].

9.6 Development of an individual consultation method

The intervention was developed to enhance individually tailored counselling. The staff members at the Krokeide Heart Rehabilitation Centre observed that the didactic and group based methods formerly applied during the cardiac rehabilitation programme, could not satisfy the great variety of individual needs and differences in motivation among cardiac patients. Such patients seek rehabilitation with needs that cannot fully be satisfied by didactic methods; or by psychotherapeutic interventions. Their needs lie in between these extremes.

The point of departure for developing our method was a common interest in cognitive behaviour modification methods in general, and especially development in a psychotherapeutic and counselling context [79, 125]. We found the cognitive model associated with CT and motivational interviewing to be applicable in terms of taking care of the need for structure, focus and concrete goals for a consultation [101, 125]. A combination of goal setting and other motivational strategies to promote health behaviour change has been recommended [126]. In addition to the cognitive strategies, this model also accommodates the use of a broad repertoire of behavioural techniques founded in behavioural and social behavioural approaches [79]. As the humanistic perspective, we chose self-determination theory with the focus on respecting autonomy, freedom to make decisions within one's own frame of reference, and also the relationship between the counsellor and the client as the key aspect of the counselling.

By providing a synthesis of a structured and cognitive-behavioural guided strategy, with a more unstructured exploratory humanistic approach, we hoped to develop a counselling method which both had identifiable strategies for assessment and interventions, and which was also highly client-determined.

10 Statement of the problems and aims of the study

The general introduction discussed the challenge of improving long-term maintenance of lifestyle changes among cardiac patients. Interventions designed to meet this challenge need to be designed and described in a way that makes it possible to replicate the intervention. We wanted to evaluate a collaborative intervention method developed at the Krokeide Rehabilitation Centre. The description and theoretical foundation of the intervention are dealt with in the last paper.

The first two research questions considered ethical aspects of offering lifestyle interventions to a group of cardiac rehabilitation patients:

1. Will socioeconomically disadvantaged patients be able to change to a heart protective lifestyle as well as those who are 'better off'?

2. If there are any differences, are they mediated by motivational problems?

The next two research questions concerned the evaluation of the individually tailored intervention compared with group-based, didactic counselling:

3. Are the improvements in dietary goals, exercise goals and smoking cessation better in the group receiving the intervention than in the group receiving standard treatment?

4. In the intervention group: is it beneficial to choose a specific lifestyle goal compared with those not choosing a specific goal or choosing another area of lifestyle achievements?

With a theory-based intervention we may be able to sort out predictors of behaviour change that could be relevant for planning and improving later interventions. This issue is the background to the last research objective:

5. Will self-efficacy, general expectancy, autonomous and controlled motivation be important predictors of lifestyle changes?

11 Material and methods:

11.1 Material

11.1.1 Study population

The study took place in a cardiac rehabilitation centre outside Bergen.

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┌─────────────────┐     ┌──────────────────────────┐
│ August 2000-     │     │    217 included and      │
│ August 2002      │     │      randomised:         │
│                  │     │  REH 110 (51% of 217)    │
└─────────────────┘     │  REH+INT 107 (49%)       │
                        └──────────────────────────┘

┌──────────────────────┐
│  Lost to follow-up:   │
│    N=41 (19%)         │
│  REH 24 (59%)         │
│  INT+REH 17 (41%)     │     ┌──────────────────┐
└──────────────────────┘     │  N=176 at 24-     │
                             │    month          │
                             │  follow-up:       │
          ┌──────────────────┘                   └──────────────────┐
┌─────────────────────┐                          ┌─────────────────────┐
│   REH N=86          │                          │    REH+INT          │
│   (49% of 176)      │                          │    N=90 (51%)       │
│                     │                          │                     │
└─────────────────────┘                          └─────────────────────┘
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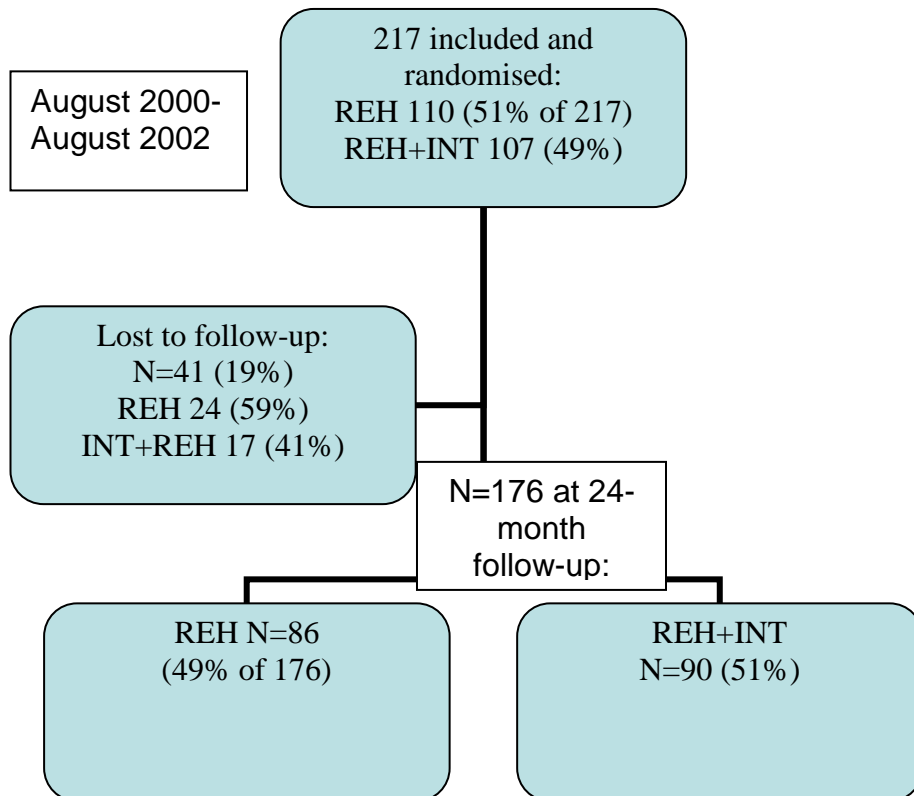
REH= standard rehabilitation group, REH+INT = intervention added group

Figure 6 Study population in the Krokeide Rehabilitation Centre Study

Patients were recruited to Krokeide on discharge from hospital after an event or were referred by their general practitioner. As outlined in the introduction, there is no standard procedure for admitting all patients or patients with certain characteristics to CR. All 266 patients attending Krokeide Rehabilitation Centre during the inclusion phase from August 2000 until August 2002 were invited to participate in the study. Of these, 217 patients agreed to participate or were excluded according to following criteria: not completing more than two weeks of the rehabilitation stay or not returning questionnaires. Forty-one patients were defined as dropouts: Five participants attended less than two weeks of the rehabilitation. Sixteen patients only completed questionnaires during the rehabilitation. Twenty participants

completed six months registrations but did not respond at 24 month follow-up. All these 41 dropouts were included in the intention-to-treat analyses. Twenty-four of the dropouts belonged to the standard treatment group. In addition, six participants did not return the questionnaires at six months.

11.1.2 Data collection

From the beginning, the project was a collaboration between Krokeide Rehabilitation Centre and the University of Bergen. The clinical staff at Krokeide was responsible for collecting the data. Clinical nurse Randi Johansen was responsible for storing the data and registering the data in a statistical database. The psychological faculty represented by Professor Odd Havik and the medical faculty represented by Professor Eivind Meland were both involved in planning the study. Together with clinical psychologist Svein Folmo and medical doctor at Krokeide, Bent Folkvord, they decided on the questionnaires for this study. They all contributed and approved the original study protocol and also had access to the data collected. The Regional Committee for Medical Research Ethics, Health Region III, and the Norwegian Data Inspectorate approved the study.

From August 1999, the staff was trained, and development and testing of the intervention was carried out. The first group of patients was invited to the study from August 2000. Each participant received a questionnaire at admission and departure from the four-week rehabilitation stay, at six months and 24 months after rehabilitation. Blood samples were also collected on admission, departure and at 24 months.

11.2 Methods

11.2.1 Study design

This is a single-centre, prospective randomised controlled trial. We chose a randomized controlled design in order to find out whether the newly developed intervention was superior to standard rehabilitation. Predictors of lifestyle changes were evaluated from the combined cohorts of this randomised, controlled trial.

11.2.2 Randomisation

Randomisation was achieved by first arranging the group of included participants in an alphabetical order. Then each of them was given a card with a three-digit, randomised number. From this set of names and numbers, the group was divided into A or B by splitting

them by the numbers. Lastly, the group receiving the intervention and those receiving the standard treatment were chosen by flipping a coin.

11.2.3 Sample sizes

Sample size was based on the exercise outcome measure. To detect a difference in change of the exercise mean score of 15% with 90% power at a 5% significance level, we needed 68 participants in each group. The estimates of standard deviations are based on results from a previous study [127].

11.3 Measures and instruments

Questionnaires were given at arrival, at departure from rehabilitation and also sent by mail at 6 and 24 months follow-up. Non-responders were phoned to improve the response rates, but not all of the participants were available. The questionnaires are presented in the appendix section.

11.4 Outcome measures

Outcome measures were measured on inclusion, at six months and at the 24-month final assessment. Exercise measures were the exercise composite score, exercise intensity score and physical capacity. Dietary measures were daily units of fruit and vegetables, the weekly number of fish dinners, and low fat diet. Self-reported smoking status was also assessed.

11.4.1 The exercise measures

11.4.1.1 Exercise composite score

The exercise measure is a construct from four questions presented in Paper I: 1) How do you evaluate your recent physical activity compared with other people your age? 2) How often do you exercise? 3) How hard do you exercise? 4) How long do you exercise each time? Three questions had previously been used in an epidemiological survey in Norway (Nord Trøndelag Health Survey) and have shown satisfactory construct validity [128]. The last question was taken from the Stanford Five City Project, and has been tested with satisfactory concurrent validity [129]. This question was also used in a primary care setting with CV patients [130].

11.4.1.2 Exercise intensity

This is one of the questions in the exercise composite score: 'How hard do you exercise?' taken from the Nord Trøndelag Health Survey [128].

11.4.1.3 Physical capacity

The physical capacity score, also known as Maximal Physical Ability (MPA), have formerly been validated in a Norwegian post-infarction study [131]. The four-item questionnaire adds to a composite mean score indicating the level to which the person is to perform specific physical activities: 1) walk at normal speed on level ground; 2) walk at normal speed uphill or up-stairs; 3) walk fast uphill or up stairs; 4) run slowly uphill or up stairs, or run on level ground.

11.4.2 Dietary measures

Questions about frequency of food intake are difficult at an individual level, but the validity has been proposed to be better at group level [132]. Generally frequency questions are reported with higher external validity than other dietary measures [133, 134]. Questions similar to those presented in this thesis have been used in the Norwegian county health surveys [132].

11.4.2.1 Daily units of fruit and vegetables

This is a single-item question: 'How many units of fruit and vegetables do you eat daily?'

11.4.2.2 Weekly numbers of fish dinners

A single item question: 'How often do you have fish for dinner weekly?'

11.4.2.3 Low fat diet

Low fat diet is a composite score measuring to what extent participants comply with a low and polyunsaturated fat diet. The composite score of the three questions was constructed for the purpose of this study. The reliability of three questions was presented in Paper I. The content validity was considered satisfactory by the investigating group. The questions constituting this score were: 1) How many times weekly do you use oil when you cook? 2) When I eat meat for dinner, it contains little fat and 3) I eat low fat cheese and sandwich spread. The sum score was recalculated with response level from 1-5.

11.4.3 Smoking status

Smoking status was assessed by the question 'Do you smoke?' on inclusion, at six months and 24-month follow-up. We computed an outcome variable from the data on inclusion and 24-month follow-up with four possible outcomes: stopped smoking, continuous non-smoker, continuous smoker and started smoking.

11.5 Motivational and emotional predicting measures

Predictors where chosen according to research on motivational factors from our main theories SCT and SDT. In addition, we found emotional, socioeconomic and other risk factors to be important factors affecting motivation. This is outlined in the introduction. Self-efficacy measures were given on discharge from rehabilitation, whilst Treatment Self-Regulation Questionnaire (TSRQ), Anxiety-Depression-Irritability (ADI) and General Expectancy (GE) questionnaires were given on admission.

11.5.1 Treatment Self-Regulation Questionnaire

The TSRQ is a set of questionnaires concerning why people engage in or would like to engage in some healthy behaviour. It assesses the degree to which a person's motivation for a particular behaviour is relatively autonomous or self-determined. There scale has three subscales: the autonomous regulatory style; the controlled regulatory style; and amotivation (which refers to being unmotivated). The amotivation subscale is not included in our analyses.

TSRQ was measured on inclusion and at 24 months. It assesses domain-specific types of motivation or regulation and has been used in various behavioural studies. The questionnaire has been tested for reliability and validity [97]. Four items rated on a seven-level Likert scale constituted the composite score for autonomous motivation. It was explored by statements like 'I personally believe that changing my lifestyle will improve my health' and 'It is challenging to try to improve my health'.

11.5.2 Anxiety-Depression-Irritability Questionnaire

State-dependent feelings of anxiety, depression and irritability, e.g. 'how do you feel today,' were assessed by the ADI questionnaire. This measure was developed among cardiac infarction patients and has shown good validity and reliability [68]. The ADI score comprises 12 pairs of adjectives rated on a seven-level Likert scale. We used the total mean score (scale 4-28) for this measure.

11.5.3 General expectancy

We constructed a GE measure to explore a person's general belief regarding future prospects. The purpose of the GE measure is to measure some relatively enduring sets of beliefs regarding whether the patient can cope effectively with his or her cardiac disease. Descriptive data and the reliability of the GE measure are presented in Paper I. The GE measure was constructed from responses to three questions, all on a seven-level Likert scale ranging from

very possible/positive to completely impossible/negative. We used the total mean for the three questions (scale 1-7) constituting this measure: 1) 'How likely is it that a person with your disease can live a good life?' 2) 'How do you regard your future prospects?' 3) 'What are your expectations of the medical treatment you receive?'. Our questions were adapted from the seven-item Positive Expectation Subscale (PES) presented in a study evaluating how positive expectations predicted health after cardiac transplantation [135]. The seven-item PES predicted physical health after six months. The construct validity of a similar GE measure and the relationship between general self-efficacy and specific self-efficacy has also been evaluated in a Norwegian setting [120].

11.5.4 Self-efficacy

We measured self-efficacy in relation to increased intake of fruit and vegetables and increased exercise. The efficacy scale of future exercise was developed in a Norwegian setting with patients in primary care [127]. These four questions were presented on a five-level Likert scale and are presented in the appendix. Self-efficacy is among the factors most strongly and consistently associated with higher consumption of fruit and vegetables [136, 137]. Our self-efficacy measures were in accordance with this literature.

11.5.5 Autonomy support

Autonomy support provided by the rehabilitation staff was measured by an adapted form of the six-item short version of the Health Care Climate Questionnaire (HCCQ) at both the six and 24-month follow-up [116]. The instrument assesses patients' perceptions of the degree to which they experience their health care providers to be autonomy supportive in the treatment setting. This instrument has been extensively validated and used in connection with various health-related issues like obesity, smoking cessation, diet improvements and regular exercise [108, 112, 113] .

11.6 Other measures

11.6.1 Socioeconomic predictors

Household income measured at 24-month follow-up was the only measure of socioeconomic status available for this survey. We also explored education, but a low response rate prohibited us from using this measure.

11.6.2 Disease severity

We dichotomised the disease measure in order to create a severity index. We assumed that experiencing myocardial infarction would be perceived as more serious than only reporting angina and other heart disease. In the group without infarction, there were also some patients who had undergone CABG surgery, PCI and heart valve surgery. Only eight patients reported diseases other than coronary diseases.

11.7 Statistical methods

Statistical significance is necessary to minimise the role of chance in any described differences [138]. We applied various statistical procedures as appropriate to the different research questions presented.

When items are used to form a scale, the items should all measure the same thing. They should be correlated with one another [139]. We calculated the internal consistencies of the measures constructed for this study. We also assessed the Cronbach's alphas for the previously validated questionnaires.

The baseline data presented the intervention group(s) and the standard treatment group using the chi-square test for dichotomous data or the independent samples t-test for continuous data.

Multiple linear regression analyses were used in order to test whether socioeconomic and health-related disadvantages influenced motivation for and the ability to make lifestyle improvements. The procedures are outlined in Paper I.

In Papers II-IV, the general linear model was chosen as the most appropriate approach. This model allowed us to explore the outcome measures at three different time points. Details are presented in the papers.

Analyses were performed using SPSS version 13.0-14.0. In the last paper, SPSS Sample Power release 2 was used for the post-hoc power analyses.

11.8 Description of the intervention and treatment programme

11.8.1 Standard rehabilitation treatment

The control rehabilitation programme (usual care) consisted of the following activities:

1) Group-based, didactic information or heart school. In a group setting they were given basic knowledge about cardiovascular disease and risk factors. Information was given about healthy diets, focusing on the 'Mediterranean' diet. This diet focuses on a low

intake of saturated fat and on increasing the intake of fish, fruit and vegetables [28]. Cooking classes, where spouses were invited, were also held. Other topics were the benefits of physical training, managing stress reactions and also a session with information about the most common drugs used in secondary, cardiac prevention.

2) Physical training in groups was organised every day of the week. A typical training session started with a warm-up and then more brisk training. During the course of a week, they combined endurance and resistance training. The group setting gave the participant a personal experience of mastering physical exercise. In addition, watching other heart patients challenge their physical limits is an important source of increasing exercise self-efficacy. Individual adaptations were given if necessary.

3) Individual, medical pre-evaluation and evaluation on departure were offered to every participant. An evaluation of cardiac status was performed weeks before attendance at a private cardiologist's office. This was done to evaluate and ensure that there were no clinical contraindications with respect to performing the exercise part of the cardiac rehabilitation. An evaluation of medications was also carried out at this session. On departure, a consultation took place with a general practitioner at the rehabilitation centre. He also provided a report to be sent to the referring institution or doctor.

4) Individual counselling. Every participant had an opportunity to meet a social worker to discuss important issues concerning return to work, financial questions and related issues. Other staff members could also provide individual information on request.

5) A smoking cessation programme was offered to all present or former smokers in group sessions. Four group sessions were offered at which the participants shared experiences and thoughts about smoking cessation. A nurse facilitated the discussions and set an agenda based on different phases of smoking cessation.

11.8.2 Description of the intervention

The intervention was a clinical counselling intervention based on four individual counselling sessions. Two sessions of approximately one hour's duration were offered during the third and fourth weeks of the four-week rehabilitation stay. Two follow-up telephone consultations were arranged at six and 24 months. These interventions were additional to the rehabilitation programme provided to all participants. The objectives of these sessions were first and foremost to reveal the most urgent problems and challenges from the patients' perspective; and to facilitate the resources that patients require to master these challenges.

We therefore based our method on a structured intervention supported by written material, but where the content of this structure was provided by the patient in a respectful dialogue with the clinician. We aimed to help the patient structure and focus on his or her tasks by providing choice and respect for the patient's autonomy and responsibility. The overall structure of the consultations started with an introduction, followed by a problem solving phase and a closing session with a plan for homework and follow-up appointments.

11.8.2.1 The introduction phase

The first task during this phase was to establish the best possible rapport. This was done by presenting the purpose and sequence of the consultations, and by attending to the patient's expectations of the consultation by inviting the client to share any immediate concerns which he or she needed help to overcome before we focused on specific items.

The next task was to develop an agenda and improve collaboration. In this phase, we completed a registration and problem-solving form with the patient that contained typical problems and challenges in the coming rehabilitation process. The form is translated from Norwegian in Appendix 1. At this point, we aimed to identify the patient's subjective understanding of the different items at issue. As shown in Appendix 1, these items varied from concern about medical problems, illness cognitions, life habits (physical activity, diet and smoking), stress, emotional reactions, social relations, work rehabilitation to other problem areas.

The patients were prepared for a discussion about these topics through their participation in the didactic group-based programme. But in this part of the session we made a point of inviting them to explore their own ideas about the items in the form. We attempted to avoid a premature leap into specific discussions, which can often lead to neglect of individual concerns and cognitions. The assessment was made in an atmosphere of respect for the patient's autonomy. Certain strategies were used, such as careful listening, inviting the patient to be verbally active, allowing the patient to think loudly, and ensuring that the dialogue was characterised by the participants taking turns, while allowing the patient to be the more verbally active party during this phase. The providers were instructed to 'follow the data' provided by the clients, and not to rely on their own presumptions. Collaboration and active participation by the patient was emphasised.

Once the best possible collaborative relationship was established, the counsellor again introduced a structuring intervention by asking the patients to give priority to the three most important or urgent items concerning their future heart condition and health in general. The

patients were asked to choose from the form. In this way, we aimed to enhance the patients' own motivation, decision-making and responsibility for change and maintenance.

11.8.2.2 The problem solving phase

The point of departure for this phase of the counselling was the three most urgent tasks concerning future mastery and management. The counsellor explored the patients' motivation, expectations and resources related to their goals. In cognitive terms, this meant making the patient conscious about his or her own specific ideas concerning the items in question. In this part of the interaction, the counsellor was free to use his or her repertoire of cognitive behavioural techniques, but in the frame of an autonomous supportive relationship and atmosphere.

The objectives were, firstly, to associate with matters discussed in the opening phase, secondly, to help patients discover challenging problems and, lastly, to help them prioritise future tasks. By utilising the chart, we also underlined the importance of providing choice and personal control. The clinicians were instructed to invite the patients to choose, and not to give (premature) advice.

For each area, the provider tried to reveal whether the objective was to make improvements and changes or to maintain important improvements already made. The problem-solving phase would normally extend to more than one consultation, and the management planning was continued in the second encounter. During this stage of the interview we tried first and foremost to help patients to be realistic concerning their aims, and to also help them to specify the three most urgent aims and the possible means necessary for reaching their objectives. These areas of priority were written on the form provided at the bottom of Appendix 1.

During the problem-solving phase, we aimed to reveal dysfunctional cognitions that might hamper the rehabilitation process. Such cognitions varied from incorrect health information to more serious cognitive distortions or global ideas concerning health issues, lifestyle and social functioning. This revealing process was explorative and non-judgemental, and the providers were advised to use Socratic questioning or other cognitive techniques in order to explore such cognitions.

A client might misinterpret symptoms of anxiety as signs of heart illness and therefore avoid what he thought was dangerous exercise, or be avoidant because he lacked energy due to depression or because he was simply shy about the strangers in the exercise group. This

example shows that a surface problem such as non-adherence to an exercise programme might have different sources.

After the priorities were decided, we discussed the practical and motivational resources necessary to reach the aims, and the barriers that might hamper patients reaching them. Revealing the patients' self-efficacy beliefs and coping strategies was important at this stage. We applied the chart provided in Appendix 2 in order to reveal maladaptive cognitions and behaviour and to explore mastering alternatives.

11.8.2.3   The closing phase

At this stage of the interview, follow-up appointments were made. Before closing, we reviewed the homework assigned and tried to check whether a shared understanding existed and decisions about the management of future changes had been made.

During telephone interviews at six and 24 months, the interview charts were used as further reminders and as auxiliary material. Necessary changes of priorities were discussed and realistic aims tested, and relevant steps to reach them were discussed. We still aimed at a facilitative role as providers, with the patient in the responsible position.

11.8.3 Dilemmas and critical intervention components

During the closing phase of the consultations, the providers were to recheck that a shared management plan was negotiated and specified as homework for the patient. The providers should ensure that the tasks were self-determined and realistic in the view of the patient. The tasks should be both attainable and of importance to the patient. Unrealistic aims should be renegotiated, and unspecified tasks should be specified.

Some patients had difficulties prioritising. The intervention method presupposed a certain degree of 'psychology-mindedness'. In cases where the client openly or implicitly resisted employing the method, the providers were instructed to give priority to the relation. Whenever the instrument and the relation were in conflict, the provider was to ensure that a respectful relation was maintained.

12 Results (synopsis of the papers)

12.1 Paper I

Mildestvedt T, Meland E. Examining the 'Matthew Effect' on the motivation and ability to make lifestyle changes in 217 heart rehabilitation patients. Scand J Public Health 2007; 35: 140-147.

We presented predictors of lifestyle changes and motivational factors for the whole group of rehabilitations patients. We chose gender, age, disease severity, emotional status, smoking and household income to be the predictors. Autonomous motivation was found to be lowest among smokers (b = -0.31, p = 0.02) and female participants (b = 0.39, p = 0.004). Participants with high scores for emotional distress predicted lower motivation for all the measures. We found no association between socioeconomic status (household income) and the ability to implement lifestyle changes. Current smoking status predicted lower ability to achieve lifestyle changes on all measures. Emotional distress was related to a lower ability to increase physical activity at six months but not at 24-months follow up.

After measuring the predictors of dietary and exercise changes we entered the motivational measures as predictors in the analyses in order to find out whether any effects were mediated by motivational factors. The association between female gender and psychical activity at both six and 24 months and the association between emotional distress and physical activity at six months were slightly attenuated by adjusting for the motivational factors. In total, we found the mediating effects of the motivational factors to be insignificant and of no clinical relevance.

12.2 Paper II

Mildestvedt T, Meland E, Eide GE. No difference in lifestyle changes by adding individual counselling to group-based rehabilitation RCT among coronary heart disease patients. Scand J Public Health 2007; 35: 591-598.

In this paper we presented the RCT data of the dietary and smoking measures. There was no clinically significant difference in improved dietary change between the two groups. The standard rehabilitation group reported a statistically significantly higher weekly fish intake (p=0.004). We found no significant difference in smoking status at any of the measuring points.

Both groups showed an overall improvement in their intake of fruit and vegetables (0.6 units or 18%, p<0.001), low saturated fat products (13%, p<0.001) and weekly fish dinners (0.1 times weekly or 3%, p=0.02) in a general linear model. The longitudinal study of the predicting variables revealed self-efficacy to be a significant predictor of increased intake of fruit and vegetables (p<0.001) and weekly fish dinners (p=0.001). Autonomous motivation was significantly associated with a low saturated fat intake (p = 0.001). Controlled motivation on inclusion was negatively associated with a low saturated fat intake (p = 0.02). A low saturated fat diet was also statistically associated with younger age (p = 0.03) and female gender (main effect p = 0.04). Older people reported a higher weekly intake of fish dinners (p < 0.001). General expectancy did not show any significant associations. None of the associations had a significant association with time. Smoking cessation was not tested for predicting factors due to the small numbers of participants changing their smoking habits. Autonomy support from the clinical staff was not perceived differently in the two groups measured at six months and 24 months.

There were significantly more dropouts among younger and male participants, and borderline significant lower general expectancy was demonstrated among dropouts. They also reported eating fish dinners less frequently. Of the 41 dropouts, 24 belonged to the standard treatment group. In an intention-to-treat analysis with worst-case scenarios, low saturated fat diet was significantly improved in the group receiving the additional intervention. In the dropout group, mean values for low saturated fat diet at baseline were significantly different in the group with additional intervention compared with the standard treatment group (mean 3.5 vs. 3.1, p=0.001 for the difference). Improvements in low saturated fat diet were no longer predicted by being young. Other main outcomes were not significantly altered by the intention-to-treat analyses.

12.3 Paper III

Mildestvedt T, Meland E, Eide, GE. How important are individual counselling, expectancy beliefs and autonomy for the maintenance of exercise after cardiac rehabilitation? Scand J Public Health 2008; 36: 832-840.

This paper presented exercise outcomes from the RCT and longitudinal data of the predicting variables. We found no statistically significant between-group differences in a general linear model. A change in autonomous motivation from baseline to 24-month follow-up was not predicted by perceived autonomy support at six months. Nor could we detect any difference in

perceived autonomy support between the groups at six or 24 months. The groups showed an overall improvement in their self-evaluated physical capacity during the two years of the study, corresponding to a 7% change in score (p < 0.001). The composite exercise score improved by 6% during follow-up (p < 0.001). The intensity of exercise activities improved by 17% from inclusion to the 24-months follow-up (p < 0.001).

Self-efficacy for increased exercise predicted higher reported physical capacity (p = 0.02) but not for other exercise measures. General expectancy predicted higher levels of physical capacity (p = 0.003) and exercise (p = 0.02). The influence of general expectancy on the exercise score decreased significantly with time (p = 0.02). Autonomous motivation was associated with increased exercise (p = 0.002) and with intensity of exercise (p < 0.001). Controlled motivation was inversely correlated to physical capacity (p = 0.01). Male participants reported higher physical capacity than female participants (p = 0.04). Seventy-five (83%) of the patients in the intervention group chose exercise as one of their prioritised goals for lifestyle changes.

We analysed the differences between dropouts and the study group and found that the dropouts were on average 5.52 years younger (95 % CI: 2.42, 8.62) and had a higher proportion of male participants, 0.14 (95 % CI: 0.04, 0.24). Dropouts reported 0.88 lower physical capacity on average (95 % CI: 0.34-1.42). Lower general expectancy was demonstrated among dropouts with a difference between sample means of 0.33 (95 % CI: -0.01, 0.67). The dropout rate was higher in the control group (24 participants vs. 17), but not to a significant level. In the intention-to-treat analyses with worst-case scenarios, general expectancy became a significant predictor (p=0.03) of exercise intensity. Main outcomes were otherwise not altered.

12.4 Paper IV

Mildestvedt T, Meland E, Folmo S, Eide GE, Williams G. Cognitive behaviour modification and autonomy support in heart rehabilitation – is personal choice beneficial? Submitted 2008

The last paper presented the intervention and discussed the importance of making a personal choice. In this paper, we compared three different groups. The intervention group was divided into two sub-groups: those choosing dietary changes and those who chose other lifestyle achievements. We wanted to examine whether intervention effects were confined to the group that chose the achievement in question.

There was no clinically significant difference in improved dietary change between the three groups. The interaction between the intervention group and reported lifestyle at three measuring points was non-significant. Adjusting for age, gender and the motivational factors

did not alter these associations. Perceived autonomy support at 24 months did not differ between the groups.

Of the 90 participants in the goal selection group, 55 (61%) chose dietary changes to be one of three prioritised lifestyle goals. Thirty-four (38%) chose other achievement areas and one person did not make a selection. Ten (18%) of the participants in the goal selection group did not report their attainments. Of those who reported their dietary attainments 96 % at six months and 100% at 24 months reported partial or full attainment of their dietary goals.

The paper discusses the importance of choice with reference to the theoretical basis for the intervention. Providing choice is presented as a delicate manoeuvre. We suggest that, in a medical setting, directive advice should be combined with exploring the patients' perspectives in order to avoid being too authoritarian and controlling.

13 Methodological considerations

13.1 Intervention

The background for and choice of intervention is presented in the introduction to this thesis. We have presented an intervention based on SDT and SCT. The strong focus on theory is a strength of this study. The individual counselling intervention focused on facilitating personal goal selection using a cognitive behavioural approach. The providers aimed to help the patients to structure and focus on their tasks by providing choice and showing respect for patients' responsibility. The detailed description of the intervention compared with standard treatment makes it possible for other practitioners and researchers to build on our findings. One important question is whether the intervention was strong enough to make a difference in relation to the already well-developed rehabilitation course. The staff at Krokeide wanted to test individually tailored and more focused counselling [70]. The intervention is in line with recent advances in clinical methods advocating patient-centeredness and stronger focus on the provider-patient relationship. The intervention only added 2 individualised sessions, with two telephone follow-ups. On the other hand, it was important to develop an intervention that was not too complex and demanding in terms of resources. An obstacle to detecting between-group differences was that elements from the intervention, such as autonomy support and improving self-efficacy were already present in the standard treatment. Both groups spent most of the time together attending the standard treatment programme, which means that contamination of effects between the study groups was possible.

We could question whether this choice of intervention was the most appropriate to promote long-term lifestyle changes. Our cognitive intervention only deals with one of four qualitatively different domains that facilitate lifestyle changes. Somatic, affective and social/practical incentives have been presented as being equally important or more important predictors of lifestyle changes [140]. The social environment in particular could either act as a constraint on maintaining lifestyle achievements or as a facilitator. Our choice of intervention may have missed important issues relating to other domains than cognitive and motivational issues. On the other hand, in the standard treatment group setting, these other domains related to lifestyle changes were addressed. Standard treatment was well established already containing the most important elements from recommended, multifaceted rehabilitation. Detecting clinical relevant improvements based on an intervention in this setting is difficult, but possible. Our intervention aimed to build on this rehabilitation programme, and we recognise this cognitive intervention as being suitable for this purpose.

The validity and generalisability of this study must be evaluated with these issues in mind. In the discussion of results, I will further elaborate on the issue of intervention effect.

13.2 Design

13.2.1 General design

This is a randomised controlled trial (RCT) in a secondary preventive setting. We wanted to evaluate the therapeutic effects of a recently developed intervention. Conducting an RCT yields the strongest evidence of whether an observed difference is a causal effect of the intervention [138]. In this thesis, we have presented data, at group level, showing that the rehabilitation patients improved on all measured lifestyle domains and also maintained these changes over the next two years. With only observational data, we would not be able to distinguish whether the newly designed intervention was superior to standard treatment and we could have wrongly concluded that the intervention was successful.

Blinding is difficult in lifestyle interventions, but not impossible. Both the participants and counsellors were aware of who received the additional intervention. Participants receiving the interventions may report better outcomes merely because of the extra attention or because they believe the intervention is beneficial. The possibility of post-randomisation bias compromises the internal validity of RCT, but this would have been a more relevant objection if the present study had revealed additional effects in favour of the intervention.

13.2.2 The study group

Patients were recruited during hospitalisation or by their general practitioner. As in most Western countries, the selection of patients and referral to rehabilitation is not standardised in Norway. Attending the rehabilitation was voluntary and we believe both personal and health-wise reasons may be important explanations why patients choose not to attend. Only some 20% of eligible cardiac patients are referred and of these less than 50% show up [58]. We believe these numbers are also applicable to the Norwegian setting. This leaves us with less information about how cardiac rehabilitation could be beneficial for the whole group of cardiac patients. None-attendees may have already made important lifestyle changes or do not want any assistance, or they may not be motivated at all. Previously presented data from a smaller sample of this group of rehabilitation patients describe an emotionally well-functioning group [67]. Participants who wanted to attend rehabilitation were probably especially positive to lifestyle changes in general. We believe they had already changed their lifestyles a great deal in advance of attending the rehabilitation course. Volunteerism is associated with better outcomes [138].

This study shares external validity problems with comparable research in a CR setting, as presented in the introduction. The recruitment process seems to favour already well-motivated patients from hospitals and cardiac rehabilitation settings. A quantitative review found that patients were more likely to participate in rehabilitation programmes when they were actively referred, educated, married, had high self-efficacy and when the programmes were easily accessible [59]. In line with other reports from a cardiac setting, the sample mainly consisted of middle-aged men. The general group of patients with cardiac diseases is older, and with increasing age more female suffer from cardiac disease [141-143]. Women are reported to achieve better dietary adherence in other studies, but are underrepresented in our study and in cardiac rehabilitation in general [2]. Women probably also have greater problems maintaining exercise improvements [131].

Forty-nine of the 266 invited patients abstained from participation (18%). We have no data from these eligible patients who did not want to attend the study. In addition, approximately 20% of the study population was lost to follow-up at 24 months. Of these, 24 (59%) were in the standard treatment group. Emotionally distressed participants dropped out from the study more often than their peers with better emotional adaptation. Women were slightly overrepresented in the intervention group (p = 0.09), possibly compromising internal validity. Dropouts were more frequently younger and of male gender. The dropouts were also reported to eat fish less frequently. Losing more males in the standard treatment group tends

to even out the gender differences at baseline. Gender differences among the dropouts would hardly result in clinically important influence. Intention-to-treat analyses with a worst-case scenario were performed in order to deal with the problem of dropouts. These analyses did not alter any of the main outcomes in any clinically important direction.

13.3 Measures and instruments

Good questionnaires should measure what they are intended to; they need to be valid. Moreover, they have to measure the same when repeated under the same and stable conditions; they need to be reliable. These qualities of an instrument must be considered before using it in the collection of data. There are different ways of assessing the validity of questionnaires. We constructed several of the measures used in this study. Content validity may be claimed for general expectancy, exercise composite score and low fat diet score. The items in these scales are all relevant to the construct. Similar questions have previously been validated and used in other papers. The questionnaires are all presented in the methods section.

We presented the internal consistencies of the measures constructed for this study. We found good reliability for all our constructs, as outlined in Paper I. Some of the items in composite scores had different scaling. They were all recalculated to the same five-level scale. To prevent individual missing items excluding responses, we calculated the mean score for all composite measures. We obtained good response rates from the different instruments. A 10% selection of the questionnaires was randomly collected and reviewed for completeness and the data checked for plotting errors. The findings were satisfactory with approximately 2% errors detected.

There are a number of possible limitations. The next section will discuss the most relevant limitations concerning the selection of measures, the construction of measures and timing of the questionnaires. A general consideration is that internal validity is compromised by the self-reported questionnaires. Their validity is affected by recall bias. Preconceptions and interpretation of the questionnaires are other limitations. For example, the participants could have an eager-to-please attitude, reporting better outcomes than would be observed or measured by standardised and objective measures. Context differences when filling in questionnaires is also a possible limitation of the validity.

13.3.1 Outcome measures

Self-reported questionnaires are most extensively applied in the evaluation of lifestyle achievements such as exercise, smoking and dietary changes. The external validity of self-reported lifestyle measures has been discussed and found to be valid for both dietary measures and exercise measures. Jacobsen et al found food frequency questions to be satisfactory when asking questions involving specific counts (numbers of cups of coffee, litres of milk etc) on an individual level. Less specific amounts, such as fish dinners weekly, were satisfactory on a group level [132].

Construct validity for the exercise measures has been proven, even though the same four questions have not been used together in a composite score [127, 129, 144]. The exercise questionnaire measured three of four recommended dimensions of exercise, namely frequency, duration and intensity [145]. The fourth dimension, seasonal variation, was not addressed. During winter season people recently reported lower levels of physical activity compared to summer season in a Norwegian setting [146]. This should not be a problem in our randomised, controlled study. A seasonal dimension is more important assessing epidemiological evidence. Other and more extensive questionnaires have lately been proposed to be more suitable instruments for measuring physical activity levels [146]. Nevertheless, short and simple questions on activity levels were found to be strongly correlated to longer and better validated questionnaires like the long International Physical Activity Questionnaire (IPAQ-L) [147]. Presently, we have no standardised method for the assessment of physical activity. Even in recent large-scale epidemiological studies in Norway, instruments that have not been validated are in use [145]. Self-efficacy to increased exercise was not found to increase self-reported exercise in our study, but was associated to increased physical capacity. This may be a validity limitation with either of the measures. However, the exercise measure showed discriminative validity in Paper I where participants reporting increased emotional distress, smokers and female reported lower levels of physical activity.

There are possible limitations regarding the self-reported achievements in the intervention group who chose diet as a prioritised goal. They were collected in telephone interviews at six and 24 months but, at the beginning, not all of the information from the patients was accurately reported (personal information from Folmo). We found that achievement data was not available for ten participants due to incomplete reporting.

13.3.2 Predicting variables

In the introduction section, the predictors are presented either as important measures associated with cardiovascular health or as determinants of human motivation. The selection of predictors was motivated by the literature and previous research conducted in this rehabilitation setting. This literature is presented in the introduction.

13.3.2.1 Socioeconomic measures

We did not find any significant association between household income and any of the outcomes. Four main socioeconomic predictors are widely explored in research settings: education level, occupational status, housing conditions and household income. The first three are reported to be equal in terms of predicting associations between socioeconomic status (SES) and all cause mortality, while household income did not discriminate mortality equally well [148]. Although household income is widely used as an important indicator of SES, this finding may indicate that it is not the most appropriate predictor of SES for studies like this. We also assessed education level, but too many data were missing on this measure to be able to use it as our socioeconomic measure. Household income was measured at 24-month follow-up. We therefore lack information for this measure from the dropout group. This is unfortunate and undermines the internal validity of this measure. Low SES is often associated with higher dropout rates.

13.3.2.2 Disease severity

Our assumption was that a myocardial infarction would be experienced as more threatening to health compared with only having angina pectoris. How a person experiences and evaluates his disease does not need to be related to the objective severity of the disease [149]. This assumption is further biased by the fact that the angina group also included patients who had undergone ACB operations and other coronary interventions. In the non-infarction group, we also found eight patients with other heart diseases, mostly valve diseases. We did not find an association between disease severity and general expectancy, a probable sign of limited construct validity for either of these measures. This is detected in an analysis not reported in any of the papers.

13.3.2.3 Emotional distress: anxiety-depression-irritability questionnaire

In studies of Norwegian coronary heart disease patients the ADI questionnaire has demonstrated good reliability and validity [68, 150]. There are more frequently and

internationally used questionnaires for assessing emotional distress. Becks depression inventory and hospital-anxiety-depression questionnaires are examples of questionnaires that would help researchers from other countries to relate to our survey [151, 152]. The ADI measure was already familiar to the research group and we also had comparable data from the same setting.

13.3.2.4   Autonomy support

We measured perceived autonomy support at six and 24 months, but this measure could not explain differences in motivation. Approximately one-third of the participants did not receive the Health Care Climate Questionnaire (HCCQ) at six months due to an administrative error. Even though autonomy support measured by the modified HCCQ is reasonably stable over time, carrying out measurements two years after the intervention is probably too late [107, 112]. Autonomy support is typically measured immediately after the intervention is over, as in a recent comparable intervention study examining exercise outcomes [106]. The most urgent problem with this measure was the extreme high scores and the lack of variability.

13.3.2.5   Autonomous and controlled motivation

Autonomous motivation at baseline was reported with a mean score of 6.2 on a seven-level Likert scale, using the TSRQ. This ceiling effect makes it difficult to detect any beneficial effects of the intervention, even though controlled motivation showed a greater variance. We believe the rehabilitation patients were a well motivated group prior to attending rehabilitation. Another interpretation could be that the questionnaires did not differentiate well enough between groups. Making the TSRQ more task-specific might be an important step in order to detect motivational changes more accurately. Recent studies have applied task-specific TSRQ questionnaires in order to evaluate this construct according to the outcome studied [153, 154]. This approach appears to be promising in further exploring how autonomy affects lifestyle changes.

13.3.2.6   General expectancy

The GE measure was constructed from responses to three questions, already applied in a Positive Expectation Score (PES) [135]. The instrument proved acceptable content validity compared with the PES score. The internal validity was excellent with a Chronbach´s alpha of 0.87, a similar result as found with the original seven-item construct [135]. We claim reasonable content validity in accordance with recent development of this construct [120].

Construct validity is reported in Paper I with lower general expectancy among emotional distressed. General expectancy is also reported to be associated with increased physical capacity during follow-up.

13.3.2.7   Domain-specific self-efficacy

Our questions were in accordance with the literature (Bandura) and with formerly validated questionnaires [127]. Some modifications were performed in order to improve the specificity of the self-efficacy measure.

13.4 Statistics and sample size considerations

The statistical power of a trial to detect a postulated difference between treatment groups depends not only on sample sizes but also on the outcome measure and compliance in the different treatment groups [138]. The power of this study was based on power estimates from the exercise outcome measure. Our study sample is a large sample, which also enables complex modelling of relationships between variables of interest. Despite this, we may not have had enough power to evaluate the dietary and smoking outcomes. Especially the last paper, containing the intervention sub-group analysis suffers from a lack of power. A risk of doing type II errors thereby existed; we may have missed a positive effect of the intervention. In post-hoc power analyses, we calculated the sample sizes needed for a study based on the daily units of fruit and vegetables outcome. We made a conservative assumption that a between-group difference of 0.5 daily units of fruits and vegetables would be clinically important. With a standard deviation of 1.3, we would have needed to randomize 77 participants in the group that chose diet as its prioritised goal and 170 participants in the group not choosing diet as its goal in order to detect such a difference with 80% probability. If the true group difference was 0.6 units, our sample sizes would have been large enough to detect a between-group difference with a power of 0.8 and significance level of 0.05. The study was too small for the smoking cessation outcome. For example, tobacco dependence intervention studies typically have up to 300 patients per group[94].

Confounding was addressed, firstly by adjusting for age and gender in the multivariate analyses. In addition, all other predictors assessed in this longitudinal study were included in the multivariate analyses. Other confounders may be claimed, but we chose our predictors according to the literature presented.

We lost more participants in the standard treatment group, and differences in characteristics among them may have influenced the results. In order to preserve as much

information as possible, mean scores were computed for all the composite scores. Individual missing items did not, therefore, lead to missing values. In addition, intention-to-treat analyses were performed. Missing values for the outcomes at 24 months were replaced by the lowest measure at baseline or six months. In this regard, we made the most conservative analyses on the basis of a worst-case scenario.

14 Discussion of main results

In Papers II-IV, we could not detect any improvement in dietary measures, exercise measures or smoking cessation in the intervention group compared with the standard treatment group. Important motivational predictors for lifestyle changes were autonomous motivation and self-efficacy. Results from Paper I did not reveal any Matthew effect among this study population except among smokers, who reported being less able to adopt healthy lifestyles.

This randomised controlled study contributes to the understanding of the maintenance of lifestyle changes among CR patients. The strengths of the present study are the randomised design and the repeated assessments of outcomes over time (24 months' follow-up). Evaluation at both six and 24 months allowed us to detect both the short and the long-term maintenance of lifestyle changes. In addition, the large study group allowed us to explore complex associations between psychosocial and motivational predictors of lifestyle changes.

This was a self-recruited rehabilitation group reporting to be well-motivated and emotionally well-functioning. Participants reported fairly beneficial lifestyles already at baseline and any substantial intervention effect would be hard to detect. It is possible that important changes took place prior to starting the rehabilitation. This might have been initiated by an increasing focus on lifestyle changes during the time from a cardiac event took place until starting the rehabilitation course. In addition dietary and smoking cessation campaigns in Norway have been important in Norway, especially since 1996 [155, 156]. Another reason for not detecting any clinically important between-group effects is the rather small additional intervention, an issue addressed above. The standard treatment group was strongly focused on lifestyle changes, but only in a group setting. Motivational measures such as autonomous motivation were reported to be very high. High scores on motivation on the TSRQ have also been reported in other health related studies, such as weight loss and smoking cessation studies [94, 112]. Patients low on motivation and depressed patients would probably not attend these courses. Overall, the intervention may have been hampered by this ceiling effect, with very motivated patients. In this situation, significant improvements and between-group effects are hard to detect.

14.1 Are personal goals an important intervention strategy?

The intervention aimed to guide the participants to adopt self-selected lifestyle goals. In addition, a cognitive and self-efficacy enhancing intervention was given in order to promote the selection and maintenance of chosen lifestyle goals. Paper IV discusses how delicate and difficult it may be to apply an intervention according to this principle. Goal setting as a strategy for health behaviour change has already been presented in a theory paper in 1995 [126]. Our strategy of linking goal selection with enhancing self-efficacy and internal reasons for change is extensively discussed and recommended in this paper. In practice, goal setting is an implicit or explicit part of almost all health-related interventions. We chose to make it explicit. Merely offering choice is not motivation in itself. According to SDT, providing choice and stimulating participants to choose between options is only motivating when basic needs are met [157-159]. The goals need to be relevant and congruent with their values, thus supporting their autonomy. The need for competence is taken care of by ensuring that choices offered are not too numerous and complex. In addition, the context of providing choices must be carefully considered in order to ensure relatedness. To what extent these needs where met at Krokeide may be questioned, but according to the description of the intervention, the elements were all addressed.

Choice and it consequences is further explored in a book chapter [160]. It is possible that providing choice had a too prominent place in our intervention. The providers withheld direct advice to the patient in order to remain 'patient-centred' and enable patient responsibility. Direct advice has the potential to be authoritarian and demotivating for patients, but that is not necessarily always the case. In everyday life, we face numerous choices, often of limited difference. There is a choice overload. This may lead people to become demotivated and despairing. People may find themselves in a situation where it is almost impossible to make a self-determined choice [161]. We also find that people's expectations of how satisfying life should be in everyday life – with work, a spouse, children, education and friends – lead to frustrations and depression when these expectations are not met. People feel they do not meet their internal standards of performance. Consequently, people strive to cope with their everyday lifestyles and resign to unhealthy lifestyles without seeing themselves as being in a position to make changes. The concept of choice overload and the feeling of failure in other achievement areas may prevent people from trying to change. In an intervention setting, more direct counselling and goal selection could improve outcomes. Also, limiting number of possible choices has been demonstrated to increase people taking action, even though shown in a purchase setting [162]. Ryan and Deci recently addressed

controversies concerning the relationship between autonomous regulation and choice [163]. They maintain that the feeling of choice leads to autonomous motivation, not the number of choices. According to these theorists, freedom in the choice process is paramount. We do not believe we gave our patients a choice overload. Participants in the intervention group who chose diet as a prioritised goal, reported excellent dietary attainments. This argues against despair and demotivation in our study

Few studies investigate the importance of goal setting or goal pursuit in a rehabilitation setting. Oldridge et al. explored the importance of goal selection, measuring how satisfied the patients were with their own achievements. This study failed to detect a superior effect of facilitating goal attainment. The intervention group did not report higher satisfaction, nor did it demonstrate better results on an exercise tolerance test [164]. In this study, they demonstrate some of the complexity of goal attainment and they question whether self-selected goals are valid outcome measures for the effectiveness of cardiac rehabilitation.

14.2 Findings from other studies that explore our objectives

Several lifestyle interventions have failed to prove any significant improvement. The Extensive Lifestyle Management Intervention (ELMI) following cardiac rehabilitation resulted in modest, non-significant benefits to global risk compared to usual care when 302 men and women were followed for one year. One possible explanation could be the high quality of care in the usual care group [165]. Recent results evaluating different expanded cardiac rehabilitation programmes have also failed to show important improvements in lifestyle and biochemical measures [52, 166]. Our results are thus in line with what we often find with lifestyle intervention in a cardiac rehabilitation setting.

Other studies support the conclusion that individual factors are of great importance in adherence research. Lifestyle changes may be initiated, but are limited if the adverse effect on quality of life is substantial [167]. There seems to be an individual 'pain limit' for lifestyle changes and it is important to prevent the experiences of powerlessness. These motivational issues are not detected by measures of self-efficacy or autonomous motivation. On the contrary, the decision not to change lifestyles may well be based on very autonomous considerations.

Other rehabilitation and lifestyle studies have addressed how intensive individual counselling must be, but the advice is conflicting. This is a multifactor intervention and an intervention to promote dietary change may need to have a different intensity compared with interventions promoting exercise or other lifestyle achivements. We do not know how

intensive the interventions need to be in order to have the most beneficial influence on dietary changes [168]. As expected, there is a tendency for more intensive interventions to produce more important changes than brief interventions [169]. Most of this research comes from non-rehabilitation settings, mostly primary care settings with diabetic patients.

Similar evaluations are presented with exercise interventions. In the CHANGE study, 250 patients were followed for one year in an intensive cognitive behavioural change counselling intervention. The main aim was to increase long-term maintenance of physical activity in the intervention group. The main finding was that longer time elapsed before the intervention group discontinued exercise [123].

Evidence has also been presented against intensive interventions. Lancaster et al. reported that a more intensive smoking cessation intervention was not very superior [170]. The first intervention study based on SDT to demonstrate a significant effect on the lifestyle outcome was conducted on 1,006 smoking patients [94]. Williams et al. found autonomy-supportive goal selection to improve smoking abstinence at 12 months. This intervention was almost twice as intensive as ours, with four consultations in six months. Williams et al. found that intervention intensity (measured in minutes) at six months predicted smoking abstinence. These results indicate that our intervention may have been too small to make a measurable difference on the outcomes.

We have based our conclusion of an association between emotional, social and motivational factors and the outcomes on longitudinal evidence. Longitudinal data can only provide us with possible relations and do not help us by providing strong evidence of a cause-effect relationship. As presented in the introduction section most of the reports on the association between autonomous motivation and health related outcomes are based on longitudinal data. Our results are in line with this literature [112, 113, 116].

We wanted to evaluate the effect of an intervention aimed at improving different lifestyle achievements, reducing stress, increasing compliance with prescribed medications and also addressing return to work. The chosen intervention had to be the only difference between the groups compared in order to explain any observed differences by the nature of the intervention. However, we must be cautious when interpreting results from multifactorial intervention settings.

14.3 Summary of limitations

We conducted an open randomised, controlled trial. The groups could have changed their lifestyles because of different expectations to the treatment leading to a post-randomisation

bias. Secondly, the selection of the study group limits the external validity. We present results that are most reliable for participants in phase II cardiac rehabilitation services. Thirdly, factors associated with the intervention have been thoroughly described and discussed, as they reveal possible limitations. Using this intervention with different intensity and frequency may have lead to other outcomes. Different providers of this cognitive and autonomy-supportive intervention could also have lead to other outcomes. Fourthly, we have discussed different limitations from the selection and assessment of outcome and predictive measures. Many of these could have been assessed differently. Autonomy support was not assessed at six months for all participants due to errors in the data collection. Household income was only measured at 24 months. Suspecting that we had more dropouts among low SES participants, this could have an impact on our results, leaving us with lower variability for this measure. Fifthly, the power of this study was adequate for most of the outcomes but too low for some outcomes. Paper IV suffered from lack of power in the intervention sub-group analyses. Moreover, the smoking cessation outcome generally needs more participants in order to detect any intervention effect. Sixthly, evidence based on longitudinal data is weaker than results from clinical controlled studies. We have presented longitudinal associations with predictors and outcomes based on the combined cohorts of this randomised controlled trial. These results do not provide unequivocal evidence for a causal relationship.

15 Conclusions and implications

15.1 Main conclusions

This is the first study to evaluate a cognitive behavioural and autonomy-supportive intervention in a cardiac rehabilitation setting. Even though we were unable to detect any between-group effects, we found important predictors of long-term maintenance of lifestyle changes. This was in accordance with research already presented**.** However, longitudinal evidence should be interpreted with caution. The present study supports probable relationships between predictors and outcomes that are important to elaborate further on. This large study with an RCT design contributes to the understanding of the maintenance of lifestyle changes in a rehabilitation setting. The 24-month follow-up and the repeated measure design is a further strength of this study. First and foremost, the negative intervention effect should not discourage others from building on this intervention. Important elements from the intervention like autonomy support, relatedness and improving self-efficacy was already present in the standard treatment. We assume that finding any intervention effects in such

settings is difficult. Our intervention was easily applied in a rehabilitation setting without adding too many resources, thus promoting external validity.

Less advantaged groups characterised by emotional problems, more severe disease or low SES were as capable as others of improving their lifestyle, especially during long-term follow-up. We found a consistent 'Matthew Effect' among smokers. Among our group of rehabilitation patients we found lifestyle interventions to be ethically justifiable.

The longitudinal study of the predicting variables revealed self-efficacy, autonomous motivation and general expectancy to be important predictors. Autonomy support from the clinical staff was not perceived differently in the two groups measured at six and 24 months. A ceiling effect, limitations of the intervention, the timing of questionnaires and loss of data at six months may explain these findings.

In the intervention sub-group analyses, we did not find choosing a specific lifestyle goal to be beneficial compared with those not choosing a specific goal or choosing another area of lifestyle achievements.

15.2 Implications and future research

Future research could build on results from this thesis and improve the limitations we have addressed. This thesis suggests the following implications for rehabilitation and future research:

➢ Supporting autonomy and self-efficacy are promising intervention strategies to improve the long-term maintenance of lifestyle changes. Such interventions are ethical justifiable in a rehabilitation setting bearing in mind that smokers seem to be less inclined to improve health behaviours in other areas.

➢ Efforts should be made to ensure that high-risk groups such as smokers are not discouraged from improving other lifestyle factors.

➢ Smokers, who are obviously at high risk for recurrence of heart disease, need clinical efforts to help them to improve other lifestyle areas. Further studies of how we may accomplish this are required.

➢ Targeting interventions at other groups with special needs, such as the emotionally distressed and those expressing motivational problems, should be addressed. Our group of cardiac rehabilitation patients are emotionally well-adjusted and already have a healthy lifestyle, and their motivation to change even further is good. They may be as well taken care of by less intensive rehabilitation.

- Medical departments at hospitals need guidelines in order to refer patients who would profit the most from phase II rehabilitation.
- Goal selection is a promising but demanding intervention style. Both personal factors among the providers and the interpretation by the participants make it challenging to evaluate the mechanism at work. More well-defined and consistent goal guiding instruction would give us more information about whether this intervention is cost-efficient.
- Facilitating choice in a cardiac rehabilitation setting is not sufficient if the goal is to stimulate long-term lifestyle changes. We recommend more research to explore how personal choice and interventions supporting autonomy and other human needs influence long-term maintenance of important lifestyles. We suggest that in a medical setting directive advice should be combined with exploring the patients' perspectives in order to avoid both authoritarianism and abandonment.
- Testing this intervention style in another rehabilitation setting, preferably with a non-rehabilitation control group would provide important and clinically relevant information.
- Measures and instruments must be carefully selected from the growing literature on motivation and lifestyle achievements. Their validity and reliability must be addressed. Outcome measures need to be valid and sensitive to longitudinal and between-group differences. In addition, selection of well-known measures and questionnaires should be done in order to stimulate comparison between studies.
- This study adds to the growing knowledge of the process of change. The individual factors need to be further explored in order to determine how lifestyle changes are achieved and maintained. Autonomous motivation and self-efficacy are important motivational factors, but we still need more research to understand how this knowledge can be used in clinical work.

`There are those who look at things the way they are, and ask why.
I dream of things that never were, and ask why not?´

Robert Kennedy

`We know what we are, but know not what we may be´

William Shakespeare

16 References

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Appendix I

Appendices

Appendix A1

The registration and problem solving form for heart rehabilitation patients

Underneath you will find problem areas linked to risk factors among patients with heart disease. Every area might not be of equal importance for everyone. We therefore want you to appraise and give priority to what areas you consider the most important to change, master or maintain concerning a healthy lifestyle for your heart.

Mark with "C" for change and "M" for maintain.

1. Mastering of disease symptoms; need for more information; be more confident concerning bodily symptoms; reduce unease and pain etc.. _____

2. Medical follow up (hospital, specialist, general practitioner, etc..) _____

3. Healthy lifestyle for your heart as concern: DIET_____ PHYSICAL ACTIVITY_____ SMOKING_____

4. Stress: REGISTER stress symptoms_____ REDUCE stress situations and strains_____ CHANGE your reactions in stressful situations_____

5. Other emotional reactions: ANXIETY_____ FEELING DOWN_____ IRRITABILITY_____

6. Social network: CHANGE network_____ IMPROVE social support_____ PRACTICAL help_____

7. Working conditions: ADJUST working conditions_____ CHANGE job_____ PARTICIPATION while at sick leave_____ PENSIONS_____ OTHER_____

8. Any other problem areas that you consider important_____

MY THREE MOST IMPORTANT AREAS DURING AND AFTER THE
REHABILITATION STAY

AREA WITH PRIORITY	MY GOALS ARE
1.	
2.	
3.	

Appendix II

Appendix A2

Typical situations and reaction patterns concerning my problem areas

SITUATIONS   PATTERNS OF REACTIONS (thoughts, feelings and behaviour)

	Before	Alternatives	Actions

Appendix III

Appendix A3

Questionnaires

Samtykkeerklæring:

Informasjon og forespørsel om deltakelse i forskningsprosjekt ved Krokeidesenteret

Samtlige som deltar på hjerterehabiliteringskurset ved Krokeidesenteret blir med dette forespurt om å delta i et forskningsprosjekt. Prosjektet tar sikte på å utvikle alternative rehabiliteringsmetoder overfor pasienter som har gjennomgått hjerte- og karsykdom. Vi ønsker å vite om det er hensiktsmessig å gi individuell rådgivning i tillegg til den gruppebaserte opplæring som vi har drevet lenge med her ved Krokeidesenteret. Dette testes ved at vi sammenlikner en gruppe som får individuell rådgivning i tillegg til gruppebasert opplæring med en gruppe som utelukkende får opplæring i gruppe. Den behandling som den enkelte får bestemmes ved hjelp av loddtrekning.

Prosjektet bruker en del spørreskjema for å kartlegge hvordan det går under kurset, og i tiden etter. Slike skjema må fylles ut under kurset, etter 6 måneder og 2 år etter kurset. Dessuten taes en fastende blodprøve ved kursets start, ved kursets avslutning og etter 2 år. Den siste prøven ber vi deg om å ta ved ditt lokale legekontor. Spørreskjemaene som skal brukes, tar ca en halv time å fylle ut per gang.

Det er fullstendig frivillig å delta i dette forskningsprosjektet. Det vil ikke få noen følger for den enkelte med hensyn til den behandling som gies ved Hjerterehabiliteringskurset hvor vidt en deltar eller ikke i forskningsprosjektet. Den enkelte kan også på et hvilket som helst tidspunkt trekke seg fra prosjektet uten konsekvenser for behandlingsforholdet ved Krokeidesenteret. Den som trekker seg fra forskningsprosjektet kan også kreve å få opplysninger slettet.

De opplysninger som innhentes i spørreskjema skal behandles med konfidensialitet. Ingen av behandlerne ved kurset vil ha tilgang på personidentifiserbare opplysninger. Svarene blir punchet av kontorpersonale som ikke er kjent med personidentitet.

Ved avslutning av dette prosjektet, to år etter oppholdet ved Krokeidesenteret, spør vi om eventuelle sykehusopphold. I noen tilfeller kan de opplysningene som du oppgir her være nødvendig å sammenholde med opplysninger ved sykehuset der du ble innlagt for å få klarhet i diagnosen som du har vært behandlet for og hvilke behandlinger som har vært gjennomført. Et eventuelt samtykke innbefatter også en tillatelse til å spørre sykehuset om hvilken sykdom du har fått behandling for og hvilken behandling som er gitt. Opplysninger fra sykehuset skal begrenses til utelukkende dette.

Det er Krokeidesenteret som gjennomfører dette forskningsprosjekt som ledd i sitt arbeid med dokumentasjon og kvalitetsforbedring. Krokeidesenteret samarbeider med Universitetet i Bergen om prosjektet. Ved spørsmål kan deltakerne kontakte Arne Huus eller Randi Johansen på telefon 55108700.

Samtykkeerklæring

Jeg har lest informasjonsskrivet og sier meg interessert i å delta i forskningsprosjektet.

Sted, dato, underskrift:

Norsk versjon av TSRQ

Det finnes mange grunner til at folk handler som de gjør. Her er vi interessert i grunner til at du kan endre livsstil som har med helsa di å gjøre. Les spørsmålene nøye og markér ved å **sette ring rundt** det svaralternativ som passer best for din oppfatning. Svar så ærlig som mulig uten å tenke deg om for lenge, og husk å svare på alle spørsmålene. Du markerer ditt svar slik:

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

Hvis jeg ble anbefalt å gjøre endringer på min livsstil (f eks å mosjonere mer, slutte å røyke eller legge om kosten), ville jeg gjort det fordi.........

1. Mine nærmeste hadde blitt skuffet eller sint hvis jeg ikke gjorde det

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

2. Jeg ville sett på det som en personlig utfordring å få en så god helse som mulig

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

3. Det ville ikke gjort noen forskjell - så jeg ville ikke prøvd

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

4. Jeg personlig tror at livsstilsendringer vil forbedre helsa mi

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

5. Jeg ville fått dårlig samvittighet hvis jeg ikke gjorde det som ble anbefalt for meg

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

6. Jeg vil at legen og andre skal synes jeg er flink til å mestre livsstilsendringene

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

7. Jeg ville sett ned på meg selv hvis jeg ikke mestret livsstilsendringer

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

8. Jeg synes at livsstilsendringer er en god måte å bedre helsen på

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

9. Det er spennende å forsøke å forbedre helsen

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

Norsk versjon av General Expectancy

I dette skjemaet er vi interessert i å vite noe om din vurdering av ulike sider ved din livssituasjon. For hvert spørsmål, vennligst sett ring rundt det tallet som best viser hvordan du har hatt det i løpet av den siste måneden

10. Hvor sannsynlig er det at en person med din sykdom kan leve et godt liv

Svært positive   1   2   3   4   5   6   7   Svært negative

11. Sett under ett, hvordan vil du vurdere fremtidsutsiktene dine?

Svært positive   1   2   3   4   5   6   7   Svært negative

12. Dine forventninger til den medisinske behandlingen/oppfølgingen du får?

Svært positive   1   2   3   4   5   6   7   Svært negative

Norsk versjon av HCCQ

De følgende spørsmål omhandler på hvilken måte du har opplevd den behandlingen som du fikk ved Krokeidesenteret. Svar på spørsmålene så ærlig som mulig uten å tenke deg alt for lenge om. Marker svaret ditt slik:

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | (6 ganske enig) | 7 svært enig |

13. Jeg følte at behandlerne ved Krokeidesenteret ga meg valgmuligheter når jeg fikk råd om livsstil

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

14. Jeg følte at jeg kunne være åpen og ærlig med behandlerne når det gjelder min livsstil

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

15. Jeg syntes at behandlerne fikk meg til å forstå betydningen av helsevaner og livsstil uten å legge press på meg

| 1 svært svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

16. Jeg synes behandlerne oppmuntret meg til å stille spørsmål om hjertet eller behandlingen

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

17. Jeg syntes behandlerne var flink til å lytte til hvordan *jeg* kan tenke meg å ta vare på min egen helse

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

18. Behandlerne prøvde å forstå hvordan *jeg* så på sykdommen min og behandlingen før de ga meg råd

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 enig |

Mestringsforventning til økt mosjon

De følgende spørsmål gjelder forventninger om egne mosjonsvaner. Under kurset har mosjonsvanene vært gode, men spørsmålene dreier seg om i hvilken grad du tror du klarer å endre mosjonsvanene i forhold til det som *tidligere var vanlig* for deg. Selv om du ikke ønsker å gjøre endringer i forhold til tidligere, ber vi deg svare på om du hadde klart det **hvis** du forsøkte. Svar på alle fire spørsmål og velg det svaralternativ som passer best ved å sette ring rundt tallet slik:

1 Klarer det **ikke** helt sikkert	2 Klarer det **ikke** nokså sikkert	3 Usikker	4 Klarer det nokså sikkert	5 Klarer det helt sikkert

19. Hvis jeg forsøker, vil jeg klare å mosjonere minst én gang oftere per uke enn det jeg har vært vant til i minst et halvt år

1 Klarer det **ikke** helt sikkert	2 Klarer det **ikke** nokså sikkert	3 Usikker	4 Klarer det nokså sikkert	5 Klarer det helt sikkert

20. Hvis jeg forsøker, vil jeg klare å mosjonere minst én gang oftere per uke enn det jeg har vært vant til i de kommende år

1 Klarer det **ikke** helt sikkert	2 Klarer det **ikke** nokså sikkert	3 Usikker	4 Klarer det nokså sikkert	5 Klarer det helt sikkert

21. Hvis jeg forsøker, vil jeg klare å mosjonere minst to ganger oftere per uke enn det jeg har vært vant til i minst et halvt år

1 Klarer det **ikke** helt sikkert	2 Klarer det **ikke** nokså sikkert	3 Usikker	4 Klarer det nokså sikkert	5 Klarer det helt sikkert

22. Hvis jeg forsøker, vil jeg klare å mosjonere minst to ganger oftere per uke enn det jeg har vært vant til i de kommende år

1 Klarer det **ikke** helt sikkert	2 Klarer det **ikke** nokså sikkert	3 Usikker	4 Klarer det nokså sikkert	5 Klarer det helt sikkert

Mestringsforventning til kostendringer

De følgende spørsmål gjelder forventninger om egne kostvaner. Under kurset har kostvanene vært litt spesielle, men spørsmålene dreier seg om i hvilken grad du tror du i fremtiden klarer å endre kostvaner i forhold til det som var det vanlige tidligere. Selv om du ikke ønsker å gjøre endringer i forhold til tidligere, ber vi deg svare på om du hadde klart det **hvis** du forsøkte. Svar på alle fire spørsmål og velg det svaralternativ som passer best ved å sette ring rundt tallet slik:

| 1 Klarer det **ikke** helt sikkert | 2 Klarer det **ikke** nokså sikkert | 3 Usikker | 4 Klarer det nokså sikkert | 5 Klarer det helt sikkert |

23. Hvis jeg forsøker, vil jeg klare å øke antall fiskemåltid med ett måltid per uke i minst et halvt år

| 1 Klarer det **ikke** helt sikkert | 2 Klarer det **ikke** nokså sikkert | 3 Usikker | 4 Klarer det nokså sikkert | 5 Klarer det helt sikkert |

24. Hvis jeg forsøker, vil jeg klare å øke antall fiskemåltid med ett måltid per uke i de kommende år

| 1 Klarer det **ikke** helt sikkert | 2 Klarer det **ikke** nokså sikkert | 3 Usikker | 4 Klarer det nokså sikkert | 5 Klarer det helt sikkert |

25. Hvis jeg forsøker, vil jeg klare å øke inntaket av frukt og grønnsaker til "fem enheter per dag" i minst et halvt år

| 1 Klarer det **ikke** helt sikkert | 2 Klarer det **ikke** nokså sikkert | 3 Usikker | 4 Klarer det nokså sikkert | 5 Klarer det helt sikkert |

26. Hvis jeg forsøker, vil jeg klare å øke inntaket av frukt og grønnsaker til "fem enheter per dag" i de kommende år

| 1 Klarer det **ikke** helt sikkert | 2 Klarer det **ikke** nokså sikkert | 3 Usikker | 4 Klarer det nokså sikkert | 5 Klarer det helt sikkert |

Mosjonsvaner

De følgende spørsmål handler om i hvilken grad du mosjonerer /driver med fysisk aktivitet. Svar ved å sette ring rundt ett svaralternativ. Svar på alle spørsmålene.

27. Hvordan vurderer du din mosjonsaktivitet den siste tid sammenliknet med andre på din egen alder?

| 1 Mye mindre mosjon | 2 Mindre mosjon | 3 Litt mindre mosjon | 4 Omtrent gjennom- snittlig mosjon | 5 Litt mer mosjon | 6 Mer mosjon | 7 Mye mer mosjon |

28. Hvor mye mosjon har du fått i år sammenliknet med i fjor?

| 1 Mye mindre mosjon | 2 Mindre mosjon | 3 Litt mindre mosjon | 4 Omtrent som i fjor | 5 Litt mer mosjon | 6 Mer mosjon | 7 Mye mer mosjon |

29. Hvor ofte driver du mosjon (ta et gjennomsnitt)?

| 1 Aldri | 2 Sjeldnere enn én gang per uke | 3 Én gang i uka | 4 To til tre ganger per uke | 5 Omtrent hver dag |

30. Hvor hardt mosjonerer du (ta et gjennomsnitt)?

| 1 Tar det rolig uten å bli anpusten og svett | 2 Blir litt anpusten og svett | 3 Blir avgjort anpusten og svett | 4 Tar meg nesten helt ut |

31. Hvor lenge holder du på hver gang (ta et gjennomsnitt)?

| 1 Mindre enn 15 minutt | 2 Seksten til 30 minutt | 3 Trettién minutt til en time | 4 Mer enn en time |

32. Hvor lenge holder du på hver gang (ta et gjennomsnitt)?

| 1 Mindre enn 15 minutt | 2 Seksten til 30 minutt | 3 Trettién minutt til en time | 4 Mer enn en time |

Kostvaner

De neste spørsmålene dreier seg om hvilke kostvaner du har for tiden (ditt gjennomsnittlige kosthold den siste måneden). Les spørsmålene nøye og marker ved å sette en ring rundt det svaralternativ som passer best for din oppfatning. Svar ærlig, uten å tenke deg om for lenge.

33. Hvor mange frukt og grønnsakenheter spiser du per dag (1 enhet er en mengde på størrelse med et eple/ appelsin / en håndfull. Potet / risporsjonen til middag regnes som en enhet. 1 glass juice kan regnes som en enhet.)

| 1 enhet | 2 enheter | 3 enheter | 4 enheter | 5 enheter | 6 eller flere enheter |

34. Hvor mange ganger i uken spiser du fisk til middag ?

| Mindre enn 1 gang | 1-2 ganger | 3-4 ganger | 5 eller flere ganger |

35. Hvor mange ganger i uken bruker du olje ved middagslaging ?

| mindre enn 1 gang | 1-2 ganger | 3-4 ganger | 5 eller flere ganger |

36. I gjennomsnitt bruker jeg fiskepålegg på

| Hver skive | hver 2. skive | hver 3. skive | hver 4. skive | hver 5.skive el mindre |

37. På skiven pleier jeg å smøre:

| meierismør/ bremykt | Fast margarin (Per , Melange o.l) | Myk margarin (Soft, Soya , Vita) | Ikke noe |

38 Når jeg spiser kjøtt / kjøttprodukter til middag er det nesten alltid lite fett i det.

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

39. Når jeg bruker ost eller kjøttpålegg er det nesten alltid magre varianter

| 1 svært uenig | 2 ganske uenig | 3 litt uenig | 4 verken enig eller uenig | 5 litt enig | 6 ganske enig | 7 svært enig |

Fysisk kapasitet

De neste spørsmålene dreier seg om din fysiske kapasitet. For hver aktivitet **setter du ring** rundt det svaralternativ som passer best. Det er din fysiske kapasitet i løpet av de siste ukene vi er interessert i at du bedømmer.

40. Jeg klarer å gå i samme tempo som andre på flat veg

1 svært uriktig	2 ganske uriktig	3 litt uriktig	4 verken riktig eller uriktig	5 litt rikig	6 ganske riktig	7 svært riktig

41. Jeg klarer å gå i samme tempo som andre opp trapper

1 svært uriktig	2 ganske uriktig	3 litt uriktig	4 verken riktig eller uriktig	5 litt rikig	6 ganske riktig	7 svært riktig

42. Jeg klarer å gå hurtig oppover bakker eller trapper eller småløpe på flat veg

1 svært uriktig	2 ganske uriktig	3 litt uriktig	4 verken riktig eller uriktig	5 litt rikig	6 ganske riktig	7 svært riktig

43. Jeg klarer å løpe på flat veg eller småløpe oppover bakker eller trapper

1 svært uriktig	2 ganske uriktig	3 litt uriktig	4 verken riktig eller uriktig	5 litt rikig	6 ganske riktig	7 svært riktig

Røykevaner

44. Røyker du?   Nei   Ja   …….år

<u>Veiledning</u> :

På neste side finner du en del ordpar som beskriver forskjellige følelser og reaksjoner som man kan ha. Vi vil be deg om å beskrive hvordan <u>du føler deg nå</u> - <u>i dag</u> - ved hjelp av disse ordparene. Nedenfor er det satt opp et eksempel som viser hvordan du skal bruke ordparene for å beskrive dine følelser og reaksjoner.

<u>Eksempel</u>:

Søvnig :___:___:___:___:___:___:___: Våken

Som du ser er det en syvdelt skala for ordparet "søvnig-våken". Hvis du mener at "søvnig" <u>passer svært godt</u> med hvordan du føler deg nå, skal du krysse av på denne måten:

Søvnig : X :___:___:___:___:___:___: Våken

Hvis du derimot mener at «våken» <u>passer svært godt</u> med hvordan du føler deg nå, krysser du av slik :

Søvnig :___:___:___:___:___:___: X : Våken

Hvis du derimot mener at enten «søvnig» eller «våken» <u>passer ganske bra</u> med hvordan du føler deg nå, krysser du av slik:

Søvnig :___: X :___:___:___:___:___: Våken

eller slik:

Søvnig :___:___:___:___:___: X :___: Våken

Hvis du mener at enten «søvnig» eller «våken» <u>passer en del</u> med hvordan du føler deg nå, krysser du av slik:

Søvnig :___:___: X :___:___:___:___: Våken

eller slik:

Søvnig :___:___:___:___: X :___:___: Våken

Hvis du mener at <u>både</u> «søvnig» og «våken» <u>passer like bra</u> med hvordan du føler deg nå, krysser du av slik:

Søvnig :___:___:___: X :___:___:___: Våken

Viktig å merke seg:

1. Plasser kryssene i mellomrommene på skalaene, <u>ikke</u> på skillelinjene.

Slik: : X :   <u>Ikke</u> slik: $\overset{X}{:_____:}$

2. Kryss av på alle skalaene. Kryss av raskt og uten å tenke på hvordan du har fylt ut tidligere. Tenk deg ikke for lenge om, det er din <u>første og umiddelbare vurdering som er best.</u>

Kryss av for hvert ordpar ut fra hvordan du føler deg nå - i dag.

188 Redd								Modig
189 Nyttig								Unyttig
190 Passiv								Aktiv
191 Irritabel								Avbalansert
192 Avslappet								Anspent
193 Ulykkelig								Lykkelig
194 Sterk								Svak
195 Vennlig								Uvennlig
196 Engstelig								Rolig
197 Frisk								Syk
198 Trassig								Føyelig
199 Trygg								Utrygg
200 Uvirksom								Virksom
201 Deprimert								Godt humør
202 Samarbeids-villig								Motvillig
203 Glad								Trist

Errata

Errata

Page 39, Exercise composite score: 'The **first** question was taken from the Stanford Five City Project.'

Article II have two published errata in bold and one layout erratum in table IV:
1) Page 594 last sentence; 'As described in Table II, both groups showed an overall improvement in their intake of fruit and vegetables (0.6 units or 18%, **p<0.005**, low saturated fat products (13%), **p<0.005** and weekly fish dinners (0.1 times weekly or 3%, **p=0.01**) in a general linear model.' These minor corrections of the p values from $p<0.001$ to $p<0.005$ and $p=0.02$ to $p=0.01$ should also be made in section 12.2, page 54, first section.
2) Page 597 first section; 'Internal validity may be compromised by more women in the **intervention added** group.'
3) Table IV, erratum in presentation of data for each of the dietary outcomes: The rows in line with motivation should be moved one line down, together with the row in line with predictor autonomous motivation. Motivation relates to either autonomous or controlled motivation and data relate to these predictors, respectively.

Article IV table I, Footnote b should be units daily, not weekly.