

**Effects of a Decision Aid with and without additional
decisional counseling for patients being examined for
coronary artery disease on cardiac risk reduction
behavior and health outcomes –
A randomized controlled trial**

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We collaborated with the developers of the Decision Aid at Ottawa Health Research Institute at Ottawa Hospital and Division of Clinical Epidemiology at Montreal General Hospital, Canada with regard to the use and translating of the DA to Norwegian language and settings.

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Abstract

Introduction

This three group randomized controlled trial evaluated the effect of a Decision Aid (DA) with and without an additional Decisional Counseling Program (DCP) for patients being examined for coronary artery disease (CAD) on patient-reported health outcomes and health related quality of life (HRQoL), mediated by adherence to cardiac risk reduction behavior. We also explored how adherence to cardiac risk reduction behavior was influenced by patients' intentions to follow recommendations for a healthy lifestyle, their knowledge about risk factors for CAD, perceived health beliefs, perceived benefits and barriers to cardiac risk reduction behavior, and decisional conflict. Furthermore, we explored relationships between adherence to cardiac risk reduction behavior, health outcomes and HRQoL.

Methods

368 patients > 18 of age were randomly assigned to: (1) the Intervention group I where patients received, for take home, the DA prior to their scheduled angiogram; (2) the Intervention group II where patients, in addition to the DA received the DCP from a trained nurse counselor in their homes prior to their angiogram; and (3) the Control group who received "usual care". Data were collected at four time points: at baseline prior to patients' angiogram, and at 2, 4, and 6 months. ANCOVA was used to compare differences in group means at 6 months following the angiogram after statistically controlling for baseline scores. Linear regression and mixed effects models were used to explore relationships between primary outcomes and mediating variables.

Results

While there were no significant differences between the Da group and the Control group on any variables, The DA+DCP group had a significant decrease in Body Mass Index compared to the Control group 6 months after the intervention. Furthermore, patients in the DA+DCP group significantly improved HRQoL on several dimensions over the study period compared to the Control group. There was also a significant decrease in perceived barriers to cardiac risk reduction behavior in the DA+DCP group compared to the Control group. We found no significant group differences in adherence to cardiac risk reduction behavior.

Greater adherence to healthy life style recommendations, better HRQoL and better health outcomes were significantly related. Intentions to follow lifestyle recommendations were significant predictors of adherence to cardiac risk reduction behavior. Increased perceived susceptibility of illness was significantly related to lower adherence to non-smoking behavior, while increased perceived barriers to cardiac risk reduction behavior was related to lower adherence to diet recommendations. Higher decisional conflict significantly predicted lower adherence to diet recommendations, activity recommendations, and taking medications. The patients appraised both the DA and the additional decisional counseling program as helpful.

Conclusion

In this study the DA alone was not sufficient to improve health behaviors and outcomes. However, the addition of the DCP had significant effects on reduced BMI, better HRQoL on several dimensions, and reduced perceived barriers to cardiac risk reduction behavior in patients being examined for CAD. The DCP supported patients to individually tailor their lifestyle changes to their health beliefs and preferences, resulting in better health outcomes and HRQoL. We do not know however, if these effects would have occurred by the DCP alone, without combining it with the DA. Finally, this study contributed to a better understanding of variables related to adherence to lifestyle recommendations and health outcomes.

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Appendix A	Decision aid for patients with coronary artery disease: in this study: “Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke”
Appendix B	Decisional Counseling Program
Appendix C	Fidelity Strategies

Abbreviations

ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
BMI	Body Mass Index
BP	Blood Pressure
CABG	Coronary artery bypass grafting.
CAD	Coronary Artery Disease
CAD-DA	Decision aid for patients with coronary artery disease: in this study: “Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke”
CCI	Charlson’s Comorbidity Index
CCS	Canadian Cardiovascular Society’s grading/classification of Angina
CI	Confidence interval
CVD	Cardiovascular Disease
DA	Decision aid
DBP	Diastolic Blood Pressure
DCP	Decisional counseling program developed for this study
DCS	Decisional Conflict Scale
DPS	Disease Perception Scale

ECG	Electrocardiography
EF	Left ventricular ejection fraction
ES	Effect size
HBM	Health Belief Model
HBS	Health Behavior Scale
HDL	High-density lipoprotein
HRQoL	Health-related quality of life
IA	Interview Assistant
LDL	Low-density lipoprotein
LHL	Landsforeningen for Hjerte og Lungesyke
M	Mean
MI	Myocardial Infarction
OR	Odds ratio
PCI	Percutaneous coronary intervention
PhD	Philosophy of Doctor
QOL	Quality of Life
QQ-plots	Probability plot (quantile) assessing normality
RCT	Randomized Controlled Trial
REK	Regional Review Board
SAQ	Seattle Angina Questionnaire
SBP	Systolic Blood Pressure
SD	Standard deviation
SF-36	Short Form 36 item version of the Medical Outcomes Study health status questionnaire
TSS	Treatment Satisfaction Scale
WHO	The World Health Organization

Chapter 1

Background

Introduction

In spite of considerable reductions in mortality rate caused by cardiovascular disease (CVD) from 49% of all deaths in Norway in 1979 to 32.6 % in 2009, CVD still remains the main cause of mortality in all adults in Norway (Statistics Norway 09.12.10). 13 489 people in Norway died of CVD in 2009; 54% were women, and 5 378 (40%) of the deaths were caused by coronary artery disease (CAD); 47 % were women. The demographic of people with CAD have changed, and older and sicker adults are surviving cardiac events. While better treatment methods and medication may explain the lower mortality over the past decades, in the recent years there has been only a minor reduction in the mortality rate caused by CAD.

Because CAD is a disease that is highly associated with lifestyle related factors and health behavior, there is much to gain from health behavior change to reduce the risk for CAD and cardiac events, such as quitting smoking, a healthy diet including increased intake of fish fatty acids, exercise, stress reduction, and adherence to blood pressure-, and cholesterol lowering medications (Edwards et al., 2006; Pedersen, Tverdal & Kirkhus, 2004; Yusuf et al., 2004). Although the relationships between these factors and CAD are well known, studies have shown that life-style changes and adherence to cardiac risk reduction behavior has considerable room for improvement (Burke et al., 1997; Rogers & Bullman, 1995; Sackett & Haynes, 1976; WHO, 2003). Data indicate that knowledge of the effects of cardiac risk reduction behavior and/or fear of a cardiac event is not enough to motivate CAD patients to maintain long-term lifestyle changes. Therefore better interventions to increase adherence to a healthy lifestyle are needed.

Cardiac risk reduction behavior is important for the general public, but it is even more important for people with CAD, because they have more at stake. They are at increased risk

for having a heart attack, a percutaneous coronary intervention (PCI), a bypass procedure, or needing more medication, but can lower their chances of experiencing an actual cardiac event and improve their physical functioning and quality of life by changing their lifestyle to a more healthy behavior. A number of studies have tested interventions to improve cardiac risk modification behavior, primarily based on cognitive-behavioral approach. However, so far interventions to produce lasting health behavior change have only shown limited effects (Ebrahim et al., 2006). Therefore there is a need to explore additional promising approaches to health behavior change that can increase adherence to a healthy lifestyle in cardiac patients.

One such promising and widely advocated approach is interventions to help patients to make decisions about health care options and to involve them in their care (Elstein et al., 2004). This has led to the development and use of decision aids (DAs) for different treatment or screening decisions with the purpose of helping patients understand treatment or screening options, potential outcomes, clarify their preferences for treatment options in light of the provided information, and prepare patients for shared decision-making with their care provider (O'Connor et al., 1998a; O'Connor et al., 1998b).

Because DAs are developed to prepare patients for shared decision-making they differ from other health education materials because of their specific, detailed, and individualized focus on possible options and outcomes. A DA developed for CAD patients may therefore help patients' with risk of CAD or CAD progression to see that a behavioral change needs to be made, to know the different options and outcomes, to assess how personal values and preferences affect the decision, to know what matters most, and to be able to discuss these matters with their health care provider, and thereby become involved in their care in preferred ways.

DAs exist today for a number of different treatment decisions, and two systematic reviews of randomized controlled trials of DAs conclude that DAs do increase a patient's participation in decision-making, increase knowledge, reduce decisional conflict, and help uncertain people to make decisions (Molenaar et al., 2000; O'Connor et al., 2009), however, the effects on outcomes of decision remains uncertain (Charles et al., 2005; Kennedy, 2003; O'Cathain & Thomas, 2004; O'Connor, Rostom et al., 1999; Sepucha & Mulley, 2003). Other consistent findings are that decisional conflict scores decreased

(Briggs et al., 2004; Davison et al., 1999; Dolan et al., 2002; Goel et al., 2001; Man-Son-Hing et al., 1999; Montgomery et al., 2003; Murray et al., 2001a, 2001b; O'Connor et al., 1998a; O'Connor et al., 1998b; Stalmeier et al., 1999; Whelan et al., 2004) and increase congruence between patients' preferences/values and actual choice are found (Barry et al., 1995; Holmes-Rovner et al., 1999; O'Connor et al., 1998a). Studies also show that patients who were well informed and considered the personal value they place on outcomes were less likely to accept ineffective or risky procedures. (Dodin, Legare, Daudelin, Tetroe & O'Connor, 2001) This was supported in three studies: the rates of coronary artery bypass surgery declined in favor of options that are more conservative without affecting patients' outcomes (O'Connor, Legare & Stacey, 2003); Morgan et al. (2000) found that patients who had seen the video of treatment options for CAD underwent less invasive procedures than the usual care group, yet there were no differences in angina scores or general health scores in the two groups at six months; and Phelan et al. (2001) found that patients had a slightly lower preference for surgery after viewing the DA video-presentation of informing patients about back surgery.

The evidence of the effects of DAs on adherence of chosen option is unclear (Charles et al., 2005). Five studies measured adherence to chosen options, warfarin versus aspirin (Man-Son-Hing et al., 1999), oral bisphosphonate medications (Oakley & Walley, 2006), blood pressure medications (Montgomery et al., 2003), and Hormone replacement therapy (Deschamps et al., 2004; Rothert et al 1997). There were no significant differences between groups in adherence to chosen options.

To which degree DAs are effective in helping people in decisions about their personal health behavior has been less explored. Only few DAs exist to help CAD patients to modify risk factors to increase a more healthy lifestyle (Koelewijn-van Loon et al., 2009, 2010; Krones et al., 2008, 2010; Lalonde, et al., 2004, 2006; Lenz et al., 2009; Pignone et al., 2004; Sheridan et al., 2006, 2010b; van Steenkiste et al., 2007, 2008). However, so far effects of DAs in this area are sparse and inconclusive. Therefore, to better understand if DAs have positive effects on risk reduction behavior and outcomes in cardiac patients, more studies are needed.

Traditionally DAs have not targeted the implementation of the decision, which is particularly important for health behavior change. For a decision to have any consequence

heavily depends on the decision maker's ability and motivation to carry it out. How well a person at risk for CAD or progression of CAD implement his or her decision about lifestyle change subsequently affect a range of other variables, including choice of options and outcomes. However, behavior change can be difficult if a person judges the inconvenience associated with the recommended lifestyle change greater than the desirability of future health benefits gained from risk reduction behavior. Patients' preferences for health behavior influence their decision to start and continue the behavior (Eraker & Sox, 1981; Eraker & Politser, 1982). Therefore it is important to assess and assist individual in identifying their beliefs, expectations, and personal preferences for health behavior change. Patients also need the motivation, confidence, or resources to implement their risk modification behavior. Patients may achieve better results from a DA if is supplemented by individual counseling to elicit their beliefs, expectations, and motivations, and to assist them in goal setting and devising action plans for how to succeed in implementing long-term lifestyle changes that are consistent with their personal preferences.

Another limitation of DAs is that they use risk estimates aggregated from many studies and patients, and the patients' individual risk profile may be far off from this average data. There is evidence that risk information is more effective if it includes individually calculated estimates (Edwards & Elwyn, 1999a; Edwards, Elwyn & Mulley, 2002). Furthermore, it has been repeatedly demonstrated that many people lack the skills necessary to critically read quantitative information (Mazur & Hickam, 1990; 1993, Woloshin, Schwartz, Moncur, Gabriel & Tosteson, 2001). Patients may still be uncertain about how relevant the numbers presented in the DA are to them and how to apply them. Patients may therefore benefit more from a DA if it is supplemented with individual counseling to help them adjust the information in the DA to their personal illness history and help them decide what cardiac risk reduction behavior they would prefer to engage in.

So far the effects of a DA with and without the benefits of additional individual decisional counseling to adjust lifestyle changes to CAD patients' individual risk profiles and personal preferences and beliefs are not known. Therefore, in addition to testing the DA for CAD patients and including health behavior and health measures as outcomes in this study, we developed a decision counseling program (DCP) to help patients clarify their beliefs and perceptions about the susceptibility and severity of potential progression of their CAD, their perceived benefits and barriers to risk modification behavior, and to guide

patients in individually designing a preference-based risk reduction behavior program that could be easier for them to maintain over time. At the concept level, the psychological situation is represented by barriers and benefits. Barriers are the perceived negative costs of health action that arouse avoidance motives. Benefits are the perceived positive payoffs that lead to health and care activities (Rosenstock, 1974).

Purpose

The specific aims of this three group randomized clinical trial (RCT) was to evaluate the effects of a DA to assist cardiac patients in lifestyle changes with and without an additional individual decisional counseling program (DCP) on health outcomes and quality of life mediated by adherence to cardiac risk reduction behavior. The DA used in this study, “Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke” (DA) was developed by Ottawa Health Research Institute at Ottawa Hospital in collaboration with investigators from the Division of Clinical Epidemiology at Montreal General Hospital (Lalonde et al., 2002). The DA provides information about options patients have for reducing their risk of heart disease and stroke by changing their lifestyle and taking medication. The additional individual decisional counseling program (DCP) was developed by the research team in this study based on principles from the Health Belief Model as described in greater detail below. The DCP was designed to systematically guide patients through the process of making decisions among options of lifestyle changes, and to help the patients decide what cardiac risk reduction behaviors they would be able to, and prefer to, engage in. At the end of the DCP the patients could write their action plan for their planned behavioral change the next 6 months.

Specifically, this RCT tested and compared the effects of the DA with and without the DCP on:

- (1) Primary health outcomes: body weight, cholesterol, blood pressure, amount of tobacco use, and Health-related quality of life (HRQoL)
- (2) Intermediate outcomes: Adherence to cardiac risk reduction behavior.
- (3) Mediating variables: knowledge about risk factors and CAD, perceived health beliefs, and perceived benefits and barriers to cardiac risk reduction behavior

To explore the relationships that may explain the mechanisms by which the two interventions (DA and DA+DCP) may affect outcome behavior we examined the relationships between primary and intermediate outcomes and mediating variables associated with behavioral change in the literature; intentions to have a healthy lifestyle, knowledge about risk factors and CAD, perceived health beliefs, perceived benefits and barriers, and decisional conflict.

The study was carried out in two phases:

Phase I: Adjustment of the previously developed Canadian DA to Norwegian language and data on risk factors in Norway; development of the DCP as described in Chapter 3; and pilot testing.

Phase II; a RCT where 368 patients > 18 of age scheduled for a coronary angiogram at Oslo University Hospital HF- Rikshospitalet were randomly assigned to: (1) The DA group where patients received, for take home, the DA prior to their scheduled angiogram; (2) The DA+DCP group where patients in addition to the DA received an individual decisional counseling program (DCP) from a trained nurse counselor in their homes prior to their angiogram; and (3) The Control group who received “usual care”. Data were collected at four time points: at baseline prior to the patients’ angiogram (T1); and two (T2), four (T3), and six (T4) months following the angiogram.

Rationale

CAD is a pathological progression, and PCI and CABG procedures are palliative treatments that do not correct or alter the progression of the disease. Therefore, patients may benefit from interventions that are designed to help them modify factors to reduce their risk. The rationale for the DA is that it may encourage the patients to engage in lifestyle changes by helping them to evaluate accurate information about options of life style changes and their consequences consistent with personal values (O’Connor, Stacey, et al., 2003). There is evidence that CAD patients often have unrealistic expectations about the long-term benefits they can achieve from PCI and CABG surgery, and may not be aware of the fact that management of the pathological progression requires changes in the individuals’ lifestyle to stabilize or reverse the atherosclerotic process (Krannich et al., 2008). Therefore it is important to offer patients information about the options they have to manage the pathologic progression of CAD by cardiac risk reduction behavior, so as to

reduce the risk of having a heart attack, a PCI, a by-pass procedure, or needing more medications.

The information in the DA used in this study is presented in a booklet and is tailored to CAD severity and major risk factors. It presents structured information about options patients have to reduce the risk of heart disease and stroke. The content is based on an extensive review of the literature with evidence from randomized trials published up to 2002 (Lalonde et al., 2002). The information in the booklet is however, aggregated from systematic reviews of the scientific literature and not tailored to the individual patients' personal risk profile that may be different from this average based data. CAD patients with a similar degree of disease differ significantly in symptom severity and tolerance (Nease et al., 1995; Nichol et al., 1996), and patients may still be uncertain about how relevant the presented numbers are to them, and how to apply them. Therefore we developed an individual decisional counseling program to help patients comprehend the information, adjust this information to their personal illness history, elicit their preferences for cardiac risk reduction behavior in light of this personalized information, and help them write a personal action plan. The underlying assumption is that people are more likely to choose an alternative which they, according to their preferences, perceive will be effective in achieving individually valued outcomes, avoiding individually undesirable outcomes, and see the ability to carry them out.

The importance of cardiac risk reduction behavior

Coronary heart disease is the most common reason for hospitalization in Norway, counting for approximately 116 000 admissions in 2010. 11 387 persons were admitted for their first MI in 2010 (<http://www.ssb.no/pasient/> 07.06.11). The incidence of CAD increases with age (Anand et al., 2008). In general, CAD hits non-smoking women about ten years later than men, mainly from 60 years of age. However, women with risk factors lose their gender advantage (Shaw et al., 2009; Folkehelseinstituttet. Hjerteinfarkt - fakta om infarkt og annen iskemisk hjertesykdom 07.06.11.) Even if the incidence and mortality of CAD is low in younger people, it is important to notice that 170 men and 38 women aged 25- 54 suffered a premature death caused by CAD in Norway in 2009 (<http://www.ssb.no/emner/03/01/10/dodsarsak/tab-2010-12-03-02.html> 07.06.11).

CAD is usually a result of multiple interacting risk factors. The occurrence of CAD strongly relates to life styles and to modifiable risk factors. Cardiac risk reduction behavior means management of the individual behavior that has a positive impact on reducing total risk of cardiac disease. Healthy lifestyle in the general population has the following characteristics: No smoking; healthy food choices; physical activity at least 30 min of moderate activity a day; Body Mass Index < 25 (kg/m²); and avoidance of central obesity; blood pressure < 140/90 mmHg; total cholesterol < 5 mmol/L; LDL cholesterol < 3 mmol/L. It is recommended that patients with established CAD and possible high risk should try to achieve Blood pressure under 130/80; Total cholesterol < 4,5mmol/L with an option of 4 mmol/L if feasible; LDL cholesterol < 2,5 mmol/l with an option of < 2 mmol/L if feasible (Graham et al., 2007).

The standard modes of treatment for CAD are coronary artery bypass graft (CABG) surgery, medication, and PCI. In 2007 mean age for PCI in Norway was 60 years and for CABG surgery five years more; approximately 40 % of patients were over the age of 60 years, and 27, 8% were women (Melberg & Svennevig, 2009). All three treatments for CAD work better when combined with cardiac risk reduction behavior (Yusuf et al., 2004). After a diagnosis and/or treatment of CAD, some people think that it is too late or not necessary to make lifestyle changes. By stopping smoking, lowering cholesterol, reducing fat in diet, watching calories, exercising regularly, and reducing stress, they may, however, still have much more to gain. (McAlister et al., 2001; Ornish et al., 1998; Selmer & Tverdal, 2003).

Patients at low risk of CAD mortality should be assisted to maintain the low risk state, while patients with multiple risk factors resulting in a $\geq 5\%$ 10 years risk of CAD mortality should receive interventions that focus on helping them achieve a healthy lifestyle (Graham et al., 2007). Interventions that focus on cardiac risk reduction behavior have shown to improve care; reduce readmission to hospital; reduce mortality especially in high risk groups and when exercise is included in the intervention (Clark, Hartling, Vandermeer, & McAlister, 2005; McAlister et al., 2001).

However, some patients may have concepts about their illness that may interfere with their ability or willingness to accept the importance of recommended treatment. They may also have varying beliefs of their own susceptibility and possible severity of illness.

Therefore it is important to design interventions that involve the patients in decisions about cardiac risk reduction behavior, to explicitly help them to consider their own perceived benefits and barriers, and support them in setting individual and achievable goals that are consistent with their individual plans as we did in this study.

Previous interventions to promote health behavior change

Current health behavior interventions are most often built on theories stating the unhealthy behavior as a deficit or a problem to be solved (Becker, 1974; Ewart, 1989; Prochaska & DiClemente, 1983). Interventions using a cognitive-behavioral approach such as self-efficacy enhancement (Cauley et al., 1987; Oman & King, 1998) and relapse prevention strategies (Marlatt & Donovan, 2005) have been shown to promote health behavior change in healthy adults. Interventions based on the stage of change (Transtheoretical model) theory (Prochaska & DiClemente, 1983) and environmental models (Humpel et al., 2002) have shown some effects in enhancing lifestyle changes. However, interventions based on these models are prescriptive and have had limited effectiveness in producing lasting behavior change (US Department of Health and Human Services, 2000). There are some theoretical models that involve less prescriptive components like motivational interviewing (Miller, 2002), learned resourcefulness (Zauszniewski, 1997), imagery (Kolcaba & Fox, 1999) and asset assessment (Delgado, 1995). However, the content and dosage of these interventions are fixed; every component of the intervention that may be necessary for any particular participant is included in the intervention, and each participant is given the same intervention. Although it is recognized that individuals may have different intervention needs, it is expected that the intervention is in no way diluted or made counterproductive if components that are particularly relevant for an individual are combined with components that may have less, or even no, relevance for that individual. Thereby they lack the ability for patients to integrate the interventions in their own lives based on individual risk profiles, personal values and preferences.

Patients' preferences

There has been an increasing focus on the influence of patients' underlying value system on their health-related decisions. Eliciting patients' preferences has been a successful strategy to assist patients making health-related decisions that are consistent with their values. For example, interventions to increase patient involvement in health-related decisions have resulted in higher satisfaction with, and more active participation in,

decision-making (O'Connor et al., 2009), better scores on general health perceptions and physical functioning (Goldstein et al., 1994; Ruland, 1999), higher compliance (Greenfield et al., 1988; Joos et al., 1996), improved knowledge (O'Connor et al., 1998b) and reduced decisional conflict (O'Connor et al., 2009). If patients can change their behavior in accordance with their preference and individual lifestyle, it may become easier to maintain the behavior over time. This study is based on an approach to promote healthy behavior that combines the elicitation of patients' preferences with individual tailoring, instead of one-size-fits all approach. Each patient is asked to devise their individual action plan based on their individual risk profile, perceived health beliefs, and personal preferences. Rating of the importance of the perceived benefits/advantages minus the importance of perceived barriers/disadvantages will provide a possibility for patients to identify critical trade-offs between perceived benefits/advantages and perceived barriers/disadvantages in a quantifiable manner.

The mechanisms by which DAs work

DAs are more effective than routine information in enabling patients to make different treatment choices (O'Connor et al., 2009). The effectiveness of DAs can be explained in terms of either the facilitation of cognitive strategies or changes to emotional processes. The mechanisms through which DAs impact on cognitive strategies are addressed briefly here. The visual representation of possible decisions/solutions provides a direct memory support that summarizes all the relevant information during decision-making (O'Connor, 1995), reduces the cognitive load during decision-making (Bekker et al., 1999; Ubel & Loewenstein, 1997), and ensures that patients' judgment is made based on complete information rather than based on memory-accessed and/or biased details (Shafir et al., 1993; Wilson et al., 1993). The eliciting of normally unarticulated cognitive mechanisms assists patients in generating more reasons for and against the options and encourages them to integrate verbally the decision information with their beliefs (O'Connor, 1995; Ubel & Loewenstein, 1997). It is likely that these techniques together (1) enable patients to justify the different choices to their individual life (Shafir et al., 1993) and (2) ensure that patients more fully explore the reasons associated with the options (Frisch & Jones, 1993). This process of systematic evaluation of decisional information against personal beliefs leads patients to develop more robust cognitions, associated with less decisional conflict and greater decisional satisfaction (Holmes-Rovner et al., 1996).

The impact of DAs on emotions is less clearly understood. One explanation may be that DAs encourage patients to evaluate relevant information rather than focusing on emotion and feelings (O'Connor, 1995). Another explanation may be that eliciting patient values about options and consequences increases patients' expression of emotions during decision-making (Pauker & Pauker, 1977). There is evidence that expression of affect about stressful events is associated with better long-term health outcomes (Pennebaker & Francis, 1996; Pennebaker, 1997). Therefore it is possible that DAs may facilitate patient decision by increasing the expression of emotions during decision-making, but this is not known.

Adherence to cardiac risk reduction behavior

Adherence to health recommendations continues to be a significant and multidimensional problem. Non-adherence is widespread, and research has established that the prevalence of non-adhering to proposed behavior is averaging 24.8 % (DiMatteo, 2004 a). It has been assumed that non-adherence to medical regimens occurs primarily because people are ignorant about the benefits or have not understood or remembered how to perform the medical regimen. Research has subsequently shown that, far from being ignorant, the understanding, concerns, and priorities among patients differ from the perceptions of their health care providers, and many patients make informed and rational decisions not to perform the prescribed medical regimen (Donovan & Blake, 1992). Non-adherence may therefore be seen as a rational choice as patients attempt to maintain their personal identity, achieve their goals, and preserve their quality of life (Conrad, 1985; Donovan & Blake, 1992; Lambert et al., 1997; Lynn & DeGrazia, 1991; Trostle et al., 1983). Furthermore, patients have their own perceived cognitive models of illness that need to be challenged in a positive way. Data indicate that adherence is influenced by health beliefs such as risk perception, perceived benefits and barriers to treatment, self-efficacy, as well as stage of change, and communication problems (Avis et al., 1989; Bellg, 2003; Lutfey & Wishner, 1999).

Increased awareness of how people reason is an important clinical skill (Redelmeier et al., 1993). The use of open-ended questions may encourage patients to participate and engage in decision-making (Donovan & Blake, 1992; Redelmeier et al., 1993). The relationship between the health care provider and the patient has been shown to have a strong effect on adherence (DiMatteo, 1994). Such communication is based on trust and good communication. DiMatteo (2004b) describes necessities of adherence as the

availability of practical and emotional support, to keep treatment simple and able to fit into patients' life, and the consideration of beliefs to make the communication effective. Interventions to promote adherence and offer a more open, cooperative relationship between the caregiver and patient as used in this study may be worthwhile.

Therefore, this study included and tested an intervention (DCP) tailored to each patients needs and preferences, designed to help patients become more involved in actions to fulfill their goals and thereby increase adherence to cardiac risk reduction behavior.

The value of DAs and additive counseling

As mentioned earlier, the quality of a decision depends on the ability of patients to carry them out. There are two important steps that are often neglected in current DAs; people need help to prepare for making a choice, and implement this choice in daily life activities. Decisions are the intersection between thoughts and actions. The competence to carry out the decision is equally important as the skills to make the decision. DAs can therefore benefit from adding information that is targeted to help prepare and implement decisions (Kennedy, 2003; Sepucha & Mulley, 2003). People also may pay more attention, process more deeply, and make greater behavioral changes when messages are tailored rather than generic (Kreuter et al., 1999; Noar et al., 2007; Skinner et al., 1999). A study on a DA for women with breast cancer demonstrated that the addition of individual counseling created even more realistic expectations, helped the uncertain become more certain, reduced decisional conflict and psychological distress, and increased intentions to improve life-style practices more than the DA only (Stacey, O'Connor, DeGrasse & Verma, 2003). This supports that more studies are needed to identify and test strategies and support systems that can improve adherence and outcomes.

Using goal setting and action plans is a useful strategy to encourage behavior change (Bandura, 1986; Handley et al., 2006; Stretcher, et al 1995). Other elements associated with improved health behavior outcomes include assessment of individual beliefs and preferences, and subsequent tailoring of intervention elements to address assessment (Ammerman et al., 2002; Babor & Higgins-Biddle, 2001; Bodenheimer et al., 2002; Glasgow et al., 2002; McAlister et al., 2001; McTigue et al., 2003; Pignone et al., 2003; Whitlock et al., 2004), interventions that include self-monitoring, identification of barriers, goal setting, and problem-solving (Babor et al., 2001; Bodenheimer et al., 2002; Fiore et al., 2008; Glasgow et al., 2002; Kahn et al., 2002; McTigue et al., 2003; Pignone et al.,

2003; Whitlock et al., 2004). Since DAs are meant to be adjuncts to counseling, the DA supplemented with an individual decisional counseling program (DCP) was developed to help patients comprehend the information, adjust this information to their personal illness history, elicit their preferences for cardiac risk reduction behavior in light of this personalized information, and set mutually-agreed and realistic goals in an action plan. The structured communication between the healthcare provider and the patient in this study was therefore hypothesized to be a powerful relationship that may enhance patients' coping with illness and adherence to recommended risk reduction strategies and medication.

When presented with more than one option for lifestyle changes, each of which has multiple characteristics, patients might find themselves in a state of uncertainty or difficulty in identifying the best alternative due to the risk or uncertainty of outcomes, and the need to make value judgments about potential gains versus potential losses (Keeney, 1988), a state that is defined as decisional conflict. O'Connor (1995) describes that decisional conflict appears from two sources; first, people are uncertain because of the inherent difficulty of the choice they face, and second the uncertainty is higher if a person feels uninformed, is unclear about personal values, and feels unsupported or pressured to choose an action. Therefore, the DCP in this study was designed to help patients to reduce the perceived uncertainty, and personalize the decision among options of lifestyle change and adherence to cardiac risk reduction behavior.

There has been a tendency that DAs have focused on a single factor (such as treatment A vs. treatment B). Based on the fact that a healthy lifestyle is a combination of several behaviors that influence each other, it is important for lifestyle change interventions to take more than one factor into consideration. The multiple behavior change approach has shown to be most effective (WHO, 2003). The DCP used in this study is a multiple behavior change intervention designed to tailor patients' perceptions regarding susceptibility and severity of potential progression of their CAD, eliciting perceived benefits and barriers likely to be derived, and guide patients to individually design a preference-based cardiac risk reduction behavior program that are easier for patients to maintain over time.

After the preliminary examination for CAD at the Cardiac Outpatient Clinic, patients are faced with possible decisions among options of lifestyle change that may significantly

affect their life. This time point represents a crucial moment of opportunity, is it now time to quit smoking, lose weight, start exercising, and do something about their stressful life? It is well known that people who feel ill tend to speak about planned lifestyle changes as some kind of intention to change. When people at least reflect and think about changing their behavior, one can assume that patients are best motivated for a lifestyle change when they are ill and under treatment. Therefore, this study enrolled the patients to be engaged in decisions about their options for lifestyle change right after the first consultation (initial visit).

Significance

So far, no known previous studies have compared the effects of a DA with and without the supplement of individual decisional counseling program (DCP) as we did in this study. Also, the degree to which patients' preferences can explain adherence with cardiac risk reduction behavior has not been a focus of empirical investigations. By systematically eliciting patients' cardiac risk reduction behavior preferences, the patients are allowed to select and determine the relative importance of behavior changes they consider important to maintain long-term cardiac risk reduction behavior. When people can perform cardiac risk reduction behavior in accordance with their preferences, it may become easier to adhere to this reduction behavior over time which in turn may improve HRQoL and health outcomes.

Theoretical framework

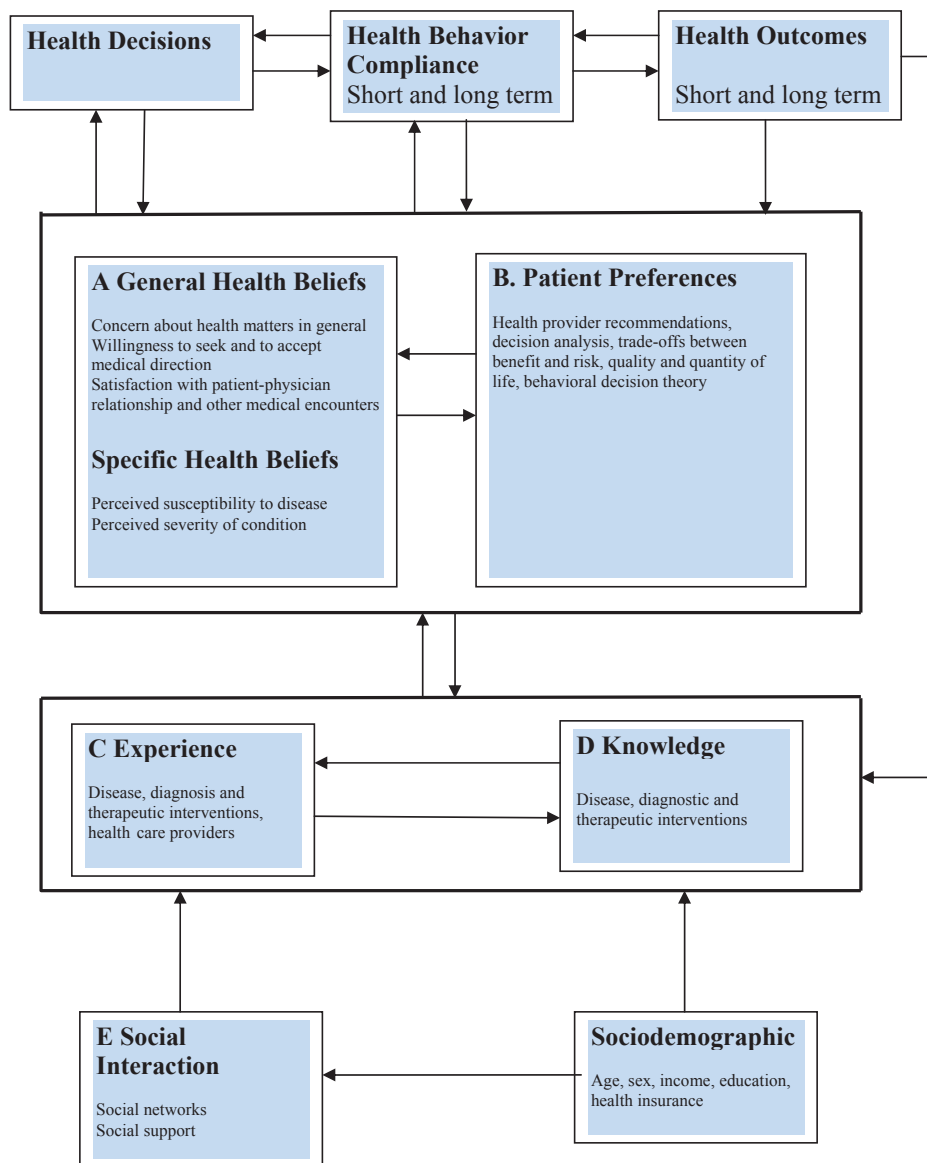
This study was guided by The Health Decision Model derived from The Health Belief Model.

The Health Belief Model was proposed in the 1950s by a group of US Public Health Service social psychologists (Hochbaum, 1958; Rosenstock, 1960; 1974), and connects theories of decision-making to individuals' decisions about alternative health behaviors. The underlying theoretical relationships in the model are that behavior depends on two

variables; (1) the value placed on a particular outcome, and (2) the individuals estimate that a given action will result in that outcome. According to this, to be able to take action to reduce the risk of a disease, a person would need to believe (1) that he was susceptible to the disease, (2) the occurrence of the disease would have at least moderate severity on some parts of life, and (3) that taking a specific action would be beneficial by reducing the susceptibility, and /or reducing the severity, and that the action taken would not involve overwhelming barriers like costs, comfort, humiliation, and pain (Eraker, Kirscht & Becker, 1984; Janz, Champion & Strecher, 2002).

The Health Decision Model is a third generation model of patient behavior developed from the Health Belief Model and deals with health decisions by combining aspects of decision analysis, behavioral decision theory, patient preferences, and health beliefs to yield a unifying model of health decisions and behavior outcome (Eraker et al., 1984; Eraker, Becker, Strecher & Kirscht, 1985). The model hypothesizes that compliance with provider advice depends to some extent on the patient's perceptions regarding susceptibility to a disease, severity of the disease if contracted, and the benefits and barriers likely to be derived and encountered relative to undertaking a recommended action. A number of general inferential rules that patients employ is identified to reduce difficult mental tasks to simpler ones. In this study decision analysis provides a quantitative means for patients to express their preferences about critical trade-offs by weighting their possible benefits against their possible constraints or barriers on a balance weight (Hershey, 1979; von Winterfeldt & Edwards, 1986; Weinstein & Fineberg, 1980). The Health Decision Model also includes the importance of other factors affecting health decisions and behavior, such as knowledge, experience, and social and demographic variables. The bidirectional arrows and feedback loops reflect the notion that adherence behavior can change health beliefs (Eraker et al., 1985). In this study we have addressed directional arrows only as shown in Figure 2.

Figure 1 Health Decision Model (Eraker, et al., 1984)



According to the Health Decision Model the perceived susceptibility varies between individuals, and refers to the individuals' subjective risks of receiving a condition. The perceived severity is judged by the degree of emotional arousal created by the thought of a disease as well as by possible difficulties the individual believes will happen if the disease

occurs. Both perceived susceptibility and severity is connected to strong cognitive components, and are at least partly dependent on knowledge. However, the acceptance of susceptibility to a disease that is considered serious will provide a need to take action, but not necessarily define the direction of action that is likely to be taken (Eraker et al., 1985).

The individual's beliefs regarding the relative effectiveness of possible available alternatives to reduce the threat are supposed to guide the direction of the action taken. The behavior is thought to depend on what benefits he believes the possible actions would be in the actual case. An action is considered as beneficial when it is related to reduction in perceived susceptibility and/or severity. The actual course the individual will take is dependent on the beliefs rather than the objective facts about availability and effectiveness. An individual may believe an action will be effective, but at the same time believe the action has some inconveniences, is expensive, discomfort or even painful. Thus it is likely that negative aspects of possible actions will serve as barriers to action and create conflicting motives of avoidance (Eraker et al., 1984).

Studies testing the Health Belief Model suggested that perceived barriers and benefits determine how much a person values health. For example, the relationship of certain health beliefs and values to influenza vaccination rates were studied among 232 high-risk patients. The patients vaccinated believed the vaccine to be more efficacious than patients not vaccinated (Larson et al., 1979). That study and others (Heinzelmann & Bagley, 1970; Parcel et al., 1980) indicated that individuals who perceive the benefits of a preventive behavior as outweighing the barriers, or disadvantages, usually have a higher health value orientation and undertake the preventive behavior. Studies of the Health Belief Model also demonstrated that perceived benefits and barriers determine participation in health care activities. Findings related to pap smear testing revealed that women who held the belief that early detection of a disease was beneficial reported more regular tests than those who did not hold this belief (Kegeles et al., 1965). Thus, individuals undertake health care activities to the extent that perceived benefits outweigh perceived barriers (Maiman et al., 1977; Oldridge, 1979; Sennott-Miller & Miller, 1987).

A number of studies that have used the HBM variables to examine preventive health behavior in cardiac patients are described in Chapter 2.

Investigated Relationships

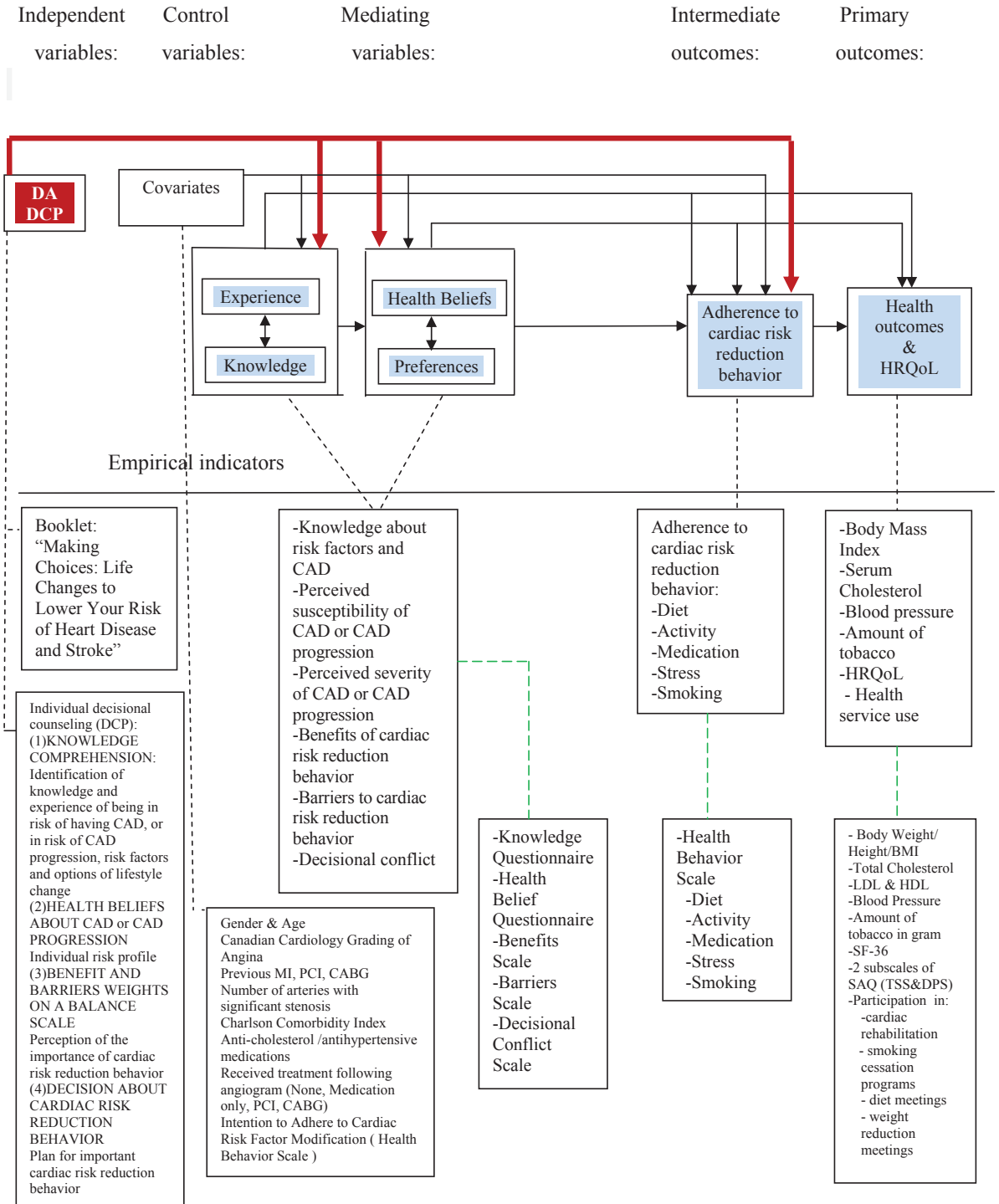
In this study we investigated the difference in effects of the two interventions DA with and without additive individual decisional counseling (DCP) and “the usual care” on several outcomes. We hypothesized that the interventions will increase the primary health outcomes and HRQoL mediated by improvement of the intermediate outcome adherence to cardiac risk reduction behavior. Behavioral theories often contain common mediating variables. These variables are usually used to explain the mechanisms through which behavioral interventions affect outcome behavior (Baranowski, Lin, Wetter, Resnicow & Davis Hearn, 1997). By designing interventions to produce change in mediating variables that in our study were knowledge about risk factors and CAD, perceived health beliefs, and perceived benefits and barriers allows us potentially to link mediating variables to outcomes of intermediate outcomes of adherence and primary health outcomes.

Several effects were investigated:

- (1) The effects of the two additive interventions on primary health outcomes: (a) body weight, cholesterol, blood pressure, and amount of tobacco, and (b) Health-related quality of life (HRQoL).
- (2) The effects of the two additive interventions on intermediate adherence outcomes.
- (3) The effects of the two additive interventions on several of the hypothesized mediating variables (knowledge about risk factors and CAD, perceived health beliefs, perceived benefits of, and barriers to cardiac risk reduction behavior).
- (4) The relationship between intermediate adherence outcomes and primary health outcomes: body weight, cholesterol, blood pressure, health service used, and amount of tobacco use.
- (5) The relationship between intermediate adherence outcomes and HRQoL.
- (6) The relationships between the primary health outcomes and HRQoL.
- (7) The relationships between the hypothesized mediating variables (intention to adhere to cardiac risk reduction behavior, knowledge about risk factors and CAD, perceived health beliefs, perceived benefits of and barriers to cardiac risk reduction behavior, and decisional conflict) and intermediate adherence outcomes.

Figure 2 displays the study variables and their proposed directional relationships in our study.

Figure 2 Study variables and their relationships



Definitions of study variables

Independent variables

The interventions in this study and thus the independent variables were

1. The DA
2. The DA with the addition of the DCP

Primary outcomes

Body weight was defined as the mass of an organism's body. Body weight is measured in kilograms. We calculated the person's body mass index (BMI) by the equation: $BMI = \text{Mass (kg)} / (\text{Height (m)})^2$

Cholesterol. Cholesterol is a lipid bound to proteins in blood plasma to form lipoproteins. Dependent of type, size, and concentration in plasma the degree to causes of possible atherosclerosis differ. HDL does actually have antiatherogenic properties, and low levels measured as HDL-cholesterol (less than 1 mmol/l in men and less than 1.2 mmol/l in women) is considered a marker of increased risk and poor outcome (Graham et al., 2007). However, most of the cholesterol in blood plasma is normally carried in LDL, and there is a strong positive association between total-cholesterol as well as LDL-cholesterol and the risk of CAD (Clarke et al., 2002; Maniolo et al., 1992; Neaton et al., 1992). A reduction of LDL, measured as LDL-cholesterol is a primary outcome for CAD patients.

Blood pressure. A number of studies have identified elevated blood pressure as a risk factor for CAD in both men and women in all groups ranging from 40-89 years of age (Graham et al., 2007). The Fourth Joint Force of the European Society of Cardiology and other Societies on Cardiovascular Disease Prevention in Clinical Practice recommend that patients qualified for treatment should try to lower blood pressure to at least below 140/90 mmHg, and that lower values are preferred if tolerated by risk subjects (Graham et al., 2007).

Amount of tobacco. The evidence of an adverse effect of tobacco is great, and related to the amount and duration of daily tobacco use. Tobacco smoking increases the risk of atherosclerotic disease in several ways. Smoking tobacco is responsible for 50% of all

avoidable deaths, and one half of these are due to CAD in long-term smokers (Graham et al., 2007). In this study we defined smoking as the daily use of tobacco products, and measured it in grams of tobacco each week including different forms of smokeless tobacco.

Health service use was in this study defined as the persons' self-reported use of four predetermined examples of health services focusing on reduction of cardiac risk, during the last two months. The four services encompassed participation in cardiac rehabilitation, quit smoking course, weight reduction courses, and diet course.

Health-related quality of life (HRQoL) in this study was defined as the self-reported and valued level of wellness and illness, taking into account the presence of biological or physiological dysfunction, symptoms, and functional impairment. The valued level of wellness and illness were in this study measured by following indicators in SF-36: the extent of patients physical functioning, the extent of their role-functioning, the intensity of their bodily pain, their perceived general health, their feeling of vitality, the extent of their social functioning, the extent of their role functioning emotionally, and their perceived mental health. The level of satisfaction with the treatment for chest pain, chest tightness, or angina, and the limits in quality of life because of chest pain, chest tightness, or angina were measured by Seattle Angina Questionnaire (SAQ) by patients regarding themselves as having angina pectoris.

Intermediate outcome

Adherence to cardiac risk reduction behavior was defined as the patients' perception of the degree to which they actually perform the prescribed actions on cardiac risk reduction regimen after their angiogram, such as healthy eating, quitting smoking, exercising regularly, taking their prescribed medications, and modifying responses to stress (Miller et al., 1982a; 1982b).

Mediating variables

Knowledge about risk factors and CAD was in this study defined as the actual knowledge of what CAD is, and what its predisposing risk factors are, and how to provide them.

Health Beliefs was defined as the perceived susceptibility and perceived severity of receiving CAD for the patients not yet diagnosed, and perceived CAD progression for patients already diagnosed.

Perceived susceptibility of CAD or CAD progression was defined as the patient's perception of how susceptible he is of CAD/potential progression of his CAD (Eraker et al., 1984).

Perceived severity of CAD or CAD progression was defined as the patient's perception of the severity of CAD/potential progression of his CAD (Eraker et al., 1984).

Perceived benefits of cardiac risk reduction behavior were theoretically defined as the perceived benefits to undertake cardiac risk reduction behavior (Murdaugh & Verran, 1987).

Perceived barriers to cardiac risk reduction behavior were theoretically defined as the perceived barriers to undertake cardiac risk reduction behavior (Murdaugh & Verran, 1987).

Decisional conflict was defined as a patient's state of uncertainty about which option to choose, the factors contributing to this uncertainty, and the effectiveness of the decision (O'Connor, 1999).

Control variables

The control variables in this study were: Gender, Age, Cardiac functional status, Previous cardiac events, Disease severity, Comorbidity, Medication intake, Received treatment and they are described in detail in Chapter 3, page 67-69.

There are several dimensions of risk: biological, environmental, social, and behavioral. Behavioral risk factors are risks identified specifically with practice, or failure to practice, an action or series of actions that are associated with health outcomes. The term cardiac risk reduction behavior is in this study used synonymously with cardiac risk factor modification, lifestyle modification, risk reduction behavior, and lifestyle behaviors. A composite of various healthy behaviors is often referred to as a healthy lifestyle. It encompasses quitting smoking, lowering cholesterol, reducing fat in diet, watching calories, exercising regularly, and reducing stress.

Hypothesis and research questions

Hypothesis

This study tested the hypothesis that patients in the DA+DCP group will achieve significantly better outcomes over the study period than patients in the DA group who in return will achieve better outcomes than the Control group (“usual care”). Particularly, for patients in the DA+DCP group we would observe:

1. Better primary health outcomes in terms of better body mass index, cholesterol, blood pressure, and less amount of tobacco, and better HRQoL
2. Better intermediate outcomes in terms of greater adherence outcomes (following the diet recommendations, activity recommendations, taking their prescribed medication, stress reduction, and no smoking)
3. Better outcomes in terms of greater knowledge about risk factors and CAD, perceived susceptibility and severity of CAD or CAD progression, and more perceived benefits and less perceived barriers to cardiac risk reduction behavior

Additional research questions

To better understand the mechanism by which these effects may occur, additional research questions explored:

1. What are the relationships between Adherence outcomes and health outcomes at two, four, and six months following the angiogram?
2. What are the relationships between Adherence outcomes and HRQoL at two, four, and six months following the angiogram?
3. What are the relationships between health outcomes and HRQoL at two, four, and six months following the angiogram?
4. What are the relationships between the intentions at baseline, knowledge about risk factors and CAD, perceived susceptibility and severity of CAD progression, perceived benefits and barriers of cardiac risk factor reduction, and decisional conflict two months following the angiogram, and adherence outcomes two, four, and six months following the angiogram?
5. What is the acceptability to patients of the DA with and without additional counseling?
6. What is the acceptability to patients of the DCP?

Study Assumptions

People are more likely to choose an alternative which they, according to their preferences, perceive will be effective in achieving individually valued outcomes and avoiding individually undesirable outcomes. Although this is not necessarily true, the assumption underlying DAs and HBM is that people make rational choices.

Chapter 2

Review of the literature

Introduction

This chapter presents a review of the literature that supports hypothesized relationships and study questions and identifies knowledge gaps that are the rationale behind this study. Particularly this review synthesizes: effects of DAs, (2) effects of individual decisional counseling, (3) the Health Belief Model (HBM) and predictors of adherence to cardiac risk reduction behavior, and (4) the relationships between adherence to cardiac risk reduction behavior, health outcomes, and HRQoL as depicted in Figure 2 page 19. Although this study was conceptualized in 2007, the review presented here includes literature until 2010.

Effects of Decision Aids

A systematic review showed that the most consistent benefits of DAs relative to usual care are better knowledge of options and possible outcomes, and more accurate perceptions of the probabilities of possible outcomes (O'Connor et al., 2009). However, decisions about lifestyle changes and interventions designed to promote adherence to a recommended behavior were excluded from the systematic review on DAs. Furthermore, decisional conflict scores decrease consistently (Briggs et al., 2004; Davison et al., 1999; Dolan & Frisina, 2002; Goel et al., 2001; Man-Son-Hing et al., 1999; Montgomery et al., 2003; Murray et al., 2001a; 2001b; O'Connor et al., 1998a; O'Connor et al., 1998b; Stahlmeier et al., 1999; Whelan et al., 2004). Greater congruence between patients' preferences/values and their actual choice has been well established in three studies (Barry et al., 1995; Holmes-Rovner et al., 1999; O'Connor et al., 1998a). However, effect sizes vary across studies, and many studies were underpowered (O'Connor et al., 2009).

The effects of DAs are most often measured in terms of their ability to increase knowledge, reduce decisional conflicts, increase participation in decision-making, the rate of people remaining undecided, the preference or uptake of options, and accurate risk perception. However, it has been argued that when the purpose of a DA is to help patients to make a decision that is consistent with the values/preferences they place on potential consequences and possible options, the effects of DAs should be judged by the extent to which a patient actually implements the decision, but only few studies address this. Furthermore, several authors have argued that increased knowledge and reduced decisional conflict are not sufficient evidence of DAs effectiveness (McCaffery et al., 2007; Nelson et al., 2007). McCaffery and colleagues (2007) are suggesting that longer-term health and quality of life outcomes should be the focus of DA evaluation. Therefore, in this study outcome measures include decision implementation and HRQoL.

To summarize the effects of DAs on lifestyle changes we performed a systematic search of the following electronic databases: MEDLINE, CINAHL, EMBASE, and PsychINFO. The search was conducted for the time period from January 2001 to December 2010. Detailed search strategies were developed for each electronic database based on the search strategy developed for MEDLINE. In each database, we searched for every term listed in Table 1 below in the database thesaurus and used the free text/key word method. We also searched for synonyms and modified versions of these terms to best utilize each database/thesaurus. The inclusion criteria were adults 19 years or older; English and Scandinavian language articles; randomized controlled trials. Excluded were studies testing interventions for assisting hypertensive patients or patients with dyslipidemia in the decision whether to start drug therapy or not.

Table 1

Overview of searches and terms as conducted in MEDLINE database

Patient	Intervention	Comparison	Outcome
Search # 1	Decision Aid		Cardiac risk factor modification behavior
<ul style="list-style-type: none"> ●Coronary Artery Disease ●Angina pectoris/ or angina , unstable ●Adults 19 or older 	<ul style="list-style-type: none"> ●Decision Support Techniques/ ●Decision-making/ ●Choice behavior/ ●decision aid\$ or decision support\$ or choice behavior\$ 	Usual care	<ul style="list-style-type: none"> ●Health behavior/ ●Patient compliance/ ●Medication Adherence/ ●Risk reduction behavior/ ●Tobacco use cessation/ ●Smoking cessation/ ●Lifestyle/ ●Life change events/ ●Sedentary lifestyle/ ●Exercise/ ●Diet/ ●Stress, Psychological/
Patient	Intervention	Comparison	Outcome
Search #2	Decisional counseling		Cardiac risk factor modification behavior
<ul style="list-style-type: none"> ●Coronary Artery Disease ●Angina pectoris/ or angina , unstable ●Adults 19 or older 	<ul style="list-style-type: none"> ●Counseling/ ●Patient education as Topic/ ●Cognition/ ●Awareness/ ●Comprehension/ ●Perception/ ●Motivation/ ●Power (psychology)/ ●Patient preference/ ●counsel\$ or aware\$ or motivat\$ or Coach\$ or empower\$ or personal\$ health plan\$ or patient preferenc\$ or value clarificat\$ or goalsetting or action plan\$ or patient experience\$ or patient percept\$ or comprehend\$ 	Usual care	<ul style="list-style-type: none"> ●Health behavior/ ●Patient compliance/ ●Medication Adherence/ ●Risk reduction behavior/ ●Tobacco use cessation/ ●Smoking cessation/ ●Lifestyle/ ●Life change events/ ●Sedentary lifestyle/ ●Exercise/ ●Diet/ ●Stress, Psychological/
Patient	Intervention	Comparison	Outcome
Search #3	Cardiac risk factor modification behavior		Health outcomes
<ul style="list-style-type: none"> ●Coronary Artery Disease ●Angina pectoris/ or angina , unstable ●Adults 19 or older 	<ul style="list-style-type: none"> ●Health behavior/ ●Patient compliance/ ●Medication Adherence/ ●Risk reduction behavior/ ●Tobacco use cessation/ ●Smoking cessation/ ●Lifestyle/ ●Life change events/ ●Sedentary lifestyle/ ●Exercise/ ●Diet/ ●Stress, Psychological/ 	Usual care	<ul style="list-style-type: none"> ●Body Mass Index/ ●Body weight/ ●Body weight changes/ ●Weight gain/ ●Weight loss/ ●Cholesterol/ ●Cholesterol HDL/ ●Cholesterol, LDL/ ●Blood pressure/ ●Quality of life/

The search on the online databases yielded 241 titles from the search. From the searches 235 were excluded after the abstract had been read, as they did not meet inclusion criteria. 6 articles were retained.

Table 2.
Randomized controlled trials of Decision Aids and lifestyle changes

Trial/Country	No of participant Age	Inclusion criteria	Treatment groups	Decision Aid	Measurement time	Outcome measures	Results
Sheridan et al., 2006 USA	75 patients DA group 41 Usual care 34 Mean age 53	No previous history of coronary heart disease (CHD) events or other serious medical condition	Decision Aid group Control group that received a list of their CHD risk factors	Heart-to Heart, a computerized DA for assessment of Coronary Heart Disease (CHD) risk and impact of risk-reduction interventions for primary interventions.	One single study visit	Patients' discussion with their doctor and their plans for CHD prevention. Perceptions that CHD prevention requires a decision Preferred participation in decision-making Risk reduction choices	16% (absolute difference; 95% CI -4 to +3.7%) more patient in DA group talked with their provider about CHD risk reduction. 13% (absolute difference; 95% CI -7% to +3.4%) more had a plan to reduce their CHD risk
Sheridan et al., 2010 USA	140 participants Non-clinical population Mean age 52,4	Hypothetical lab-based study	DA alone (DA) Explicit values clarification exercise (DA+VC)	Heart-to Heart, a computerized DA for assessment of CHD risk and impact of risk-reduction interventions for primary interventions + an explicit values clarification exercise to their DA	One single study visit	Decisional conflict, Intent for screening, Perceived value concordance Self-efficacy	No significant group differences
Van Steenkiste et al. 2007 The Netherlands	34 GPs 490 consultations/patients: 276 in intervention and 214 in control Mean age patients 54	Without cardiovascular disease(CVD)	DA group received the DA and worksheet Control received only written educational materials on the content of the Dutch guidelines on cholesterol.	A 16 paged booklet in two versions: diabetic using persuasive tone on the importance of lifestyle changes, non-diabetic using more reassuring tone. Both included a simplified version of the Dutch risk charts for CVD prevention.	Baseline and six months	Risk perception Anxiety Appropriateness of perceived risk and anxiety Self-reported lifestyle Self-efficacy	Significant group differences in self-reported lifestyle: men in DA group increased their physical activity significant more than men in the control group did (odds ratio 3.8; 95% CI 1.7 to 8.7).
Koelwijn-Loon et al., 2009 & 2010 The Netherlands	25 GPs 615 patients included, 613 received conditions Included in final analysis: 488 Intervention 252 usual care 236	Present or receiving treatment for: BP \geq 140mmHg Total cholesterol \geq 6,5 mmol/L, smokers, diabetes, family history of CVD or visible obesity)	Intervention group received from trained practice nurses: 1 Risk assessment 2 Risk communication 3 DA 4 Motivational interviewing	A 16 paged booklet in two versions: diabetic using persuasive tone on the importance of lifestyle changes, non-diabetic using more reassuring tone. Both included a simplified version of the Dutch risk charts for	Baseline and 12 months	Adherence to lifestyle advice and drug treatment (Intake of fruit, fat, vegetables, alcohol, Smoking, Physical activity, Adherence to medical treatment)	No significant group differences

Trial/Country	No of participant Age	Inclusion criteria	Treatment groups	Decision Aid	Measurement time	Outcome measures	Results
Krones et al., 2008 Germany	Patient mean age Intervention 56 Control 58 14 merged CME groups with 162 practices 550 patients recruited in intervention, and 582 in control arm. 206 lost to follow up, leaving 460 in intervention and 466 in control arm Mean age Intervention 59,1 Control 58,6	Patients having their cholesterol level measured during a specific time period	DA group Usual care group	CVD prevention ARRIBA-Hertz comprising a booklet, risk calculator and an individual summary sheet for patient	Baseline and six months	Cholesterol level BP, BMI 10-years risk of CVD Patient participation and satisfaction Decisional regret Knowledge	The DA group showed significant better scores in satisfaction and participation in decision-making process compared to usual care group at six months (difference .80, p< .001). Knowledge did not improve during study period. The intervention group reported significant less decisional regret than controls at six months (difference 3.39, p=. 02).
Lalone et al., 2006 Canada	42 patients Ages 30-74	Started lipid-lowering or antihypertensive pharmacotherapy in the previous 12 months.	DA group(DA) Personal risk profile group (PRP) PRP consisted of a risk profile and a four -page information handout on general information on CVD, CVD risk factors and recommended lifestyle changes.	Booklet and personal worksheet The DA provides information about options patients have for reducing their risk of heart disease and stroke by changing their lifestyle and taking medication.	Baseline, two weeks and 3 months after consultation	Knowledge Risk perception Decisional conflict Acceptability	No statistically significant group differences

As shown in Table 2 we found only one study (van Steenkiste et al., 2007) that showed significant lifestyle improvements resulting from an intervention to promote shared decision-making. Therefore we also assessed studies testing DA on other outcomes related to lifestyle change.

To summarize; the evidence of the effects of DAs on adherence to a chosen option is unclear. Five studies measured adherence to the options chosen, warfarin versus aspirin (Man-Son-Hing et al., 1999), oral bisphosphonate medications (Oakley & Walley, 2006), blood pressure medications (Montgomery et al., 2003), and Hormone replacement therapy (Deschamps et al., 2004; Rothert et al., 1997). There were no significant differences between groups in adherence to options chosen. Holmes-Rovner and colleagues (1999) measured the correlation between patients' subjective expected value of hormone treatment and their likelihood of taking hormones. The results showed that the DA with an explicit value clarification exercise had higher consistency between expected values and taking medication than decision support without explicit value clarification.

Several studies have compared DAs to usual care in terms of general health outcomes using the SF-36 or the SF-12 as outcome measures. These studies found no significant statistical differences between the DA and the usual care group (Bernstein et al., 1998; Morgan et al., 2000; Murray et al., 2001a; Stewart, 1995). One Canadian study (Liao, Jollis, DeLong, Peterson, Morris, & Mark, 1996) and one American study (Morgan et al., 2000) that tested the effects of a treatment DA for CAD patients compared to usual care, found that patients had increased confidence in their treatment choice (Liao, et al., 1996), higher knowledge scores, and demonstrated increased decision-making autonomy, without apparent impact on quality of life (Morgan et al., 2000). Barry and colleagues (1997) found that physical functioning and general health outcomes were significantly better in the DA group compared to the usual care group for men considering treatment for benign prostate disease. Kennedy and colleagues (2002) reported that women considering treatment for abnormal uterine bleeding showed a statistically significant improvement in the role physical function variable in the SF-36. Altogether, there has been very little research to measure the effect of DAs for health behavior change and health outcomes.

Effects of individual decisional counseling

A large number of studies have supported positive effects of individual counseling. There is evidence of the positive effects of medium to high intensity dietary counseling delivered by trained clinicians to high risk patients (Pignone et al., 2003; U.S. Preventive Service Task Force, 2003a). A patient-centered counseling model has been found to enhance long-term dietary adherence (Rosal et al., 2001). There is also fair- to good evidence that high intensity counseling and behavioral intervention strategies that address physical activity, dietary improvement, or both, can produce moderate sustained weight loss in obese patients (McTigue et al., 2003; U.S. Preventive Service Task Force, 2003b). In addition, behavioral risk reduction interventions can reduce smoking (Fiore et al., 2008). These interventions include brief advice and counseling, interventions that are feasible in outpatient clinical settings. Steptoe and colleagues (1999) found that a brief behavioral counseling for men and women who were at increased risk of CAD resulted in reduced dietary fat intake, decreased number of cigarettes smoked per day, and increased physical activity in the experimental group at 4 and 12 months. Intensive counseling compared to brief counseling did not show any significant difference in smoking relapse in five studies (Landcaster & Stead, 2005).

Several studies suggest that goal setting and action plans may be more effective in promoting behavioral change than traditional advice (Ammerman et al., 2002; Cullen et al., 2001; Handley et al., 2006; Moore & Kramer, 1996; Shilts, et al., 2004). Counseling is used as a method to help patients develop an individualized tailored action plan (Ammerman et al., 2002; Babor et al., 2001; Bodenheimer et al., 2002; Fiore et al., 2008; Glasgow et al., 2003; Lorig & Holman, 2003; McTigue et al., 2003; Pignone et al., 2003; Whitlock et al., 2004). Data indicate that people are more likely to translate their good intentions into action when they make an action plan: intentions foster an action plan, and the action plan fosters behavioral change (Gollwitzer & Sheeran, 2006). It is argued that the action plan must be clear and accurate because mixed messages and health misinformation affect involvement in the plan (Woodard et al., 2005). In our study we therefore included development of an individual action plan based on patients' preferences for cardiac risk reduction behavior in the DCP.

Significant progress has been made in developing effective health behavior change interventions that address single factors (Goldstein et al., 2004; Moore et al., 2006), but large gaps remain in the development of effective methods for addressing multiple behaviors (Glasgow et al., 2004; Goldstein et al., 2004; Orleans, 2004). The most promising evidence for addressing multiple behavior risk factors comes from interventions that address secondary prevention among patients with existing CAD. Once illness is present, there is a growing body of evidence to support the impact of multimodal risk factor interventions on a variety of outcomes, including adherence to cardiac risk reduction behavior (Appel et al., 2003; Ebrahim et al., 2006; Ketola et al., 2000; Knowler et al., 2002; McAlister et al., 2001; Murchie et al., 2003). Koertge and colleagues (2003) found that a multicomponent lifestyle change program for diet, activity, stress reduction, and social support can improve health outcomes and HRQoL, when maintained over a period of one year.

Feedback and assessment enhance the success of health behavior counseling interventions and are often used in multiple risk behavior interventions (Bodenheimer et al., 2002; Fiore et al., 2008; Glasgow et al., 2001; Glasgow, 2003; Glasgow et al., 2003; Pignone et al., 2003; van Steenkiste et al., 2007; Wasson et al., 2003; Whitlock et al., 2004). Patient involvement in medical decisions has been shown to impact adherence (Cooper et al., 2002). Patients need to be informed, motivated, and skilled in the use of strategies if they are to cope efficiently with recommendations regarding their illness. While DAs can provide patients with helpful knowledge if supplemented with individual counseling this may be even more effective. No known previous studies have compared the effects of a CAD-DA with and without the supplement of individual decisional counseling as we did in this study.

The short- and long-term success of CABG surgery depends on the occlusion rate of the bypass grafts and the ongoing occlusion of the native coronaries. Krannich and colleagues (2008) noticed that many CABG patients assume that they are completely cured after surgery when symptoms and pain are no longer present. Within the first year after CABG surgery about 12-20% of the vein grafts are occluded again, and after 10 years this ratio increases to 41-50 % (Zellweger et al., 2001). Therefore, after surgery patients risk perception is weakened, pointing to the fact that people generally do not know that CAD is a chronic condition. Krannich and colleagues (2008) found that motivation for lifestyle changes decreases shortly after CABG surgery and argue that patients should be informed about their option for secondary cardiac prevention as early as possible. In our study we therefore

included patients before the angiogram to ensure early start of introducing options for a healthy lifestyle.

Programs that allow individuals to choose any number of their own unhealthy behaviors to reform, can provide risk reduction for a broad spectrum of patients, with a wide range of traditional risk factors (Calfas et al., 2002; Grant, 2003). These strategies should work by effecting favorable changes in patient behavior, which would then lead to improved cardiovascular risk by modifying a number of risk factors and improving control of several risk conditions (Gæde et al., 2003; Koertge et al., 2003; Strandberg et al., 2006). The DCP intervention in our study was developed based on this strategy and to structure situations where patients were able to discover the importance of choosing any number of healthy choices in diet, activity, stress reduction, and smoking cessation, thereby preventing CAD or CAD progression. It was designed to improve patients' cognitive and affective understanding of the importance of a healthy lifestyle, and elicit their preferences for change.

A review by Ashenden et al. (1997), found evidence that interventions in general practice have a modest and variable effect on lifestyle and concluded that the small changes in behavior that was found not seem to produce substantial changes. This is supported in a review by Ebrahim et al. (2006) that evaluated the effects of multiple risk factor interventions for reducing cardiovascular risk factor among adults with no clinical cardiovascular disease. A Cochrane review shows that there is limited evidence of long-term effectiveness of interventions for promoting physical activity (Foster et al., 2005). The Norwegian Knowledge Centre (Flottorp et al., 2008) summarized Cochrane reviews on the effects of non-pharmacological interventions to support lifestyle changes and found that several interventions may have small or moderate positive effects on smoking, physical activity, overweight, and diet. Sebregts et al. (2000) suggest in their review of risk factor modification behavior through non pharmacological interventions in CAD patients that it is important to scrutinize the quality of information that patients receive. The DA in our study provided thorough information. DAs are developed to encourage patients to engage in decision-making. They differ from other health education materials because of their specific, detailed, and personalized focus on options and outcomes. DAs deliver information in various ways, including: (a) written materials, (b) oral (audio) presentation of information combined with written and/or visual materials (c) video programs (d) computer programs, and, (e) individual counseling /explicit value clarification exercises, often combined with written and/or visual

information. The DA in this study contained text, graphics, and exercises to illustrate and personalize the provided information. DAs are designed to help patients: (1) recognize that a decision needs to be made, (2) understand the options and outcomes, (3) see how values and preferences affect the decision, (4) understand what matters most, and can discuss these matters with their health care providers, and (5) become involved in preferred ways (Molenaar, et al., 2000; O'Connor, Rostom, et al., 1999; O'Connor et al., 2009).

The Health Belief Model (HBM) and predictors of adherence

Janz and colleagues (2002) identified the HBM as one of the most studied theories in health education, used successfully with varying populations, health conditions, and interventions. The HBM has been used to examine risk reduction behaviors such as breast-self-examination, undergoing mammography, and quitting smoking. Support for the HBM variables to predict behaviors are not consistent across studies.

Health beliefs and adherence.

Ali (2002) tested several predictors of CAD preventive behaviors derived from the HBM in a sample of 178 healthy women. Susceptibility and severity of CAD, knowledge of risk factors, and general health motivation explained a substantial amount of variance in healthy behavior practice. For example women who perceived themselves as significantly more likely to get a heart disease, and believed that heart disease was a serious condition were more likely to use hormone replacement therapy (Ali, 2002).

In a study comparing a smoking prevention intervention with an approach based on the HBM among women showed no significant difference (Schmitz, et al., 1999). At baseline women with established CAD perceived themselves as being more susceptible to cardiac health problems related to future smoking, but gave relatively lower ratings regarding the severity of such problems than at-risk women. Furthermore, women with established CAD reported fewer benefits of quitting. Data indicated that having already suffered from the negative effects of smoking these women felt highly threatened by their current behavioral patterns yet they did not believe that change would be beneficial in reducing the perceived threat. One of the most important findings in Schmitz and colleagues' (1999) study was the

significance of sample characteristics as a predictor of outcome. The odds of being abstinent at 6 months were 2.2 times greater for at-risk women when compared with women with established CAD. This appears inconsistent with other literature suggesting that the presence of a disease condition itself is generally a robust predictor of smoking cessation (Burling et al., 1984; Gritz et al., 1993; Perkins, 1988). To enroll patients at the initial visit at the Cardiac Outpatient Clinic may therefore increase the likelihood of quitting smoking.

It is commonly believed that CAD is not feared as much as cancer, and is often seen as a quick preferable death (Emslie, et al., 2001). The perceived severity of the disease threat has shown mixed results regarding adherence to cardiac rehabilitation. In a study by Oldridge & Streiner (1990) the perceived severity was associated with adherence to cardiac rehabilitation, while other studies found small associations between perceived severity and adherence to cardiac rehabilitation (Muench, 1987; Tirrell & Hart, 1980). Patients' perceived severity of, and susceptibility to CAD have been shown to be positively related to adherence to antihypertensive medication, and smoking cessation (Janz, 1988; Janz & Becker, 1984). Thus data indicate that beliefs about risk and disease are an important component in adherence to recommended guidelines and influence adherence. We therefore included perceived susceptibility and severity as key components in our DCP.

Perceived benefits and barriers, and adherence.

The concept of perceived benefits and barriers to an action are known as decisional balance, or benefits/advantages minus barriers/disadvantages, pros minus cons, where patients intellectually think about the advantages and the disadvantages of engaging in a particular action. Perceived benefits have been associated with adherence to cardiac rehabilitation (Ades et al., 1992; Al-Ali & Haddad, 2004; Moore et al., 2003; Oldridge et al., 1990). Counseling on perceived benefits has been demonstrated to help motivate weight loss, patients to begin exercising, and eating low-fat diets (Clark, et al., 1996). Counseling on the perceived barriers have had mixed effects based on the type of intervention. Perceived barriers such as side effects and complexity have been found to be negatively related to adherence (Sackett, et al., 1975), and associated with non-adherence to cardiac rehabilitation (Oldridge et al., 1985; Oldridge et al., 1990). After discussing the perceived barriers of the time it takes to do a breast examination, women more often reported performance of breast examination (Champion, 1993). During the discussion of the barriers the patient may reflect on how to overcome these barriers and find solutions for performing the new behavior.

Sustaining change is difficult even for the most motivated person, and when the effect of the intervention fades, the adherence decreases. Adherence also decreases when patients do not perceive any benefit in changing their behavior (Schaffer & Yoon, 2001). Thus data indicate that perceived benefits are important factors for behavioral change. In our study we therefore included assessment and weighting of individual perceived benefits and barriers of cardiac risk reduction behavior in our DCP.

Relapse and relapse prevention.

The prevalence rate of adherence to medical recommendations is on average, 75.2 % in a meta-analysis of the literature from 1948-1998 (DiMatteo, 2004a). Adherence to healthy behaviors, diet, and exercise yield lower adherence averages, each is significantly lower than its comparison with other regimens: Healthy behavior adherence is 69.7 %, exercise adherence is 72.0 %, and diet adherence is 59.3 %. The average adherence in studies of CAD patients showed a mean adherence of 76.6 % (DiMatteo, 2004a).

Non-adherence was significantly higher among patients with age less than 45 years (Sherbourne et al., 1992). Older patients, despite greater difficulties due to higher medical complexity, may have developed a stronger allegiance to their provider by virtue of greater dependency and greater utilization of the health care system. Cardiac patients with higher education, who were older, and those who were dissatisfied with the technical quality of care were more likely to adhere to a specific recommendation. DiMatteo (2004a) states that the relationship between education and adherence is weaker in the acute care than in the care of chronic disease, and he reports that in chronically ill patients adherence is positively correlated with patient education. Adherence is also positively correlated with income and socioeconomic status. Data indicate that changeable factors like depression and support have greater effects on adherence than non-changeable factors like age and gender. Unrecognized clinical depression might bring about poor adherence and post treatment outcomes, particularly for heart disease (Ziegelstein et al., 2000, DiMatteo et al., 2000). Depression is also a significant predictor of HRQoL after CABG (Krannich et al., 2007).

Reasons for poor medication adherence can be non-intentional such as carelessness or forgetfulness, or intentional when making an active choice to deviate from the treatment regimen (Lowry et al., 2005). Non-adherence to cardiovascular medications has been

associated with increased risk of morbidity and mortality (Rasmussen et al., 2007; Spertus, Kettelkamp et al., 2006b). Studies show that adherence continues to decline during the long-term follow up phase for CAD. Jackevicious and colleagues (2008) found that almost 25% of patients did not even fill their cardiac medication seven days after discharge for acute myocardial infarction. Another study (Ho et al., 2006) found that 34 % stopped at least one of the medications (statins, beta-blockers, and aspirin) and 12 % of all medication within one month after discharge for acute myocardial infarction. Economic limitations that prevent patients from following drug regimen are small in Norway because of the economic support of medication by government paid “blue” prescriptions and a ceiling level for high expenses. Because cardiac risk-reducing medical treatments and risk reduction behavior are poorly maintained over time (Haynes, 2001), it is important to design and test interventions that may increase the adherence to cardiac risk reduction behavior which was a purpose in this study.

There are certainly patients who are simply unwilling to follow medical advice or to adhere to complex medical regimens (Ho et al., 2009). Adherence is not fostered by convincement but rather through a partnership based on communication that builds trust. Sherbourne and colleagues (1992) found that satisfaction with medical care was a predictor of patient adherence. A relationship between caregiver and patient that is positive and supportive is a key to effective communication (DiMatteo et al., 2002). Burke & Dunbar-Jacobs (1995) emphasize the mutual responsibility between patient and provider, and reinforce the commitment of the health care provider to help the patient implement and follow their treatment plan. Aspects of healthy provider-patient communication might increase the chance of patient adherence, and therefore improve the outcomes of medical treatment (DiMatteo, 1994). Finally, it is important to consider the perspective of patients, many of whom may view non-adherence as a rational choice (Donovan et al., 1992). Therefore, it is necessary to work more collaboratively with patients to develop and expand the possible solutions that better fit the patient’s preferences and needs. Our study was designed to create such a collaborative environment in the individual counseling sessions.

Generally, patients are more likely to choose an alternative that they perceive will be effective in achieving valued outcomes and avoiding undesirable outcomes. When presented with more than one option of choice, each of which has multiple characteristics, patients might find themselves in a state of uncertainty or difficulty in identifying the best alternative due to the uncertainty of outcomes, and they need to make value judgments about potential

gains versus potential losses (Keeney, 1988). This state is defined as decisional conflict. Multiple studies have investigated the relationship between DAs and decisional conflict. The most often used measurement was the Decisional Conflict Scale (DCS) (O'Connor, 1995) which measures the following dimensions: a person's personal uncertainty in making a choice about health care options, the modifiable factors contributing to this uncertainty, and the quality of the decision made. Remarkably consistent results have emerged. These findings show that DAs help the patient to lower decisional conflict, feel less uninformed, and feel less unclear about personal values (O'Connor et al, 2009).

Even with good adherence to a healthy behavior, relapse is common. There has been a wide acceptance in recent years that behavior change is a process, not an event. To undertake initial behavior change and maintain behavior change are different, and require different types of interventions. For example, to maintain non-smoking requires self-management and coping strategies, establishment of new patterns of behavior, increased perceived control, and confidence to avoid temptation. Our study, therefore addresses the individuals' beliefs regarding the perceived risk associated with certain behaviors, patients' preferences and experiences, the vulnerability to worsening disease, a decisional balance assessment, and taking action to change behavior in order to decrease the risk of CAD or CAD progression.

Relationship between adherence to cardiac risk reduction behavior and health outcomes

Adherence is generally associated with one's ability to maintain the behaviors associated with a plan of care. Adherence in the healthcare literature is also referred to as compliance and maintenance. Compliance is viewed by some as a paternalistic term, and maintenance is used more often when describing persistent health behavior such as exercise and weight loss. Adherence, compliance and maintenance are measured from short-term behaviors like a single point, to long-term behavior over several years (Shay, 2008).

Since the first empirical studies on adherence in the late 1960s, researchers have attempted to assess, understand, predict, and change patients' responses to medical advice because, it is argued, adherence to treatment improves outcomes. Patients' adherence to

medical recommendations is believed to be an important mediator between physicians' therapeutic expertise and patient outcomes. Self-care is a central element in the overall management of chronic diseases. Despite an assumed linkage between adherence and health outcomes in chronic disease, empirical studies have yielded mixed results (DiMatteo et al., 2007; Roter et al., 1998). Therefore, the magnitude of the relationship between adherence and treatment outcomes remains to be determined.

The adherence-outcomes complexity.

The adherence-outcome relationship is complex. Factors like the strength and efficacy of recommendations and treatments, genetic variances in response rate, adverse drug reactions, misdiagnosis, and limitations in current understanding of the disease can affect outcomes. Studies with non-disease specific outcome measures like pain and health-related quality of life yielded higher effects than did those with disease-specific outcomes measures like blood pressure and cholesterol levels. There were no differences between studies on prevention and those of treatment or between studies in which patients were asked to adhere to one versus more than one regimen (DiMatteo et al., 2002). On average 26% more patients experienced a good outcome by adhering than by not adhering, consistent with a review on adherence and heart disease outcomes (McDermott, et al., 1997).

Factors that modify the adherence-outcome relationship, particularly those involving the nature of the disease and of patient characteristics, appear to be complex. For example, the adherence-outcome relationship is higher in studies of chronic conditions than studies of acute conditions (DiMatteo et al., 2002). One possible explanation is that acute illness might be more self-limiting, making adherence less important in the acute care. Chronic conditions involve more non-medical regimens, are less serious, and studies of chronic illness are more likely to use continuous measures of adherence, all factors associated with higher adherence-outcome correlations. The adherence-outcome relationship was lower in studies of more serious conditions, a finding that could be explained by a correlation with other moderating factors, or by the possibility that a patient's adherence behavior makes a greater difference under less extreme medical circumstances (DiMatteo et al., 2002). Perceptions of poor health were related to a tendency toward non-adherence, and avoidance as a coping style was found to be an important predictor of non-adherence. Those reporting use of avoidance like hope for a miracle tended to be less likely to adhere to advice and recommendations (Sherbourne et al., 1992).

Studies have found that adherence to pharmacological therapy, even if it is adherence to a placebo, is associated with better outcomes than for patients who are non-adherent to active treatment (Epstein, 1984; Horwitz et al., 1990; Irvine et al., 1999; The Coronary Drug Project Research Group, 1980). This effect is often named “healthy adherer” effect (Simpson et al., 2006). The healthy adherer effect implies that a lower risk of adverse outcomes associated with adherence may be a surrogate marker for overall healthy behavior. Irvine and colleagues (1999) analyzed potential predictors of adherence and found few relationships that explained the positive, nonspecific effects of adherence to placebo. Further research on adherence and relationships to outcomes are necessary.

Positive expectations might influence both outcomes and motivation to adhere (DiMatteo et al., 2002). Patients who are more likely to adhere might have personality characteristics (optimism, conscientiousness, personal adjustment) that are positively correlated with better health outcomes. Certain life circumstances like socioeconomic status might make it easier for patients to adhere and more likely to achieve positive health outcomes. Reverse causality may also play an important role (DiMatteo et al., 2002), so that a good outcome may promote subsequent adherence, particularly during long courses of treatment.

Adherence and measurement.

The conception and operation of measurement appears to be critical to understanding the adherence-outcome relationship. Quality of measurement affects the adherence-outcome relationship, underscoring the importance of effective adherence assessment. Three aspects of adherence measurement (scale, number of measures and use of self-report) moderated the adherence-outcome effect, although the scale of adherence measurement was the only significant predictor (DiMatteo et al., 2002). These findings suggest that whenever possible, research should use measures that are continuous instead of dichotomous, use more than one measure of adherence, and include self-report. In adherence research self-reports can be direct, simple, and inexpensive, and although limited somewhat by memory (DiMatteo, 2004a). It is important to note that adherence and treatment outcomes, while correlated, are distinctly different conceptually and empirically, and outcomes should never be used as proxies for adherence in adherence research (DiMatteo et al., 2002).

Risk factors and CAD.

In apparently healthy and asymptomatic people, the incidence of CAD is explained by the modifiable risk factors: serum total cholesterol and high LDL, blood pressure, poor diet, lack of exercise, and cigarette smoking (Edwards et al., 2006; Yusuf et al., 2004). Secondary prevention of CAD involves risk factor reduction through control of health behaviors such as diet, physical activity, smoking, and medication adherence using a coordinated approach and referrals to health professionals. Modification of risk factors such as blood cholesterol, blood pressure, physical inactivity, smoking, and obesity can reduce cardiovascular events, the need for coronary revascularization and improved HRQoL (McAlister et al., 2001). Studies of cardiac rehabilitation that include comprehensive lifestyle modifications before the era of statin therapy and improved coronary interventions also revealed a modest reduction of coronary artery stenosis (Haskell et al., 1994; Ornish et al., 1990; Ornish et al., 1998; Schuler et al., 1992).

A systematic review by Buckley and colleagues (2010) showed weak evidence that secondary prevention services with regular planned recalls for appointments, monitoring of risk factors, and education can increase the proportion of patients whose total cholesterol levels and blood pressure are within target levels. The authors did not find significant effects of interventions on body mass index, cholesterol levels, mean blood pressure, or smoking status (Buckley et al., 2010). Studies of less intensive cardiac rehabilitation programs indicate that lifestyle and risk factors do not improve or even deteriorate (Lear et al., 2003; Willich et al., 2001).

Diet and health outcomes.

There is evidence that lowering lipids both by dietary means, which includes reduced intake of saturated fat, and use of lipid-lowering drugs, have positive effects on lowering cardiovascular risk, and the effect is clearly related to the effect on the most important lipid fraction in blood (LDL). Effects on lipids are generally regarded as the most important of the dietary changes, but interventions to reduce obesity are also important. Each incremental 25% increase in the proportion of days covered with statin medications was associated with an approximately 3.8 mg/dl reduction in LDL cholesterol (Ho et al., 2006).

Several studies have delivered specific interventions on changing risk factor status (Campbell et al., 1998; DeBusk et al., 1994; Heller et al., 1993; Jolly et al., 1999; Kirkman et al., 1994; Racelis et al., 1998; Vale et al., 2002). Two were effective (Campbell et al., 1998;

De Busk et al., 1994) in showing a significant difference in lipid concentrations between the intervention group and the control group. The effects in those studies may be explained by the increased uptake of lipid-lowering drug therapy, compared with the control group. In contrast, Vale and colleagues (2002) found that the effects of their coaching intervention best were explained by both adherence to drug therapy and adherence to lifestyle advice. The other four studies aimed to modify diet and other behavior according to therapeutic guidelines and were not effective in modifying lipid levels. The objective of those studies was to influence the process towards risk reduction. Achievement of goals related to this process did not result in improved risk factor levels. In the study of Heller et al., (1993) and Kirkman et al. (1994) there was found improvement in self-reported adherence to regimens that might reduce coronary risk, but this was not reflected in the objective measures of risk factors.

Vale and colleagues (2003) and Jelinek and colleagues (2009) reported that an intensive coaching intervention program improved cardiac risk factors from entry to exit of the program. The coaching was aimed to train patients to take responsibility for the achievement and maintenance of the target lipid levels by visiting their doctors and following appropriate nutritional guidelines. The coaching was performed by a dietician trained in patient education. Six months later there was a small decline in the risk status and after 24 months the cardiac risk factors status and adherence to medications was slightly less than measured at the end of the intensive coaching intervention. Nearly all variables were significantly better after 24 months. The authors concluded that the cardiac risk factor status was maintained and better than at the entry of the study.

Medication intake and health outcomes.

Several trials have documented preventive effects with blood pressure-lowering drugs. High adherence to antihypertensive medication was associated with higher odds of blood pressure control compared to those with medium or low levels of adherence (Bramley et al., 2006). However, due to side effects of pharmacological interventions any intervention that could lower blood pressure or prevent its increase would be preferred. It has been shown that a change in diet to lower levels of salt intake can significantly lower blood pressure (Sacks et al., 2001; Sacks & Campos, 2010).

Physical activity and health outcomes.

Yusuf and colleagues (2004) have shown that low physical activity is an independent risk factor for MI. Regular physical activity may decrease morbidity and mortality rates associated with CAD through multiple mechanisms (Franklin et al., 2004). In a randomized trial of 101 men with stable CAD and an angiographically documented stenosis amenable to PCI, the authors compared a 12 month exercise training program and medical therapy with standard PCI and reported that participants in the exercise group had a longer event-free survival and increased exercise capacity at lower costs (Hambrecht et al., 2004). Physical activity can prevent and treat established risk factors, such as elevated blood pressure (Fagard & Cornelissen, 2007). The recommendation to adopt moderate-intensity physical activity does not suggest an all-or-nothing approach, but rather that it is important to consider physical activity on a continuum and that incremental change in behavior is important. It is more likely that a sedentary individual will adopt moderate-intensity activity first, and later adopt vigorous-intensity physical activity. Further, adopting moderate-intensity physical activity is likely to be easier and safer for sedentary patients. Recommending moderate-intensity physical activity can provide more options to patients, while recognizing that the greatest benefits are associated with vigorous-intensity activity (Fagard, 2001). It is generally agreed that physical activity is important to prevent weight increase. No interventions supported the value of increased physical activity on CAD incidence, but there are found positive effects from physical activity on blood lipids and general well-being. With the relatively small risk for adverse effects, increased activity is generally recommended.

Smoking and health outcomes.

There is overwhelming evidence for an adverse effect of smoking (US Department of Health and Human Services, 2004). There is a graded relationship between the amount of tobacco consumed and CAD morbidity, but it is also documented that there is no level of smoking that is safe. There is evidence for long-term positive effects on smoking cessation interventions, including brief behavioral counseling and pharmacotherapy delivered in the primary care setting (Pinto et al., 2005).

Relationships between adherence to cardiac risk reduction behavior and HRQoL.

Health-related quality of life (HRQoL) is a measure of perceived well-being and ability to function-physically, mentally, emotionally and socially. Prior research has documented profound negative effects of cardiac disease on HRQoL as demonstrated in studies of post-bypass, post myocardial infarction, and patients undergoing PCI (Bosworth et al., 2000; Mendes de Leon et al., 1998; Myles et al., 2001; Pocock et al., 2000). Poor preoperative HRQoL and low scores in the physical functioning QoL domain among CAD patients have been associated with poorer post-hospitalization general health, higher admission rates, and increased mortality among CAD patients (Rumsfeld et al., 1999; Rumsfeld et al., 2001).

Multiple studies have demonstrated that HRQoL improves, on average after CABG (Krannich et al., 2007; Lindsay et al., 2000; Rumsfeld et al., 2001) with women scoring lower than men (Lindquist et al., 2003). Christian and colleagues (2007) found that HRQoL is reduced among women hospitalized for CAD with average scores 13 points below normative data compared to healthy adults. The major predictors of HRQoL among these women six months later were baseline HRQoL, adherence to physical activity goal (≥ 3 days/week, at ≥ 30 min/day), and being married.

Aldana and colleagues (2006) found that the intensive Ornish program may affect significant greater improvements' in HRQoL compared to traditional cardiac rehabilitation, while the poorest outcomes in HRQoL was seen in the control group who received standard care.

Hays and colleagues (1994) could not conclude that assessing patients with hypertension and post myocardial infarction to adhere to their physicians' recommendations will necessarily lead to better health over time. They examined the relationship between self-reported adherence to medical recommendations and health outcomes over time for patients with one or more of these conditions; diabetes, hypertension, congestive heart failure, and recent myocardial infarction with or without symptoms of depression. There was a very small association between improvement in health outcomes and patient adherence. For patients with recent myocardial infarction the authors found a significant beneficial effect of adherence on

emotional well-being. Physical health improved for diabetic patients with recent MI or CAD when they adhered to a diabetic diet. Hays and colleagues (1994) concluded that the relationship between health outcomes and adherence is more complex than assumed.

Summary

For patients to adhere to treatment or life style recommendations, they must know what to do, be committed to doing it, and have the resources to be able to do it. The literature clearly documents that adhering to a healthy life-style and reducing risk factors is particularly important for CAD patients, and that there is a relationship between healthy behavior, secondary CAD prevention and health outcomes. Whilst many of the lifestyle interventions show promise in effecting small changes in behavior, none appears to produce substantial changes. It is clear that if lifestyle interventions are to be effective in a public health sense, a greater number of health care providers will need to be involved in promoting behavior change than the literature suggest is currently occurring.

DAs have been widely used to assist patients in treatment decision-making, but few studies have evaluated DAs designed to assist in behavioral change or have attempted to address multiple behavioral risk factors. Also, evidence of the effects of DAs on adherence to an option chosen by the patient is unclear. Furthermore, the literature reports that not all patients are able to use the information in a DA to arrive at a decision, and need additional help to combine evidence with their personal values that enables them to choose among several possible courses of action.

Research findings have shown that brief individual counseling interventions can effectively address lifestyle changes and are feasible in routine practice. While perceived risk is an important aspect of decision-making, no previous known studies have included personal risk profiles together with eliciting patient preferences for behavioral change in a decisional counseling intervention. Combining DAs with decisional counseling to address patients' individual risk files and help them comprehend information provided in a DA may therefore, be worthwhile. So far no previous studies have compared the effect of a DA with and without additional individual preference-based decisional counseling on behavioral change and health

outcomes. The literature review therefore, supports the need for our study to test the effects of DA with and without an individual preference-based decisional counseling on health outcomes and HRQoL mediated by adherence to cardiac risk reduction behavior.

Chapter 3

Methods

Introduction

This study consisted of two phases. Phase I included the translation and adjustment of the Canadian version of the DA into Norwegian, development of an individual decisional counseling program (DCP), and pilot testing of the adjusted DA and the DCP. In Phase II we conducted a three group RCT to evaluate the effects of the DA, with and without the additional DCP, on patient outcomes in 368 patients scheduled for a coronary angiogram at Oslo University Hospital HF-Rikshospitalet.

Phase I: Translation and adjustment of the DA, development of the DCP, and pilot testing

The research team had an agreement with the developers of the DA from Canada to translate and use the DA: “Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke” in this study. The DA was designed as a booklet and presented information about CAD, the possible risks, and how to lower risks by making healthy choices. The content of the DA is based on an extensive review of the literature with evidence from randomized trials published up to 2002, expert content, and focus groups with patients and clinicians. The information in the DA is conveyed as a combination of pictures, text, graphs, and tables that present how to live a healthy life with CAD (Lalonde et al., 2002).

Text, pictures, and tables in the DA were translated and back translated by translators into Norwegian using the forward – backward method as described later. The content presented in the Canadian DA was compared to Norwegian treatment recommendations in 2007, and some adjustments were made in collaboration with the Canadian research team.

Design and development of the DCP intervention

The purpose of developing an individual decisional counseling program (DCP) was to design a program that structures situations in which patients can adjust the information in the DA to their personal illness story. In light of this personalized information they can identify the types of cardiac risk reduction behavior that are important for them to accomplish. The design phase consisted of several steps including identification of theory, modeling process, and expected outcomes. The DCP encompassed the following components and features (see Appendix B):

- (1) CAD knowledge comprehension after reading the DA
- (2) Health beliefs about CAD and CAD progression after presentation of individual risk profile
- (3) Identification of perceived benefits and barriers to cardiac risk reduction behavior
- (4) Finally, patients, together with the counselor, developed a written action plan for cardiac risk reduction behavior.

Table 3 shows an overview of the structure and the content in the DCP.

Table 3.

An overview of the structure and content of the intervention “Decisional Counseling Program” (DCP)

TOPIC	SECTION/ OUTCOME	TOPIC AREA	TEACHING METHODS	INSTRUMENTS
Introduction	Process issues are identified	Goal for counseling Desired participation No right or wrong answers	Conversation	Presentation guide
TOPIC 1.				
Knowledge Experience	Diagnosis Prognosis Health recommendations	Short repetition if necessary Help to comprehend. Adjustment to personal illness history and future.	Booklet prior to counseling Interview, questioning	DA prior to counseling Interview guide
TOPIC 2.				
General health beliefs Specific health beliefs	The perceived susceptibility of CAD or CAD progression	Individual risk profile Help to comprehend the possible risks	Presentation of individual Risk profile (computation) Conversation	“HeartScore [®] ” Interview guide
TOPIC 3.				
Perceived Benefits and Barriers	Believe the action is beneficial (reduced perceived susceptibility and severity) Believe there are no overwhelming barriers	Rating of importance of potential actions Assessment of all perceived benefits Assessment of all perceived barriers	Questionnaire Worksheet Balance scale	“Perception of Importance of Cardiac risk reduction behavior” “Work sheet Cardiac Risk Reduction Behavior”
TOPIC 4.				
Decision	Cardiac risk reduction behavior: selection Action items Barriers and resources Social support Action plan for Cardiac risk reduction behavior	What is best? Written plan Who needs to do what and by when? What do you need to perform the behavior chosen?	Complete the decision in a form Evaluation of the counseling	Interview guide “ My plan for Cardiac Risk Modification Behavior” “1 Minute evaluation”

The Health Belief Model with its concepts provided a map for addressing the topics covered in the DCP. The model makes assumptions about behaviors that may reduce the risk for health problems in cardiac patients that are logical, consistent with everyday practice, are used in previous successful programs, and are supported by research in the CAD area (Clark & Becker, 1998; Croog & Richards, 1977; Miller et al., 1988).

The Health Belief Model emphasizes the individual's perceptions of the threat posed by a health problem (perceived susceptibility and severity of CAD), the perceived benefits of avoiding the threats, and factors influencing the decision to act (barriers, cues to action, and self-efficacy). The researcher combined these theoretical assumptions, identified variables consistent with the Health Belief Model, specified the additional procedural elements of the DCP, and developed an observation system of fidelity (see Appendix C). The DCP also utilized principles from decision theory that provides quantitative means for patients to express their preferences about critical trade-offs between perceived benefits and barriers of cardiac risk reduction behavior.

The major criterion to implement a choice is the extent to which a patient can feel significantly related to it (Brown, 1975). Cognitions, feelings, emotion, action, and motivation are easily separated by theoretical abstractions, but no single one of these can function independently of the others. These components interact, and influence one another. The counseling methods used in the DCP were designed to stimulate the awareness and intention by convergent and cognitive processes integrated with, or parallel to patient experience.

One example of such a process used in the DCP is a Sentence completion form which uses open non-directional sentences the patient had to complete. The sentence completion form makes it possible to make the implicit explicit, to discover what is most important, and what is not by integrating the subject matter and the personal awareness. Sentences are started and the patient is asked to finish them. The lesson helps create an involvement that starts an ongoing spontaneous activity of writing here and now, creative and inventive. The empty spaces in the sentence can contribute to an increased number of answers than without these open spaces (Brown, 1975; Grendstad, 1986). The purpose is to structure situations that help the patient to recognize his personal position and relationship towards perceived benefits and barriers to cardiac risk reduction and the problems that can occur related to CAD. The method allows patients to arrive at solutions to their problems by examining their own thoughts,

feelings, emotions, and motivation. This aids patients in finding their own solutions to their problems. Patients can then decide for themselves in what ways they need or want to change. The counselor's role is that of a facilitator with the goal to provide a comfortable environment, rather than to drive and direct the patient toward the "right" solution.

Strict standardization of the intervention was inappropriate in this study because the actual intervention may work better if a specified degree of adaptation to local circumstances (individual risk profile) is allowed for in the protocol. Therefore, the DCP was designed to let the content in the topic area (the means of intervening) vary according to individual patient risk profiles, while the function (theorized mechanism) of the DCP remained unchanged over place and time. The local circumstances that were allowed to be changed or adapted in this study were: individual risk profile, individual's perceived benefits of potential action taken, individual's barriers to potential action taken, and the individual's decision that resulted in the individual plan for cardiac risk reduction behavior.

During the design period the researcher specified procedural elements of the DCP and developed an observational system to check the fidelity of the intervention (Bellg et al., 2004; Borrelli et al., 2005; Resnick et al., 2005). Procedural elements encompass incorporated, informal, and training materials like teaching/counseling methods, instruments, written interview guides, worksheets, and training manuals for the counselor. Fidelity is not always straightforward in relation to an intervention that takes place in different settings (Craig et al., 2008). Therefore, the observational system encompassed tools to control the way in which the intervention was implemented to assess fidelity and quality of implementation. The intervention fidelity strategies described how much change or adaptation is permissible and the counselor records variations in implementation so that fidelity can be assessed in relation to the degree of standardization required by the study protocol.

Once the first preliminary DCP with procedures and instruments were developed, simulated patients were used to test the preliminary DCP outside the normal clinical setting. The simulation made an identification of the likely outcome for a range of simulations (Oakly, Strange et al., 2006). This way of modeling the DCP provided important information about improvement, and allowed the research team to redesign the DCP several times. As the intervention emerged in stages, it was repeatedly "tested" in simulations and counseling from

advisors. At last, a prototype did not provide more revisions and the developed DCP intervention was tested clinically in this study.

After a preliminary Norwegian version of the DA and the DCP was ready, a focus group with expert clinicians (cardiologists, nurses) and CAD patients who had different treatment experiences were asked to critically review the content, design, and layout of the program, evaluate it for clarity, appropriateness, wording, and format, and add comments. Suggestions for revisions based on these evaluations were discussed in the expert clinician group and the DA and the DCP were adjusted accordingly. We collaborated with the Canadian team on the translations and adjustments on the DA prior to the main study.

Translation of instruments into Norwegian. All instruments that were not yet available in Norwegian (Health Service Used; Health Behavior Scale; Knowledge Questionnaire; Health Belief Questionnaire; Benefits Scale; Barriers Scale; Decisional Conflict Scale; Acceptability Questionnaire) were translated and back translated. Two bilingual translators were used. One translator translated the text and instructions from English into Norwegian. The second translator translated the Norwegian version back into English. Secondly, a refinement group consisting of the two translators and the investigator reconciled and further refined the translations and grammar/syntax (Acquadro et al., 2004; Brislin, 1970; Brislin, Lonner, & Thronkike, 1973).

Prior to launching the RCT, the Norwegian version of the DA, the instruments, and the DCP were pilot tested in a sample of 15 CAD patients (5 per group) following the same procedures as in the RCT described below. Looking for feasibility of all study procedures, no corrections were seen as necessary.

Phase II: Randomized clinical trial

Research design

To answer the research questions, the proposed study used a three-group RCT design with four repeated measurement points over six months. Patients were randomly assigned to either (1) the DA group where patients received, to take home, the DA prior to their scheduled angiogram; (2) the DA+DCP group where patients, in addition to the DA, received an individual decisional counseling program (DCP) from a trained nurse counselor in their homes prior to their angiogram; and (3) the Control group who received “usual care”.

Data was collected from all three groups at baseline at their initial visit to the Cardiac Outpatient Clinic (T1), and two (T2), four (T3), and six (T4) months after their angiogram. Analysis evaluated the effects of providing DA with and without the additional DCP on: (1) Primary health outcomes: (body weight, cholesterol, blood pressure, and amount of tobacco), and Health-related quality of life (HRQoL), (2) Intermediate outcomes of adherence to cardiac risk reduction behavior, (3) Mediating variables: Knowledge about risk factors and CAD, perceived susceptibility and severity of CAD or CAD progression, and perceived benefits and barriers to cardiac risk reduction behavior. Furthermore we (4) explored the relationships between intermediate adherence outcomes and primary health outcomes and HRQoL; between primary health outcomes and HRQoL, and between possible mediating variables (baseline intentions, knowledge about risk factors and CAD, perceived susceptibility and severity of CAD and CAD progression, perceived benefits and barriers of cardiac risk reduction behavior, and decisional conflict), and adherence to cardiac risk reduction behavior.

The four measurement points were used to capture the variance in health status following the paths for CAD treatments like CABG, PCI, and medication therapy. The first measurement point (at initial visit before the angiogram) provided baseline measurements of the patients before randomizing them into different groups. The time of the angiogram was used as an anchor for measurement over time. The second measurement point (two months after the angiogram) permitted assessment of intermediate adherence outcomes and mediating variables. The third measurement point (four months after the angiogram) allowed capturing the variance in health status following different paths for CAD treatments. The last measurement point (six months after the angiogram) was selected because it is the assumed

usual time of completion of recovery and resuming functional status and normal roles after CABG surgery.

Interventions– independent variables

Decision Aid (DA). The DA “Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke” (Lalonde et al., 2002) is a 49 page booklet for the patients to take home in both intervention groups (see appendix A). Patients were asked to read the DA at least once before their scheduled angiogram, or as often as they wished.

Decisional Counseling Program (DCP). Patients in the DA+DCP group received both the DA and the DCP performed by a trained nurse counselor (the PhD student) in one home visit. This home visit was scheduled at the patients’ initial visit for a home appointment before their follow-up visit for an angiogram. The reason for using a home visit was the large possibility of diffusion of the intervention if the intervention took place at the hospital during the day of the angiogram. Patients were instructed to read the DA prior to the home visit. The components and features in the DCP were (see appendix B):

(1) CAD knowledge comprehension

The nurse counselor helped the patient to understand the information presented in the DA and how it might apply to his or her own illness history, answered questions, and discussed possible lifestyle options and the necessity of cardiac risk reduction behavior.

(2) Health beliefs about CAD and CAD progression.

The patient’s risk of CAD (HeartScore®) was presented and discussed together with the patient. HeartScore® (<http://www.heartscore.org/se/Pages/Welcome.aspx>) is an interactive tool for predicting and managing the risk of heart attack and stroke in Europe, and can be used to support clinicians to better identify patients at high total risk of developing cardiovascular disease, and through this information help individuals to engage in cardiac risk factor reduction behavior. The risk estimation is based on the following risk factors: gender, age, smoking, systolic blood pressure, and total cholesterol. The threshold for high risk for fatal cardiovascular events is defined as "higher than 5%".

(3) Identification of perceived benefits and barriers to cardiac risk reduction behavior.

The patients' perception of the importance of different cardiac risk reduction behavior was assessed by using a visual analog scale that allowed patients to assign importance weights ranging from 0 ("not at all important to me") to 10 ("extremely important to me") for (a) quitting smoking, (b) healthy diet (c) reach or maintain a healthy body weight, (d) exercise regularly, and (e) reduce stress. Patients were then instructed to use a work sheet to identify what perceived benefits and barriers for cardiac risk reduction behavior that were important to them. The perceived benefits and barriers to the perceived important cardiac risk reduction behavior were graded and recorded on a balance scale. The balance scale provided visualization of the strength/weight of perceived benefits and barriers to important cardiac risk reduction behavior for the patient.

(4) Finally, patients, together with the counselor, *developed a written action plan for cardiac risk reduction behavior* for the next six months.

Usual care. In the Control group patients received usual care which means that they did not receive the DA and/or the DCP. There were pamphlets available at the clinic to take home if the patients asked for it. The pamphlets were developed by the Norwegian Health Association, the Norwegian Directorate of Health, and The Norwegian Heart and Lung Patient Organization, LHL.

Fidelity of the interventions. The intervention DCP took place in patients' homes and was monitored strictly. The delivery of the intervention and monitoring of potential change over time were guided by training procedures, detailed manuals, and flow-charts that were monitored by personnel logs, personnel debriefing, and personnel monitoring of intervention delivery (see Appendix C).

The risk for the potential influence from other ongoing research studies/interventions in the department was monitored by communication with the administration staff and other potential investigators. During the study period there were no systematic interventions regarding cardiac risk reduction behavior at the Cardiac Outpatient clinic. To control for possible diffusion of the intervention among DA group, DA+DCP group and the Control group the patients were told not to share information from DA and/or DCP to other patients. They were asked twice (T2 and T4) for any other information they may have looked up, or

received during the study period; particularly any information learned in discussion with study patients in other study groups.

Research setting.

Patients were recruited at their initial visit at the Cardiac Outpatient Clinic at Oslo University Hospital HF -Rikshospitalet, which is a large cardiac outpatient clinic in Norway. Approximately 1700 patients per year with risk of CAD or CAD progression are referred electively to the clinic for work-up; 92-96% (n= 1600) are referred to a coronary angiogram approximately 1-5 days after this initial visit. Approximately 35% (n= 600) of the patients who have an angiogram undergo PCI during the procedure. Treatment options for the remaining 65% (n= 1100) are medication or CABG surgery.

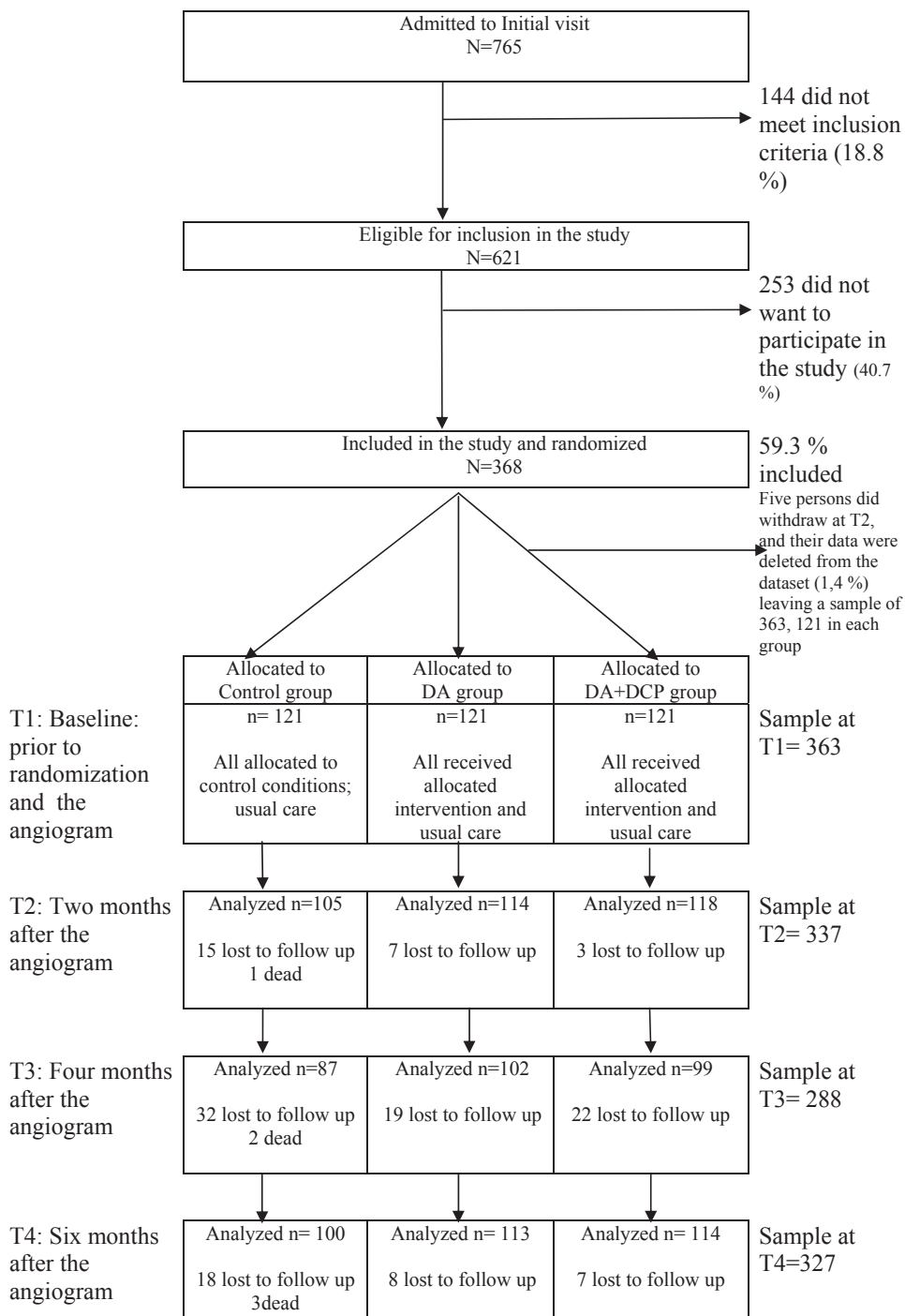
Participants

Sample eligibility criteria. All patients with risk of CAD or CAD progression referred to an elective coronary angiogram at the Cardiac Outpatient Clinic were candidates for this study if they were (1) age 18 and older, (2) able to read, write, and speak Norwegian, (3) lived within approximately 200 km of Oslo because of the distance to drive for the counselor, and (4) had a telephone. They were not eligible for the study if they had cognitive impairments.

Sample size. The sample size was determined using the power analysis procedures described by Cohen (1988). To estimate the effect size for the proposed study, previous studies on the same population of similar variables were reviewed (Chew et al., 1998; Morgan et al., 2000; Thanavaro et al., 2006). Given the effect sizes from the above studies, the proposed study used a medium effect size $ES=.25$. A sample size for Analysis of Covariance (ANCOVA) was computed for two sets of dependent variables, where a probability level of .05 and a power of .80 was selected based on the minimum basis for rejecting the null hypothesis using two tailed tests of significance (Lipsey, 1990). The Bonferroni correction was used to prevent inflation of the alpha level when testing three hypotheses on differences between the two intervention groups and the control group. According to the sample size table (Cohen, 1988) and G*Power analysis program (G*Power analysis program (<http://www.psych.uni-duesseldorf.de/aap/projects/gpower/>)) the estimated sample size was 106 per group. Accounting for an estimated 10% attrition rate over the 6 month study period, the sample size of 120 patients per group, or a total of 360 patients were required (Cohen, 1988).

The flow of patients during the study. Figure 3 shows the flow of patients through the study. Five patients told us they wanted to withdraw from the study at T2, and their data from baseline were deleted from the dataset, leaving 121 patients in each group at baseline. As seen in Figure 3 we received less questionnaires at T3, however, the patients remained enrolled in the study, and we received their measurement at T4, leaving more measurements in the study at T4 than at T3.

Figure 3. Flowchart of patient enrollment, randomization, and follow up through the study



The patients who did not meet the inclusion criteria were monitored by their age and gender and reason for not meeting inclusion criteria. The patients who did not want to be enrolled in the study were monitored by their age and gender. An overview of patients' age and gender are summarized in Table 4.

Table 4

Age and gender of participants and non-participants

	Male				Female				All		
	n	%	Age	SD	n	%	Age	SD	n	Age	SD
Admitted to Initial visit	464	60.7	62.94	(10.94)	301	39.3	61.94	(11.52)	765	62.55	(11.17)
Did not meet inclusion criteria	83	57.6	63.65	(11.31)	61	42.4	56.97	(14.71)	144	60.82	(13.23)
Eligible for inclusion in the study	381	61.4	62.79	(10.86)	240	38.6	63.20	(10.22)	621	62.95	(10.61)
Did not want to be enrolled in the study	152	60.1	63.53	(11.72)	101	39.9	64.92	(10.74)	253	64.09	(11.33)
Included in the study and randomized	229	62.2	62.29	(10.26)	139	37.8	61.96	(9.67)	368	62.17	(10.03)
Sample analyzed at T1	224	61.7	62.41	(10.27)	139	38.3	61.96	(9.67)	363	62.24	(10.03)
Control	75	62.0	63.25	(12.02)	46	38.0	61.41	(10.20)	121	62.55	(11.35)
DA	76	62.8	62.66	(9.32)	45	37.2	63.20	(9.61)	121	62.86	(9.39)
DA+DCP	73	60.3	61.29	(9.24)	48	39.7	61.31	(9.30)	121	62.24	(10.03)

Note: Values are presented as Mean (Standard Deviation), count and percent. Age is measured in years

Patients who did not meet inclusion criteria were younger and a larger proportion was women. The causes for not meeting the inclusion criteria were: not referred to coronary angiogram (58, 3 %); not speaking Norwegian (19.4 %); referred to examination before valve surgery (13.9%); and problems due to aphasia, deafness, dyslexia, or dementia (8.3%). Patients who did not want to participate in the study were older than those enrolled.

Measurement

Measurement of variables and instruments in the RCT

Study concepts, variables, and instruments are summarized in Table 5 and described in the paragraphs that follow.

Table 5.

Study variables and their measurements

Variables	Instruments	Authors	Data Source	T1 Base- line	T2 Two months after angio- gram	T3 Four months after angio- gram	T4 Six months after angio- gram
Primary outcome							
Body weight	Self-report Recorded in medical record	Self-constructed questionnaire	Self administrated questionnaire Medical record	X	X	X	X
Blood Cholesterol level	Blood test recorded in medical record Self-report	Self-constructed questionnaire	Self administrated questionnaire Medical record	X	X	X	X
Blood pressure	Self-report Recorded in medical record	Self-constructed questionnaire	Self- administrated questionnaire Medical record	X	X	X	X
Health service use	Patient diary	U.S. Congress, Office of Technology Assessment, 1990	Diary	X	X	X	X
Smoking and Amount of tobacco	Self report	Self-constructed questionnaire	Self- administrated questionnaire/	X	X	X	X
Health-related quality of life	SF-36 Seattle Angina Questionnaire (SAQ)	Medical Outcomes Study; Stewart et al., 1992 Spertus et al., 1995	Self administrated questionnaire	X	X	X	X
Intermediate Outcome							
Adherence to cardiac risk modification behavior	Health Behavior Scale (HBS)	Miller et al. 1982a; 1982b, 1990	Self- administrated questionnaire		X	X	X
Mediating variables							
Intentions to adhere to cardiac risk modification behavior	Health Behavior Scale (HBS) – modified	Miller et al. 1982a; 1982b, 1990	Self- administrated questionnaire	X			
Knowledge about risk factors and CAD	Knowledge Questionnaire	(http://www.healthline.com/sw/qz-heart-disease-prevention-quiz)	Self- administrated questionnaire	X	X		

Variables	Instruments	Authors	Data Source	T1	T2	T3	T4
				Base-line	Two months after angiogram	Four months after angiogram	Six months after angiogram
Health Beliefs: Perceived susceptibility and severity of CAD progression	Health Belief Questionnaire	Mirotnik et al., 1995	Self-administrated questionnaire	X	X		
Perceived benefits and barriers of cardiac risk reduction behavior	Benefits Scale Barriers Scale	Murdaugh & Verran, 1987	Self-administrated questionnaire	X	X		
Decisional conflict	Decisional Conflict Scale	O'Connor, 1995; 1999	Self-administrated questionnaire		X		
Control variables							
Demographics	Gender & Age	Self-constructed questionnaire	Self-administrated questionnaire/Medical record	X			
Cardiac functional status	Canadian Cardiovascular Society's Grading of Angina Pectoris- CCS Ejection Fraction	Campeau, 1972; 2002	Self-administrated questionnaire Medical record	X	X	X	X
Previous cardiac events	Previous MI, PCI, CABG	Self-constructed questionnaire	Medical record	X			
Disease severity	Result from the angiogram, number of arteries with significant stenosis	Self-constructed questionnaire	Medical record	X			
Comorbidity	Charlson Comorbidity Index (www.medalreg.com).	Charlson, et al., 1987	Patient/Medical record	X			
Medication intake: - anti-cholesterol medicine - antihypertensive medicine	Taking medication Taking medication	Self-constructed questionnaire	Self-administrated questionnaire/ Medical record	X	X	X	X
Received treatment	CABG surgery, PCI, Medication only, None	Self-constructed questionnaire	Medical record	X			
Descriptive variables							
Demographic	Marital status, Education level, Total household income, Risk factors associated with CAD, and Smoking history.	Self-constructed questionnaire	Self-administrated questionnaire	X			
Acceptability of DA and DCP	Acceptability Questionnaire	Ottawa Hospital Research Institute-Ottawa Hospital, Canada(http://decisionaid.ohri.ca/docs/develop/Tools/Acceptability_osteoporosis.pdf)	DA group and DA+DCP group only. Self-administrated questionnaire		X		
Diffusion of intervention	Measure of possible intervention diffusion between groups	Self-constructed questionnaire	Self-administrated questionnaire		X		X

Primary outcomes

Body weight, serum cholesterol, and blood pressure were collected from medical records and patient questionnaires as these measures were not always available in the medical record. Body mass index (BMI) was calculated based on patients' self-reported body weight and height. A baseline measurement of blood pressure (BP) was collected from the medical record at patients' initial visit at the Cardiac Outpatient Clinic. Baseline measurement of cholesterol levels were analyzed at Oslo University Hospital HF- Rikshospitalet as a part of patients' examination at the hospital and were collected from medical records. Total cholesterol, Low-density lipoprotein (LDL), and High-density lipoprotein (HDL) were measured in mmol/L. All follow-ups of Cholesterol levels and BP were measured by patients' primary physician and sent as self-report.

Health service use was measured using an adapted version of the 21-item U.S. Congress, Office of Technology Assessment (1990) tool for health service use. The patients were able to select their use of four predetermined examples of health services focusing on reduction of cardiac risk during the last two months. The four services encompassed participation in cardiac rehabilitation, smoking cessation programs, diet meetings, and weight reduction meetings.

Smoking and amount of tobacco used were measured as self-reported yes/no, if yes: how many cigarettes and/or Packs of tobacco, and/or packs of snuff the patient smoked/used per week. These numbers were re-calculated into grams tobacco consumed every week.

Health-related quality of life was measured with the SF-36, originated from the Medical Outcomes Study (Stewart, Hays & Ware, 1992) and 2 subscales from the Seattle Angina Questionnaire (SAQ). The SF-36 is a generic 36 item health status questionnaire that reports HRQoL on the following scales: Physical functioning, Role functioning-physical, Bodily pain, General health, Vitality, Social functioning, Role functioning-emotional and Mental health (Ware Jr & Sherbourne, 1992). The raw scores on the scales are transformed to a score from 0-100, with higher value indicating a better level of functioning. The SF 36 was used in this study as it is widely used as the "standard" reference measure of HRQoL across patient populations and has been validated and used in patients with CAD (Brown et al., 1999; Dempster & Donnelly, 2000; Dougherty et al., 1998; Failde & Ramos, 2000; McHorney et al., 1994; Smith et al., 2000; Ware et al., 2000). It allows comparisons between

this study and other patient populations from the literature. The reliability of the SF 36 has been well established in many studies. We used SF-36 Norwegian version 2.0. In this study the reliability measured as Cronbach's alpha ranged from .75 to .94 at baseline, and all subscales showed increased Cronbach's alpha throughout the study period on the SF-36 subscales. Cronbach's alpha as a measure of reliability at T4 in this study ranged from .83 to .96.

The patient's level of satisfaction with the treatment for chest pain, chest tightness, or angina, and the limits in quality of life because of chest pain, and chest tightness were measured with 2 subscales from the Seattle Angina Questionnaire (SAQ) which is a disease specific, self-administrated instrument designed to measure CAD patients' symptoms, function and quality of life. It has well-established validity, reproducibility, sensitivity to clinical change, reliability, and prognostic value (Dempster & Donnelly, 2000; Pettersen et al., 2005; Spertus et al., 1995; Spertus et al., 2002a; Spertus et al., 2006a). It has been used to assess outcomes in clinical trials, measure quality of care and support patient management (MacDonald et al., 1998; Spertus et al., 2002a, 2002b). In this study we only used the Treatment Satisfaction Scale (TSS) (4 items) quantifying satisfaction with current treatment of angina; and the Disease Perception Scale (DPS) (3 items), characterizing how patients perceive the disease to affect their quality of life (Rumsfeld, 2002). Items are scored on 5- or 6-points scales. Each score on the two scales is calculated as the sum of item scores in the domain, and scores are standardized to a 0-100 scale with higher value reflecting better health and functioning (Bernstein et al., 1998; Spertus et al., 1995). In this study, Cronbach's alpha as a measure of internal consistency was .91 and .66 respectively.

Intermediate adherence outcomes

Adherence to cardiac risk reduction behavior was defined as the actual performance of prescribed actions on cardiac risk reduction regimen, (Miller et al., 1982b) and was hypothesized as an intermediate outcome. Adherence to cardiac risk modification behavior was measured using the Adherence to Cardiac Risk Factor Modification Health Behavior Scale (HBS) (Miller et al., 1982b; Miller et al., 1990). The HBS assesses the behavior of an individual performance or non-performance of prescribed cardiac risk reduction behavior. HBS for adherence is a 20-item scale to which patients respond on a 5-point Likert scale ranging from 1 ("rarely") to 5 ("almost always"). The wording is 'I follow' two, four, and six months after the angiogram and elicits patients' self-assessment of actual following diet, stop

smoking, performing activity, taking medications, and modifying responses to stress. The average total score range is 5-25 with higher score indicating greater adherence. Cronbach's alpha for the HBS have ranged from 0.81 to 0.99 (Miller et al., 1990). Content validity was established by experts in nursing, medicine, and psychology (Miller et al., 1982a; Miller et al., 1982b). In this study, Cronbach's alpha as a measure of internal consistency ranged from .89 to .93.

Mediating variables

A set of mediating variables was hypothesized to be a mechanism by which the interventions were affecting the intermediated outcomes and the primary outcomes.

Intention to adhere to cardiac risk reduction behavior was defined as the intention of performing the prescribed actions on a cardiac risk factor reduction regimen. (Miller et al., 1982b). Intentions to adhere to cardiac risk modification behavior were measured using the Adherence to Cardiac Risk Factor Modification Health Behavior Scale (HBS) (Miller et al., 1982b; Miller et al., 1990) as described above. The HBS for intention have response categories from 1 ("unlikely") to 5 ("likely"). The wording is 'I will follow in the future'. The average total score range is 5-25 with higher score indicating greater intention to adhere to cardiac risk reduction behavior. Content validity was established by experts in nursing, medicine and psychology (Miller, et al., 1982a; 1982b). Cronbach's alpha for the HBS have ranged from 0.81 to 0.99 (Miller et al., 1990). In this study, Cronbach's alpha as a measure of internal consistency ranged from .79 to .92.

Knowledge about risk factors and CAD. Patients' knowledge about steps to reduce their risk for heart disease was assessed using a Heart Disease Prevention Quiz (<http://www.healthline.com/sw/qz-heart-disease-prevention-quiz>). The quiz contains 10 questions that assess knowledge about causes of heart disease, effects of restricted or blocked arteries, non-modifiable risk factors, borderline level for total cholesterol, considerations of "high blood pressure", effects of smoking on heart disease, necessary minutes of daily exercise to prevent heart disease, the rise of risk when body mass index is more than 24.9, effects of too much alcohol, and symptoms of heart attack. Each question may have several correct answers. Scores range from 0-21 with higher scores indicating more correct answers regarding risk factors and CAD.

Health Beliefs is defined as perceived susceptibility and perceived severity of receiving CAD or CAD progression for the patients already diagnosed.

Perceived susceptibility of CAD or CAD progression was measured using the subscale for perceived susceptibility to illness from the Health Beliefs Questionnaire. The questionnaire was developed through operationalizing the dimensions in the Health Belief Model in the context of CAD patients to predict adherence to a rehabilitation exercise program. (Mirotznik et al., 1995; Mirotznik, Ginzler, Zagon & Baptiste, 1998). The perceived susceptibility subscale is an 8 item 5-point Likert scale ranging from 1 (“Strongly agree”; “Not easily at all”; “Much less susceptible”; “Very unlikely”; “Not at all at risk”; “No chance at all”) to 5 (Strongly disagree”; “Extremely easily”; “Much more susceptible”; “Very likely”; “At very large risk”; “A very good chance”). To obtain a total score each item is summed up and averaged. The average total score range is 1-5. Higher scores mean higher perceived susceptibility to illness. In this study, Crohnbach’s alpha as a measure of internal consistency was .66.

Perceived severity of CAD or CAD progression was measured using the subscale for perceived severity of illness from the Health Beliefs Questionnaire (Mirotznik et al., 1995; Mirotznik et al., 1998). The questionnaire was developed through operationalizing the dimensions in the Health Belief Model (Eraker et al., 1984) and the context of CAD patients. The questionnaire was used to predict adherence to a rehabilitation exercise program. The perceived severity subscale is 11 item 5-point Likert scale ranging from 1 “Very unlikely”; 5 “Very likely”. To obtain a total score each item is summed and averaged. The average total score range is 1-5. Higher scores indicate higher perceived severity of illness. In this study, Crohnbach’s alpha as a measure of internal consistency was .88.

Psychometric assessment indicated that perceived susceptibility and severity had various internal consistency reliability (mean alpha .80, range from .69 - .89) as well as test-retest stability (mean Pearson r correlation .75, range from .71 to .80). The construct validity of the Health Belief Model measures was established in a confirmatory factor analysis (Personal note from J. Mirotznik, 2006).

Perceived benefits of cardiac risk reduction behavior were measured using the Benefits Scale (Murdaugh & Verran, 1987). The Benefits Scale measure the perceived benefits to undertake cardiac risk reduction behavior and is self-report questionnaire consisting of 12 statements describing benefits to undertaking preventive behaviors. Participants indicate the extent of their agreement or disagreement with each statement using a 4-point Likert scale ranging from 1 (“Strongly disagree”) to 4 (“Strongly agree”). To obtain a total score each item is summed and averaged. The average total score range is 1-4. Higher scores indicate greater perceived benefits of cardiac risk modification behavior. The statements for the Benefits scale were generated from a review of studies testing the Health Belief Model, and construct validity was estimated with factor analysis; one rotated factor accounted for 85% of the variance obtained for the benefit scale (Murdaugh & Verran, 1987). The coefficient alpha reliability was .72 to .79 indicating it was a reliable tool for assessing barriers of undertaking cardiac risk factor modification behavior in healthy adults (Murdaugh & Verran, 1987). In this study, Crohnbach’s alpha as a measure of internal consistency was .85.

Perceived barriers to cardiac risk reduction behavior were measured using the Barriers Scale (Murdaugh & Verran, 1987). The Barriers Scale measures the perceived barriers to undertake cardiac risk reduction behavior, and is self-report questionnaire consisting of 12 statements describing barriers to undertaking preventive behaviors. Participants indicate the extent of their agreement or disagreement with each statement using a 4-point Likert scale. Responses range from 1 (“Strongly disagree”) to 4 (“Strongly agree”). To obtain a total score each item is summed and averaged. The average total score range is 1-4. Higher scores indicate greater perceived barriers to cardiac risk modification behavior. The statements for the Barriers scale were generated from a review of studies testing the Health Belief Model, and construct validity was estimated with factor analysis; two rotated factors accounted for 85% of the variance obtained for the Barriers scale. One factor loaded personal barriers and the other loaded general barriers (Murdaugh & Verran, 1987). The coefficient alpha reliability was .72 to .76 indicating it was a reliable tool for assessing barriers of undertaking cardiac risk factor modification behavior in healthy adults (Murdaugh & Verran, 1987). In this study, Crohnbach’s alpha as a measure of internal consistency was .85.

Decisional conflict was defined as a patient's state of uncertainty about which option to choose, the factors contributing to this uncertainty, and the effectiveness of the decision. (O'Connor, 1999). Decisional conflict was measured using the 16 item Decisional Conflict Scale (O'Connor, 1995, 1999) that measures a person's perception of the difficulty making a decision, ranging on a 5-point Likert scale from 0 ("strongly agree") to 4 ("strongly disagree"). This study used the Statement format. Total score for Decisional Conflict range from 0 (no decisional conflict) to 100 (extremely high decisional conflict). There are five subscores: their perceived (1) Uncertainty in choosing between options: 3 items with scores range from 0 (feels extremely certain about best choice) to 100 (feels extremely uncertain about best choice). Three modifiable factors contributing to uncertainty such as (2) Feeling uninformed subscore; 3 items with scores range from 0 (feels extremely informed) to 100 (feels extremely uninformed); (3) Feeling unclear about personal values subscore; 3 items with scores range from 0 (feels extremely unclear about personal values for benefits and risks) to 100 (feels extremely unclear about personal values), and (4) Feeling unsupported in decision making subscore; 3 items with scores range from 0 (feels extremely supported in decision making) to 100 (feels extremely unsupported in decision making). The last subscore is (5) Quality of choice selected subscore, which is defined as informed, consistent with personal values, with which a person expresses satisfaction and expects to maintain 4 items . In previous studies the test, re-test, and alpha coefficients for this instrument exceeded 0.78, were sensitive to change (O'Connor et al., 1998a; Drake, Engler-Todd, O'Connor, Suhr, & Hunter, 1999; Fiset, O'Connor, Evans, Graham, DeGrasse, & Logan, 2000), and discriminated between different decision support interventions (Man-Son-Hing, et al. 1999; O'Connor et al., 1998b). Scores lower than 25 are associated with implementing decisions; scores exceeding 37, 5 are associated with decision delay or feeling unsure about implementation (O'Connor, 2005). In this study, Cronbach's alpha as a measure of internal consistency was .93.

Control variables

Gender is a dichotomous, categorical variable and was measured by self report.

Age was measured on a ratio level scale defined as present age in years, collected at baseline by the patient's response to a self reported question of age in years.

Cardiac functional status was measured in two ways: (1) the Canadian Cardiovascular Society's Grading of Angina: Grade 0: Asymptomatic; Grade I: Angina only during strenuous or prolonged physical activity, Grade II: Slight limitation, with angina only during vigorous physical activity Grade III: with mild exertion: a. Walking 1-2 level blocks at normal pace, b. Climbing one flight of stairs at normal pace, Grade IV: Inability to perform any activity without angina or angina at rest, i.e., severe limitation (Campeau, 1976; 2002). (2) The ejection fraction (EF). The EF is the fraction of blood ejected by the left ventricle relative to its end-diastolic volume and is reported as a percentage (interval scale measurement). The EF was extracted from the patient's medical record after the angiogram as a clinical index to evaluate the inotropic status of the heart. However, EF was missing in medical record unless the patient had CABG surgery.

Previous cardiac events were collected from medical record and categorized in previous myocardial infarction (MI), previous PCI, and previous CABG surgery.

Disease severity was defined as the objective seriousness of the patient's cardiac disease based on the findings in the angiogram measured as the numbers of vessels with significant (> 50%) stenosis.

Comorbidity was assessed using the Charlson's Comorbidity Index (CCI) developed to ascertain the presence of comorbid conditions that contribute significantly to the overall burden of disease as well as being significant predictors of morbidity and mortality. The CCI is a weighted index, composed of 16 conditions, with higher numbers representing a poorer prognosis. The index predicts mortality immediately after hospitalization and after 10 years, which supports its predictive validity. Also, validity has been supported through significant correlations with six-week hospital mortality, and length of stay (Charlson, Pompei, Ales, & MacKenzie, 1987). Data to ascertain the CCI was collected from the patient's medical record and entered without personal identification into a computerized version of CCI (<http://www.medal.org/OnlineCalculators/ch1/ch1.13/ch1.13.01.php>).

Medication intake was collected by self-report about; taking anti cholesterol medication or not, and taking antihypertensive medication or not (yes/no).

Received treatment was obtained from the medical record based on the treatment following the angiogram into; (1) CABG with or without valve surgery, (2) PCI, (3) medication treatment only, and (4) no medication or medical treatment.

Descriptive variables

Demographics included: marital status, education level, total household income, risk factors associated with CAD (patients' response to their subjective presence or not to increased body weight, increased blood pressure, emotional stress, diabetes, increased cholesterol levels, lack of regular physical activity, and heredity for CAD), and smoking history. Smoking was measured as the number of cigarettes and/or packs of tobacco, and/or packs of snuff the patient smoked/used per week. Two data collection forms were used to describe demographic variables. One form to collect data from the patient's medical record, and one form for the patients to complete.

Acceptability of the DA and DCP was assessed by self-report using open- and closed-ended questions based on an acceptability questionnaire developed by the Ottawa Hospital Research Institute, Ottawa Hospital, Canada: (http://decisionaid.ohri.ca/docs/develop/Tools/Acceptability_osteoporosis.pdf). Closed-ended questions elicited feedback on the ways the information was presented, length, amount, and usefulness of the information, and whether the information was presented in a balanced manner.

Diffusion of the intervention was measured to control for eventual leak of information from patients in DA group and DA+DCP group to the others by asking patients of sources of information during study period twice, two months (T2), and six months (T4) following the angiogram.

Procedures

Information to staff. Administrators at Oslo University Hospital HF- Rikshospitalet were approached for permission to recruit patients, and the head of the department gave his support. Prior to the patient recruitment period, a meeting between the research staff and

clinical staff was conducted, and clinicians who were expected to see patients were informed about the study and asked for their support.

Patient enrollment. During the recruitment period three persons, either one of the two study's Interview Assistants (IAs) or the PhD student went to the Cardiac Outpatient Clinic every morning. Patients coming for their initial work-up visit had received a letter at home before this first visit with information about the study and an invitation to participate. Those who were referred to an angiogram and met the other inclusion criteria were identified by the nurse or primary physician during the consultation and referred to the present IA waiting in the next room. The IA ensured that the inclusion criteria were met by explicitly asking the nurse and /or primary physician for the patients' orientation for time, person, and place before further approach. The patient then had the purpose of the study explained and asked for their written informed consent. Intervention assignments were not computed until after participants had completed baseline questionnaires. Because of the anesthetic drugs used during the angiogram we enrolled the patients on their initial work-up visit and not at the visit when they had their angiogram done. The recruitment period took place from April 2008 to January 2009.

Randomization and data collection from patients. Patients who gave their consent to participate were asked by the IA to complete baseline measurements as described in Table 5. After completion of these baseline measures patients were randomly assigned to study groups by the IA. A computer program was used in the allocation sequence, and the program used the minimization method for random assignment (Zeller, Good, Anderson, & Zeller, 1997). The computerized minimization algorithm simultaneously capitalized on the benefits of random assignment and, at the same time, equalized the proportion of cases on covariates, so that differences between groups on covariates did not emerge based on the "randomness" of random assignment. To ensure that the sample was as equalized as possible for the population the study groups were equalized on gender. The assignment of participants to groups was done with the patient present. The IA selected the correct gender on the computer screen and entered the "Auto assign group". The patients' assigned ID number and group assignment showed immediately at the computer screen, and the IA showed the patients their group assignment and told them what it involved. Patients in the DA group and DA+DCP group received the DA to take home at this visit. In addition, for DA+DCP group an appointment was set up for a home visit by the nurse counselor. Patients were instructed to read the DA

prior to this home visit. Patients in the Control group were told that they would receive the DA by mail when they had completed the data collection six months later, which they did. Due to the nature of the intervention, blinding was not possible in this study.

Approximately two months (T2), four months (T3), and six months (T4) after the angiogram, all patients were asked to complete the T2, T3, and T4 questionnaires that were mailed to them along with a stamped, addressed envelope for the return of questionnaires. To minimize attrition and maximize response rate, a phone call was made to patients who have not returned the questionnaires one week after two, four and six months after the date of the angiogram and they were offered to answer the questionnaires by interview over the phone. The data collection was completed in August 2009.

Chart abstraction. Data collection from patients' medical record was done by the researcher. Chart abstraction included blood pressure and lipids at the initial visit, previous cardiac events, and the results from the angiogram including following treatment.

Human subjects and ethical considerations

Prior to the Phase II, approval was obtained from the Regional Review Board (REK) the 18th of February 2008 and The Data Inspectorate the 19th of February 2008. The proposed study involved the recruitment of 368 patients who were scheduled for an angiogram. Patients received a written description stating the purpose, nature, risks, and benefits of the study, and were asked to sign a written informed consent. They kept a copy of the consent form that included the phone number of the PhD student who was available for any questions and concerns. Patients were assured that their participation was voluntary and that they could withdraw from the study at any time. There were no costs to patients, and they were not being paid for participation. There were no anticipated physical risks from any data collection procedures. Any psychological risks were likely to be restricted to the degree that the study may have focused patients' attention on their serious health condition. To safeguard confidentiality, patients were assigned a sequential record number (computer generated) at the time of enrollment. No names appeared on any data collection forms. All personal identification was separated from the data set except for the coding list with identification numbers; that list was kept in a locked file cabinet in the PhD student's office, and destroyed

at the end of the study. All results were reported in aggregated form. No breach of confidentiality occurred.

Data analysis

Collected data were entered into SPSS statistical software version 16 (SPSS Inc., Chicago, IL) and R version 2.9.1 (Venables, Smith and the R Development Core Team) for subsequent analysis of research questions. Exploratory data analytic techniques were used to ensure the appropriateness of data for the proposed analyses. Between group baseline comparisons of variables were evaluated with Chi-square tests and a simple analysis of variance (ANOVA).

To test the hypothesis 1-3 the *effects* of the interventions were assessed using analysis of covariance (ANCOVA) to investigate changes in the variables at six months controlled for baseline values.

To answer research questions 1-4 analyzing relationships between intermediate adherence outcomes and primary health outcomes and HRQoL; between primary health outcomes and HRQoL, and between possible mediating variables (knowledge about risk factors and CAD, perceived susceptibility and severity of CAD and CAD progression, perceived benefits and barriers of cardiac risk reduction behavior, and decisional conflict), and adherence to cardiac risk reduction behavior, the data was analyzed using linear mixed effect models which is interested in the pattern of change over time (Pineiro & Bates, 2000). The slope of a line represents the rate of change over time by analyzing the slope of the line that most accurately fits the four data points; baseline, two, four, and six months following the angiogram. The results of these models indicate whether changes in the values of a trait from baseline to follow-up. A slope of 0 indicates no change. To investigate the overall relationships in the proposed model, the mixed effect model included all available follow-up data. The model included random effects in intercept and slope. If the model was unstable, we included random effects in intercept only.

Research questions 5 and 6 asking about the acceptability to patients of the DA group and DA+DCP group were answered using descriptive statistics and Chi-square tests.

Chapter 4

Results

Preliminary data analysis

Data was entered into SPSS statistical software version 16 (SPSS Inc., Chicago, IL) and R version 2.9.1 (Venables, Smith and the R Development Core Team) and 10% were randomly assessed a second time to ensure accuracy. Descriptive analyses were conducted to examine the data for frequency distributions, out of range values, outliers, and missing data. Frequencies of all variables revealed no out of range values.

Missing data

There was a small amount of randomly missing data that was replaced according to manuals and literature when at least 50% of the questions were answered (Ware, Kosinski, & Dewey, 2000; Ware, Kosinski, & Gandek, 2000). The adherence scales and SAQ scales showed most missing data. The amount of missing data is addressed in superscript or by numbers (n) in the following tables.

Testing the assumptions for data analysis techniques

To evaluate the assumptions for regression analysis and the presence of potential influential data points and multicollinearity, a regression diagnostic was run (Tabachnick & Fidell, 2001). The residuals were normally distributed assessed by QQ-plots. The variance of the residuals at one point was equal to the variance at another point (homoscedasticity), assessed by the scatter plot to look for an even random scatter or a scatter spread around the zero line. To detect potential highly correlated IVs, the Tolerance was examined, and there were no high correlations between independent variables.

Preliminary checks were conducted to ensure that there were no violation of the assumptions of normality, linearity, homogeneity of variances, homogeneity of regression slopes, and reliable measurement of the covariate.

Baseline data

Testing for equivalence among groups

Even if the patients were randomly assigned to groups, we tested groups for equivalence on variables that could have influenced the results. Groups were compared on demographic variables, covariates, and risk factors.

Demographic characteristics of the study sample are summarized in Table 6, 7, 8 and 9. As seen in these tables there were no significant differences in baseline measures between study groups.

Table 6

Age and gender of participants during the study period

	Male				Female				All		
	n	%	Age	SD	n	%	Age	SD	n	Age	SD
Sample analyzed at T1	224	61.7	62.41	(10.27)	139	38.3	61.96	(9.67)	363	62.24	(10.03)
Control	75	62.0	63.25	(12.02)	46	38.0	61.41	(10.20)	121	62.55	(11.35)
DA	76	62.8	62.66	(9.32)	45	37.2	63.20	(9.61)	121	62.86	(9.39)
DA+DCP	73	60.3	61.29	(9.24)	48	39.7	61.31	(9.30)	121	62.24	(10.03)
Sample analyzed at T2	210	62.3	62.46	(10.28)	127	37.7	62.69	(9.14)	337	62.55	(9.85)
Control	69	65.7	63.26	(12.29)	36	34.3	62.83	(9.24)	105	63.11	(11.29)
DA	70	61.4	62.81	(8.96)	44	38.6	63.61	(9.31)	114	63.12	(9.06)
DA+DCP	71	60.2	61.34	(9.36)	47	39.8	61.70	(8.99)	118	61.48	(9.18)
Sample analyzed at T3	184	63.9	62.97	(9.57)	104	36.1	63.04	(8.57)	288	62.99	(9.21)
Control	57	65.5	64.70	(10.83)	30	34.5	62.93	(8.94)	87	64.09	(10.20)
DA	66	64.7	62.50	(9.27)	36	35.3	63.31	(8.54)	102	62.78	(8.99)
DA+DCP	61	61.6	61.85	(8.51)	38	38.4	62.87	(8.54)	99	62.24	(8.49)
Sample analyzed at T4	203	62.1	62.66	(10.29)	124	37.9	62.87	(8.77)	327	62.74	(9.73)
Control	65	65.0	63.52	(12.38)	35	35.0	62.37	(8.94)	100	63.12	(11.26)
DA	70	61.9	62.81	(8.96)	43	38.1	64.02	(9.01)	113	63.27	(8.96)
DA+DCP	68	59.7	61.66	(9.41)	46	40.3	62.17	(8.48)	114	61.87	(9.02)

Note: Values are presented as Mean (Standard Deviation), count and percent. Age is measured in years

Table 7

Group mean and SD at baseline for age, amount of tobacco, body weight, BMI, cholesterol levels, blood pressure, CCS, HeartScore[®], and comorbidity

	n	Control group		DA group		DA+DCP group		Total sample N=363		F	p-value
		M	SD	M	SD	M	SD	M	SD		
Age	363	62.55	(11.35)	62.86	(9.39)	61.3	(9.23)	62.24	(10.03)	0.823	.440
Amount of tobacco	87	62.21	(48.58)	62.97	(66.06)	69.17	(54.17)	64.78	(56.16)	.132	.877
Body Weight	363	81.67	(16.59)	84.70	(16.70)	82.29	(16.13)	82.89	(16.53)	1.14	.322
BMI	363	27.16	(4.10)	27.88	(4.95)	27.34	(4.25)	27.46	(4.44)	0.869	.420
Cholesterol levels											
Total cholesterol	362	4.52	(1.02)	4.49 ⁻¹	(0.97)	4.56	(0.98)	4.53	(0.99)	0.174	.841
LDL	362	2.63	(0.87)	2.61 ⁻¹	(0.88)	2.74	(0.85)	2.66	(0.87)	0.768	.465
HDL	362	1.36	(0.56)	1.35 ⁻¹	(0.42)	1.31	(0.36)	1.34	(0.46)	0.468	.627
Blood Pressure											
SBP	363	145.31	(22.27)	148.65	(20.35)	147.63	(22.45)	147.2	(21.70)	0.751	.473
DBP	363	78.98	(10.54)	80.01	(11.70)	79.50	(11.35)	79.49	(11.18)	0.257	.773
HeartScore[®]											
Baseline HeartScore [®]	362	4.54	(3.85)	5.10 ⁻¹	(3.94)	4.52	(3.80)	4.72	(3.86)	0.887	.417
Treatment goal HeartScore [®]	362	2.42	(1.74)	2.48 ⁻¹	(1.58)	2.31	(1.63)	2.40	(1.65)	0.358	.699
Comorbidity											
Weighted index of comorbidity	363	0.95	(1.10)	1.12	(1.3)	1.02	(1.20)	1.03	(1.20)	0.633	.532
Combined condition and age related scores	363	2.78	(1.72)	2.93	(1.65)	2.73	(1.60)	2.81	(1.66)	0.513	.599
Estimated 10 years survival	363	70.69	(27.72)	69.92	(28.32)	73.42	(26.01)	71.34	(27.33)	0.547	.579

Note: Values are presented as Mean (Standard Deviation). Numbers in superscript are the amount of missing data

Age= years of age; Amount of tobacco= gram tobacco consumed each week; Body weigh measured in kilogram; BMI =Body Mass Index calculated by weight in kg/height in m²; Total Cholesterol/Low-density lipoprotein(LDL)/ High-density lipoprotein (HDL) measured in mmol/L; Blood pressure=Systolic Blood pressure(SBP)and Diastolic Blood Pressure (DBP) measured in mmHg; HeartScore[®] is total CVD risk and refers to the 10-year risk mortality in percent; Comorbidity= Weighted index of comorbidity, Combined condition and age-related score and Estimated 10 year survival in percent

Table 8

Group distribution of demographic variables at baseline: gender, marital status, education, total household income, subjective risk factors, medication intake, grading of angina, and previous cardiac events

Demographic variables	Control group		DA group		DA+DCP group		Total sample	
	n	%	%	%	%	χ^2	p	
Gender	363					0.163	.922	
Male	224	62.0	62.8	60.3	61.7			
Female	139	38.0	37.2	39.7	38.3			
Marital status	363					5.840	.829	
Married	214	63.6	69.4	68.6	67.2			
Live-in partner	38	11.6	9.9	9.9	10.5			
Unmarried	13	5.0	2.5	3.3	3.6			
Separated	3	0.8	1.7	0.0	0.8			
Divorced	35	8.3	10.7	9.9	9.6			
Widowed	30	10.7	5.8	8.3	8.3			
Education level	363					2.467	.872	
Primary/Elementary School	94	29.8	22.3	25.6	25.9			
Secondary School	166	42.1	47.1	47.9	45.7			
College/University up to 4 years	66	19.0	19.0	16.5	18.2			
College/University more than 4 years	37	9.1	11.6	9.9	10.2			
Total household income	354					4.890	.769	
Less than 200 000NOK	38	8.3	12.9	11	10.7			
200 000-399 999 NOK	109	34.2	28.4	29.7	30.8			
400 000-599 999 NOK	104	28.3	32.8	27.1	29.4			
600 000-799 999 NOK	58	17.5	12.1	19.5	16.4			
More than 800 000NOK	45	11.7	13.8	12.7	12.7			
Subjective perceived risk factors associated with heart disease								
Increased body weight/obesity	347	37.6	50.4	47.8	45.2	4.315	.116	
High Blood Pressure	343	43.6	50.0	51.8	48.4	1.715	.424	
Emotional stress	334	41.6	50.5	49.1	47.0	2.050	.359	
Diabetes	339	12.1	14.8	14.8	13.9	0.476	.788	
High Cholesterol	321	40.6	39.6	46.2	42.1	1.079	.583	
Lack of regular physical activity	343	53.0	59.1	55.8	56.0	0.868	.648	
Smoking	363	24.0	24.0	24.0	24.0	0.000	1.00	
Heredity for CAD	350	51.3	54.7	50.8	52.3	0.416	.812	

Demographic variables	Control group		DA group	DA+DCP group	Total sample		p
	n	%	%	%	%	χ^2	
Medication intake							
Anti cholesterol medication	360	80.0	75.6	74.4	76.7	1.170	.557
Antihypertensive medication	358	68.9	68.6	69.4	69.0	0.018	.991
Self-reported Canadian Cardiology Society Grading of Angina	350					9.125	.322
Grade 0 No angina symptom	94	26.3	29.1	25.2	26.9		
Grade I	57	21.1	16.2	11.8	16.3		
Grade II	95	22.8	27.4	31.1	27.1		
Grade III	57	20.2	12.0	16.8	16.3		
Grade IV	47	9.6	15.4	15.1	13.4		
Previous cardiac events	363						
Previous myocardial infarction (MI)	90	25.6	22.3	26.4	24.8	0.621	.733
Previous PCI	75	16.5	24.0	21.5	20.7	2.117	.347
Previous CABG	47	13.2	10.7	14.9	12.9	0.929	.629

Note: Values are presented as Count and Percent

The study population had an average age of 62.2 (10.1). 38.3 % were women, about two third (67.2 %) were married, and 71.6 % had no further education after secondary school. The most often perceived risk factors were lack of physical activity (56.0 %), and heredity of early CAD (50.8%). The 87 smokers (24.0%) used an average amount of tobacco 64.78 gram (56.16) per week. The mean HeartScore® data at baseline was 4.72 (3.86), and the treatment goal based on the HeartScore® was 2.40 (1.65). Weighted index of comorbidity was 1.03 (1.20) with the estimate of 10 years survival at 71.34 (27.33).

76.7 % of the patients used anti- cholesterol medication, and 69.0 % used antihypertensive medication. 24.8 % had a previous MI, 20.7 % previous PCI, and 12.9 % previous CABG surgery.

We also compared groups for equivalence of results from the angiogram and further treatment after the angiogram. The angiogram results and further treatment are summarized in Table 9.

Table 9

Group distribution of results from the angiogram and further treatment

Demographic variables	n	Control group	DA group	DA+DCP group	Total sample	χ^2	p
		%	%	%	%		
Number of arteries with significant stenosis						10.396	.109
No significant vessels disease	165	37.2	52.1	47.1	45.5		
One vessel disease	76	29.8	15.7	17.4	20.9		
Two vessels disease	60	17.4	14.9	17.4	16.5		
Three vessels disease	62	15.7	17.4	18.2	17.1		
Received treatment						8.139	.228
None	48	15.7	12.4	11.6	13.3		
Medication only	179	41.3	53.7	52.9	49.3		
PCI	84	29.8	21.5	18.2	23.1		
CABG surgery	52	13.2	12.4	17.4	14.3		

Note: Values are presented as Count and Percent

Significant stenosis refers to > 50% stenosis in one or more of the coronary arteries

The angiogram revealed that 45.5 % had no significant vessel disease. The most frequent treatment after the angiogram was medication only (49.3 %), followed by PCI (23.1 %), CABG 14.3 %, 13.3 % of the patients received no treatment or medication for CAD.

There were no statistically significant differences in baseline characteristics, including potentially confounding variables such as angina symptoms, gender, age, previous cardiac

events, results from the angiogram, and treatment following the angiogram, and we therefore did not include these variables as covariates in the analysis.

Analysis of hypotheses and research questions

Effects on primary outcomes

Before we analyzed the effects of the interventions on primary outcomes, we computed means and SD for the three groups at each measurement point, regarding the primary health outcomes and HRQoL summarized in Table 10 and 11.

Table 10

Group mean and SD for health outcomes at baseline, two, four, and six months following the angiogram

Dependent variables	Group	n	Baseline			Two months			Four months			Six months		
			M	SD	n	M	SD	n	M	SD	n	M	SD	
Body Mass Index	Control	121	27.16	(4.10)	105	27.07	(4.04)	87	27.29	(3.94)	100	27.23	(4.23)	
	DA	121	27.88	(4.95)	114	27.59	(4.84)	102	27.75	(5.05)	113	27.54	(4.81)	
	DA+DCP	121	27.34	(4.25)	118	27.01	(4.12)	98	26.80	(3.88)	114	26.77	(3.97)	
Total Cholesterol	Control	121	4.52	(1.02)	21	4.68	(1.24)	24	4.48	(1.00)	26	4.70	(0.94)	
	DA	120	4.49	(0.97)	20	4.06	(1.01)	23	3.98	(0.60)	29	4.62	(1.01)	
	DA+DCP	121	4.57	(0.98)	30	4.12	(0.85)	41	4.27	(1.27)	24	4.80	(1.57)	
HDL	Control	121	1.36	(0.56)	14	1.31	(0.36)		1.31	(0.44)	15	1.42	(0.73)	
	DA	120	1.35	(0.42)	15	1.31	(0.49)	18	1.28	(0.42)	20	1.39	(0.27)	
	DA+DCP	121	1.31	(0.36)	23	1.22	(0.30)	37	1.28	(0.33)	19	1.40	(0.37)	
LDL	Control	121	2.63	(0.87)	14	2.32	(0.71)	20	2.57	(0.86)	15	2.32	(0.57)	
	DA	120	2.61	(0.88)	16	2.22	(0.75)	18	2.17	(0.59)	22	2.64	(0.85)	
	DA+DCP	121	2.74	(0.85)	26	2.26	(0.60)	34	2.28	(0.74)	19	3.03	(1.75)	
SBP	Control	121	145.31	(22.27)	48	131.42	(16.11)	39	133.05	(16.10)	42	134.83	(13.47)	
	DA	121	148.65	(20.35)	41	131.37	(14.47)	51	132.00	(12.95)	56	136.55	(17.64)	
	DA+DCP	121	147.63	(22.45)	53	133.57	(23.31)	52	134.44	(17.38)	64	135.23	(20.38)	
DBP	Control	121	78.98	(10.54)	48	76.85	(9.12)	39	77.54	(7.96)	42	78.52	(7.74)	
	DA	121	80.01	(11.70)	40	79.93	(9.32)	51	77.24	(9.99)	56	78.84	(10.20)	
	DA+DCP	121	79.50	(11.35)	52	77.06	(9.10)	52	78.19	(9.47)	64	81.75	(11.52)	
Amount of TOBACCO per week	Control	29	62.21	(48.58)	17	61.94	(34.15)	13	65.69	(54.42)	16	50.69	(26.59)	
	DA	29	62.97	(66.06)	19	56.89	(35.96)	17	59.77	(48.07)	19	53.21	(43.80)	
	DA+DCP	29	69.17	(54.17)	20	52.85	(46.70)	13	59.85	(46.79)	17	49.82	(47.48)	

Note: Values are presented as Mean (standard deviation).

Domain abbreviations and unit of measure as for Table 7.

Table 11

Group mean and SD for HRQoL at baseline, two, four, and six months following the angiogram

Dependent variables	Group	Baseline		Two months after the angiogram		Four months after the angiogram		Six months after the angiogram	
		M	SD	M	SD	M	SD	M	SD
Physical Functioning	Control	67.30	(21.76)	71.65	(23.44)	72.83	(24.07)	72.91	(24.45)
	DA	67.76 ⁻³	(24.41)	70.87 ⁻¹	(24.72)	72.96 ⁻³	(23.41)	73.04	(25.17)
	DA+DCP	68.29	(20.78)	72.89 ⁻¹	(22.86)	75.07	(22.86)	76.79 ⁻¹	(21.36)
Role Functioning - Physical	Control	56.63 ⁻¹	(29.84)	58.60 ⁻²	(33.82)	62.72	(32.10)	62.62	(31.37)
	DA	58.88 ⁻²	(29.86)	62.05 ⁻²	(31.15)	67.06 ⁻²	(30.51)	69.40 ⁻¹	(29.05)
	DA+DCP	56.00 ⁻²	(31.32)	62.97 ⁻²	(30.69)	72.11 ⁻¹	(26.68)	71.60 ⁻²	(27.38)
Bodily Pain	Control	54.44	(23.74)	60.28	(29.13)	63.11	(24.58)	61.61 ⁻¹	(27.67)
	DA	54.28	(25.35)	60.30 ⁻¹	(27.15)	65.29 ⁻¹	(27.80)	63.76 ⁻¹	(27.09)
	DA+DCP	53.41 ⁻¹	(24.55)	61.48 ⁻²	(26.85)	66.41 ⁻¹	(26.18)	63.26 ⁻¹	(26.90)
General Health	Control	56.87 ⁻⁷	(20.67)	57.24 ⁻³	(22.89)	59.79	(23.55)	58.53 ⁻²	(25.05)
	DA	54.32 ⁻¹	(20.95)	59.54 ⁻⁴	(23.29)	58.97 ⁻⁴	(22.85)	59.07 ⁻²	(22.60)
	DA+DCP	55.91 ⁻³	(19.17)	60.22 ⁻¹	(20.40)	61.50 ⁻⁴	(22.10)	63.35 ⁻²	(22.25)
Vitality	Control	42.85 ⁻⁵	(23.23)	46.14 ⁻³	(23.58)	49.28	(23.41)	49.14 ⁻¹	(25.05)
	DA	44.25	(22.75)	49.89 ⁻³	(22.07)	50.49 ⁻⁵	(22.31)	52.29 ⁻³	(22.14)
	DA+DCP	43.50 ⁻²	(21.58)	48.81 ⁻¹	(21.24)	54.43 ⁻³	(23.07)	54.20 ⁻¹	(22.64)
Social Function	Control	67.98	(27.14)	68.69	(28.80)	74.86	(23.15)	74.25	(26.10)
	DA	74.38	(25.86)	75.88	(28.01)	78.09 ⁻¹	(25.46)	77.23 ⁻¹	(27.33)
	DA+DCP	72.40 ⁻¹	(26.87)	75.21 ⁻¹	(25.69)	80.43	(24.82)	78.87 ⁻¹	(24.50)
Role Functioning - Emotional	Control	71.36 ⁻³	(27.53)	68.77 ⁻²	(34.02)	72.22	(28.29)	72.25	(30.13)
	DA	74.86 ⁻³	(28.01)	79.32 ⁻²	(26.83)	81.85 ⁻¹	(24.87)	80.21 ⁻¹	(25.73)
	DA+DCP	74.79 ⁻¹	(27.91)	80.10 ⁻²	(25.32)	82.14 ⁻¹	(26.62)	82.67 ⁻¹	(22.88)
Mental Health	Control	73.22 ⁻⁵	(17.37)	70.33 ⁻³	(19.54)	73.36	(19.36)	71.40 ⁻¹	(19.83)
	DA	74.50	(17.20)	74.16 ⁻⁴	(17.32)	75.99 ⁻⁵	(17.19)	76.11 ⁻³	(18.24)
	DA+DCP	74.75 ⁻²	(17.38)	74.27 ⁻¹	(17.46)	77.10 ⁻³	(19.19)	76.88 ⁻¹	(17.68)
Treatment satisfaction	Control	77.00 ⁻¹⁶	(19.13)	79.45 ⁻¹⁶	(22.49)	81.97 ⁻¹²	(20.20)	76.73 ⁻¹²	(23.18)
	DA	78.58 ⁻⁸	(20.17)	80.15 ⁻¹²	(23.15)	79.28 ⁻⁷	(24.76)	79.47 ⁻¹⁰	(25.17)
	DA+DCP	82.10 ⁻¹¹	(17.62)	79.57 ⁻²⁴	(20.89)	83.82 ⁻¹⁸	(19.71)	80.83 ⁻²⁰	(22.83)
Disease Perception	Control	51.56 ⁻¹⁴	(21.51)	65.50 ⁻¹⁹	(24.33)	66.00 ⁻¹²	(23.33)	67.94 ⁻¹⁸	(24.24)
	DA	52.32 ⁻⁸	(22.00)	68.96 ⁻¹⁴	(22.62)	69.78 ⁻⁷	(23.29)	71.20 ⁻¹⁰	(23.35)
	DA+DCP	51.21 ⁻¹¹	(22.68)	67.06 ⁻²²	(25.04)	73.66 ⁻¹⁸	(22.33)	74.82 ⁻¹⁹	(21.29)

Note: Each observation is presented as Mean (standard deviation). Numbers in superscript are the amount of missing data.

For all scales, higher scores indicate better health, satisfaction or quality of life. Scale range 0-100.

As seen in table 10 and 11 there was a trend that DA+DCP group reported higher scores than the other two groups in most HRQoL variables.

Hypothesis 1. We had hypothesized that the patients in DA+DCP group would report significantly better primary health outcomes (body mass index, cholesterol, blood pressure, and amount of tobacco), and HRQoL at six months following the angiogram than patients in DA group who in return would achieve better outcomes than the Control group. We used ANCOVA to compare the difference in group means at six months following the angiogram after statistical adjustment for the effect of the baseline scores. Six months was selected because it is the usual time of completion of recovery and resuming to functional status and normal roles.

Table 12 and 13 shows the group differences for each of the health outcomes variables and HRQoL variables at six months, controlling for baseline scores

Table 12

Group differences in health outcomes at six months following the angiogram controlling for baseline scores

Dependent variables	Control group			DA group			DA+DCP group			F	p-value
	n	M	SD	n	M	SD	n	M	SD		
Body Mass Index	100	27.41	(0.12)	113	27.20	(0.11)	114	26.95	(0.11)	4.17	.016
Total Cholesterol	26	4.75	(0.19)	29	4.71	(0.18)	24	4.71	(0.20)	0.01	.987
HDL	15	1.50	(0.11)	20	1.37	(0.09)	19	1.35	(0.10)	0.59	.556
LDL	15	2.36	(0.28)	22	2.83	(0.25)	19	2.80	(0.26)	0.93	.400
SBP	42	135	(2.64)	56	137	(2.29)	64	135	(2.14)	0.28	.758
DBP	42	78.38	(1.56)	56	79.02	(1.35)	64	81.69	(1.26)	1.70	.187
Amount of tobacco	16	51.72	(10.07)	19	53.83	(9.23)	17	48.16	(9.81)	0.09	.915

Note: The differences are adjusted for covariate = the baseline scores

Alpha = .05.

Domain abbreviations and unit of measure as for Table 7.

After adjusting for baseline scores, there was a significant difference between the three groups on post-intervention (T4) scores of Body Mass Index. The Scheffé post hoc test was conducted to determine which IV groups were significantly different. Results show that DA+DCP group is significantly better than the Control group.

Table 13

Group differences in HRQoL outcomes at six months following the angiogram controlling for baseline scores

Dependent variables	Control group n=100		DA group n=113		DA+DCP group n=114		F	p-value	eta ²
	M	SD	M	SD	M	SD			
Physical Functioning	72.84	(1.83)	73.16	(1.75)	76.87 ⁻¹	(1.73)	1.63	.197	.010
Role Functioning Physical	63.21	(2.42)	68.92 ⁻¹	(2.29)	72.52 ⁻²	(2.30)	3.93	.021	.024
Bodily Pain	61.82 ⁻¹	(2.28)	63.41 ⁻¹	(2.14)	64.18 ⁻¹	(2.14)	0.29	.745	.002
General Health	57.44 ⁻²	(1.85)	59.67 ⁻²	(1.09)	63.50 ⁻²	(1.70)	3.04	.049	.019
Vitality	48.56 ⁻¹	(1.98)	51.70 ⁻³	(1.84)	55.89 ⁻¹	(1.84)	3.74	.025	.023
Social Functioning	76.65	(2.08)	75.16 ⁻¹	(1.96)	78.95 ⁻¹	(1.96)	0.95	.388	.006
Role Functioning Limitation	74.01	(2.40)	80.27 ⁻¹	(2.27)	82.43	(2.24)	3.49	.032	.022
Mental health	72.39 ⁻¹	(1.53)	75.44	(1.42)	76.88 ⁻¹	(1.41)	2.38	.094	.015
Treatment Satisfaction	78.61 ⁻²¹	(2.41)	80.37 ⁻¹⁵	(2.15)	79.83 ⁻²⁴	(2.27)	0.15	.858	.001
Disease Perception	65.85 ⁻²⁵	(2.31)	70.27 ⁻¹⁵	(2.02)	75.91 ⁻²²	(2.09)	5.30	.006	.039

Note: The differences are adjusted for covariate = the baseline scores.

Alpha = .05

Each observation is presented as Mean (standard deviation). Numbers in superscript are the amount of missing data.

For all scales, higher scores indicate better health or quality of life.

Scale range 0-100.

We found a significant difference in 50 % of the HRQoL variables. The calculated effect sizes for each factor indicate that small proportions of HRQoL are accounted for by

each factor. The Scheffé post hoc test was conducted to determine which groups were significantly different. Results show that the DA+DCP group is significantly better than the Control group. Thus, hypothesis 1 was partly supported.

Effects on intermediate adherence outcomes

Before we analyzed the effects of the interventions on intermediate adherence outcomes, we computed means and SD for the three groups at each time point, for the adherence outcomes summarized in Table 14.

Table 14

Group mean and SD for adherence outcomes at baseline, two, four, and six months following the angiogram

Dependent variables	Group	Baseline Intentions		Two months after the angiogram		Four months after the angiogram		Six months after the angiogram	
		M	SD	M	SD	M	SD	M	SD
		Control: n=121 DA: n=121 DA+DCP: n=121		Control: n=105 DA: n=114 DA+DCP: n=118		Control: n= 87 DA: n=102 DA+DCP: n= 99		Control: n=100 DA: n=113 DA+DCP: n=114	
Adherence to Diet recommendations	Control	15.08 ⁻³	(3.29)	12.92 ⁻²⁰	(3.48)	14.13 ⁻¹⁹	(3.70)	13.34 ⁻¹⁰	(3.67)
	DA	15.43 ⁻⁷	(3.34)	12.61 ⁻¹⁶	(3.66)	13.40 ⁻¹³	(3.43)	13.53 ⁻¹⁴	(3.74)
	DA+DCP	15.38 ⁻⁹	(3.76)	13.67 ⁻¹	(3.52)	14.04 ⁻¹⁰	(3.08)	14.12 ⁻¹⁴	(3.07)
Adherence to activity recommendations	Control	14.29 ⁻⁷	(4.19)	11.07 ⁻²⁹	(4.48)	12.33 ⁻²³	(4.63)	11.31 ⁻²²	(4.64)
	DA	14.91 ⁻⁸	(3.80)	11.28 ⁻²²	(4.80)	12.21 ⁻¹⁷	(4.75)	11.91 ⁻²²	(4.92)
	DA+DCP	15.29 ⁻¹²	(3.87)	11.63 ⁻²¹	(4.40)	12.71 ⁻¹⁷	(3.88)	12.84 ⁻¹⁹	(3.96)
Adherence to stress reduction	Control	13.69 ⁻⁶	(4.28)	14.09 ⁻²¹	(3.91)	14.03 ⁻¹⁶	(3.70)	14.32 ⁻¹¹	(3.68)
	DA	14.56 ⁻⁷	(3.91)	14.03 ⁻¹⁶	(3.53)	14.15 ⁻⁹	(3.50)	13.97 ⁻¹²	(3.55)
	DA+DCP	14.59 ⁻¹⁰	(3.68)	14.35 ⁻⁸	(3.72)	14.48 ⁻⁹	(3.40)	14.17 ⁻¹³	(3.76)
Adherence to taking their medication	Control	19.63 ⁻³	(1.41)	19.45 ⁻²⁴	(1.95)	19.63 ⁻¹⁷	(1.78)	19.11 ⁻¹⁷	(3.25)
	DA	19.78 ⁻⁸	(0.96)	19.70 ⁻¹³	(1.00)	19.18 ⁻¹³	(2.80)	19.19 ⁻¹⁶	(3.02)
	DA+DCP	19.52 ⁻⁴	(1.57)	19.52 ⁻¹⁴	(1.80)	19.55 ⁻¹⁰	(2.19)	19.69 ⁻¹⁶	(1.28)
Adherence to no smoking	Control	18.74 ⁻⁴	(3.16)	18.84 ⁻²	(3.20)	18.75 ⁻²	(3.55)	19.14 ⁻²	(2.30)
	DA	19.07 ⁻⁴	(2.59)	18.54 ⁻¹	(3.68)	19.15 ⁻⁴	(2.65)	19.11 ⁻⁴	(2.72)
	DA+DCP	18.94 ⁻⁵	(2.78)	18.88 ⁻³	(3.09)	19.14 ⁻³	(2.80)	18.96 ⁻³	(3.11)

Note: Each observation is presented as Mean (standard deviation). Numbers in superscript are the amount of missing data.

For all scales, higher scores indicate higher adherence

Scale range is 5-25

Table 14 depicts that the intention to adhere to the actual recommendations were higher at baseline than the actual adherence reported two months later, except an increase in adherence to stress recommendations and taking their medication for DA group. The greatest decrease between intentions and actual adherence two months later was found for activity and diet. There was only a small change in adherence scores from two months to six months following the angiogram. The greatest increase was found in adherence to activity. Adherence to stress reduction showed a small decrease in both intervention groups, while the adherence to taking medication showed a decrease in the Control group and DA group.

Hypothesis 2. We tested the hypothesis that patients in DA+DCP group would report significantly greater adherence outcomes (following the diet recommendations, activity recommendations, no smoking, taking their prescribed medication and stress reduction) after six months than patients in DA group who in turn would achieve better outcomes than the Control group. We compared groups mean differences for the five adherence to cardiac risk reduction categories at six months controlling for scores at baseline. ANCOVA analysis was used to examine group differences at six months following the angiogram controlling for scores at baseline. Table 15 shows the group differences for each of the adherence outcomes variables at six months, controlling for baseline scores.

Table 15

Group differences in adherence outcomes at six months following the angiogram controlling for baseline scores

Dependent variables	Control group			DA group			DA+DCP group			F	p-value
	n	M	SD	n	M	SD	n	M	SD		
Adherence to diet recommendation	87	13.24	(3.66)	94	13.46	(3.81)	93	14.01	(3.11)	1.06	.348
Adherence to activity recommendation	76	11.54	(4.62)	88	12.01	(4.91)	88	12.71	(3.82)	1.42	.243
Adherence to stress reduction	85	14.20	(3.64)	95	14.99	(3.77)	93	14.20	(3.77)	0.10	.906
Adherence to taking medication	80	19.08	(3.31)	93	19.18	(3.06)	96	19.69	(1.29)	1.39	.251
Adherence to no smoking	94	19.10	(2.35)	105	19.08	(2.76)	106	19.06	(2.82)	0.01	.994

Note: The differences are adjusted for covariate = the baseline scores

Alpha =.05

Each observation is presented as Mean (standard deviation).

For all scales, higher scores indicate higher adherence

Average scale range is 5-25

Table 15 shows no significant group differences in any of the adherence outcomes. Hypothesis 2 was not supported. However, during the study period the proportion of individuals who succeeded to quit smoking in the DA+DCP group was higher (31.0%) than in DA group (20.7 %), which was higher than in the Control group (17.2 %). Table 16 shows the group differences for number of adherent quitters at the three measurement points.

Table 16

Quitters of smoking at three measurement points by groups

Dependent variables	Control group		DA group		DA+DCP group		Total	
	n	%	n	%	n	%	n	%
Quitters at T2	5	17.2	7	24.1	7	24.1	19	21.8
Quitters at T3	4	13.8	6	20.7	7	24.1	17	19.5
Quitters at T4	5	17.2	6	20.7	9	31.0	20	23.0

Note: Number of smokers at T1 was 87.

Each observation is presented as count of people who reports quitting smoking at this measurement and percent.

In the Control group seven (24.1 %) patients reported that they had tried to quit smoking during the study period, and five reported adherence in quitting smoking six months after the angiogram. In DA group seven (24.1%) patients reported that they had tried to quit smoking during study period, and six (20.7 %) reported adherence in quitting smoking six months after the angiogram. In DA+DCP group eleven (37.9 %) patients reported that they had tried to quit smoking during the study period, and nine reported adherence (31.0%) in quitting smoking at six months. These differences are based on very small numbers.

Effects on other outcomes

Before we analyzed the effects of the interventions on the mediating variables, we computed means and SD for the three groups at baseline and two month for the mediating variables summarized in Table 17.

Table 17

Group mean and SD for knowledge scores, perceived health beliefs, perceived benefits and barriers at baseline and at two months following the angiogram

Dependent variables	Group	Baseline		Two months following the angiogram	
		M	SD	M	SD
		Control: n=121		Control: n=105	
		DA: n=121		DA: n=114	
		DA+DCP: n=121		DA+DCP: n=118	
Knowledge about risk factors and CAD	Control	14.51	(4.42)	15.75 ⁻¹	(4.01)
	DA	14.40	(4.41)	16.18	(3.47)
	DA+DCP	14.90	(4.01)	16.70 ⁻¹	(3.46)
Perceived Susceptibility of CAD or CAD progression	Control	3.05 ⁻²	(0.58)	2.95	(0.63)
	DA	3.07 ⁻⁶	(0.57)	3.00	(0.69)
	DA+DCP	3.06 ⁻¹	(0.58)	2.90	(0.61)
Perceived Severity of CAD or CAD progression	Control	3.45 ⁻²	(0.67)	3.57 ⁻¹	(0.56)
	DA	3.38 ⁻⁸	(0.65)	3.42 ⁻³	(0.71)
	DA+DCP	3.41 ⁻³	(0.54)	3.41 ⁻²	(0.56)
Perceived Benefits of cardiac risk reduction	Control	3.28 ⁻¹	(0.42)	3.34	(0.37)
	DA	3.26 ⁻³	(0.40)	3.38	(0.36)
	DA+DCP	3.37 ⁻²	(0.40)	3.40 ⁻²	(0.37)
Perceived Barriers to cardiac risk reduction	Control	1.84 ⁻²	(0.41)	1.87 ⁻³	(0.50)
	DA	1.85 ⁻⁵	(0.45)	1.81 ⁻²	(0.41)
	DA+DCP	1.77 ⁻³	(0.38)	1.68 ⁻¹	(0.40)

Note: Each observation is presented as Mean (standard deviation). Numbers in superscript are the amount of missing data.

Knowledge: scores range is 0-21 with higher scores indicating more correct answers regarding risk factors and CAD.

Susceptibility: average scores range is 1-5 with higher scores indicating higher perceived susceptibility of CAD or CAD progression

Severity: average scores range is 1-5 with higher scores indicating higher perceived severity of CAD or CAD progression

Benefits: average scores range is 1-4 with higher scores indicating higher perceived benefits of cardiac risk modification behavior.

Barriers: average scores range is 1-4 with higher scores indicating greater perceived barriers to cardiac risk modification behavior.

Improvements in knowledge scores were evident in all three groups, the most in DA+DCP group. The Control and DA group increased their perceived severity of CAD or CAD progression, while DA+DCP group kept their perceived severity stable. Regarding the perceived barriers of cardiac risk reduction behavior, the DA and DA+DCP groups decreased their perceived barriers, while the Control group increased their perceived barriers.

Hypothesis 3. We hypothesized that patients in DA+DCP group would report significantly greater knowledge about risk factors and CAD, perceived susceptibility and severity of CAD progression, and perceived benefits and barriers of cardiac risk reduction behavior two months following the angiogram (T2) than patients in the DA group who in turn would achieve better outcomes than the Control group. We compared group differences for the dependent variables at two months controlling for baseline scores. ANCOVA analysis was used to examine group differences at two months following the angiogram, controlling for scores at baseline. Table 18 shows the group differences for each of the adherence outcomes variables at six months, controlling for baseline scores.

Table 18

Group differences in knowledge scores, perceived health beliefs, perceived benefits and barriers at two months following the angiogram controlling for baseline scores

Dependent variables	n	Control group		DA group			DA+DCP group			F	p-value
		M	SD	n	M	SD	n	M	SD		
Knowledge about risk factors and CAD	104	16.13	(0.29)	114	16.19	(0.28)	117	16.88	(0.27)	2.28	.104
Perceived Susceptibility of CAD and CAD progression	103	2.99	(0.05)	109	3.02	(0.05)	117	2.88	(0.05)	1.91	.150
Perceived Severity of CAD or CAD progression	102	3.53	(0.05)	106	3.47	(0.05)	114	3.40	(0.05)	1.89	.152
Perceived Benefits of cardiac risk reduction	104	3.36	(0.03)	112	3.39	(0.03)	115	3.36	(0.03)	0.33	.720
Perceived Barriers to cardiac risk reduction	100	1.86	(0.04)	108	1.78	(0.04)	115	1.71	(0.04)	3.94	.020

Note: The differences are adjusted for covariate = the baseline scores

Alpha = .05

Each observation is presented as Mean (standard deviation).

Unit of measure and scores range as for Table 17.

Controlling for baseline scores, there was a significant difference between the three groups on post-intervention (T2) scores of perceived barriers to cardiac risk reduction behavior. The Scheffé post hoc test was conducted to determine which groups were significantly different. Results show that DA+DCP group is significant better than the Control group. Therefore, hypothesis 3 was partly supported.

Relationships between adherence outcomes and health outcomes at two, four, and six months following the angiogram

Slopes were compared between the Adherence variables and the health outcomes variables using mixed-effects models. The model included random effects in the intercept and the slope. If the model was unstable we included random effects in the intercept only. Table 19 shows the relationship per months (slope) for the variables.

Table 19

Relationships between adherence outcomes and health outcomes at two, four, and six months following the angiogram

	Adherence to diet recommendation		Adherence to activity recommendation		Adherence to taking their medication		Adherence to stress reduction		Adherence to no smoking	
	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value
Body Mass Index	-0.036	.043	-0.003	.840	0.021	.338	0.011	.418	0.025	.407
Total Cholesterol	0.033	.178	-0.014	.398	-0.058	.164	0.031	.043	0.030	.570
LDL	0.007	.751	-0.005	.752	-0.006	.864	0.027	.062	0.024	.637
HDL	0.017	.072	-0.010	.140	-0.058	.002	0.001	.880	-0.021	.417
SBP	-0.105	.214	-0.029	.907	-0.124	.778	-0.387	.133	0.477	.211
DBP	-0.143	.469	-0.048	.751	0.001	.998	-0.080	.619	-0.058	.798
Amount of TOBACCO per week in gram	1.667	.239	-1.350	.250	0.367	.719	-0.491	.623	-2.071	.052

Note: Alpha = .05
Domain abbreviations as for Table 7.

Findings show that greater adherence to diet recommendation was significantly related to lower Body Mass Index.

Relationships between adherence outcomes and HRQoL at two, four, and six months following the angiogram

Slopes were compared between the Adherence variables and the HRQoL variable using mixed-effects model. The model included random effects in the intercept and the slope. If the model was unstable we included random effects in the intercept only. Table 20 shows the relationship per month (slope) for the variables.

Table 20

Relationships between adherence outcomes and HRQoL outcomes at two, four, and six months following the angiogram

	Adherence to diet recommendation		Adherence to activity recommendation		Adherence to taking their medication		Adherence to stress reduction		Adherence to no smoking	
	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value
Physical Functioning	0.823	.008	0.204	.402	-1.101	.005	0.186	.457	0.413	.161
Role Functioning-Physical	0.958	.021	0.210	.520	-0.806	.126	0.275	.413	0.521	.187
Bodily Pain	0.806	.025	0.198	.488	-0.822	.072	0.200	.489	0.300	.398
General Health	0.616	.040	0.336	.160	-0.168	.658	0.097	.687	0.309	.306
Vitality	0.349	.261	0.518	.036	-0.167	.672	0.214	.393	0.338	.264
Social Function	0.539	.124	0.159	.565	-0.027	.952	0.225	.427	0.616	.071
Role Functioning-Emotional	1.289	.0004	-0.177	.537	-0.111	.810	0.083	.776	0.630	.076
Mental Health	0.514	.029	-0.012	.951	0.136	.646	0.148	.428	0.552	.025
Treatment Satisfaction	0.391	.393	0.247	.462	-0.076	.933	0.101	.780	-0.068	.888
Disease Perception	0.352	.445	0.472	.162	1.346	.138	0.152	.671	0.871	.076

Note: Alpha =.05

Findings show that greater Adherence to recommendation was significantly related to better HRQoL on several variables.

Relationships between health outcomes and HRQoL at baseline, two, four, and six months following the angiogram

Slopes were compared between the three groups for each outcome variable using mixed-effects model. The model included random effects in the intercept and the slope. If the model was unstable we included random effects in the intercept only. Table 21 shows the relationship per month (slope) for the variables.

Table 21

Relationships between health outcomes and HRQoL outcomes at baseline, two, four, and six months following the angiogram

	Body Mass Index		SBP		DBP		Health Service used	
	Slope	p -value	Slope	p -value	Slope	p -value	Slope	p -value
Physical Functioning	-0.78	.0004	-0.07	.152	0.11	.227	2.00	.282
Role Functioning-Physical	-0.17	.543	-0.10	.104	-0.05	.701	0.95	.710
Bodily Pain	-0.64	.009	0.03	.530	-0.12	.262	4.08	.048
General Health	0.22	.312	-0.01	.846	-0.02	.814	3.40	.046
Vitality	-0.26	.249	0.02	.688	-0.01	.973	5.32	.005
Social Function	-0.22	.402	0.06	.255	-0.04	.725	2.77	.184
Role Functioning-Emotional	0.01	.962	0.04	.484	-0.08	.492	2.09	.361
Mental Health	0.12	.505	0.04	.247	0.01	.877	1.65	.220
Treatment Satisfaction	-0.69	.011	0.07	.221	-0.13	.291	-0.18	.941
Disease Perception	-0.68	.024	-0.11	.071	-0.04	.766	4.52	.089

Note: Alpha =.05

Domain abbreviations as for Table 7.

Findings show that higher BMI was significantly related to HRQoL regarding lower physical functioning, greater bodily pain, less treatment satisfaction, and more limits in quality of life because of chest pain. Attendance in cardiac rehabilitation, courses in quitting smoking, weight reduction, and diet were significantly related to HRQoL in terms of less bodily pain, better general health, and increased vitality.

Relationships between the intentions at baseline, and adherence outcomes two, four, and six months following the angiogram.

Slopes were compared between the variables using the mixed-effects model. The model included random effects in the intercept and the slope. If the model was unstable we included random effects in the intercept only. Table 22 shows the relationship per month (slope) for the variables.

Table 22

Relationships between intentions and adherence outcomes at two, four, and six months following the angiogram

	Diet Intention		Activity Intention		Medication Intention		Stress reduction Intention		No Smoking Intention	
	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value	Slope	<i>p</i> -value
Adherence to diet recommendation	0.27	<.0001	0.11	.025	0.11	.398	-0.00	.962	0.10	.096
Adherence to activity recommendation	-0.07	.373	0.43	<.0001	-0.05	.794	-0.01	.853	-0.03	.694
Adherence to taking their medication	0.02	.678	-0.00	.943	0.16	.109	0.00	.935	0.01	.840
Adherence to stress reduction	0.02	.780	0.00	.967	-0.20	.130	0.16	.0002	0.08	.236
Adherence to no smoking	-0.09	.041	0.03	.498	-0.25	.008	-0.03	.330	0.85	<.0001

Note: Alpha =.05

Findings revealed that intention to adhere at baseline was significantly related to actual adherence in several variables during the study period.

Relationships between the knowledge about risk factors and CAD, perceived susceptibility and severity of CAD or CAD progression, perceived benefits and barriers of cardiac risk reduction behavior, and decisional conflict two months following the angiogram, and adherence outcomes two, four, and six months following the angiogram.

Slopes were compared between the variables using mixed-effects model. The model included random effects in the intercept and the slope. If the model was unstable we included random effects in the intercept only. Table 23 shows the relationship per month (slope) for the variables.

Table 23

Relationships between knowledge scores, perceived health beliefs, perceived benefits and barriers, and decisional conflict at two months, and adherence outcomes at two, four, and six months following the angiogram

	Knowledge of CAD and risk factors		Perceived Susceptibility of CAD or CAD progression		Perceived Severity of CAD or CAD progression		Perceived Benefits of cardiac risk reduction behavior		Perceived Barriers to cardiac risk reduction behavior		Decisional conflict	
	Slope	p-value	Slope	p-value	Slope	p-value	Slope	p-value	Slope	p-value	Slope	p-value
Adherence to diet recommendation	0.09	.124	-0.73	.069	0.11	.716	-0.19	.735	-0.96	.041	-0.04	.003
Adherence to activity recommendation	0.05	.518	-0.99	.073	0.61	.155	0.388	.608	-1.08	.099	-0.06	.002
Adherence to taking their medication	0.02	.637	0.08	.777	-0.23	.309	-0.45	.260	-0.58	.117	-0.02	.026
Adherence to stress reduction	-0.01	.845	-0.30	.441	0.60	.050	0.23	.668	0.19	.665	0.01	.523
Adherence to no smoking	0.04	.531	-1.63	<.0001	0.438	.160	-0.61	.260	0.59	.195	-0.02	.179

Note: Alpha =.05

Higher decisional conflict was significantly related to lower adherence to diet, activity, and taking medications recommendations. There was also a significant relationship between increased perceived susceptibility of CAD or CAD and lower adherence to no smoking.

Patients' acceptability of the DA with and without the DCP

We evaluated patients perceived usefulness of DA overall, and investigated if patients perceived the usefulness of the DA differently if they also received the DCP.

The Chi-square tests was used to test differences in perceived DA usefulness between DA group and DA+DCP group. In both groups approximately 90% of the patients perceived the presentation of major risk and presentation of the options for lifestyle changes in the DA as good or excellent, and there were found no significant differences between DA group and DA+DCP group on these variables. However, patients in DA+DCP group perceived the information in the DA significantly more useful if they in addition had received the DCP for the following elements: calculating risks, thinking about possible changes, making the action plan and the information in the worksheet (Table 22). This suggests that when patients received the DCP in addition to the DA, they were more able to utilize the information in the DA.

Table 24

The presentation of the options for lifestyle changes in the DA

		POOR	FAIR	GOOD	EXCELLENT		
	n					χ^2	p-value
Calculate your risk							
DA group	99	2.8	14.1	68.7	11.1		
DA+DCP group	117	0.9	9.4	68.4	21.4	0.199	.031
Thinking about possible changes							
DA group	97	1.9	9.3	79.4	7.2		
DA+DCP group	117	0.0	6.8	70.1	23.1	0.250	.003
Making your own action plan							
DA group	98	9.2	12.2	71.4	7.1		
DA+DCP group	116	0.9	14.7	67.2	17.3	0.235	.006
Monitoring your progress							
DA group	96	9.4	15.6	65.6	9.4		
DA+DCP group	114	2.6	17.5	62.3	17.5	0.178	.076
Information in worksheet							
DA group	64	1.6	17.2	75.0	6.2		
DA+DCP group	90	0.0	6.7	77.8	15.6	0.222	.047

Note: Each observation is presented as Number and Percent

Approximately 80% of the patients perceived the length of presentation and the amount of information in the DA as just right, and nearly 87 % perceived the risk information versus information about life changes as balanced. Again there were no significant differences between DA group and DA+DCP group. However, patients in DA+DCP group considered the influence of the DA on the decision of life changes as significantly easier than patients in DA group ($\chi^2 = 0.178, p = .015$), significantly more useful ($\chi^2 = 0.216, p = .002$), and they also considered the way the risk was presented in the DA as significantly easier than DA group ($\chi^2 = 0.177, p = .013$).

Patients' acceptability of the DCP

To understand how the patients in DA+DCP group assessed the DCP after receiving the DA, we asked them specifically about the usefulness of the additive counseling.

90-95 % of the patients in DA+DCP group perceived the form of communication in the DCP about the importance of the lifestyle change and options as good or excellent. 93% perceived the length of the individual decisional counseling, and the amount of information in the individual decisional counseling as just right. 95% of the patients perceived the risk information versus the information about life changes in the individual decisional counseling as balanced, while 96% perceived that the influence of the DCP on the decision of life changes made the decision easier. 93 % of the patients perceived the DCP as useful, and that the amount of information in the DCP was adequate. 96 % considered the way that the risk was communicated in the individual decisional counseling as easy.

Diffusion of intervention

The questionnaires at T2 and T4 asking where or from whom the patients had received information during the study period revealed that three patients in the Control group and one from the DA group had discussed CAD and lifestyle changes with other patients, but not with patients from our study. We could therefore not confirm any diffusion of information from the interventions between the three groups.

Chapter 5

Discussion, significance, and recommendations

Overview

The purpose of this three group randomized clinical trial was to evaluate the effects of a Decision Aid (DA) with and without the additional individual decision counseling program (DCP) on health outcomes and health-related quality of life (HRQoL) mediated by adherence to cardiac risk reduction behavior. We also investigated possible relationships between these variables as presented in Figure 2 page 19.

One of the study's main hypothesis was uphold on the following outcomes: The DA+DCP group had a significant decrease in Body Mass Index, and significantly improved HRQoL on several dimensions compared to the Control group six months after the intervention. There was also a significant decrease in perceived barriers to cardiac risk reduction behavior in the DA+DCP group compared to the Control group at two months. There were no significant differences between The DA group and the Control group on any variables. The DA alone was not sufficient to achieve any effects. Our data indicate that combining a DA with additional decisional counseling may be more effective in achieving better outcomes than with the DA alone. We found no significant differences in adherence to cardiac risk reduction behavior between any of the groups.

There were significant relationships between greater adherence to healthy life style recommendations, better HRQoL and better health outcomes. Intentions to follow lifestyle recommendations were significant predictors of adherence to cardiac risk reduction behavior. Increased perceived susceptibility of illness was significantly related to lower adherence to non- smoking behavior, while increased perceived barriers to cardiac risk reduction behavior were related to lower adherence to diet recommendations. Higher decisional conflict significantly predicted lower adherence to diet recommendations, activity recommendations, and taking medications. The patients considered both the Decision Aid and the additional

decisional counseling program as helpful. The patients in the DA+DCP group perceived the information in the DA significantly more useful than those only receiving the DA on the following elements: calculating risks, thinking about possible changes, making an action plan, and the information in the worksheet. This suggests that when patients received the DCP in addition to the DA, they were able to utilize the information in the DA more.

Methodological considerations

In this study we used the design of a randomized controlled trial (RCT) to test the effects of the interventions. Many challenges may occur when performing a RCT in clinical settings and in patients' homes. The contribution to the quality of cumulative research is based on methodological assessment of the reliability and validity of the study. In the following some important threats to reliability, validity and generalization in our work are discussed.

Reliability

Reliability refers to the degree of consistent results of the scores on an instrument (Carmines & Zeller, 1979). If the scores are variable and fluctuating the measure is assessed as unreliable. An instrument is internally consistent to the extent that its items are highly inter-correlated. Random error affects reliability. When random error is low, reliability is high. We performed several strategies to reduce random error in our study. The questionnaires were pilot tested in 15 patients first, all data entry into SPSS were double checked, and 10% of the imputed data were randomly assigned to be checked a second time. Internal consistency in the measures in our study was comparable to previous validation studies, suggesting that the scores were performing as expected.

The patients in our study answered many questionnaires several times, and the burden of answering so many questionnaires was the main reason for the decision not to perform a test-retest procedure to assess for stability of responses. That is a limitation of our study.

Validity

The degree of validity is the extent to which the instrument used actually reflects the abstracts construct being examined. Validity addresses the appropriateness, meaningfulness, and usefulness of the specific inferences made from instrument scores (Carmines & Zeller, 1979).

Internal validity refers to whether the covariation of the presumed independent variable and dependent variable results from a causal relationship: did the experimental treatments make a difference in this specific experimental instance? Threats to internal validity are experimental procedures, treatments, or experiences of the participants that threaten the ability to draw correct inferences from the data in an experiment. Possible threats involved in our study will be presented.

Mass media coverage and attention on lifestyle changes for cardiac patients occurring coincidentally with the time interval between pretest and posttest measurement could have influenced the responses from the participants in our study. Therefore we read national newspapers and listened to national news from April 2008 to August 2009 to assess possible large attentions on cardiac patients and lifestyle changes that could interfere with our intervention. We found no large focus on cardiac patients in Norway during this time period.

Repeated use of the same questionnaires might have resulted in a memory effect that could have influenced patients' responses to questionnaires at measurement T2-T4. The baseline knowledge scores about cardiac risk factor reduction were conducted at the hospital without any sources of information available, while the T2 measurement was completed at home with possible knowledge sources available as internet, books, and family caregivers.

The measurement of blood pressure may have created systematic errors of measurement. The measurement varied through different doctors and different circumstances. The first blood pressure was measured at the initial visit at the Cardiac Outpatient clinic. The patients BP were measured simultaneously as the nurse was preparing the patients for the ECG. The protocol of letting the patient sit down for two minutes before measuring the blood pressure was not always met.

The observed effects of the interventions could have been reduced because of possible contamination between patients because they shared room before and after angiogram, or at the setting in the Hospital Hotel area for those staying there. We attempted to prevent this bias by telling patients not to share with other patients what they had received of information through the study, and later asked them to describe what and from whom they had received information about lifestyle. No patients reported that they had discussed or received information from other patients enrolled in the study.

The control participants might feel disadvantaged by the absence of the treatment in contrast to participants in the DA- and DA+DCP group and thus were motivated to compete for equity. To reduce the possibility of competition of this kind we told the participants in control group that they would receive the DA when T4 was completed, which they did.

A strength in the study was that the interventions were conducted by the same person to promote consistency in delivering the counseling. We were monitoring the intervention delivery by training and the use of manuals. To monitor intervention adherence we used personal logs, and 10 % of the home visits were randomly picked to be observed by another nurse counselor to secure the fidelity of the DCP intervention.

Threats to construct validity occur when investigators use inadequate definitions and measure of variables. Relevant outcomes variables are crucial for answering causal questions as in our study. This study used instruments derived from the Health Belief Model and thereby ensured that the definitions and instruments represent the variables in the model described in Figure 2. By measuring the intentions to adhere, rather than the actual adherence to cardiac risk reduction at baseline, we lost important information about the actual adherence to cardiac risk reduction prior to angiogram. Previous analysis has shown that the strongest predictor of adherence is past adherence (Sherbourne et al., 1992). The actual adherence at baseline, rather than their intentions the next months would have resulted in more valid measures to compare the differences in adherence at six months, when controlling for baseline scores. The bidirectional arrows and feedback loops in the Health Decision Model reflect the notion that adherence behavior can change health beliefs (Eraker et al., 1985). In this study we only addressed the directional arrows as shown in Figure 2. Thus, we were not able to discover reverse causality in that a good outcome may have promoted subsequent adherence in our study.

External validity asks the question of generalizability: to what populations, settings, treatment variables, and measurement variables can this effect be generalized? Both the representativeness of the participants and the experimental settings was considered in our study. External validity threats arise when experiments draw incorrect inferences from the sample data to other settings, and past or future situations. Factors affecting generalization (representativeness) are presented.

Sample characteristics. The willingness to participate in a study of lifestyle may impact the results. Those already interested in changing health behavior may have preferred to be included in a study like ours. However, we found no significant differences in age and gender among patients completing the study with those who were not included or refused to participate or were lost to follow up.

A particular threat in longitudinal studies occurs if participants are systematically dropping out of one treatment condition more than another. Unequal numbers of lost to follow up occurred in our study: 50% of the lost to follow up at six months came from the control group.

Due to the lack of the possibility of stating “I have no pain in the chest” in the Treatment Satisfaction Scale (TSS) and Disease Perception Scale (DPS) it is reasonable to think that this may have been the reason for the large amount of missing data in the SAQ subscales. Participants with no chest pain were not able to find a statement suited for them. In the adherence scales, participants had to indicate their extent of carrying out the actions in four different environments: “When at work...”; “When I participate in sports or recreational activities..”; “When I participate in social activities...”. It is reasonable to think that patients who were not working/not employed, not participating in sports or social activities skipped these items.

The intervention took place in patients’ home, and the effects obtained are therefore not necessarily applicable to other settings that would be different from original setting. The environment of settings varies widely and most people would probably assume that their home is a nicer place to learn than in a hospital setting. The interaction between the setting (patients home) and the intervention is therefore, a threat to generalizability in our study.

Patients could choose the time for the DCP appointment, and were told that a potential partner could participate if the patients invited them into the counseling session.

The question whether the effects obtained are applicable only to the specific time period within which the study is conducted is important. Unusual occurrences that coincide with study period can make the extrapolation of results to other periods of time questionable. Even that we controlled for media focus on cardiac patients during study period, other interactions could have occurred and make extrapolation of results to future time period difficult.

As a result of sensitization to lifestyle changes due to information in the informed consent, participants in the control group could have initiated lifestyle changes soon after the research was begun. Thus the findings cannot be generalized to all patients admitted to coronary angiogram. However, if this was the case, group differences would be harder to detect. It is also important to be aware of the possible “Hawthorne effect” in our study. The “Hawthorne effect” is the reactive effects created by individuals’ knowledge that they are participating in an experiment.

Lack of blinding may also have caused a “Hawthorne effect” among clinicians who knew about the study and may have wanted to do their best in providing patients with information about lifestyle changes. Some patients brought their DA with them to the angiogram, and nurses thereby could identify patients belonging to one of the intervention groups. This may have had an impact on their communication with the patients. We do not know whether the communication with patients changed at the ward during the study period.

Our sample was quite heterogeneous with regard to previous cardiac events. Participants were selected on the basis of the admittance to coronary angiogram with no regard to previous illness history. The total sample encompassed healthy people with no significant stenosis in their coronary arteries to those receiving their second CABG surgery.

There are some important differences between primary and secondary prevention of cardiac risk and the content in the DA and DCP covered these differences. The patient’s risk of CAD (HeartScore®) was presented to DA+DCP group. HeartScore® is a tool for predicting and managing the risk of heart attack and stroke in Europe, and used to support clinicians to better identify patients at high total risk of developing cardiovascular disease.

The threshold for high risk for fatal cardiovascular events is defined as "higher than 5%". HeartScore® is made for patients less than 65 years of age with no previous cardiac events, and should be used in primary prevention. We calculated HeartScore® for all patients, and told patients older than 65 that this was an estimate for younger persons, and told people with established CAD that HeartScore® estimated their risk as if they had no previous cardiac events, and that they were automatically at a higher risk than the HeartScore® showed because the presence of their cardiac illness. We used the Swedish version of the HeartScore® to calculate the risk because it was based on newer data than the European version that are estimating too high risk in the Norwegian population.

The DA used in this study was based on literature published up to 2002. To make it up to date we adjusted the literature in the Norwegian version with new references, in collaboration with the Canadian development team.

It is well-known that the use of self-reported symptoms in research can be subject to bias caused either by differing perceptions of what constitutes a particular symptom or set of symptoms, failure to report symptoms, or various psychological characteristics of the patient. Despite the inherent bias, the self-reporting of symptoms continues to be used as a gold standard in research on cardiac risk reduction behavior. Possible memory bias must be acknowledged in our study. The period of recall was either the last four weeks or the last two months. The use of the last two months may have been a source of recall errors.

Our study did not intervene to increase adherence by using behavioral strategies such as reminder systems, cues, self-monitoring, feedback, and reinforcement. This may have led to the knowing-doing gap: because although someone might know what the best thing to do was, the person still may not know how to do it.

On the other hand the study has a number of strengths. The generalizability of the findings was enhanced given that data were collected longitudinally from a broad sample of patients both in primary and secondary prevention needs. The length and the timing of the intervention were considered to be appropriate. Strict standardization was inappropriate in this intervention because the intervention was tailored to local circumstances (individual risk profile) as described in Chapter 3. The DCP was designed to let the content in topic area (the means of intervening) vary according to individual patient risk profile, while the function (theorized

mechanism) of the DCP remained unchanged over place and time. The local circumstances that have the permission to be changed or adapted in our study were: individual risk profile, individuals' benefits of potential action taken, individuals' barriers to potential action taken, and the individuals' decision ruled out in an individual plan for cardiac risk reduction behavior.

Due to the limitations mentioned above, caution should be used when drawing causal conclusions. Despite positive results for some of the main outcomes, the clinical impact of the DA and the DA+DCP was small. The changes in outcomes were modest for BMI and barriers to cardiac risk reduction behavior. The heterogeneity of participants in the study with some relatively low-risk patients, may have reassured them that their risk was low, and this may have reduced the overall perceived needs for changing lifestyle in the sample.

Contribution to science

Our study was guided by concepts and their relationships derived from the Health Behavior Model, one of many existing theories in health behavior change that stating the unhealthy behavior as a deficit or a problem to be solved (Becker, 1974; Ewart, 1989; Prochaska & DiClemente, 1983). Numerous models of health-related decisions and behavior have been developed that emphasize the processes of rational, cognitive appraisal of threat and response. In studies of health behavior change in CAD patients it has been found difficult to elucidate causal mechanisms that are empirically demonstrated. When carefully conducted, randomized trials, with treatment as usual care as the comparison condition, are undertaken to evaluate health behavior change interventions, they are typically found to produce modest effects on behavior change (Ebrahim et al., 2006; Noar et al., 2008).

In contrast to previous studies guided by theories in health behavior change, our study added a new approach to promote healthy behavior by combining the use of a DA to help the patients understand treatment options, potential outcomes, and prepare them to shared decision-making with their care provider, and the use of counseling (DCP) to help them elicit their individual preferences and individually tailor their preferred behavior change, instead of

a one-size-fits all approach. We thereby recognize that individuals have different intervention needs and added several new approaches into the behavioral intervention.

DAs are rooted in models of rational decision-making which view the actions as reasoned and intentional, requiring conscious control. DAs alone have shown limited effects in health behavior change (Koelewijn-van Loon et al., 2009, 2010; Kronen et al., 2008, 2010; Lalonde, et al., 2004, 2006; Lenz et al., 2009; Pignone et al., 2004; Sheridan et al., 2006, 2010b; van Steenkiste et al., 2007, 2008).

We added a more comprehensive approach to try to understand behavior change. By developing and adding a DCP derived from the Health Belief Model which encompasses adjusting the information in the DA to patients' personal illness history, elicit their preferences for lifestyle changes and help them make their own action plan has, to our knowledge not been done before. The DCP proposed two systems of information processing: (1) the process of reflective, reasoned, thinking, and (2) the process of learned associations that are outside of conscious awareness, have a strong emotional component, and provides a possible urge to act. The empty spaces in the open-ended sentences can simultaneously evoke some kind of motivating excitement that contributes to more possible answers than without these open spaces. The purpose is to structure situations so that the patient can become aware of his preferences, emotions, and the relationship between benefits and barriers and the health problems that can occur.

Other ingredients that may have contributed to the results in our study is the offering of choice in a situation where there are several management options, based on individual need and preference, a method that enhances active patient orientation (Coulter & Ellins, 2007; Ruland & Moore, 2001). It is also suggested that options offered as a menu of strategies, as we did in the DCP, are more successful because they encourage each patient's task to be one of choosing rather than one of refuting. Providing choice allows different people to respond in different ways based on each person's needs. Facilitating a collaborative relationship, as we did in the DCP, shared decision-making and communication of expectations in a supportive environment may help to motivate and contribute to the disease management process (Coulter et al., 2007). Studies have demonstrated that encouraging patients to participate in treatment decisions improves health status (Brody et al., 1989; Stewart, 1995) and treatment outcomes (Roter, 1977).

The Health Belief Model presents one view of health behavior change. Findings from our study support several of the concept relationships derived from the Health Belief Model. Our study may therefore contribute to the usefulness of the concept in Health Belief Model to explain important factors related to changing behavior in CAD patients when adding approaches from shared decision-making theory.

Consistency with previous research

Effects of the interventions

Effects on primary health outcomes. Small but statistically significant group differences were found in Body Mass Index (BMI). The Control group showed an increased mean in BMI, while DA- and DA+DCP groups lost body weight; the DA+DCP group most. This is noteworthy, because a number of studies have not found significant effects of interventions on Body Mass Index (Cupples & McKnight, 1994; Jolly et al., 1999; Murphy et al., 2009). BMI is considered an important risk factor for CAD, therefore this is an important outcome. Also, it is known that obesity and increased body weight raise blood pressure levels, and that weight loss as well as increased physical activity is beneficial (Fagard et al., 2007; Sacks et al., 2001). As our study consists of multiple components it is difficult to determine the crucial component that achieved this effect. The active ingredients of the intervention can be seen as the combined effects of the DA with the DCP that both emphasized the importance to reach and/or to maintain a healthy body weight. We do not know if it is the DCP alone or the combination with the DA that achieved the effects. The mean BMI was still higher than normal BMI for all three groups six months following angiogram, but a weight loss makes physical activity easier to accomplish, and is a step in the right direction.

No further group differences were found between groups in biological risk factors. This is consistent with other studies (Cupples et al., 1994; Howard-Pitney et al., 1997). Studies with disease-specific outcomes like blood pressure and cholesterol levels yielded lower effects than did those with non-disease specific outcome measures like pain and experience of symptoms. A number of factors affect outcomes, such as the strength and efficacy of recommendation, current understanding of the disease, adverse drug reactions, and

misdiagnosis. Reverse causality may also play an important role so that a good outcome may promote subsequent adherence. (DeMatteo et al., 2002).

Effects on HRQoL. In our study there were significantly higher mean scores for patients in the DA+DCP group than in the Control group on several dimensions of the HRQoL. The DA+DCP group had statistically significantly less problems with work or other daily activities as a result of physical health and/or emotional problems, better personal health, and greater feelings of pep and energy all of the time. Statistical significance does not itself provide concise information about a given intervention's clinically meaningful effects (Kendall, 1999). However, a difference in score of five or more points, as we found on the SF-36 scales from 0 to 100, has been regarded as clinically significant (Pettersen, Reikvam, Rollag, & Stavem, 2008).

We also found statistically significant differences in the DA+DCP group in less perceived burden of CAD on their quality of life compared to the Control group. Clinically important change in Disease Perception as measured by the Seattle Angina Questionnaire (SAQ) scores has previously been considered to be between 5 and 8 points (Dougherty et al., 1998). Based on these premises the results of our study show that there was a clinically important change in all three groups regarding the perceived change in the disease perceptions in terms of limits on quality of life because of chest pain, chest tightness, or angina from baseline to six months following the angiogram. Again, only the differences between the DA+DCP group and the Control group were found statistically significant.

Also, the findings in our study are supported by research showing that interventions that combine psychosocial and psycho-educational components, as we did in the DCP, with usual cardiological care can significantly improve quality of life (Aldana et al., 2006; Blumenthal et al., 2005; Dusseldorp et al., 1999; Linden et al., 1996; McAlister et al., 2001).

Effects on adherence outcomes. We found no significant group differences in adherence to cardiac risk reduction behavior during the study period. Our findings are consistent with a recent study by Krones and colleagues (2008) who found that DAs enhance decisions without an impact on the actual adherence to the decision, and therefore only have a small impact on health outcomes. Sheridan and colleagues (2010b) tested the addition of a ranking and rating exercise to a cardiac DA in a hypothetical lab-based study and found no improvement in

patients' intention to reduce their cardiac risk behavior. Since one of the central objectives of health behavior change interventions are to modify and shape healthy lifestyle behaviors, adherence measures are both primary behavioral outcome measures, and important determinants of biological responsiveness. The identification and tracking of behavioral adherence measures is therefore important when evaluating the efficacy of the intervention in our study.

Although not statistically significant, an interesting finding in our study was that during the six months there were more smokers in the DA+DCP group that attempted to quit (Control: 24.1%; Intervention I: 24.1%; Intervention II: 37.5%) and were adherent to quitting smoking at six months following the angiogram (Control: 17.2%; Intervention I: 20.7%; Intervention II: 31.0%). Data in our study indicate that the DCP together with the DA may initiate a cognitive and emotional process and thus help patients to see what is most important to them and what they prefer to do, which may have led to higher quitting rates. This is supported by Rosen (2000) who found that cognitive processes were used more in early stages of changing smoking habits, and Barth and colleagues (2008) who found that the psychosocial smoking cessation interventions compared to usual care were effective in achieving smoking cessation in CAD patients. Patients receiving specific psychosocial interventions had more than 60% higher odds of quitting. However, in the review of Barth and colleagues (2008) the effects must be interpreted with caution since there was a great heterogeneity in the patient sample.

There may be several reasons why there were no direct effects of our study's interventions on adherence to cardiac risk reduction behavior. One might be that our adherence measure lacked the sensitivity to measure the effect of the intervention on adherence, and the variance was low. The instrument was chosen because it is a questionnaire with evidence of validity and reliability in CAD patients.

Other explanations might be that the action plan in our study included only the planning part, and did not allow for patients to monitor their progress which may have decreased the effect of the intervention over time. Bandura (1986) found that not only goal setting, but also monitoring has been shown to be important for the ability to control behavior. Lippke and colleagues (2009) reported recently that action plans mediated the actual behavior change if the level of self-efficacy was high. When patients lack self-efficacy the action plan was not

working. An initial visible success in the monitoring part of the action plan may increase self-efficacy and motivation that may help patients maintain their behavior in health-related settings (Stretcher et al., 1995). It is extremely challenging for patients to develop and maintain consistent behavior and activities that entails major long-term changes in lifestyle. Our study lacked the possibility for patients to receive reminders or follow-up assessment and support that could have helped the patients in the long run. Only one consultation, as in our study, might not have enough impact on the adherence outcomes measured. A similar response was recently reported by Krones and colleagues (2010) who assessed CAD risk at six months' follow-up primarily to exclude a deterioration of risk factors caused by the intervention, and concluded that the influence of only one consultation cannot be assumed to have a high impact on the maintenance of healthy behavior.

In our study, the DA+DCP group was presented with their individual risks using the HeartScore[®], and both Intervention groups were able to calculate their own risk by looking in the DA. The recent review of Sheridan and colleagues (2010a) demonstrated that providing risk information improves the accuracy of risk perception and the probability of the intention to start risk reduction behavior among adults at moderate to high risk. Further, they stated that risk information is a tool to be used together with repeated interventions like counseling or risk feedback to promote adherence and risk reduction. Therefore, providing global risk presentation only once, as in our study, may not be sufficient to promote risk reduction behavior.

Another possible reason for the lack of a direct effect on a patient's adherence may be the influence of other factors unrelated to the effect of the experimental intervention on adherence. Variables in the literature found to be associated with patient non-adherence are physical disabilities, a sense that "nothing helps" regarding their disease progression, or a perception that their heart disease is cured through PCI (Peterson et al., 2010). Sherbourne and colleagues (1992) found that patients who reported that their physical and role functioning was poor, and reported feelings of frustration, despair, and other negative emotions about their health problems tended to be less likely to adhere to medical recommendations. This could explain the fact that these patients are sicker, and less able to manage the complexity of treatment regimens that has been recommended. These possible sources of variation were not encompassed by our intervention, nor were they measured or controlled for in our study.

Effects on Knowledge, Perceived Health Beliefs, and Perceived Benefits and Barriers of cardiac risk reduction behavior. The perceived barriers to cardiac risk reduction behavior were significantly lower in the DA+DCP group than in the Control group. This may be explained by explicitly addressing perceived benefits and barriers to cardiac risk reduction in the DCP. Addressing both is known as decisional balance, or pros minus cons. The idea is that individuals engage in relative weighing of the pros and cons, which are basic to models of rational decision-making, in which people intellectually think about the advantages and disadvantages, obstacles and facilitators, perceived benefits and barriers, pros and cons, of engaging in a particular action. In the DCP we enlarged the thinking focus on the perceived benefits and the barriers of cardiac risk reduction through the use of open-ended sentences that may have increased the person's awareness of the personal importance of perceived benefits and barriers here and now. The DCP intervention was thereby tailored to each patient's needs and preferences, and aimed to change the way people think about barriers to cardiac risk reduction behavior in an individualized way.

When patients are faced with information about life threatening situations such as cardiac risk, they may react in several ways: They can become fearful, which can trigger denial or avoidance, or they can become alert to danger and motivated to do whatever is necessary to alleviate the threat. To present patients with their individual risk profile that showed an elevated risk of dying of cardiac disease in the next ten years may trigger their fear reactions. Such fear was not measured as increased perceived susceptibility or severity of CAD or CAD progression among patients in our study. In the DCP in our study, the risk presentation was coupled with efficacy messages. The information about effective ways to reduce the risk of dying from CAD or CAD progression in the DA and the DCP was probably contributing to reduce the fear related to the presentation of risk scores.

In our study we did not find any group differences in knowledge scores. This conflicts with other studies showing that DAs have been effective in improving patients' understanding of options, and for increasing knowledge about these options and potential outcomes, both positive and negative (O'Connor et al., 2009). An explanation for our findings may be that the knowledge of risk factors and CAD in our study was measured two months after the decision, while most of the evaluations of DAs on knowledge have been evaluating the knowledge scores at the time of the decision.

Relationships

Relationships between Intentions to adhere to cardiac risk reduction behavior, Perceived Health Beliefs, Perceived Benefits and Barriers of cardiac risk reduction, Decisional Conflict, and Adherence outcomes. Results in this study show that intentions to adhere to cardiac risk reduction behavior were significantly related to several adherence outcomes over the study period. The intentions were measured before the randomization, and indicated how strongly the patients believed they would perform the behavior over the next two months. Higher intention to follow a healthy diet was significantly related to greater adherence to diet recommendations over the next six months. Higher intention to follow recommended activities was significantly related to greater adherence to diet recommendations and to activity recommendations over the next six months. The latter finding is supported by Rosen (2000) who found that physical activity and dietary change increased together, and suggested that the patterns of change differ across health areas. We know that some patterns exist, because some habits and behaviors co-occur, like weight, activity and diet, and also drinking and smoking. There has been proposed a need for a sequential behavior change process that first identifies risk-related behaviors and then lets the patient decide the importance and priorities of the risk-related behaviors to change, and finally to sequentially intervene on the prioritized behaviors (Strecher et al., 2002). Additional research supports that certain health risk behavior occurs in combination and tend to cluster within individuals (Strecher et al., 2002; Orleans, 2004). When multiple health behavior risk factors tend to occur in the majority of the population this creates the need for intervening broadly, comprehensively and efficiently on more than one risk behavior at a time (Calfas et al., 2002) as we did. Our study findings supports that it is feasible to let CAD patients decide to change two or more behaviors simultaneously.

Results in our study show that higher perceived susceptibility of CAD and /or CAD progression was significantly related to lower adherence to non-smoking recommendations. This is supported by Schmitz and colleagues (1999) who compared two strategies related to smoking cessation in women with established CAD and in women at risk of, but not established, CAD. Women with established CAD perceived themselves as being more susceptible to future smoking-related health problems, they had lower ratings on the perceived severity of such problems, and reported fewer benefits of quitting smoking than women who were at risk of, but not established, CAD. Women with established CAD, who

already suffered from negative effects of smoking, felt highly threatened by their smoking habits, but did not believe that quitting smoking would be beneficial in reducing the threat.

In our study, greater perceived severity of CAD was significantly related to greater adherence to stress reduction. This is supported by DiMatteo and colleagues (2007) who show that greater perceived disease severity is associated with better adherence. In other studies of more serious diseases that are amounting with poorer health and who rate their disease severe, patients are significantly less adherent than healthier patients with a less serious disease (DiMatteo et al., 2007). This may be due to the fact that cardiovascular disease risk is often underestimated and thought to be a natural part of aging (Emslie et al., 2001). Although CAD is not always seen as a chronic disease, 66% who had a heart attack do not make a complete recovery (Centers for Disease Control and Prevention, 2004).

In this study, higher perceived barriers to cardiac risk reduction were significantly related to lower adherence to diet recommendations. When the perceived barriers are high, the perceived benefits must also be high to make a change. The perceived benefits must outweigh the costs and perceived barriers to adherence for change in health behavior to occur. (Linde et al., 2006). It is well known that CAD patients often have a sense that “nothing helps” regarding their disease progression, or a perception that their heart disease is cured through PCI (Peterson et al., 2010). Therefore, it is important to help patients to consider perceived benefits together with perceived barriers of cardiac risk reduction as we did in the DCP in our study, because this may be the mechanisms of helping patients to succeed in cardiac risk reduction behavior. Allowance must be made for a latency time until the benefits of controlling the risk factors are evident. The problems may be that the perceived benefits of a healthy lifestyle may take some time to obtain. It is important to structure situations where patients meet opportunities to appreciate both the perceived benefits and the barriers of cardiac risk reduction behavior as we did. Only when the importance of perceived benefits is appreciated on a personal level is a change in behavior possible.

Results from our study show that higher decisional conflict was significantly related to lower adherence to diet-, activity-, and stress recommendations. Factors related to higher decisional conflict include feeling uninformed, unrealistic expectations, and unclear values (O'Connor et al., 2009). Data from our study indicate that it is important to consider factors that may reduce the decisional conflict because scores of 25 or lower are associated with

follow-through with decision, whereas scores that exceed 38 are associated with delay in decision-making (O'Connor et al., 1998b).

Relationships between adherence outcomes, primary health outcomes, and HRQoL. In this study, greater adherence to diet recommendations were significantly related to lower BMI and might be the mechanisms by which lower BMI was achieved. A healthy diet is associated with being low in fat and cholesterol, low in salt, high in dietary fiber, high in omega-3 fatty acids, and low in alcohol. Compared to an unhealthy diet there are fewer calories, which will result in weight loss. Adherence to diet recommendations was also significantly related to several better scores on HRQoL: Physical functioning, Role functioning physically, bodily pain, general health, role functioning emotionally, and mental health.

Findings from our study show that adherence to activity recommendations was significantly related to increased vitality. This is consistent with other research that have noted small improvements in quality of life among cardiac populations adhering to physical activity recommendations, or rehabilitation and education interventions (Belardinelli et al., 2001; Clark et al., 2005; Thompson et al., 2003).

Results from our study show that greater adherence to taking their medication was significantly related to lower physical functioning. This may be due to the fact that patients needing medications may be sicker and thereby less able to perform physical activity. Greater adherence to taking medications was also associated with lower HDL. CAD patients are often on cholesterol medication, and people who need to lower their LDL cholesterol often have low HDL cholesterol.

The findings in our study underscore the idea that adherence might not be a unified construct: measurement of adherence and the context of research are important determinants of research results. This is supported by DiMatteo and colleagues (2002) who reported that when adhering, 26 % more patients experienced good outcomes compared to patients not adhering, and the adherence outcome relationships vary between the regimen, measurements and disease studied.

Since cardiac risk reduction is in general the same as good health practice, it is not clear from our study that patients were practicing the behavior to promote wellness, to protect the

occurrence, and/or deterioration of CAD or both. Furthermore, adherence does not necessarily have specific effects. Studies of medication have found that adherence is related to better outcomes, not only when the drug is an active one, but also when it is a placebo (Epstein, 1984; Horwitz et al., 1990).

Relationships between primary health outcomes and HRQoL. Results from our study show that there was a significant relationship between lower BMI and better physical functioning, less body pain, higher treatment satisfaction, and better disease perception. Also, there were significant relationships between the patients attending health services such as cardiac rehabilitation, smoking cessation programs, diet meetings, and weight reduction meetings, with perceived less bodily pain, better general health, and better vitality. A Cochrane review shows that patients with angina without having a MI and/or a CABG surgery appear less likely to receive appropriate secondary preventive care (Buckley et al., 2010). Findings in our study indicate that it may be important to offer cardiac rehabilitation to angina patients following an angiogram even if they did not receive any treatment like PCI and/or CABG surgery.

Additional findings

Patients' appraisal of the usefulness of the DA and the decisional counseling program (DCP). When asked specifically about the DA booklet the patients' (DA and DA+DCP group) responses were predominantly very positive about the presentation of major risks, and the options for lifestyle changes. Overall, positive responses included the amount and length of the presentations, and most patients reported the DA as balanced between risk and options. There were some interesting significant differences between the two groups. The DA+DCP group, who received both the DA and the DCP, rated the calculation of risk, the thinking of possible changes, the making of their own action plan, and the use of the information on the worksheet significantly higher than the DA group. Besides, the DA+DCP group thought that the decision of cardiac risk reduction became significantly easier, that the way the risk was presented was easier, and thought the DA was more useful than the DA group did. The reason may be that the combination of the DA with the additive DCP gave an extra "dose" to enforce and strengthen the effect on the usefulness of the DA.

Research shows that tailored print communication increases recall and is perceived as a credible source of health information (Skinner et al., 1999). DCP uses tailored counseling and

involves messages that are individualized, and based on the personal assessments. Therefore, a combination of a DA and additional counseling like in our study, may be particular helpful for patients.

Based on the appraisal from the patients in our study there is a need for developing and testing educational materials and counseling to support both the communication and the decision-making process. This is supported by van Steenkiste and colleagues (2004) who state that it is not easy to explain cardiovascular risk to patients with the help of just a risk table. Shared decision-making are a valuable approach in prevention, and DAs could support the caregiver and the patients (Edwards & Elwyn, 1999b), though the effect of such DAs remain to be investigated. A test using a patient workbook for self-assessment of coronary risk yielded promising results (Paterson et al., 2002), as in our study.

The patients' responses to the DCP (DA+DCP group) were also predominantly positive about the form of communication about the importance of cardiac risk reduction and options for cardiac risk reduction behavior in the counseling session. The length and amount of the counseling was mostly reported as just right. Most patients evaluated the proportion between risk and options as balanced, and that the risk was easily communicated. Only 3.5 % of the patients in DA+DCP group found the way the risk was communicated in the counseling to be difficult. Overall, positive responses were found, including the influence of the counseling on the decision of life changes, the usefulness of the counseling, and that the counseling included enough information to help them decide what to do next.

DA is helping patients to understand what they prefer, and thereby be able to discuss their preferences with their doctor. The DA and the DCP were asking about patients' values and asking them how they felt about what they have heard and read, and what they might be doing with the information. The great appreciation of the DA and the DCP in our study supports the importance of eliciting patients' preferences for cardiac risk reduction behavior in the counseling. Just as the physical examination is important, patients' preferences are too.

Contribution to clinical practice

The interventions in this study were feasible, were done in real practice and in patients' homes, and supported several mechanisms regarding initiating cardiac risk reduction behavior in patients with risk of CAD or CAD progression. Counseling is an important role in nursing, and the cooperation between the nurse counselors and the physician may relieve the physician in promoting healthy behavior interventions to CAD patients in cardiac outpatient clinics.

This study provided a way to engage patients in the decision-making process about their options for lifestyle changes and possible cardiac risk reduction behavior. The DCP provided a structured counseling process that helped patients articulate their individual questions and concerns, as well as disclose and evaluated perceived benefits and barriers of cardiac risk reduction behavior. Patients are demanding more involvement in decisions about their care. To respond, health care providers need practical tools to help encourage patients' participation and, at the same time, support high-quality decisions that are acted upon. Decision-making is more than the effect on the decision process, the results of the decision matters.

Recent data from the Research Council of Norway shows that 98.5 % of the inhabitants have been assigned to a regular general practitioner. The average duration of the doctor-patient relationship was 7.7 years in 2003. The sub-group of CAD patients shows that the mean duration of relationship between CAD patients and their doctor was 8.4 years. The longitudinal nature of this relationship provides multiple opportunities for clinicians and the nurses to provide health behavior advice and counseling over long periods of time to CAD patients in Norway. Patients with angina alone appear less likely to receive appropriate secondary preventive care (Buckley et al., 2010) than patients with MI and/or CABG surgery. Based on the association between cardiac rehabilitation and health outcomes found in our study may be important to offer cardiac rehabilitation to the angina patients following angiogram too, not only patients with MI and/or CABG surgery.

Recommendations for future research

Interventions addressing multiple risk factors and including more comprehensive approaches to understand behavioral change is important. Incorporating processes that stimulate the emotions can give a sense of the wider theoretical context that may explain some effects of behavioral interventions. Existing behavioral theories and models using only rational processing can be reframed when adding new or even total different approaches to see if it can better explain the behavior change. It is important to challenge existing behavioral theories so we can expand behavioral theories. Including DAs and add decisional counseling can be tested in other settings, like a cardiac outpatient ward.

Several suggestions for future research are recommended. The use of a comprehensive, valid, reliable measure of adherence to cardiac risk reduction behavior is important. Another suggestion is the inclusion of actual adherence at baseline, instead of intentions to adhere. Also, the large unexplained variance in adherence suggests that additional variables may better explain adherence to cardiac risk reduction. Findings in previous studies revealed that self-efficacy (Senécal et al., 2000) and reinforcement (Burke et al., 1995) are significant predictors of adherence among patients with chronic illness. Based on the results in our study we will suggest a greater dose of intervention to promote adherence including structured reminder systems, cues, self-monitoring, feedback, and reinforcement.

Many factors like patients' knowledge and beliefs about their illness, motivation and ability to engage in risk-reduction behavior, expectations regarding outcomes of lifestyle behavior, and consequences of poor adherence, interact in ways not yet fully understood. It is important to recognize that understanding the role of adherence in treatment outcomes requires further analysis of the conceptual and methodological factors that affect this relationship. DiMatteo and colleagues (2002) note that patient adherence is linked to greater positive outcomes than non-adherence, and therefore, that adherence may be a valuable goal of interventions at the individual level. Whether because of improved treatment effects, classical conditioning, positive expectations, or the inner pharmacy of neuroendocrine and immune responses mediated by the emotional experience that attends good care, data indicate that adherence promote patients' health and recovery. Efforts to improve patients' adherence, particularly in the context of active patient involvement and responsibility in collaboration

with their physicians, continue to represent a worthwhile enterprise. Therefore, we must explore how we can make clinical decisions about health behavior better. It is known that DA has limited effects on health outcomes (O'Connor et al., 2009). The best advantage of DAs is the chance to present the topic as best we can to the patients, and in doing so, we have the opportunity to standardize the information, eliminate or minimize biases, and present the information in a format that allows patients to assess their own values, and come to a personalized decision. If involvement is to be effective, adequate discussions of risks and perceived benefits associated with different choices is often required (Edwards et al., 2006). Therefore, an additive individual decisional counseling is still important. Discussion of personal risk factors are relevant to the decision, which means that the individuals' own characteristics are taken into account in assessing their actual risk or elevated risk status relative to others (Edwards et al., 2006).

Trying to achieve and maintain a healthy weight can be accomplished through particular changes in a variety of specific behavior. The specific actions taken may vary greatly from person to person and such an approach puts a focus on the issue of choice. For example, whereas an individual may choose to have a very strict diet and only limited physical activity, another individual may make fewer dietary changes, but focus more on adopting vigorous physical activities. Such an approach would focus on the outcome of healthy weight as a conceptual category to organize, and ultimately drive, a multitude of possible behavioral changes. As such, the intervention is organized around the healthy heart.

Most people who attempt multiple behavioral changes in the context of cardiovascular risk reduction are not successful (EUROASPIRE II Study Group, 2001). We suggest that interventions should guide people in making choices based on an assessment of which behavioral changes are likely to be most easily and readily adopted, not necessarily the behavior that is likely to yield the most immediate health benefit. Selecting such a behavior may increase the likelihood that the individual will gain confidence and then attempt more difficult and potentially more beneficial behaviors.

One central idea that has gained wide acceptance in recent years is the notion that behavior change is a process, not an event. It involves more than someone deciding one day to stop smoking, and the next day becoming a non-smoker for the rest of their life. Even if there is good initial compliance to a health related behavior using change advice or attempts relapse

is common. An important question is whether in fact there is a common set of principles of health behavior changes that make an impact on health behavior, and whether or not there are theoretical differences in additive versus non-additive behaviors, on-time behaviors versus those that are maintained, and adoption behaviors versus cessation behaviors. To maintain, for example, smoking cessation behavior requires developing self-management and coping strategies, and establishing new behavior patterns that emphasize perceived control, environmental management, and improved confidence in one's ability to avoid temptation. Therefore, additional meta-analytic projects across behaviors are necessary to assess potential common and /or unique mechanisms of health behavior and health behavior change.

This is the first study comparing the effect of a DA with and without additional individual preference-based decisional counseling on behavioral change and health outcomes and should therefore be repeated with a larger sample size before final conclusions about intervention effectiveness should be drawn.

Summary

In this study combining the DA with the DCP supported patients to individually tailor their cardiac risk reduction behavior to their health beliefs and preferences, resulting in better health outcomes and HRQoL on some dimensions. The DA alone did not improve health behaviors and outcomes. We do not know if these effects would have occurred by the DCP alone, without combining it with the DA. Finally, this study contributed to a better understanding of variables related to adherence to lifestyle recommendations and health outcomes.

References

- Acquadro, C., Conway, K., GirouDET, C., & Mear, I. (2004). *Linguistic validation manual for patient-reported outcomes (pro) instruments*. MAPI Research Institute, Lyon, France. ISBN: 2-9522021-0-9
- Ades, P.A., Waldmann, M.L., McCann, W.J., & Weaver, S.O. (1992). Predictors of cardiac rehabilitation participation in older coronary patients. *Archives of Internal Medicine*, *152*(5), 1033-1035.
- Al-Ali, N., & Haddad, L.G. (2004). The effect of the Health Belief Model in explaining exercise participation among Jordanian myocardial infarction patients. *Journal of Transcultural Nursing*, *15*(2), 114-121.
- Aldana, S.G., Whitmer, W.R., Greenlaw, R., Avins, A.L., Salberg, D.T.A., Greenwell, A., Lipsenthal, L., & Fellingham, G.W. (2006). Effect of intense lifestyle modification and cardiac rehabilitation on psychosocial cardiovascular disease risk factors and quality of life. *Behavior Modification* *30*(4), 507-525.
- Ali, N.S. (2002). Prediction of coronary heart disease preventive behaviors in women: A test of the Health Belief Model. *Women & Health*, *35*(1), 83-96.
- Ammerman, A.S., Lindquist, C.H., Lohr, K.N., & Hersey, J. (2002). The efficacy of behavioral interventions to modify dietary fat and fruit and vegetable intake: a review of the evidence. *Preventive Medicine*, *35*(1), 25-41.
- Anand, S.S., Islam, S., Rosengren, A., Franzosi, M.G., Steyn, K., Yusufali, A.H., Keltai, M., Diaz, R., Rangarajan, S., & Yusuf, S. (2008). Risk factors for myocardial infarction in women and men: insights from the INTERHEART study. *European Heart Journal*, *29*(7), 932-940.
- Appel, L.J., Champagne, C.M., Harsha, D.W., Cooper, L.S., Obarzanek, E., Elmer, P.J., Stevens, V.J., Vollmer, W.M., Lin, P.H., Svetkey, L.P., Stedman, S.W., & Young, D.R. (2003). Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *The Journal of the American Medical Association*, *289*(16), 2083-2093.
- Ashenden, R., Silagy, C., & Weller, D. (1997). A systematic review of the effectiveness of promoting lifestyle change in general practice. *Family Practice*, *14*(2), 160-175.

- Avis, N.E., Smith, K.W., & McKinlay, J.B. (1989). Accuracy of perceptions of heart attack risk: what influences perceptions and can they be changed? *American Journal of Public Health, 79*(12), 1608-1612.
- Babor, T.F., & Higgins-Biddle, J.C. (2001). *Brief intervention for hazardous and harmful drinking: a manual for primary care*. Geneva: World Health Organization, Department of Mental Health and Substance Dependence.
- Bandura, A. (1986). *Social foundations for thoughts and action: A social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall.
- Baranowski, T., Lin, L.S., Wetter, D.W., Resnicow, K., & Davis Hearn, M. (1997). Theory as mediating variables: why aren't community interventions working as desired? *Annals of Epidemiology, 7*(S7), S89-S95.
- Barry, M.J., Fowler, F.J., Mulley, A.G jr., Henderson, J.V jr., & Wennberg, J.E. (1995). Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. *Medical Care, 33*(8), 771-782.
- Barry, M.J., Cherkin, D.C., Chang, Y., Fowler, F.J., & Skates, S. (1997). A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for Benign Prostatic Hyperplasia. *Disease Management and Clinical Outcomes, 1*(1), 5-14.
- Barth, J., Critchley, J.A., & Bengel, J. (2008). Psychological interventions for smoking cessation in patients with coronary heart disease. *Cochrane Database of Systematic Reviews*, 2008, Issue 1. Art.No. CD006886.DOI: 10.1002/1465858.CD006886.
- Becker, M.H., & Rosenstock, I.M. (1987). Comparing social learning theory and the health belief model. In: W.B. Ward (Ed). *Advances in health education and promotion*, 245-249. Greenwich, CT: JAI Press.
- Bekker, H., Thornton J.G., Airey, C.M., Connelly, J.B., Hewison, J., Robinson, M.B., Lilleyman, J., MacIntosh, M., Maule, A.J., Michie, S., & Pearman, A.D. (1999). Informed decision making: an annotated bibliography and systematic review. *Health Technology Assessment (Winchester, England), 3*(1), 1-156,
- Belardinelli, R., Paolini, I., Cianci, G., Piva, R., Georgiou, D., & Purcaro, A. (2001). Exercise training intervention after coronary angioplasty: the ETICA trial. *Journal of the American College of Cardiology, 37*, 1891-1900.
- Bellg, A.J. (2003). Maintenance of health behavior change in preventive cardiology. Internalization and self-regulation of new behaviors. *Behavior Modification, 27*(1), 103-131.

- Bellg, A.J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D.S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., & Czajkowski, S. (2004). Enhancement treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443-451.
- Bernstein, S.J., Skarupski, K.A., Grayson, C.E., Starling, M.R., Bates, E.R., & Eagle KA. (1998). A randomized controlled trial of information-giving to patients referred for coronary angiography: Effects on outcome of care. *Health Expectations, 1*, 50-61.
- Blumenthal, J.A., Sherwood, A., Babyak, M.A., Watkins, L.L., Waugh, R., Georgiades, A., Bacon, S.L., Hayano, J., Coleman, R.E., & Hinterliter, A. (2005). Effects of exercise and stress management training on markers of cardiovascular risk in patients with ischemic heart disease: a randomized controlled trial. *The Journal of the American Medical Association, 293*(13), 1626-1634.
- Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *The Journal of the American Medical Association, 288*, 2469-2475.
- Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A.J., Czajkowski, S., Breger, R., DeFrancesco, C., Levesque, C., Sharp, D.L., & Ogedegbe, G. (2005). A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *Journal of Consulting and Clinical Psychology, 73* (5), 852-860.
- Bosworth, H.B., Siegler, I.C., Olsen, M.K., Brummett, B.H., Barefoot, J.C., Williams, R.B., Clapp-Channing, N.E., & Mark, D.B. (2000). Social support and quality of life in patients with coronary artery disease. *Quality of Life Research, 9*(7), 829-839.
- Bramley, T.J., Gerbino, P.P., Nightengale, B.S., & Frech-Tamas, F. (2006). Relationship of blood pressure control to adherence with antihypertensive monotherapy in 13 managed care organizations. *Journal of Managed Care Pharmacy, 12*(3),239-245.
- Briggs, L.A., Kirchhoff, K.T., Hammes, B.J., Song, M-K., & Colvin, E.R. (2004). Patient-centered advance care planning in special patient populations: A pilot study. *Journal of Professional Nursing, 20*(1), 47-58.
- Brislin, R.W. (1970). Back-translation for cross-cultural research. *Journal of Cross-cultural Psychology, 1*, 185-216.
- Brislin, R.W., Lonner, W.J., & Thondike, R.M. (1973). *Cross-Cultural Research Methods*. New York: John Wiley & Sons.

- Brody, D.S., Miller, S.M., Lerman, C.E., Smith, D.G., & Caputo, G.C. (1989). Patient perception of involvement in medical care: relationship to illness attitudes and outcomes. *Journal of General Internal Medicine*, 4, 506-511.
- Brown, G.I. (1975). Human is as confluent does. In: G.I. Brown, T. Yeomans & L. Grizzard (Eds). *The live classroom. Innovation through confluent education and gestalt*. pp 99-108. An Esalen Book, The Viking Press, New York; NY
- Brown, N., Melville, M., Gray, D., Young, T., Munro, J., Skene, AM., & Hampton, J.R. (1999). Quality of life four years after acute myocardial infarction: short form 36 scores compared with a normal population. *Heart*, 81(4), 352-358.
- Buckley, B.S., Byrne, M.C., & Smith, S.M. (2010). Service organisation for the secondary prevention of ischaemic heart disease in primary care. *Cochrane Database of Systematic Reviews*, 2010, Issue 3. Art.No.:CD006772.DOI:10.1002/14651858.CD006772.pub2.
- Burke, L.E., & Dunbar-Jacob, J.M. (1995). Adherence to medication, diet, and activity recommendations: from assessment to maintenance. *Journal of Cardiovascular Nursing*, 9(2), 62-79.
- Burke, L.E., Dunbar-Jacob, J.M. & Hill, M.N. (1997). Compliance with cardiovascular disease prevention strategies: A review of the research. *Annals of Behavioral Medicine*, 19(3), 239-263.
- Burling, T.A., Singleton, E.G., Bigelow, G.E., Baile, W.F., & Gottlieb, S.H. (1984). Smoking following myocardial infarction: a critical review of the literature. *Health Psychology*, 3(1), 83-96.
- Calfas, K.J., Sallis, J.F., Zabinski, M.F., Wilfley, D.E., Rupp, J., Prochaska, J.J., Thompson, S., Pratt, M., & Patrick, K. (2002). Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. *Preventive Medicine*, 34(2), 153-161
- Campbell, N.C., Ritchie, L.D., Thain, J., Deans, H.G., Rawles, J.M., & Squair, J.L. (1998). Secondary prevention in coronary heart disease: a randomized trial of nurse led clinics in primary care. *Heart*, 80, 447-452.
- Campeau, L. (1976). Grading of Angina Pectoris (letter). *Circulation*, 52, 522-523
- Campeau, L. (2002). The Canadian Vascular Society grading of angina pectoris revised 30 years later. *Canadian Journal of Cardiology*, 18(4), 371-379.
- Carmines, E.G., & Zeller, R.A. (1979). *Reliability and validity assessment*. Sage University Series on Quantitative Applications in the Social Sciences, series no. 07-017. Newbury Park, CA: Sage

- Cauley, J.A., Kriska, A.M., LaPorte, R.E., Sandler, R.B., & Pambianco, G. (1987). A two year randomized exercise trial in older women: effects on HDL-cholesterol. *Atherosclerosis*, 66(3), 247-58
- Centers for Disease Control and Prevention. (2004). *The burden of chronic diseases and their risk factors: national and state perspectives*.
<http://www.cdc.gov/nccdphp/burdenbook2004/> retrieved 01.12.10
- Champion, V.L. (1993). Instrument refinement for breast cancer screening behaviors. *Nursing Research*, 42(3), 139-143.
- Charles, C., Gafni, A., Whelan, T., & O'Brien, M.A. (2005). Treatment decision aids: conceptual issues and future directions. *Health Expectations*, 8(2), 114-125
- Charlson, M.E., Pompei, P., Ales, K.L., & MacKenzie, C.R. (1987). A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *Journal of Chronic Disease*, 40, 373-383.
- Chew, F., Palmer, S., & Kim, S. (1998). Testing the influence of the health belief model and a television program on nutrition behavior. *Health Communication*, 10(3), 227-245
- Christian, A.H., Cheema, A.F., Smith, S.C., & Mosca, L. (2007). Predictors of quality of life among women with coronary heart disease. *Quality of Life Research*, 16,363-373
- Clark, A.M., Hartling, L., Vandermeer, B., & McAlister, F.A. (2005). Meta-analysis: secondary prevention programs for patients with coronary heart disease. *Annals of Internal Medicine* 143(9), 659-672.
- Clark, M.M., Pera, V, Goldstein, M.G., Thebarga, R.W., & Guise, B.J. (1996). Counseling strategies for obese patients. *American Journal of Preventive Medicine*, 12, 266-270.
- Clark, N.M., & Becker, M.H. (1998). Theoretical models and strategies for improving adherence and disease management. In: S.A. Schumaker, E.B. Schron, J.K. Ockene and W.L. McBee (Eds) *The Handbook of Health Behavior Change-2nd Ed*. New York, NY: Springer Publishing Company, pp: 5-32.
- Clarke, R., Lewington, S., Youngman, L., Sherliker, P., Peto, R., Collins, R. (2002). Underestimation of the importance of blood pressure and cholesterol for coronary artery disease mortality in old age. *European Heart Journal*, 23(4), 286-293.
- Cohen, B.J. (1988). *Statistical power analysis for the behavioral sciences (2nd Ed.)* Hillsdale, NJ: Lawrence Erlbaum Associates.
- Conrad, P. (1985). The meaning of medications: another look at compliance. *Social Science & Medicine*, 20(1), 29-37.

- Cooper, L.A., Hill, M.N., & Powe, N.R. (2002). Designing and evaluating interventions to eliminate racial and ethnic disparities in health care. *Journal of General Internal Medicine, 17*(6), 477-486.
- Coulter, A., & Ellins, J. (2007). Effectiveness of strategies for informing, educating, and involving patients. *British Medical Journal, 335*(7609), 24-27.
- Craig, P., Dieppe, P., Macintyre, S., Mitchie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new medical research Council guidance. *British Medical Journal, 337*, 979-983.
- Croog, S.H., & Richards, N.P. (1977). Health beliefs and smoking patterns in heart patients and their wives: a longitudinal study. *American Journal of Public Health, 67*(10), 562-566.
- Cullen, K.W., Baranowski, T., & Smith, S.P. (2001). Using goal setting as a strategy for dietary behavior change. *Journal of American Dietetic Association, 101*, 562-566.
- Cupples, M.E., & McKnight, A. (1994). Randomised controlled trial of health promotion in general practice for patients at high cardiovascular risk. *British Medical Journal, 309*(6960), 993-996.
- Davison, B.J., Kirk, P., Degner, L.F., & Hassard, T.H. (1999). Information and patient participation in screening for prostate cancer. *Patient Education and Counseling, 37*, 255-263.
- DeBusk, R.F., Miller, N.H., Superko, H.R., Dennis, C.A., Thomas, R.J., Lew, H.T., Berger, W.E. 3rd., Heller, R.S., Rompf, J., Gee, D., Kraemer, H.C., Bandura, A., Ghandour, G., Clark, M., Shah, R.V., Fisher, L., & Taylor, C.B. (1994). A case-management system for coronary risk factor modification after acute myocardial infarction. *Annals of Internal Medicine, 120*(9), 721-9.
- Delgado, M. (1995): Community Asset Assessment and Substance Abuse Prevention. A Case Study Involving the Puerto Rican Community. *Journal of Child & Adolescent Substance Abuse, 4*(4), 57-78
- Dempster, M., & Donnelly, M. (2000). Measuring the health related quality of life of people with ischaemic heart disease. *Heart, 83*(6), 641-644.
- Deschamps, M.A., Taylor, J.G., Neubauer, S.L., & Whiting, S. (2004). Impact of pharmacist consultation versus a decision aid on decision making regarding hormone replacement therapy. *International Journal of Pharmacy Practice, 12*(1), 21-28.
- DiMatteo, M.R. (1994). Enhancing patient adherence to medical recommendations. *The Journal of the American Medical Association, 271*(1), 79, 83

- Di Matteo, M.R. (2004a). Variations in patients' adherence to medical recommendations. A quantitative review of 50 years of research. *Medical Care*, 42(3), 200-209.
- DiMatteo, M.R. (2004b). Evidence-based strategies to foster adherence and improve patient outcomes. *Journal of the American Academy of Physician Assistants*, 17, 18-21.
- DiMatteo, M.R., Lepper, H.S., & Croghan, T.W. (2000). Depression is a risk for noncompliance with medical treatment: a meta-analysis of the effects of anxiety and depression on patient adherence. *Archives of Internal Medicine*, 160 (14), 2101-2107.
- DiMatteo, M.R., Giordani, P.J., Lepper, H.S., & Croghan, T.W. (2002). Patient adherence and medical treatment outcomes. A meta-analysis. *Medical Care*, 40(9), 794-811.
- DiMatteo, M.R., Haskard, K.B., & Williams, S.L. (2007). Health beliefs, disease severity, and patient adherence. A meta-analysis. *Medical Care*, 45(6), 521-528.
- Dodin, S., Legare, F., Daudelin, G., Tetroe, J., & O'Connor, A. (2001). Making a decision about hormone replacement therapy. A randomized controlled trial. *Canadian Family Physicians*, 47, 1586-1593. (Abstract only)
- Dolan, J.G., & Frisina, S. (2002). Randomized controlled trial of a patient decision aid for colorectal cancer screening. *Medical Decision Making*, 22(2), 125-139.
- Donovan, J.L., & Blake, D.R. (1992). Patient non-compliance: deviance or reasoned decision-making? *Social Science and Medicine*, 34, 507-513.
- Dougherty, C.M., Dewhurst, T.A., Nicol, W.P. & Spertus, J. A. (1998). Comparison of three quality of life instruments in stable angina pectoris: Seattle Angina Questionnaire, Short Form Healthy Survey (SF-36), and Quality of Life Index-Cardiac version III. *Journal of Clinical Epidemiology*, 51(7), 569-575.
- Drake, E.R., Engler-Todd, L., O'Connor, A.M., Suhr, L.C., & Hunter, A. (1999). Development and evaluation of a decision aid about prenatal testing for women of advanced maternal age. *Journal of Genetic Counseling*, 8(4), 217-233.
- Dusseldorp, E., van Elderen, T., Maes, S., Meulman, J., & Kraaij, V. (1999). A meta-analysis of psychoeducational programs for coronary heart disease patients. *Health Psychology*, 18, 506-519.
- Ebrahim, S., Beswick, A., Burke, M., & Davey Smith, G. (2006). Multiple risk factor interventions for primary prevention of coronary heart disease. *Cochrane Database of Systematic Reviews*, 2006, Issue4. Art.No.: CD001561. DOI: 10.1002/14651858.CD001561.pub2.

- Edwards, A., & Elwyn, G. (1999a). How should effectiveness of risk communication to aid patients' decisions be judged? A review of the literature. *Medical Decision Making*, 19(4), 328-434.
- Edwards, A., & Elwyn, G. (1999b). The potential benefits of decision aids in clinical medicine. *The Journal of the American Medical Association*, 282 (8), 779-780.
- Edwards, A., Elwyn, G., & Mulley, A. (2002). Explaining risks: Turning numerical data into meaningful pictures. *British Medical Journal*, 324, 827-830.
- Edwards, A.G.K., Evans, R., Dundon, J., Haigh, S., Hood, K., & Elwyn, G.J. (2006). Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database of Systematic Reviews*, 2006, Issue 4 Art. No.: CD001865. DOI:10.1002/14651858.CD001865.pub2.
- Elstein, A.S., Fryback, D.G., Weinstein, M.C., Pauker, S.G., Holmes-Rovner, M., Young, M.J., Barry, M.J., Eckman, M.H., Hunink, M., Tsevat, J., & Wong, J.B. (2004). Presidential reflections on the 25th anniversary of the Society for Medical Decision Making. *Medical Decision Making*, 24(4), 408-420.
- Emslie, C., Hunt, K., & Watt, G. (2001). "I'd rather go with a heart attack than drag on": Lay images of heart disease and the problems they present for primary and secondary prevention. *Coronary Health Care*, 5 (1), 25-32.
- Epstein, L.H. (1984). The direct effects of compliance on health outcome. *Health Psychology*, 3(4), 385-393.
- Eraker, S.A., & Sox, H.C. (1981). Assessment of patients preferences for therapeutic outcomes. *Medical Decision Making*, 1, 29-39.
- Eraker, S.A., & Politser, P. (1982). How decisions are reached: physician and patient. *Annals of Internal Medicine*, 97, 262-268.
- Eraker, S.A., Kirscht, J.P., & Becker, M.H. (1984). Understanding and improving patient compliance. *Annals of Internal Medicine*, 100, 258-268.
- Eraker, S.A., Becker, M.H., Strecher, V.J., & Kirscht, J.P. (1985). Smoking behavior, cessation techniques, and the health decision model. Review. *The American Journal of Medicine*, 78(5), 817-825.
- EUROASPIRE Study Group (2001). Lifestyle and risk factor management and use of drug therapies in coronary patients in 15 countries. Principal results from EUROASPIRE II Euro Heart Programme. *European Heart Journal*, 22, 554-572.

- Ewart, C.K. (1989). A social problem-solving approach to behavior change in coronary heart disease. In: S.A. Shumaker, E.B. Schron & J.K. Ockene, Eds. *The Handbook of Health Behavior Change*. New York: Springer Publishing Company. pp153-190.
- Fagard, R.H. (2001). Exercise characteristics and the blood pressure response to dynamic physical training. *Medicine & Science in Sports & Exercise*, 33(6 Suppl), S484-492.
- Fagard, R.H., & Cornelissen, V.A. (2007). Effects of exercise on blood pressure control in hypertensive patients. *European Journal of Cardiovascular Prevention and Rehabilitation*, 14(1),12-17.
- Failde, I., & Ramos, I. (2000). Validity and reliability of the SF-36 Health Survey Questionnaire in patients with coronary artery disease. *Journal of Clinical Epidemiology*, 53(4), 359-365.
- Fiore, M.C., Jaen, C.R., Baker, T.B., Bailey, W.C., Bennet, G., et al. (2008). A clinical practice guideline for treating tobacco use and dependency: 2008 Update. A U.S. Public Health Service Report. *American Journal of Preventive Medicine*, 35(2), 158-176.
- Fiset, V., O'Connor, A.M., Evans, W.K., Graham, I., DeGrasse, C., & Logan, J. (2000). The development and evaluation of a decision aid for patients with stage IV non-small cell lung cancer. *Health Expectations*, 3(2), 125-136.
- Flottorp, S., Farah, M.G., Thürmer, H., Johansen, M., & Fretheim, A. (2008). Ikke medikamentelle tiltak for å redusere risiko for hjerte- og karsykdommer: en oppsummering av systemiske oversikter. *Kunnskapsoppsummering. Rapport fra Kunnskapscenteret nr 19*.
- Folkehelseinstituttet. Hjerterinfarkt - fakta om infarkt og annen iskemisk hjertesykdom. Elektronisk publikasjon <http://www.fhi.no/artikler/?id=41609> Sist oppdatert 04.01.2011.
- Foster, C., Hillsdon, M., & Thorogood, M. (2005). Interventions for promoting physical activity. *Cochrane Database of Systematic Reviews*, 2005, Issue 1. Art.No.: CD003180.DOI: 10.1002/14651858.CD003180.pub2.
- Franklin, B.A., de Jong, A., Kahn, J.K., & McCullough, P.A. (2004). Fitness and mortality in the primary and secondary prevention of coronary artery disease: does the effort justify the outcome? *American Journal of Medical Sports*, 6, 23-27.
- Frisch, D., & Jones, S.K. (1993). Assessing the accuracy of decisions. *Theory and Psychology*, 3(1), 115-135.
- G*Power analysis program (<http://www.psych.uni-duesseldorf.de/aap/projects/gpower/>)

- Glasgow, R.E. (2003). Translating research to practice: lessons learned, areas for improvement, and future directions. *Diabetes Care*, 26(8), 2451-2456.
- Glasgow, R.E., Hiss, R.G., Anderson, R.M., Friedman, N.M., Hayward, R.A., Marrero, D.G., Taylor, C.B., & Vinicor, F. (2001). Report of the health care delivery work group: behavioral research related to the establishment of a chronic disease model for diabetes care. *Diabetes Care*, 24(1), 124-130.
- Glasgow, R.E., Funnell, M.M., Bonomi, A.E., Davis, C., Beckham, V., & Wagner, E.H. (2002). Self-management aspects of the improving chronic illness care breakthrough series: implementation with diabetes and heart failure teams. *Annals of Behavioral Medicine*, 24, 80-87.
- Glasgow, R.E., Davis, C.L., Funnell, M.M., & Beck, A. (2003). Implementing practical interventions to support chronic illness self-management. *Joint Commission Journal on Quality & Safety*, 29(11), 563-574.
- Glasgow, R.E., Goldstein, M.G., Ockene, J.K., & Pronk, N.P. (2004). Translating what we have learned into practice: principles and hypotheses for interventions addressing multiple behaviors in primary care. *American Journal of Preventive Medicine*, 27(2, Suppl 1), 88-101.
- Goel, V., Sawka, C.A., Thiel, E.C., Gort, E.H., & O'Connor, A.M. (2001). Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer. *Medical Decision Making*, 21, 1-6.
- Goldstein, M.G., Whitlock, E.P., & DePue, J. (2004). Multiple behavioral risk factor interventions in primary care. Summary of research evidence. *American Journal of Preventive Medicine*, 27(2Suppl), 61-79.
- Goldstein, M.K., Clarke, A.E., Michelson, D., Garber, A.M., Bergen, M.R., & Lenert, L.A. (1994). Developing and testing a multimedia presentation of a health-state description. *Medical Decision Making*, 14(4), 336-344.
- Gollwitzer, P.M., & Sheeran, P. (2006). Implementation intentions and goal achievement: a meta-analysis of effects and processes. *Advances in Experimental Social Psychology*, 38, 69-119.
- Graham, I., Atar, D., Borch-Johnsen, K., Boysen, G., Burell, G., Cifkova, R., et al. (2007). European guidelines on cardiovascular disease prevention in clinical practice: Full text. *European Journal of Cardiovascular Prevention and Rehabilitation*, 17(Suppl 2), S1-S113.

- Grant, A.M. (2003). The impact of life coaching on goal attainment, metacognition and mental health. *Social Behavior and Personality: an international journal*, 31(3), 253-263.
- Greenfield, S., Kaplan, S.H., Ware, J.E.jr., Yano, E.M., & Frank, H.J. (1988). Patients' participation in medical care: Effects on blood sugar control and quality of life in diabetes. *Journal of General Internal Medicine*, 3(5), 448-457.
- Grendstad, N.M. (1986). *Å lære er å oppdage. Prinsipper og arbeidsmåter i konfluent pedagogikk*. Didakta Norsk Forlag a.s., Oslo.
- Gritz, E.R., Kristeller, J.L., & Burns, D.M. (1993). Treating nicotine addiction in high-risk groups and patients with medical co-morbidity. In: C.T. Orleans, J. Slade., Eds. *Nicotine addiction: Principles and Management*. New York: Oxford University Press, pp. 279-309.
- Gæde, P., Vedel, P., Larsen, N., Jensen, G.V.H., Parving, H-H., & Pederson, O. (2003). Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *The New England Journal of Medicine*, 348, 383-393.
- Hambrecht, R., Walther, C., Möbius-Winkler, S., Gielen, S., Linke, A., Conradi, K., Erbs, S., Kluge, R., Kendziorra, K., Sabri, O., Sick, P., & Schuler, G. (2004). Percutaneous coronary angioplasty compared with exercise training in patients with stable coronary artery disease. A randomized trial. *Circulation*, 109, 1371-1378.
- Handley, M., MacGregor, K., Schillinger, D., Sharifi, C., Wong, S., & Bodenheimer, T. (2006). Using action plans to help primary care patients adopt healthy behaviors: a descriptive study. *Journal of the American Board of Family Medicine*, 19(3), 224-231.
- Haskell, W.L., Alderman, E.L., Fair, J.M., Maron, D.J., Mackey, S.F., Superko, H.R., Williams, P.T., Johnstone, I.M., Champagne, M.A., Krauss, R.M., & Farquhar, J.V. (1994). Effects of intensive multiple risk factor reduction on coronary atherosclerosis and clinical cardiac events in men and women with coronary artery disease. The Stanford Coronary Risk Intervention Project (SCRIP). *Circulation*, 89(3), 975-990.
- Haynes, R.B. (2001). Improving patient adherence: state of the art, with a special focus on medication taking for cardiovascular disorders. In L.E. Burke, & I.S. Ockene, (Eds) *Compliance in Healthcare and Research*. Futura Armonk, NY, pp 2-21.
- Hays, R.D., Kravitz, R.L., Mazel, R.M., Sherbourne, C.D., DiMatteo, M.R., Rogers, W.H., & Greenfield, S. (1994). The impact of patient adherence on health outcomes for patients with chronic disease in the Medical Outcome Study. *Journal of Behavioral Medicine*, 17(4), 347-360

- Heinzelmann, F., & Bagley, R.W. (1970). Response to physical activity programs and their effects on health behavior. *Public Health Reports, 85(10)*, 905-911.
- Heller, R.F., Knapp, J.C., Valenti, L.A., & Dobson, A.J. (1993). Secondary prevention after acute myocardial infarction. *American Journal of Cardiology, 72(11)*, 759-762.
- Hershey, J. C. (1979). Formalization of the health belief model: Measuring health beliefs in compliance studies. Unpublished working paper, University of Pennsylvania, Philadelphia.
- Ho, P.M., Rumsfeld, J.S., Masoudi, F.A., McClure, D.L., Plomondon, M.E., Steiner, J.F., & Magid, D.J. (2006). Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Archives of Internal Medicine, 166(17)*, 1836-1841.
- Ho, P.M., Bryson, C.L., & Rumsfeld, J.S. (2009). Medication adherence: its importance in cardiovascular outcomes. *Circulation, 119(23)*, 3028-3035.
- Hochbaum, G.M. (1958). Public Participation in Medical Screening Programs: A Sociopsychological Study. *PHS publication no. 572. Washington, D.C.: Government Printing Office.*
- Holmes-Rovner, M., Kroll, J., Schmitt, N., Rovner, D.R., Breer, M.L., Rothert, M.L., Padonu, G., & Talarczyk, G. (1996). Patient satisfaction with health care decisions: the satisfaction with decision scale. *Medical Decision Making, 16(1)*, 58-64
- Holmes-Rovner, M., Kroll, J., Rovner, D.R., Schmitt, N., Rothert, M., Padonu, G., & Talarczyk, G. (1999). Patient decision support intervention: Increased consistency with decision analytic models. *Medical Care, 37(3)*, 270-284.
- Horwitz, R.I., Viscoli, C.M., Berkman, L., Donaldson, R.M., Horwitz, S.M., Murray, C.J., Ransohoff, D.F., & Sindelar, J. (1990). Treatment adherence and risk of death after myocardial infarction. *Lancet, 336(8714)*, 542-545.
- Howard-Pitney, B., Winkleby, M.A., Albright, C.L., Bruce, B., & Fortmann, S.P. (1997). The Stanford nutrition action program: a dietary fat intervention for the low-literacy adults. *American Journal of Public Health, 87(12)*, 1971-1976.
- Humpel, N., Owen, N., & Leslie, E.(2002). Environmental factors associated with adults' participation in physical activity: a review. *American Journal of Preventive Medicine, 22(3)*, 188-99

- Irvine, J., Baker, B., Smith, J., Jandciu, S., Paquette, M., Cairns, J., Connolly, S., Roberts, R., Gent, M., & Dorian, P. (1999). Poor adherence to placebo or amiodarone therapy predicts mortality: results from the CAMIAT study. *Psychosomatic Medicine*, *61*(4), 566-575.
- Jackevicius, C.A., Li, P., & Tu, J.V. (2008). Prevalence, predictors, and outcomes of primary nonadherence after acute myocardial infarction. *Circulation*, *117*, 1028-1036.
- Janz, N.K. (1988). The health belief model in understanding cardiovascular risk factor reduction behaviors. *Cardiovascular Nursing*, *24*(6), 39-41.
- Janz, N.K., & Becker, M.H. (1984). The health belief model: A decade later. *Health Education Quarterly*, *11*(1), 1-47.
- Janz, N.K., Champion, V.L., & Strecher, V.J. (2002). The Health Belief Model. In: K. Glanz, B.K. Rimer, F.M. Lewis (Ed): *Health Behavior and Health Education -Theory, Research, and Practice 3rd Ed.* Jossey-Bass. A Wiley Imprint, 989 Market Street, San Francisco, CA 94103-1741
- Jelinek, M.V., Vale, M.J., Liew, D., Grigg, L.E., Dart, A.M., Hare, D.L., & Best, J.D. (2009). The COACH program produces sustained improvements in cardiovascular risk factors and adherence to recommended medications- two years follow-up. *Heart, Lung and Circulation*, *18*, 388-392.
- Jolly, K., Bradley, F., Sharp, S., Smith, H., Thompson, S., Kinmonth, A.L., & Mant, D. (1999). Randomised controlled trial of follow up care in general practice of patients with myocardial infarction and angina: final results of the Southampton heart integrated care project (SHIP). The SHIP Collaborative Group. *British Medical Journal*, *318* (7185), 706-711.
- Joos, S.K., Hickam, D.H., Gordon, G.H., & Baker, L.H. (1996). Effects of a physician communication intervention on patient care outcomes. *Journal of General Internal Medicine*, *11*(3), 147-55
- Kahn, E.B., Ramsey, L.T., Brownson, R.C., Heath, G.W., Howze, E.H., Powell, K.E., Stone, E.J., Rajab, M.W., & Corso, P. (2002). The effectiveness of interventions to increase physical activity. A systematic review. *American Journal of Preventive Medicine*, *22*(4Supl), 73-107.
- Keeney, R.L. (1988). Building models of values. *European Journal of Operational Research*, *37*(2), 149-157.

- Kegeles, S.S., Kirscht, J.P., Haefner, D.P., & Rosenstock, I.M. (1965). Survey of beliefs about cancer detection and taking Papanicolaou tests. *Public Health Reports*, 80(9), 815-23
- Kendall, P.C. (1999). Clinical significance. *Journal of Consulting and Clinical Psychology*, 67(3), 283-284.
- Kennedy, A.D.M. (2003). On what basis should the effectiveness of decision aids be judged? *Health Expectations*, 6, 255-268.
- Kennedy, A.D., Sculpher, M.J., Coulter, A., Dwyer, N., Rees, M., Abrams, K.R., Horsley, S., Cowley, D., Kidson, C., Kirwin, C., Naish, C., & Stirrat, G. (2002). Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs: a randomized controlled trial. *The Journal of the American Medical Association*, 288(21), 2701-2708.
- Ketola, E., Sipilä, R., & Mäkelä, M. (2000). Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors. *Annals of Medicine*, 32(4), 239-251.
- Kirkman, M.S., Weinberger, M., Landsman P.B., Samsa, G.P., Shortliffe, E.A., Simel, D.L., & Feussner, J.R. (1994). A telephone-delivered intervention for patients with NIDDM. Effects on coronary risk factors. *Diabetes Care*, 17(8), 840-846.
- Knowler, W.C., Barrett-Connor, E., Fowler, S.E., Hamman, R.F., Lachin, J.M., Walker, E.A., & Nathan, D.M. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. Diabetes Prevention Program Research Group. *The New England Journal of Medicine*, 346(6), 393-403.
- Koelewijn-van Loon, M.S., van der Weijden, T., van Steenkiste, B., Ronda, G., Winkens, B., Severens J.L., Wensing, M., Elwyn, G., & Grol, R. (2009). Involving patients in cardiovascular risk management with nurse-led clinics: a cluster randomized controlled trial. *Canadian Medical Association Journal*, 181(12), E267-E274.
- Koelewijn-van Loon, M.S., van der Weijden, T., Ronda, G., van Steenkiste, B., Winkens, B., Elwyn, G., & Grol, R. (2010). Improving lifestyle and risk perception through patient involvement in nurse-led cardiovascular risk management: a cluster-randomized controlled trial in primary care. *Preventive Medicine*, 50, 35-44
- Koertge, J., Weidner, G., Elliott-Eller, M., Scherwitz, L., Merritt-Worden, T.A., Marlin, R., Lipsenthal, L., Guarneri, M., Finkel, R., Sauders, D.E., McCormac, P., Scheer, J.M., Collins, R.E., & Ornish, D. (2003). Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration project. *American Journal of Cardiology*, 91, 1316-1322.

- Kolcaba, K., & Fox, C. (1999). The effects of guided imagery on comfort of women with early stage breast cancer undergoing radiation therapy. *Oncology Nursing Forum*, *26(1)*, 67-72.
- Krannich, J-H., Lueger, S., Weyers, P., & Elert, O. (2007). Health-related quality of life two days before, ten days and one year after coronary artery bypass graft surgery. *Thoracic & Cardiovascular Surgeon*, *55(5)*, 288-292.
- Krannich, J-H., Weyers, P., Lueger, S., Schimmer, C., Faller, H., & Elert, O. (2008). The effectiveness of a motivation programme for lifestyle change in the course of aortocoronary bypass graft surgery. *Clinical Rehabilitation*, *22*, 3-13.
- Kreuter, M.W., Strecher, V.J., & Glassman, B. (1999). One size does not fit all: The case for tailoring print materials. *Annals of Behavioral Medicine*, *21(4)*, 276-283.
- Krones, T., Keller, H., Sönnichsen, A., Sadowski, E-M., Baum, E., Wegscheider, K., Rochon, J., & Donner-Banzhoff, N. (2008). Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial. *Annals of Family Medicine*, *6(3)*, 218-227.
- Krones, T., Keller, H., Becker, A., Sönnichsen, A., Baume, E., & Donner-Banzhoff, N. (2010). The theory of planned behavior in a randomized trial of a decision aid on cardiovascular risk prevention. *Patient Education and Counseling*, *78*, 169-176.
- Lalonde, L., O'Connor, A., Grover, S.A. & Lowensteyn, I. (2002). *Making ChoicesTM: Life Changes to Lower Your Risk of Heart Disease and Stroke*. Ottawa Health Research Institute, 1053 Carling Avenue, Ottawa, Ontario, Canada K1Y 4E9.
- Lalonde, L., O'Connor, A.M., Drake, E., Duguay, P., Lowensteyn, I., & Grover, S.A. (2004). Development and preliminary testing of a patient decision aid to assist pharmaceutical care in preventing of cardiovascular disease. *Pharmacotherapy*, *24(7)*, 909-922.
- Lalonde, L., O'Connor, A.M., Duguay, P., Brassard, J., Drake, E., & Grover, S.A. (2006). Evaluation of a decision aid and a personal risk profile in community pharmacy for patients considering options to improve cardiovascular health: the OPTION pilot study. *The International Journal of Pharmacy Practice*, *14(1)*, 51-62.
- Lambert, B.L., Street, R.L., Cegala, D.J., Smith, D.H., Kurtz, S., & Schofield, T. (1997). Provider-patient communication, patient-centered care, and the mangle of practice. *Health Communication*, *9(1)*, 27-43.
- Landcaster, T., & Stead, L.F. (2005). Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews*, 2005, Issue 2, Art.No.: CD001292. DOI: 10.1002/14651858.CD001292.pub2.

- Larson, E.B., Olsen, E., Cole, W., & Shortell, S. (1979). The relationship of health beliefs and a postcard reminder to influenza vaccination. *Journal of Family Practice, 8*(6), 1207-1211.
- Lear, S.A., Ignaszewski, A., Linden, W., Brozic, A., Kiess, M., Spinelli, J.J., Pritchard, P.H., & Frohlich, J.J. (2003). The extensive lifestyle management Intervention (ELMI) following cardiac rehabilitation trial. *European Heart Journal, 24*(21), 1920-1927.
- Lenz, M., Kasper, J., & Mühlhauser, I. (2009). Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes – rationale, design and pilot testing. *German Medical Science(GMS) Psycho-Social-Medicine, 6*, Doc05 (20091019) <http://www.egms.de/static/pdf/journals/psm/2009-6/psm000061.pdf>
- Liao, L., Jollis, J.G., DeLong, E.R., Peterson, E.D., Morris, K.G., & Mark, D.B. (1996). Impact of an interactive video on decision making of patients with ischemic heart disease. *Journal of General Internal Medicine, 11*, 373-376.
- Linde, J.A., Rothman, A.J., Baldwin, A.S., & Jeffery, R.W. (2006). The impact of self-efficacy on behavior change and weight change among overweight participants in a weight loss trial. *Health Psychology, 25*(3), 282-291.
- Linden, W., Stossel, C., & Maurice, J. (1996). Psychosocial interventions for patients with coronary artery disease: a meta analysis. *Archives of Internal Medicine, 156*(7), 745-752.
- Lindquist, R., Dupuis, G., Terrin, M.L., Hoogwerf, B., Czajkowski, S., Herd, J.A., Barton, F.B., Tracy, M.F., Hunninghake, D.B., Treat-Jacobsen, D., Schumaker, S., Zyzanski, S., Goldenberg, I., & Knatterud, G.L. (2003). Comparison of health-related quality-of-life outcomes of men and women after coronary artery bypass surgery through 1 year: findings from the POST CABG Biobehavioral Study. *American Heart Journal, 146*(6), 1038-1044.
- Lindsay, G.M., Hanlon, P., Smith, L.N., & Wheatley, D.J. (2000). Assessment of changes in general health status using the short-form 36 questionnaire 1 year following coronary artery bypass grafting. *European Journal of Cardio-Thoracic Surgery, 18*(5), 557-564.
- Lippke, S., Wiedermann, A.U., Ziegelmann, J.P., Reuter, T., & Schwarzer, R. (2009). Self-efficacy moderates the mediation of intentions into behavior via plans. *American Journal of Health Behavior, 33*(5), 521-529.
- Lipsey, M.W. (1990). *Design sensitivity. Statistical power for experimental research*. Newbury Park, CA: Sage Publications, Inc.

- Lorig, K.R., & Holman, H.R. (2003). Self-management education: history, definitions, outcomes, and mechanism. *Annals of Behavioral Medicine, 26*(1), 1-7.
- Lowry, K.P., Dudley, T.K., Oddone, E.Z., & Bosworth, H.B. (2005). Intentional and unintentional nonadherence to antihypertensive medication. *The Annals of Pharmacotherapy, 39*(7-8), 1198-1203.
- Lutfey, K.E., & Wishner, W.J. (1999). Beyond “compliance” is “adherence”. Improving the prospect of diabetes care. *Diabetes Care, 22*(4), 635-639.
- Lynn, J., & DeGrazia, D. (1991). An outcomes model of medical decision making. *Theoretical Medicine, 12*, 325-343.
- MacDonald, P., Stadnyk, K., Cossett, J., Klassen, G., Johnstone, D., & Rockwood K. (1998). Outcomes of coronary artery bypass surgery in elderly people. *Canadian Journal of Cardiology, 14*(10), 1215-1222.
- Maiman, L.A., Becker, M.H., Kirscht, J.P., Haefner, D.P., & Drachman, R.H. (1977). Scales for measuring health belief model dimensions: a test of predictive value, internal consistency, and relationships among beliefs. *Health Education Monographs, 5*(3), 215-230.
- Manolio, T.A., Pearson, T.A, Wenger, N.K., Barrett-Connor, E., Payne, G.H. (1992). Cholesterol and heart disease in older persons and women. Review of an NHLBI workshop. *Annals of Epidemiology, 2*(1-2), 161-176
- Man-Son-Hing, M., Laupacis, A., O'Connor, A.M., Biggs, J., Drake, E., Yetisir, E., & Hart, R.G. (1999). A patient decision aid regarding antithrombotic therapy for stroke prevention in atrial fibrillation: A randomized controlled trial. *The Journal of the American Medical Association, 282*(8), 737-743.
- Marlatt, G.A., & Donovan, D.M. (2005). *Relapse prevention: A self-control strategy for the maintenance of behavior change, 2nd ed.* New York: Guilford Press.
- Mazur, D.J., & Hickam D.H. (1990). Treatment preferences of patients and physicians: Influences of summary data when framing effects are controlled. *Medical Decision Making, 10*(1), 2-5.
- Mazur, D.J., & Hickam, D.H. (1993). Patient interpretations of terms connoting low probabilities when communicating about surgical risk. *Theoretical Surgery, 8*, 143-145.
- McAlister, F.A., Lawson, F.M., Teo, K.K., & Armstrong, P.W. (2001). Randomised trials of secondary prevention programmes in coronary heart disease: systematic review. *British Medical Journal, 323*(7319), 957-962.

- McCaffery, K., Irwig, L., & Bossuyt, P. (2007). Patient decision aids to support clinical decision making: evaluating the decision or the outcomes of the decision. *Medical Decision Making, 27*, 619-625.
- McDermott, M.M., Schmitt, B., & Wallner, E. (1997). Impact of medication nonadherence on coronary heart disease outcomes. A critical review. *Archives of Internal Medicine, 157(17)*, 1921-1929.
- McHorney, C.A., Kosinski, M., & Ware, J.E Jr. (1994). Comparisons of the costs and quality of norms for the SF-36 health survey collected by mail versus telephone interview: results from a national survey. *Medical Care, 32(6)*, 551-567
- McTigue, K.M., Harris, R., Hemphill, B., Lux, L., Sutton, S., Bunton, A.J., & Lohr, K.N. (2003). Screening and interventions for obesity in adults: summary of evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine, 139(11)*, 933-949.
- Melberg, T., & Svennevig, J.L. (2009). Norsk koronar intervensjonstatistikk 2006-07. *Hjerteforum, 22(2)*, 69-73.
- Mendes de Leon, C.F., Krumholz, H.M., Vaccarino, V., Williams, C.S., Glass, T.A., Berkman, L.F., & Kas, S.V. (1998). A population-based perspective of changes in health-related quality of life after myocardial infarction in older men and women. *Journal of Clinical Epidemiology, 51(7)*, 609-616.
- Miller, P., Wikoff, R., McMahon, M., Garrett, M.J., & Johnson, N. (1982a). Development of a health attitude scale. *Nursing Research, 31(3)*, 132-136.
- Miller, P., Johnson, N.L., Garrett, M.J., Wikoff, R., & McMahon, M. (1982b). Health beliefs of and adherence to the medical regimen by patients with ischemic heart disease. *Heart & Lung, 11*, 332-339.
- Miller, P., Wikoff, R., McMahon, M., Garrett, M.J., & Ringel, K. (1988). Influence of a nursing intervention on regimen adherence and societal adjustments postmyocardial infarction. *Nursing Research, 37(5)*, 297-302.
- Miller, P., Wikoff, R., Garrett, M.J., McMahon, M., & Smith, T. (1990). Regimen compliance two years after myocardial infarction. *Nursing Research, 39*, 333-336.
- Miller, W.R. (2002). Facilitating change. In: W.R. Miller & S. Rollnick *Motivational interviewing: preparing people for change* 2nd ed. New York: Guilford Press.
- Mirotnik, J., Feldman, L., & Stein, R.(1995).The health belief model and adherence with a community center-based, supervised coronary heart disease exercise program. *Journal of Community Health, 20(3)*, 233-247.

- Mirotznik, J., Ginzler, E., Zagon, G., & Baptiste, A. (1998). Using the health belief model to explain clinic appointment-keeping for the management of a chronic disease condition. *Journal of Community Health, 23*(3), 195-210.
- Molenaar, S., Sprangers, M.A.G., Postma-Schuit, F.C.E., Rutgers, E.J., Noorlander, J., Hendriks, J., & De Haes, H.C.J.M. (2000). Feasibility and effects of decision aids. *Medical Decision Making, 20*(1), 112-127.
- Montgomery, A.A., Fahey, T., & Peters, T.J. (2003). A factorial randomised controlled trial of decision analysis and an information video plus leaflet for newly diagnosed hypertensive patients. *British Journal of General Practice, 53*(491) 446-453.
- Moore, S.M., & Kramer, F.M. (1996). Women's and men's preferences for cardiac rehabilitation program features. *Journal of Cardiopulmonary Rehabilitation, 16*(3), 163-168.
- Moore, S.M., Dolansky, M.A., Ruland, C.M., Pashkow, F.J., & Blackburn, G.G. (2003). Predictors of women's exercise maintenance after cardiac rehabilitation. *Journal of Cardiopulmonary Rehabilitation, 23*(1), 40-49.
- Moore, S.M., Charvat, J.M., Gordon, N.H., Pashkow, F., Ribisl, P., Roberts, B.L., & Rocco, M. (2006). Effects of a CHANGE intervention to increase exercise maintenance following cardiac events. *Annals of Behavioral Medicine, 31*(1), 53-62.
- Morgan, M.W., Deber, R.B., Llewellyn-Thomas, H.A., Gladstone, P., Cusimano, R.J., O'Rourke, K., Tomlinson, G., & Detsky, A.S. (2000). Randomized, controlled trial of an interactive videodisc decision aid for patients with ischemic heart disease. *Journal of General Internal Medicine, 15*(10), 685-693.
- Muench, J. (1987). Health beliefs of patients with coronary heart disease enrolled in a cardiac exercise program. *Journal of Cardiopulmonary Rehabilitation, 7*(3), 130-135.
- Murchie, P., Campbell, N.C., Ritchie, L.D., Simpson, J.A., & Thain, J. (2003). Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *British Medical Journal, 326*(7380), 84
- Murdaugh, C.L., & Verran, J.A. (1987). Theoretical modeling to predict physiological indicators of cardiac preventive behaviors. *Nursing Research, 36*(5), 284-291.
- Murphy A.W., Cupples, M.E., Smith, S.M., Byrne, M., Byrne M.C., Newell, J. (2009). Effect of a tailored practice and patient care plans on secondary prevention of heart disease in general practice: cluster randomized controlled trial. For the SPHERE Study Team *British Medical Journal, (Clinical Research Ed), 339*, b4220.

- Murray, E., Davis, H., See Tai, S., Coulter, A., Gray, A., & Haines, A. (2001a). Randomized controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care. *British Medical Journal*, *323*, 493-496.
- Murray, E., Davis, H., See Tai, S., Coulter, A., Gray, A., & Haines, A. (2001b). Randomized controlled trial of an interactive multimedia decision aid on hormone replacement therapy in primary care. *British Medical Journal*, *323*, 490-493.
- Myles, P.S., Hunt, J.O., Fletcher, H., Solly, R., Woodward, D., & Kelly, S. (2001). Relation between quality of recovery in hospital and quality of life at 3 months after cardiac surgery. *Anesthesiology*, *95*(4), 862-867.
- Nease, R.F. Jr, Kneeland, T., O'Connor, G.T., Sumner, W., Lumpkins, C., Pryor, S., & Sox, H.C. (1995). Variation in patient utilities for outcomes management in chronic stable angina: Implications for clinical practice guidelines in Ischemic Heart Disease Patient Outcomes Research Team. *The Journal of the American Medical Association*, *273*(15), 1185-1190.
- Neaton, J.D, Blackburn, H., Jacobs, D., Kuller, L., Lee, D.J., Sherwin, R., Shih, J., Stamler, J., & Wentworth, D. (1992). Serum cholesterol level and mortality findings for men screened in the Multiple Risk Factor Intervention Trial. Multiple Risk Factor Intervention Trial Research Group. *Archives of Internal Medicine*, *152*(7), 1490-1500.
- Nelson, W.L., Han, P.K.J., Fagerlin, A., Stefanek, M., & Ubel, P.A. (2007). Rethinking the objectives of decision aids: a call for conceptual clarity. *Medical Decision Making*, *27*(5), 609-618.
- Nichol, G., Llewellyn-Thomas, H.A., Thiel, E.C., & Naylor, C.D. (1996). The relationship between cardiac functional capacity and patients' symptom-specific utilities for angina. *Medical Decision Making*, *16*(1), 78-85.
- Noar, S.M., Benac, C.N., & Harris, M.S. (2007). Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. *Psychological Bulletin*, *133*(4), 673-693.
- Noar, S.M., Chabot, M., & Zimmerman, R.S. (2008). Applying health behavior theory to multiple behavior change: Considerations and approaches. *Preventive Medicine*, *46*(3), 275-280.
- Oakley, A., Strange, V., Bonell, C., Allen, E. & Stephenson, J. (2006). Process evaluation in randomised controlled trials of complex interventions. *British Medical Journal*, *332*, 413-416.

- Oakley, S., & Walley, T.A. (2006). A pilot study assessing the effectiveness of a decision aid on patient adherence with oral bisphosphonate medication. *Pharmaceutical Journal*, 276(7399), 536-538.
- O’Cathain, A., & Thomas, K.J. (2004). Evaluating decision aids- where next? *Health Expectations*, 7, 98-103.
- O’Connor, A.M. (1995). Validation of a decision conflict scale. *Medical Decision Making*, 15, 25-30.
- O’Connor, A.M. (1999). *Decisional conflict scale 4th Edition*. Ottawa Hospital – Loeb Health Research Institute, Ottawa, Ontario, Canada.
- O’Connor, A.M. (2005,). *User Manual - Decisional conflict Scale* www.ohri.ca/decisionaid
- O’Connor, A.M., Tugwell, P., Wells, G.A., Elmslie, T., Jolly, E., Hollingworth, G., McPherson, R., Bunn, H., Graham, I., & Drake, E. (1998a). A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. *Patient Education and Counseling*, 33(3), 267-279.
- O’Connor, A.M., Tugwell, P., Wells, G.A., Elmslie, T., Jolly, E., Hollingworth, G., McPherson, R., Drake, E. Hopman, W., & Mackenzie, T. (1998b). Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Medical Decision Making* 18(3), 295-303.
- O’Connor, A.M., Rostom, A., Fiset, V., Tetroe, J., Entwistle, V., Llewellyn-Thomas, H., Holmes-Rovner, M., Barry, M., & Jones, J. (1999). Decision aids for patients facing health treatment or screening decisions: Systematic review. *British Medical Journal*, 319, 731-734.
- O’Connor, A.M., Légaré, F., & Stacey, D. (2003). Risk communication in practice: The contribution of decision aids. *British Medical Journal*, 327, 736-740.
- O’Connor, A.M., Bennett, C.L., Stacey, D., Barry, M.J, Col, N.F., Eden, K.B., Entwistle, V.A., Fiset, V., Holmes-Rovner, M., Khangura, S., Llewellyn-Thomas, H., & Rovner, D.R. (2009). Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*, 2009, Issue 3. Art. No.: CD001431.DOI: 10.1002/14651858.CD001431.pub2.
- Oldridge, N.B. (1979). Compliance of post myocardial infarction patients to exercise programs. *Medicine & Science in Sports*, 11(4), 373-375.
- Oldridge, N.B., & Spencer, J. (1985). Exercise habits and perceptions before and after graduating or dropout from supervised cardiac exercise rehabilitation. *Journal of Cardiopulmonary Rehabilitation*, 5, 313-319.

- Oldridge, N.B., & Streiner, D.L. (1990). The health belief model: predicting compliance and dropout in cardiac rehabilitation. *Medicine and Science in Sports and Exercise*, 22(5), 678-683.
- Oman, R.F., & King, A.C. (1998). Predicting the adoption and maintenance of exercise participation using self-efficacy and previous exercise participation rates. *American Journal of Health Promotion*, 12(3), 154-61,
- Orleans, C.T. (2004). Addressing multiple behavioral health risks in primary care. Broadening the focus of health behavior change research and practice. *American Journal of Preventive Medicine*, 27(2 Suppl), 1-3.
- Ornish, D., Brown, S.E., Scherwitz, L.W., Billings, J.H., Armstrong, W.T., Ports, T.A., McLanahan, S.M., Kirkeeide, R.L., Brand, R.J., & Gould, K.L. (1990). Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet*, 336(8708), 129-133.
- Ornish, D., Scherwitz, L.W., Billings, J.H., Gould, K.L., Merritt, T.A., Sparler, S., Armstrong, W.T., Ports, T.A., Kirkeeide, R.L., Hogeboom, C., & Brand, R.J. (1998). Intensive lifestyle changes for reversal of coronary heart disease. *The Journal of the American Medical Association*, 280(23), 2001-2007.
- Ottawa Hospital Research Institute-OHRI. Acceptability (of a Decision Aid)
http://decisionaid.ohri.ca/docs/develop/Tools/Acceptability_osteoporosis.pdf
- Parcel, G.S., Nader, P.R., & Tiernan, K. (1980). A health education program for children with asthma. *Journal of Developmental & Behavioral Pediatrics*, 1(3), 128-132.
- Paterson, J.M., Llewellyn-Thomas, H.A., & Naylor, C.D. (2002). Using disease estimates to guide risk factor interventions: field test of a patient workbook for self-assessing coronary risk. *Health Expectations*, 5, 3-15
- Pauker, S.P., & Pauker, S.G. (1977). Prenatal diagnosis: a directive approach to genetic counseling using decision analysis. *Yale Journal of Biology & Medicine*, 50(3), 275-89.
- Pedersen, J.I., Tverdal, A., & Kirkhus, B. (2004). Kostendringer og dødelighetsutvikling av hjerte- og karsykdommer i Norge. *Tidsskrift for den norske Lægeforening*, 124, 1532-1536.
- Pennebaker, J. W. (1997). Writing about emotional experiences as a therapeutic process. *Psychological Science*, 8, 162-166.
- Pennebaker, J. W., & Francis, M.E. (1996). Cognitive, emotional, and language processes in disclosure. *Cognition and Emotion*, 10, 601-626.

- Perkins, K.A. (1988). Maintaining smoking abstinence after myocardial infarction. *Journal of Substance Abuse, 1*(1), 91-107.
- Peterson, J.C., Allegrante, J.P., Pirraglia, P.A., Robbins, L., Lane, K.P., Boschert, K.A., & Charlson, M.E. (2010). Living with heart disease after angioplasty: a qualitative study of patients who have been successful or unsuccessful in multiple behavior change. *Heart & Lung, 39*(2), 105-115.
- Pettersen, K.I., Reikvam, A., & Stavem, K. (2005). Reliability and validity of the Norwegian translation of the Seattle Angina Questionnaire following myocardial infarction. *Quality of Life Research, 14*(3), 883-889.
- Pettersen, K.I., Reikvam, A., Rollag, A., & Stavem, K. (2008). Understanding sex differences in health-related quality of life following myocardial infarction. *International Journal of Cardiology, 130*, 449-456.
- Phelan, E.A., Deyo, R.A., Cherkin, D.C., Weinstein, J.N., Ciol, M.A., Kreuter, W., et al. (2001). Helping patients decide about back surgery. A randomized trial of an interactive video program. *Spine 26*(2), 206-212.
- Pignone, M.P., Ammerman, A., Fernandez, L., Orleans, C.T., Pender, N., Woolf, S., Lohr, K.N., & Sutton, S. (2003). Counseling to promote a healthy diet in adults: A summary of the evidence for the U.S. Preventive Services Task Force. *American Journal of Preventive Medicine, 24*(1), 75-92.
- Pignone, M., Sheridan, S.L., Lee, Y.Z., Kuo, B.A., Phillips, C., Mulrow, C., & Zeiger, R. (2004). Heart to Heart: A computerized decision aid for assessment of coronary heart disease risk and the impact of risk-reduction interventions for primary prevention. *Preventive Cardiology, 7*, 26-33.
- Pinheiro, J.C. & Bates, D.M. (2000). *Mixed- Effects Models in S and S-PLUS*. Springer Verlag, New York.
- Pinto, B.M., Rabin, C., & Farrell, N. (2005). Lifestyle and coronary heart disease prevention. *Primary Care: Clinics in Office Practice, 32*, 947-961.
- Pocock, S.J., Henderson, R.A., Clayton, T., Lyman, G.H., & Chamberlain, D.A., for the RITA-2 trial Participants (2000). Quality of life after coronary angioplasty or continued medical treatment for angina; three-year follow-up in the RITA-2 trial. *Journal of the American College of Cardiology, 35*(4), 907-914.
- Prochaska, J.O, & DiClemente, C.C. (1983). Stages and processes of self-change of smoking: toward an integrative model of change. *Journal of Consulting & Clinical Psychology, 5*(3), 390-395.

- Racelis, M.C., Lombardo, K., & Verdin, J. (1998). Impact of telephone reinforcement of risk reduction education on patient compliance. *Journal of Vascular Nursing, 16*(1), 16-20.
- Rasmussen, J.N., Chong, A., & Alter, D.A. (2007). Relationship between adherence to evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction. *The Journal of the American Medical Association, 297*(2), 177-186.
- Redelmeier, D.A., Rozin, P., & Kahneman, D. (1993). Understanding patients' decisions. Cognitive and emotional perspectives. *The Journal of the American Medical Association, 270*(1), 72-76.
- Resnick, B., Bellg, A.J., Borrelli, B., DeFrancesco, C., Breger, R., Hecht, J., Sharp, D.L., Levesque, C., Orwig, D., Ernst, D., Ogedegbe, G., & Czajkowski, S. (2005). Examples of implementation and evaluation of treatment fidelity in the BCC Studies: Where we are and where we need to go. *Annals of Behavioral Medicine, 29* (Special Supplement), 46-54.
- Rogers, P.G., & Bullman, W.R. (1995). Prescription medicine compliance: a review of the baseline of knowledge. A report of the National Council on Patient Information and Education. *Journal of Pharmacoepidemiology, 2*, 3-36.
- Rosal, M.C., Ebbeling, C.B., Lofgren, I., Ockene, J.K., Ockene, I.S., & Hebert, J.R. (2001). Facilitating dietary change: the patient-centered counseling model. *Journal of the American Dietetic Association, 101*(3), 332-341.
- Rosen, C.S. (2000). Is the sequencing of change processes by stage consistent across health problems? A meta-analysis. *Health Psychology, 19*(6), 593-604.
- Rosenstock, I.M. (1960). What Research in Motivation Suggests for Public Health. *American Journal of Public Health, 50*, 295-301
- Rosenstock, I.M. (1974). Historical Origins of the Health Belief Model. *Health Education Monographs, 2*, 328-335
- Roter, D.L. (1977). Patient participation in patient-provider interaction: the effects of patient question asking on the quality of interaction, satisfaction and compliance. *Health Education & Behavior, 5*, 281-315.
- Roter, D.L., Hall, J.A., Merisca, R., Nordstrom, B., Cretin, D., & Svarstad, B. (1998). Effectiveness of interventions to improve patient compliance: A meta-analysis. *Medical Care, 36*(8), 1138-1161.
- Rothert, M.L., Holmes-Rovner, M., Rovner, D., Kroll, J., Breer, L., Talarczyk, G.J., Schmitt, N., Padonu, G., & Wills, C. (1997). An educational intervention as decision support for menopausal women. *Research in Nursing & Health Care, 20*(5), 377-387.

- Ruland, C.M. (1999). Decision support for patient preference-based care planning: effects on nursing care and patient outcomes. *Journal of the American Medical Informatics Association*, 6(4), 304-312.
- Ruland, C.M. & Moore, S.M. (2001). Eliciting exercise preferences in cardiac rehabilitation: initial evaluation of a new strategy. *Patient Education and Counseling*. 44(3), 283-91.
- Rumsfeld, J.S. (2002). Health status and clinical practice: when will they meet? *Circulation*, 106, 5-7.
- Rumsfeld, J.S., MaWhinney, S., McCarthy, M.Jr., Shroyer, A.L., VillaNueva, C.B., O'Brien, M., Moritz, T.E., Henderson, W.G., Grover, F.L., Sethi, G.K., & Hammermeister, K.E. (1999). Health related quality of life as a predictor of mortality following coronary artery bypass graft surgery. Participants of the department of Veterans Affairs Cooperative Study Group on Processes, Structures, and Outcomes of Care in Cardiac Surgery. *The Journal of the American Medical Association*, 281(14), 1298-1303.
- Rumsfeld, J.S., Magid, D.J., O'Brian, M., McCarthy, M. Jr., MaWhinney, S., Shroyer, A.L., Moritz, T.E., Henderson, W.G., Sethi, G.K., Grover, F.L., & Hammermeister, K.E. (2001). Changes in health-related quality of life following coronary artery bypass graft surgery. *The Annals of Thoracic Surgery*, 72(6), 2026-2032.
- Sackett, D.L., Haynes, R.B., Gibson, E.S., Hackett, B.C., Taylor, D.W., Roberts, R.S., & Johnson, A.L. (1975). Randomised clinical trial of strategies for improving medication compliance in primary hypertension. *The Lancet*, May 31, 1205-1207.
- Sackett, D.L., & Haynes, R. (1976). *Compliance with therapeutic regimens*. Baltimore, MD: John Hopkins University Press.
- Sacks, F.M., Svetkey, L.P., Vollmer, W.M., Appel, L.J., Bray, G.A., Harsha, D., Obarzanek, E., Conlin, P.R., Miller, E.R. 3rd., Simons-Morton, D.G., Karanja, N., & Lin, P.H. (2001). Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. *The New England Journal of Medicine*, 344(1), 3-10.
- Sacks, F.M., & Campos, H. (2010). Dietary therapy in hypertension. *The New England Journal of Medicine*, 362(22), 2102-2112.
- Schaffer, S.D., & Yoon, S.J. (2001). Evidence-based methods to enhance medication adherence. *Nurse Practitioner*, 26(12), 44, 50, 52, 54.
- Schmitz, J.M., Spiga, R., Rhoades, H.M., Fuentes, F., & Grabowski, J. (1999). Smoking cessation in women with cardiac risk: a comparative study of two theoretically based therapies. *Nicotine & Tobacco Research*, 1, 87-94.

- Schuler, G., Hambrecht, R., Schlierf, G., Niebauer, J., Hauer, K., Neumann, J., Hoberg, E., Drinkmann, A., Bacher, F., Grunze M., & Kübler, W. (1992). Regular physical exercise and low fat diet. Effects on progression of coronary heart disease. *Circulation*, *86*(1), 1-11.
- Sebregts, E.H., Falger, P.R., & Bär, F.W. (2000). Risk factor modification through nonpharmacological interventions in patients with coronary heart disease. *Journal of Psychosomatic Research*, *48*(4-5), 425-441.
- Selmer, R., & Tverdal, A. (2003). Serum kolesterol og dødelighet av iskemisk hjertesykdom, alle sirkulasjonssykdommer og alle årsaker. *Norsk Epidemiologi*, *13*, (1), 115-125.
- Senécal, C., Nouwen, A., & White, D. (2000). Motivation and dietary self-care in adults with diabetes: are self-efficacy and autonomous self-regulation complementary or competing constructs? *Health Psychology*, *19*(5), 452-457.
- Sennott-Miller, L., & Miller, J. L. L. (1987). Difficulty a neglected factor in health promotion *Nursing Research* *36*, 268-272.
- Sepucha, K.R., & Mulley, A.G. (2003). Extending decision support: preparation and implementation. *Patient Education and Counseling*, *50*(3), 269-271.
- Shafir, E., Simonson, I., & Tversky, A. (1993). Reason-based choice. *Cognition*, *49*(1-2), 11-36.
- Shaw, L.J., Bugiardini, R., & Bairey Merz, C.N. (2009). Women and Ischemic Heart Disease: Evolving Knowledge. *Journal of the American College of Cardiology*. *54*(17), 1561-1575.
- Shay, L.E. (2008). A concept analysis: adherence and weight loss. *Nursing Forum*, *43*(1), 42-52.
- Sherbourne, C.D., Hays, R.D., Ordway, L., DiMatteo, M.R., & Kravitz, R.L. (1992). Antecedents of adherence to medical recommendations: Results from the Medical Outcomes Study. *Journal of Behavioral Medicine*, *15*(5), 447-468.
- Sheridan, S.L., Shadle, J., Simpson Jr, R.J., & Pignone, M.P. (2006). The impact of a decision aid about heart disease prevention on patients' discussion with their doctor and their plans for prevention: a pilot randomized trial. *BMC Health Services Research*, *6* (121)
- Sheridan, S.L., Viera, A.J., Krantz, M.J., Ice, C.L., Steinman, L.E., Peters, K.E., Kopin, L.A., & Lungelow, D. (2010a). The effect of giving global coronary risk information to adults. A systematic review. *Archives of Internal Medicine*, *170*(3), 230-239.

- Sheridan, S.L., Griffith, J.M., Behrend, L., Gizlice, Z., Cai, J., & Pignone, M.P. (2010b). Effect of adding a values clarification exercise to a decision aid on heart disease prevention: a randomized trial. *Medical Decision Making, 30*(4), E28-39.
- Shilts, M.K., Horowitz, M., & Townsend, M.S. (2004). Goal setting as a strategy for dietary and physical activity behavior change: a review of the literature. *American Journal of Health Promotion, 19*(2), 81-93.
- Simpson, S.H., Eurich, D.T., Majumdar, S.R., Padwal, R.S., Tsuyuki, R.T., Varney, J., & Johnson, J.A. (2006). A meta-analysis of the association between adherence to drug therapy and mortality. *British Medical Journal, 333*(7557), 15-18.
- Skinner, C.S., Campbell, M.K., Rimer, B.K., Curry, S., & Prochaska, J.O. (1999). How effective is tailored print communication? *Annals of Behavioral Medicine, 21*(4), 290-298.
- Smith, H.J., Taylor, R., & Mitchell, A. (2000). A comparison of four quality of life instruments in cardiac patients: SF-36, QLI, QLMI, and SEIQoL. *Heart, 84*(4), 390-394
- Spertus, J.A., Winder, J.A., Dewhurst, T.A., Deyo, R.A., Prodzinski, J., McDonell, M., & Fihn, S.D. (1995). Development and evaluation of the Seattle Angina Questionnaire: A new functional status measure for coronary artery disease. *Journal of the American College of Cardiology, 25*(2), 333-341.
- Spertus, J.A., Dewhurst, T.A., Dougherty, C.M., Nichol, P., McDonell, M., Bliven, B., & Fihn, S.D. (2002a). Benefits of an "angina clinic" for patients with coronary artery disease: a demonstration of health status measures as markers of health care quality. *American Heart Journal, 143*(1), 145-150.
- Spertus, J.A., Jones, P., McDonell, M., Fan, V.S. & Fihn, S.D. (2002b). Health status predicts long-term outcome in outpatients with coronary disease. *Circulation, 106*, 43-49.
- Spertus, J.A., Dawson, J., Masoudi, F.A., Krumholz, H.M., Reid, K.J., Peterson, E.D., & Rumsfeld, J.S. (2006a). Prevalence and predictors of angina pectoris one month after myocardial infarction. *The American Journal of Cardiology, 98*(3), 282-288.
- Spertus, J.A., Kettelkamp, R., Vance, C., Decker, C., Jones, P.G., Rumsfeld, J.S., Messenger, J.C., Khanal, S., Peterson, E.D., Bach, R.G., Krumholz, H.M., & Cohen, D.J. (2006b). Prevalence, predictors, and outcomes of premature discontinuation of thienopyridine therapy after drug-eluting stent placement: results from the PREMIER registry. *Circulation, 113*(24), 2803-2809.

- Stacey, D., O'Connor, A.M., DeGrasse, C., & Verma, S. (2003). Development and evaluation of a breast cancer prevention decision aid for higher-risk women. *Health Expectations*, 6, 3-18.
- Stalmeier, P.F.M., Unic,I.J., Verhoef, L.C.G., & van Daal, W.A.J. (1999). Evaluation of a shared decision making program for women suspected to have a genetic predisposition to breast cancer. Preliminary results. *Medical Decision Making*, 19(3), 230-241.
- Statistics Norway: <http://www.ssb.no>
- Steptoe, A., Doherty, S., Rink, E., Kerry, S., Kendrick, T., & Hilton, S. (1999). Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *British Medical Journal*, 319, 943-947.
- Stewart, AL., Hays, R.D., & Ware, J.E. Jr. (1992). Methods of Constructing Health Measures. In A.L. Stewart & J.E. Ware Jr. (Ed). *Measuring Functioning and Well-Being: The Medical Outcomes Approach*. Durham, NC: Duke University Press. pp. 67-85.
- Stewart, M.A. (1995). Effective physician-patient communication and health outcomes: a review. *Canadian Medical Association Journal*, 152(9), 1423-1433.
- Strandberg, T,E., Pitkala, K.H., Berglind, S., Nieminen, M.S., & Tilvis, R,S. (2006). Multifactorial intervention to prevent recurrent cardiovascular events in patient 75 years or older: the Drug and Evidence-Based medicine in the Elderly (DEBATE) study: a randomized, controlled trial. *American Heart Journal*, 152(3), 585-92.
- Strecher, V.J., Seijts, G.H., Kok, G.J., Latham, G.P., Glasgow, R., DeVellis, B., Meertens, R.M. & Bulger, D.W. (1995). Goal setting as a strategy for health behavior change. *Health Education Quarterly*, 22(2), 190-200.
- Strecher, V., Wang, C., Derry, H., Wildenhaus, K., & Johnson, C. (2002). Tailored interventions for multiple risk behaviors. *Health Education Research*, 17(5), 619-626.
- Tabachnick, B.G., & Fidell, L.S. (2001). *Using Multivariate Statistics*. 5th Edition. Needham Heights, MA: Allyn&Bacon.
- Thanavaro, J.L., Moore, S.M., Anthony, M., Narsavage, G., & Delicath, T. (2006). Predictors of health promotion behavior in women without prior history of coronary heart disease. *Applied Nursing Research*, 19, 149-155.
- The Coronary Drug Project Research Group. (1980). Influence of adherence to treatment and response of cholesterol on mortality in the Coronary Drug Project. *The New England Journal of Medicine*, 303(18), 1038-1041.

- Thompson, P.D., Buchner, D., Pina, I.L., , Balady, G.J., Williams, M.A., Marcus, B.M., Berra, K., Blair, S.N., Costa, F., Franklin, B., Fletcher, G.F., Gordon, N.F., Pate, R.R., Rodriguez, B.L., Yancey, A.K., & Wenger, N.K. (2003). Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease. *Circulation*, *107*, 3109-3116.
- Tirrell, B.E., & Hart, L.K. (1980) The relationship of health beliefs and knowledge to exercise compliance in patients after coronary bypass. *Heart & Lung*, *9*(3), 487-493.
- Trostle, J.A., Hauser, W.A., & Susser, I.S. (1983). The logic of noncompliance: management of epilepsy from patient's point of view. *Culture, Medicine & Psychiatry*, *7*(1), 35-56.
- Ubel, P.A., & Loewenstein, G. (1997). The role of decision analysis in informed consent: choosing between intuition and systematicity. *Social Science & Medicine*, *44*(5), 647-56
- U.S. Congress, Office of Technology Assessment. (1990). *Confused minds, burdened families: finding help for people with Alzheimer's & other dementias* (Report NO. OTA-BA-403). Washington, DC: U.S. Government Printing Office.
- U.S. Department of Health and Human Services. (2000). *Healthy People 2010: Understanding and Improving Health*. 2nd ed. Washington DC: US Government Printing Office
- U.S. Department of Health and Human Services. (2004). *Surgeon General's Report: The Health Consequences of Smoking*. http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm Washington, DC.
- U.S. Preventive Service Task Force. (2003a). Behavioral counseling in primary care to promote a healthy diet: recommendations and rationale. *American Journal of Preventive Medicine*, *24*(1), 93-100.
- U.S. Preventive Service Task Force. (2003b). Screening for obesity in adults: recommendations and rationale. *Annals of Internal Medicine*, *139*(11), 930-932.
- Vale, M.J., Jelinek, M.V., Best, J.D., & Santamaria, J.D. (2002). Coaching patients with coronary heart disease to achieve the target cholesterol: a method to bridge the gap between evidence-based medicine and the "real world" – randomized controlled trial. *Journal of Clinical Epidemiology*, *55*, 245-252.
- Vale, M.J., Jelinek, M.V., Best, J.D., Dart, A.M., Grigg, L.E., Hare, D.L., Ho, B.P., Newman, R.W., & McNeil, J.J. (2003). Coaching patients on achieving cardiovascular health. (COACH). A multicentre randomized trail in patients with coronary heart disease. *Archives of Internal Medicine*, *163*(22), 2775-2783.

- van Steenkiste, B., van der Weijden, T., Timmermans, D., Vaes, J., Stoffers, J., & Grol, R. (2004). Patients' ideas, fears and expectations of their coronary risk: barriers for primary prevention. *Patient Education and Counseling*, *55*, 301-307.
- van Steenkiste, B., van der Weijden, T., Stoffers, H.E. J.H., Kester, A.D.M., Timmermans, D.R.M., & Grol, R. (2007). Improving cardiovascular risk management: a randomized controlled trial on the effect of a decision support tool for patients and physicians. *European Journal of Cardiovascular Prevention and Rehabilitation*, *14*(1), 44-50.
- van Steenkiste, B., van der Weijden, T.M, Stoffers, J.H.E.H., & Grol, R.P.T.M. (2008). Patients' responsiveness to a decision support tool for primary prevention of cardiovascular disease in primary care. *Patient Education and Counseling*, *72*, 63-70.
- Venables, W.N., Smith, D.M., & the R Development Core Team (2009). *An introduction to R. Version 2.9.1* (2009-06-26). ISBN 3-900051-12-7.
- Von Winterfeldt, D., & Edwards, W. (1986). *Decision Analysis and Behavioral Research*. New York: Cambridge University Press
- Ware, J.E. Jr., Sherbourne, C.D. (1992). The MOS 36-item short form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, *30*(6), 473-483.
- Ware, J.E., Kosinski, M., & Dewey, J.E. (2000). *How to Score Version 2 of the SF-36® Health Survey*. Lincoln, RI: QualityMetric Incorporated.
- Ware, J.E., Jr., Kosinski, M., & Gandek, B. (2000). *SF-36® Health Survey: Manual & Interpretation Guide*. Lincoln, RI: QualityMetric Incorporated.
- Wasson, J.H., Godfrey, M.M., Nelson, E.C., Mohr, J.J., & Batalden, P.B. (2003). Microsystems in health care: Part 4. Planning patient-centered care. *Joint Commission Journal on Quality & Safety*, *29*(5), 227-237.
- Weinstein, A.S., & Fineberg, H.V. (1980). *Clinical Decision Analysis*. Philadelphia: WB Saunders
- Whelan, T., Levine, M., Willan, A., Gafni, A., Sanders, K., Mirsky, D., Chambers, S., O'Brien, M.A., Reid, S., & Dubois, S. (2004). Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: A randomized trial. *The Journal of the American Medical Association*, *292*(4), 435-441.
- Whitlock, E.P., Polen, M.R., Green, C.A., Orleans, T., & Klein, J. (2004). Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*, *140*, 557-568.

- WHO. (2003). *Adherence to long-term therapies. Evidence for action*. World Health Organization, Geneva, Switzerland
http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf 01.05.10
- Willich, S.N., Müller-Nordhorn, J., Kulig, M., Binting, S., Gohlke, H., Hahmann, H., Bestehorn, K., Krobot, K., & Völler, H., for the PIN Study Group. (2001). Cardiac risk factors, medication, and recurrent clinical events after acute coronary disease, a prospective cohort study. *European Heart Journal*, 22(4), 307-313.
- Wilson, T.D., Lisle, D.J., Schooler, J.W., Hodges, S.D., Klaaren, K.J., & LaFleur, S.J. (1993). Introspecting about Reasons can Reduce Post-Choice Satisfaction. *Personality and Social Psychology Bulletin*, 19, 331-339.
- Woloshin, S., Schwartz, L.M., Moncur, M., Gabriel, S., & Tosteson, A.N.A. (2001). Assessing values for health: Numeracy matters. *Medical Decision Making*, 21(5), 382-390.
- Woodard, L.D., Hernandez, M.T., Lees, E., Petersen, L.A. (2005). Racial differences in attitude regarding cardiovascular disease prevention and treatment: a qualitative study. *Patient Education and Counseling*, 57(2), 225-231.
- Yusuf, S., Hawken, S., Ounpuu, S., Dans, T., Avezum, A., Lanas, F., McQueen, M., Budaj, A., Pais, P., Varigos, J., & Liseng, L. (2004). Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): Case-control study. *Lancet*, 364(9438), 937-952.
- Zauszniewski, J.A. (1997). Teaching resourcefulness skills to older adults. *Journal of Gerontological Nursing*, 23(2), 14-20.
- Zeller, R., Good, M., Anderson, G.C., & Zeller, D.L. (1997). Strengthening experimental design by balancing potentially confounding variables across treatment groups. *Nursing Research*, 46(6), 345-349.
- Zellweger, M.J., Lewin, H.C., Lai, S., Dubois, E.A., Friedman, J.D., Germano, G., Kang, X., Sharir, T., & Berman, D.S. (2001). When to stress patients after coronary artery bypass surgery? Risk stratification in patients early and late post-CABG using stress myocardial perfusion SPECT: implications of appropriate clinical strategies. *Journal of the American College of Cardiology*, 37(1), 144-152.
- Ziegelstein, R.C., Fauerbach, J.A., Stevens, S.S., Romanelli, J., Richter, D.P., & Bush, D.E. (2000). Patients with depression are less likely to follow recommendations to reduce cardiac risk during recovery from a myocardial infarction. *Archives of Internal Medicine*, 160(12), 1818-1823.

Appendix A

CAD-DA

The Norwegian version of

**Making Choices:
Life Changes to Lower Your Risk of Heart Disease and Stroke**

Gjøre valg™:

Livsendringer for å redusere
din risiko for hjertesykdom og
hjerneslag



Et beslutningsstøtteverktøy for pasienter

Lalonde, O'Connor & Grover 2002

Oversatt fra engelsk til norsk av Liv Wensaas. Tilbakeoversatt fra norsk til engelsk av Gail Adams Kvam

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Velkommen

Dette beslutningsstøtteverktøyet passer for deg hvis:

- Du er interessert i å lære om din egen risiko for hjertesykdom og hjerneslag. Med hjertesykdom menes her det som kalles iskemisk hjertesykdom, det vil si hjerteinfarkt og angina pectoris.
- Du er bekymret for kolesterolet eller blodtrykket ditt
- Du er klar til å overveie livsendringer for å redusere din risiko for hjertesykdom og hjerneslag

Dette heftet og de personlige arbeidsarkene vil hjelpe til med å forberede deg til en samtale med legen din, en farmasøyt eller sykepleier om valgmuligheter du har for å redusere din risiko for hjertesykdom og hjerneslag. Disse valgmulighetene kan omfatte forandring av livsstilen din og det å ta medisiner.

Dette beslutningsstøtteverktøyet ble utviklet av et team av leger, sykepleiere, farmasøyter og forskere og er basert på de beste tilgjengelige studier. Disse studiene er vist til i teksten i heftet med små tall og er ført opp under referanser bakerst i heftet.

Faguttrykk er definert i ordboken som du finner bakerst i heftet.

For å få mest ut av dette beslutningsstøtteverktøyet bør du:

- Gjennomgå og svare på spørsmålene i heftet
- Fylle ut ditt personlige arbeidsark
- Ta med de utfylte arbeidsarkene når du møter legen din eller på apoteket for å diskutere måter å redusere din risiko for hjertesykdom og hjerneslag.

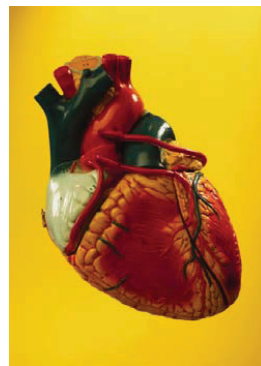
For å redusere din risiko for hjertesykdom og hjerneslag må du tenke på langtidsforandringer. Dette kan omfatte livsstilsendringer og det å ta medisiner.

Hjertesykdom og hjerneslag

Hjertesykdom (hjerteinfarkt og angina pectoris) og hjerneslag skjer når blodårene dine blir trangere. Det er stort sett de samme risikofaktorene som øker faren for både hjertesykdom og hjerneslag.

Når blodårene som forsyner selve hjertemuskelen med blod blir trange kan det medføre at hjertemuskelen får for lite surstoff i forhold til behovet, noe som kalles angina pectoris.

Hvis blodårene som forsyner hjertemuskelen med blod går helt tett, stanser blodtilførselen til et område i hjertemuskelen, dette området vil etter hvert bli omdannet til et arr. Denne prosessen med skade på hjertemuskelen kalles hjerteinfarkt. Et hjerteinfarkt kommer plutselig. Både ved angina pectoris og hjerteinfarkt kan personen oppleve smerter i brystet: sammensnørende, klemmende, trykkende eller sviende. Smertene kan stråle ut til armene, kjeven eller ryggen. Noen kan få tung pust eller generell kraftløshet i stedet for, eller sammen med, brystmerter. Det er ikke uvanlig at symptomene er mindre tydelige og annerledes hos kvinner enn hos menn. Kvinner kan for eksempel oppleve symptomer som tretthet, kortpustethet og kvalme. Pasienter med hjerteinfarkt må raskt på sykehus fordi effektiv, moderne behandling kan redusere risiko for å dø eller få varig skade på hjertet.



Omlag (85%) av hjerneslag skyldes blodpropp i en av blodårene som frakter blod opp til hjernen. Bare 15% skyldes hjerneblødning hvor en av hjernens blodårer har sprukket. Utfallet er at den delen av hjernen som normalt får sin blodtilførsel gjennom blodåren som er rammet blir skadet. Hjerneslag forårsaker ofte tap av bevegelse eller tale. Tapet avhenger av hvilken del av hjernen som blir skadet. Et hjerneslag kan komme uten varsel, men ofte har det i forkant vært forbigående lammelser, synsforstyrrelse eller problemer med å snakke (TIA-anfall eller ”drypp”).

Hjerte- karsykdommer er den hyppigste dødsårsaken hos nordmenn.

Hjertesykdom og hjerneslag

La oss se på hva som skjer med personer som har hjerteinfarkt eller hjerneslag:1-2



Av 100 personer som får hjerteinfarkt...

- ☹️ Omlag 20 vil dø innen et halvt år (20 %)
- 😐 Omlag 20 vil måtte begrense sine aktiviteter pga brystmerter eller kortpustethet (20 %)
- 😊 Omlag 60 vil bli i stand til å gå tilbake til sine normale aktiviteter etter noen få uker (60 %)



Av 100 personer som får hjerneslag...

- ☹️ Omlag 30 vil dø innen tre måneder (30 %)
- ☹️ Omlag 15 vil være på institusjon etter tre måneder fordi de trenger hjelp til å gå, spise eller komme seg på toalettet (15 %)
- 😐 Omlag 15 kan bo hjemme, men vil ha et varig fysisk handikap som for eksempel noe problemer med å gå eller snakke (15 %)
- 😊 Omlag 40 vil bli i stand til å returnere hjem og gjenvinne helsen fullstendig (40 %)

Viktige risikofaktorer

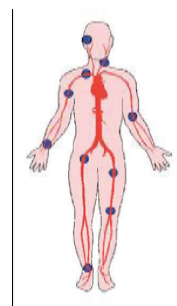
Personlige faktorer (for eksempel å være stresset) og livsstil (for eksempel røyking) øker din risiko for hjertesykdom og hjerneslag. De seks viktigste risikofaktorene er:

- Unormale kolesterolverdier i blodet
- Høyt blodtrykk
- Mangel på regelmessig fysisk aktivitet eller mosjon
- Røyking
- Overvekt eller fedme
- Stress

Hvis du lider av diabetes eller hvis du har hatt hjerteinfarkt eller hjerneslag tidligere, er din risiko for utvikling eller forverring av hjerte-karsykdom høyere. La oss se nærmere på risikofaktorene og lære hva du kan gjøre for å redusere dem.

UNORMALE KOLESTEROLVERDIER I BLODET³

Kolesterol er et fettliknende stoff. Det er nødvendig for å hjelpe kroppsfunksjonene. Imidlertid er for mye kolesterol skadelig fordi det kleber seg til veggene i blodårene og gjør dem trangere. Dette betyr at det blir vanskeligere for blodet å passere gjennom blodårene



Viktige risikofaktorer

Det finnes to typer kolesterol i blodet.

LDL-kolesterol (det "dårlige" kolesterolet)

- Det blir kalt *det "dårlige" kolesterolet* fordi det er et kolesterol som avleires på veggene i blodårene dine.
- Personer med høye verdier av LDL-kolesterol har en større risiko for å få hjertesykdom og hjerneslag.

HDL-kolesterol (det "gode" kolesterolet)

- Det blir ofte kalt *det "gode" kolesterolet* fordi det er et kolesterol som fraktes til leveren som kvitter seg med det. Dette hjelper til å åpne blodårene og gjøre dem vide. Så et høyere HDL-kolesterol er bra.
- Personer som har lave verdier av HDL-kolesterol har større risiko for å få hjertesykdom og hjerneslag.

Anbefalte kolesterolverdier

- Anbefalte LDL-kolesterolverdier for en person:
 - Med diabetes, hjertesykdom eller hjerneslag, et nivå på 2,0 eller om mulig lavere
 - Uten andre risikofaktorer, et nivå på 2,5 eller lavere
- Anbefalte HDL-kolesterolverdier er 1.2 eller høyere for kvinner, og 1.0 eller høyere for menn.
- Anbefalte totalkolesterolverdier for en person:
 - Med diabetes, hjertesykdom eller hjerneslag, et nivå på 4,5 eller om mulig lavere
 - Uten andre risikofaktorer, et nivå på 5,0 eller lavere

Personer som har for mye av det "dårlige" kolesterolet (høyt LDL-kolesterol) og for lite av det "gode" kolesterolet (lavt HDL-kolesterol) har en større risiko for hjertesykdom og slag

Viktige risikofaktorer

HØYT BLODTRYKK⁴⁻⁶

Blodtrykket ditt måler hvor mye hjertet ditt må arbeide for å pumpe blodet gjennom kroppen din. Det er målt i millimeter (mm) kvikksølv (Hg) og benevnes med to tall, slik som for eksempel: ”135 over 85”



Det høyeste tallet, 135, er **det systoliske blodtrykket**. Det er trykket i blodårene dine når hjertet ditt slår et slag.

Det laveste tallet, 85, er **det diastoliske blodtrykket**. Det er trykket i blodårene dine når hjertet ditt hviler (mellom slagene).

Tabellene nedenfor er eksempler på høyt, høyt-normalt og anbefalt blodtrykk.

Systolisk	Diastolisk
HØYT 140 eller høyere	HØYT 90 eller høyere
HØYT-NORMALT 130-139	HØYT-NORMALT 85-89
ANBEFALT 129 eller lavere	ANBEFALT 84 eller lavere

Blodtrykk endrer seg i løpet av dagen. For å finne ut om du har høyt blodtrykk må legen din sjekke blodtrykket ditt ved 3-5 legebesøk og ta flere målinger etter at du har vært i ro en stund. En kan også bruke tekniske hjelpemidler som du bærer med deg og som måler blodtrykket ditt periodevis i 24 timer.

Du har høyt blodtrykk dersom et av tallene er høyere enn det anbefalte ved flere legebesøk

Viktige risikofaktorer

MANGEL PÅ REGELMESSIG FYSISK AKTIVITET ELLER MOSJON

Mangel på regelmessig mosjon eller fysisk aktivitet kan gi deg høyere risiko for å få høyt blodtrykk, usunne kolesterolverdier og høyt blodsukker. Høyt blodsukker kan forårsake diabetes.

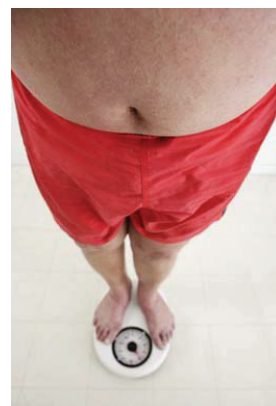


RØYKING

Røyking øker din risiko for hjertesykdom og hjerneslag. Det øker også din risiko for å få lungekreft og andre kreftformer. Røyking forårsaker også kroniske lungelidelser som kronisk bronkitt.

OVERVEKT ELLER FEDME^{68,70}

Å være overvektig kan føre til høyt blodtrykk, høyt kolesterol, diabetes, hjertesykdom og hjerneslag. For å vurdere vekt brukes i dag oftest kroppsmasseindex (KMI) som er et uttrykk for vekt i forhold til høyde. En person som er 1,80 m høy har i følge Verdens helseorganisasjon (WHO) en normal vekt på 60-81 kg, forstadium til fedme når vekten er 81-97 kg, og fedme når vekten er over 97 kg. Tilsvarende har en person med høyde 1,65 m en normalvekt på 50-68 kg, forstadium til fedme når vekten er 68-82 kg og fedme når vekten er over 82 kg. Forstadium til fedme øker risiko for hjertesykdom med 17%, fedme øker risiko for hjertesykdom med 45%



STRESS

Stress kan medvirke til at hjertesykdom bryter ut. Ikke minst innvirker stress på behandlingsforløpet.

Valgmuligheter for livsendringer

Det er mange valg du kan gjøre for å redusere din risiko for hjertesykdom og hjerneslag. Du kan velge å endre livsstilen din og/eller å ta medisiner.



Valgmuligheter for livsstil omfatter:

- Ha et sunt og hjertevennlig kosthold
- Gjøre mer regelmessig fysisk aktivitet eller mosjon
- Ikke røyke eller slutte å røyke
- Oppnå eller beholde en sunn vekt
- Kontrollere stresset i livet ditt

Hvis livsstilsendringer ikke resulterer i de ønskede eller forventede forandringer, kan du ta medisiner for å kunne kontrollere kolesterolnivået eller blodtrykket ditt bedre.

Valgmuligheter for livsstil

Kostholdet ditt⁷⁻²³



Et sunt og hjertevennlig kosthold inneholder:

- Lite fett og kolesterol
- Lite salt
- Mye kostfiber fra mat som kli, grønnsaker og frukt
- Mye omega-3 fettsyrer fra fet fisk eller kapsler med fiskeolje
- Lite alkohol

Et sunt og hjertevennlig kosthold reduserer:

- LDL-kolesterolet ditt med 5%
- Blodtrykket ditt med 5-9mmHg
- Risikoen din for å få hjerteinfarkt
- Risikoen din for å få hjerneslag

Bruk et minutt på å se på tabellene på de to neste sidene og kryss av (✓) alle valgmuligheter som du allerede har forsøkt...

Valgmuligheter for livsstil

Mål	Valgmuligheter
<p>Redusere inntak av fett og kolesterol</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Spis mindre porsjoner med kjøtt (omkring størrelsen av håndflaten din) og noen måltider uten kjøtt, bare grønnsaker. <input type="checkbox"/> Velg magert kjøtt (som fugl og fisk) og fjern synlig fett før tilberedning <input type="checkbox"/> Velg meieriprodukter med lavt fettinnhold som skummet eller ekstra lett melk, cottage cheese og lett-yoghurt <input type="checkbox"/> Lag mat med lite eller ikke noe fett, eller bruk små mengder vegetabiliske oljer som olivenolje, rapsolje, maisolje, solsikkeolje og peanøttolje i matlagingen. <input type="checkbox"/> Unngå produkter som croissanter, muffins og berlinerboller. <input type="checkbox"/> Stek maten heller i ovn enn i panne
<p>Redusere bruk av salt</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Begrens bruk av salt i matlagingen din <input type="checkbox"/> Begrens bruk av salt ved bordet <input type="checkbox"/> Unngå salte matvarer som f.eks. spekemat og potetgull <input type="checkbox"/> Bruk ferske eller frosne matvarer i stedet for hermetikk og ferdigmat fra ferskdisk <input type="checkbox"/> Unngå ferdigmat og sauser fra hylledisk på grunn av fett- og saltinnholdet <input type="checkbox"/> Les innholdsfortegnelsen på matvarene for å bli kjent med mengden fett og salt som er brukt. <input type="checkbox"/> Bruk smakstilsetninger som urter, krydder, sitronsaft og hvitløk i stedet for salt

Valgmuligheter for livsstil

Mål	Valgmuligheter
Øke inntaket av fiber	<input type="checkbox"/> Spis 5-10 porsjoner frukt og grønnsaker hver dag <input type="checkbox"/> Spis 5-10 porsjoner kornprodukter som havre, bygg, naturris, bokhvete og grov hvete hver dag
Øke inntaket av omega-3 fettsyrer	<input type="checkbox"/> Spis 2-3 måltider med fet fisk som for eksempel laks, ørret, makrell eller tunfisk hver uke <input type="checkbox"/> Bland linfrø inn i kornblandinger, bakevarer og gryteretter <input type="checkbox"/> Spis salatblader, soyabønner og valnøtter.
Redusere alkohol inntaket	<p>Hvis du drikker for mye alkohol kan det øke blodtrykket og risikoen for hjertesykdom og hjerneslag</p> <input type="checkbox"/> Menn: Begrens alkoholemengden til ikke mer enn 2 små flasker øl, 2 små glass vin eller 60 ml med sprit (gin, whisky, vodka) hver dag. <input type="checkbox"/> Kvinner: begrens alkoholemengden til ikke mer enn 1 liten flaske øl, 1 lite glass vin eller 30 ml sprit hver dag.

Valgmuligheter for livsstil

Ditt mosjons- eller fysiske aktivitetsnivå 15, 24, 29-39

Du bør mosjonere regelmessig på et moderat intensitetsnivå

Dette kan føre til at du:

- Senker LDL-kolesterolverdien din med 4 % fra f. eks 5.6 til 5.3
- Øker HDL-kolesterolverdien din med 5 %
- Senker blodtrykket ditt med 5-7 mm Hg
- Reduserer din risiko for hjertesykdom og hjerneslag



Du kan øke din fysiske aktivitet på mange måter. Noen aktiviteter krever mer innsats enn andre og vil ha ulik effekt, slik det er vist i tabellen på neste side.

Valgmuligheter for livsstil

Bruk tabellen som følger for å krysse av (✓) alle aktiviteter du liker å gjøre.

INNSATS	AKTIVITET	EFFEKTER
Lett innsats 60 minutter hver dag	<input type="checkbox"/> Lett gange <input type="checkbox"/> Volleyball <input type="checkbox"/> Lett hagearbeid <input type="checkbox"/> Bøy og tøy (stretching)	Hjelper deg å: <ul style="list-style-type: none"> • Gå ned i vekt og holde den vekten
Moderat innsats 30-45 minutter de fleste dager i uken	<input type="checkbox"/> Rask gange <input type="checkbox"/> Sykling <input type="checkbox"/> Rake løv <input type="checkbox"/> Svømme <input type="checkbox"/> Danse <input type="checkbox"/> Bassengtrening	Hjelper deg å: <ul style="list-style-type: none"> • Gå ned i vekt og holde den vekten • Redusere blodtrykket • Senke LDL-kolesterol • Øke HDL-kolesterol
Stor innsats 20-30 minutter 3 ganger i uken	<input type="checkbox"/> Aerobic <input type="checkbox"/> Jogge <input type="checkbox"/> Hockey <input type="checkbox"/> Basketball <input type="checkbox"/> Rask svømming <input type="checkbox"/> Rask dansing	Hjelper deg å: <ul style="list-style-type: none"> • Gå ned i vekt og holde den vekten • Senke LDL-kolesterol • Øke HDL-kolesterol

Hvis du mosjonerer på et nivå med en moderat innsats i 30-45 minutter de fleste dager i uken vil det hjelpe deg å redusere din risiko for hjertesykdom og hjerneslag

Valgmuligheter for livsstil

Røyking ⁴⁰⁻⁴⁵

Hvis du slutter å røyke reduserer du din risiko for hjertesykdom og hjerneslag.

Men det er ikke lett.

Bare 2-5 % av de som prøver å slutte å røyke på egenhånd er røykfrie 6 til 12 måneder etterpå. Det er årsaken til at det finnes flere måter å hjelpe røykere til å slutte.



I tabellen på neste side vil du finne forskjellige metoder som kan hjelpe deg å slutte å røyke. Tabellen viser antall personer av 100 som prøver å slutte å røyke ved hjelp av hver metode og som fremdeles er røykfrie etter 6 til 12 måneder.

Hvis du har forsøkt å slutte å røyke, bruk tabellen til å krysse av (✓) metodene som du har prøvd som hjelp til å slutte.

Valgmuligheter for livsstil

METODE	RØYKFRIE ETTER 6-12 MÅNEDER
<input type="checkbox"/> Slutte på egenhånd uten noe hjelp	2-5 av 100
<input type="checkbox"/> Akupunktur Nåler satt gjennom huden	Langtidseffekt er ikke sett.
<input type="checkbox"/> Hypnose Lar pasienten konsentrere seg dypt, noe som kan føre til en forandring i pasientens syn på røyking.	Langtidseffekt er ikke sett
<input type="checkbox"/> Gruppeveiledning Tilbyr taktikk og tips og sørger for støtte fra gruppen.	14 av 100
<input type="checkbox"/> Individuell veiledning Møter med en kursleder i røykeavvenning	14 av 100
<input type="checkbox"/> Nikotinplaster Avgir nikotin gjennom huden.	8 av 100
<input type="checkbox"/> Nikotintyggegummi Avgir nikotin gjennom munnen	8 av 100
<input type="checkbox"/> Bupropion (Zyban) Tabletter mot depresjon som tas via munnen	15 av 100
<input type="checkbox"/> Nikotinplaster og bupropion	15 av 100
<input type="checkbox"/> Varenicline (Champix)	23 av 100

De fleste metodene er tilgjengelige uten resept. Spør etter tilleggsinformasjon på apoteket.

Valgmuligheter for livsstil

Vekten din^{15, 25-28}

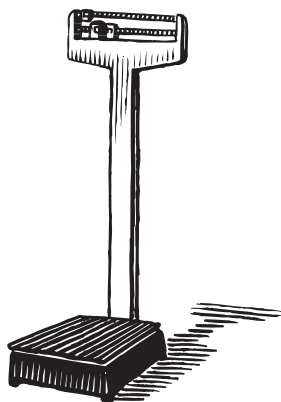
Fedme er forbundet med mange helseproblemer.

Imidlertid kan et vekttap på så lite som 4.5 kg:

- Senke LDL-kolesterolverdien din med 3 %.
Dette vil si at din LDL-kolesterolverdi vil kunne gå fra 5.60 til 5.40
- Øke HDL-kolesterolverdien din med 4 %. Dette vil si at din HDL-verdi vil kunne øke fra 1.00 til 1.04
- Senke blodtrykket ditt med 7 til 12 mm Hg



I tabellen på neste side vil du finne en liste over flere metoder å gå ned i vekt på.



Valgmuligheter for livsstil

Hvis du har forsøkt å gå ned i vekt, kryss av (✓) for metodene du har prøvd.

METODER	LANGTIDS VEKTTAP ETTER 6-12 MÅNEDER
<input type="checkbox"/> Kosthold med mindre kalorier og regelmessig mosjon <ul style="list-style-type: none"> • 1200- 1800 Kcal daglig • Lett til moderat mosjon 30-60 minutter de fleste dager i uken 	Du vil kunne gå ned 6 til 7 kg
<input type="checkbox"/> Veiledning sammen med kostholdsendring og regelmessig mosjon Kurs individuelt eller i grupper for å hjelpe til med omlegging av kosthold og regelmessig mosjon	Kan hjelpe til med å holde vekten hvis du fortsetter veiledning og regelmessig mosjon
<input type="checkbox"/> Medisiner Reduserer appetitt eller hindrer fett fra å bli fullstendig absorbert av kroppen.	Ikke vist seg å virke over tid
<input type="checkbox"/> Kirurgi (for de som har alvorlig fedme) Reduserer appetitten og forhindrer kroppen i å absorbere fett.	Du vil kunne gå ned 28 til 46 kg i vekt

Å følge et kosthold med lavere kaloriinntak og regelmessig mosjon kan føre til et langtids vekttap på 6-7 kg

Valgmuligheter for livsstil

Ditt stress⁴⁶

Stress oppstår når det ikke lenger er balanse mellom krav og påkjenninger vi utsettes for og vår mulighet for å mestre eller oppfylle disse. Når dette skjer over tid er sjansene for å reagere kroppslig og psykisk stor.



Nedenfor kan du markere ditt samlede stressnivå:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ikke stresset i det hele tatt				Ekstremt stresset

Hvis du allerede har høyt blodtrykk så kan stress øke blodtrykket ditt



Vi kan ikke utrydde stress fra tilværelsen, men vi kan gjøre noe med måten vi forholder oss til stressfaktorer på. Ikke minst er det viktig å sørge for aktiviteter som høyner trivsel og livskvalitet.

Valgmuligheter for livsstil

Hvis du har forsøkt å redusere stressnivået i livet ditt kryss av (✓) for metodene du har prøvd...

Metoder	Effekter på blodtrykket
<input type="checkbox"/> Bruke en av disse metodene: Meditasjon, avspenning	Ikke tydelig at dette hjelper til å redusere stress
<input type="checkbox"/> Bruke mer enn en av disse metodene til å redusere stress: En kombinasjon av meditasjon og avspenning	Kan senke blodtrykket med 7 til 10 mm Hg
<input type="checkbox"/> Personlig veiledning for å diskutere og lære om: <ul style="list-style-type: none"> · Årsaker til og respons på stress · Ferdighetstrening i kommunikasjon · Ferdigheter i problemløsning · Mestring av negative følelser · Avspenning/regelmessig mosjon 	Kan senke blodtrykket med 9 til 15 mm Hg

Personlig veiledning om stress eller en kombinasjon av flere metoder som meditasjon og avspenning kan senke blodtrykket.

Valgmuligheter blant medisiner

Medisiner er **ikke** ment å erstatte en sunn livsstil. Ingen medisiner kan kurere høyt kolesterol eller blodtrykk, men de kan bli brukt for å redusere din risiko for å utvikle hjertesykdom når livsstilsendringer ikke alene er nok for å senke verdiene dine til en sunt nivå.

Medisiner for å senke kolesterol 47-57

Kolesterolsenkende medisiner hjelper til å kontrollere blodkolesterolnivået. Hver enkelt av disse medisinene har ulik effekt på LDL- og HDL-kolesterol. Disse medisinene er bare virksomme hvis du tar dem regelmessig resten av livet ditt.



Alle medisiner kan gi bivirkninger og noen virker bedre for noen personer enn for andre. Av denne grunn kan du måtte prøve mer enn en type medisin for å finne den rette for deg.

Det er grovt sett fire typer medisiner tilgjengelig:

- Statiner
- Fibrater
- Resiner
- Nikotinsyrer

Tabellen på neste side gir en oversikt over forskning om effekter av disse familiene av medikamenter. Den første kolonnen inneholder virkestoff og navn på medisinen. Den andre kolonnen inneholder navnet på type medisin. Den tredje kolonnen inneholder informasjon om hvordan kroppen din kan reagere på medisinen. Den fjerde kolonnen viser hvor mye medisinen er i stand til å senke LDL og øke HDL.

Valgmuligheter blant medisiner

Virkestoff og navn på medisinen	Type medisin	Merknader og bivirkninger	Effekter på kolesterol
Atorvastatin (<i>Lipitor</i>) Fluvastatin (<i>Lescol</i>) Lovastatin (<i>Lovastatin, Mevacor</i>) Pravastatin (<i>Pravachol</i>) Rosuvastatin (<i>Crestor</i>) Simvastatin (<i>Simvastin, Zokor</i>)	Statiner	Bivirkninger er milde og påvirker bare noen pasienter. Ikke kjent hva langtidsvirkningen er, om det er noen. Mest vanlige bivirkninger er uvelhet i magen, oppblåsthet, muskelkramper. Kan påvirke leveren.	Senker LDL verdien (20-50%) Øker HDL verdien (5-10 %)
Ezetimib (<i>Ezetrol</i>)		Milde og forbigående. Magesmerter, hodepine	Hemmer opptak av kolesterol fra tarm
Bezafibrate (<i>Bezalip</i>) Fenofibrate (<i>Lipanthyl</i>) Gemfibrozil (<i>Lopid</i>)	Fibrater	Bivirkninger er ofte milde og ikke hyppige. De kan omfatte uvelhet i magen, eller muskelsmerte. Kan påvirke leveren.	Senker LDL verdien (10-20%) Øker HDL verdien (0-30 %)
Colesevelam (<i>Cholestagel</i>) Kolestyramin (<i>Questran</i>) Kolestipol (<i>Lestid</i>)	Resiner	Ubehagelig å ta, men sikker å ta over lang tid fordi kroppen ikke tar det opp. Kan forårsake oppblåsthet, tarmgasser, kvalme, føle seg forstoppet	Senker LDL verdien (15-25%) Øker HDL verdien (0-5 %)
Niacin (<i>Niaspan</i>)	Nikotinsyre	Personer stopper ofte å ta det på grunn av bivirkninger som: varmfølelse i ansikt og kropp hudkløe, utslett, kvalme.	Senker LDL verdien (20 %) Øker HDL verdien (20-40%)

Valgmuligheter blant medisiner

Medisiner for å senke blodtrykk⁵⁸⁻⁶⁶

Du og legen din kan bestemme at du trenger å ta medisin for å senke blodtrykket ditt. Det finnes mange medisiner som kan behandle blodtrykk, men valget er oftest basert på to faktorer. Den første faktoren er personens medisinske tilstand. Den andre faktoren er hvor mye personen er i stand til å leve med av bivirkninger av en spesifikk blodtrykksmedisin.



Hvis du tar medisin for å senke blodtrykket kan det redusere systolisk blodtrykk med omkring 7 til 15 mm Hg, og diastolisk blodtrykk med 5 til 10 mm Hg. Slik at hvis det systoliske blodtrykket ditt nå er 140, kan en av disse medisinene senke det ned til mellom 125-133. Hvis ditt diastoliske blodtrykk nå er omkring 90, kan det gå ned til 80-85. Noen personer kan hende trenger å ta mer enn en medisin.

De mest hyppigst brukte medisiner er beskrevet i tabellen på neste side. Andre medisiner for høyt blodtrykk finnes også på markedet.

I gjennomsnitt kan en enkelt blodtrykksmedisin senke systolisk blodtrykk med omkring 7 til 15 mm Hg og diastolisk blodtrykk med 5 til 10 mm Hg ⁶⁷

Valgmuligheter blant medisiner

Virkestoff og navn på medisin	Type medisin	Bivirkninger	Effekter på blodtrykk
Bumetanid (<i>Burinex</i>), Hydroklortiazid (<i>Esidrex</i>), Amilorid (<i>Moduretic mite</i> , <i>Normorix mite</i>), Spironolakton (<i>Aldactone</i> , <i>Spirix</i>)	Diuretika (<i>vann drivende</i>)	Kan føle seg trøtt, ha hodepine, utslett, bli overfølsom for solen, være kvalm	Senker systolisk 7 til 15 mm Hg. Senker diastolisk 5 til 10 mm Hg.
Atenolol (<i>Tenormin</i> , <i>Unilol</i>) Labetalol (<i>Trandate</i>) Metoprolol (<i>Selo-Zok</i> , <i>Seloken</i>) Propranolol (<i>Inderal retard</i> , <i>Pranolol</i>) Timolol (<i>Blocadren</i>)	Beta-blokkere	Kan føle seg trøtt, ha langsom puls, endring i søvnmønster, forverre pusteproblemer.	Samme som ovenfor
Enalapril (<i>Renitec</i>) Kaptopril (<i>Captopril</i> , <i>Capoten</i>) Lisinopril (<i>Vivatec</i> , <i>Zestril</i>) Ramipril (<i>Triatec</i>)	Angiotensin -converting enzyme (ACE) hemmere	Kan føle seg trøtt, ha tørrhoste, føle seg svimmel	Samme som ovenfor
Irbesartan (<i>Aprovel</i>) Kandesartan (<i>Atacand</i>) Losartan (<i>Cozaar</i>) Telmisartan (<i>Micardis</i>) Valsartan (<i>Diovan</i>)	Angiotensin- II-blokkere	Kan føle seg trøtt, svimmel	Samme som ovenfor
Amlodipin (<i>Norvasc</i>) Felodipin (<i>Plendil</i>) Nifedipin (<i>Adalat</i>) Diltiazem (<i>Cardizem retard</i> , <i>Cardizem uno</i>) Verapamil (<i>Isoptin</i> , <i>Veracard</i>)	Kalsium- blokkere	Kan føle seg trøtt, ha hevelse i ankler, hodepine, lav puls, føle seg forstoppet (verapamil)	Samme som ovenfor

Fire trinn for å redusere din risiko

Nå er tiden kommet til å lære hvordan sette all informasjonen du har fått sammen til en løsning som er riktig for deg.

Bla om for å lære om de fire trinnene for å redusere din risiko.

Fire trinn for å redusere din risiko

Vi har tatt med noen personlig arbeidsark sammen med dette heftet som kan hjelpe deg å bestemme hva som er de beste måtene for å redusere din risiko for hjertesykdom og hjerneslag. Arbeidsarkene vil hjelpe deg til å:

- Vurdere din egen risiko for å dø av hjertesykdom og hjerneslag
- Tenke over livsendringer som kan redusere din risiko
- Lage handlingsplanen din
- Registrere framgangen din over tid med fastlegen din



Fire trinn for å redusere din risiko

Arbeidsarket er delt inn i fire trinn:

På **Trinn 1** i arbeidsarket vil du se på dine egne risikofaktorer og finne ut hva disse betyr i lys av din nåværende risiko for å dø av hjerteinfarkt eller hjerneslag. Se på tabell side 40.

På **Trinn 2** i arbeidsarket vil du se på mulige fordeler ved forskjellig livsstil og valgmuligheter blant medisiner og forestille deg hvor viktige de er for deg. Du vil gjøre dette ved å rangere hvor viktig hver av fordelene er. Du vil gi 5 stjerner for forandringer som du synes er veldig viktige og færre stjerner for de du synes er mindre viktige. Du vil også se hvordan det å gjøre forandringer vil redusere din nåværende risiko for hjerteinfarkt eller hjerneslag.

På **Trinn 3** vil du lage din egen handlingsplan ved å sette opp de forandringer som du er interessert i å overveie å gjøre de neste 6 måneder.

Tilslutt på **Trinn 4** vil du kunne registrere framgangen din over tid med fastlegen din.

For å hjelpe deg å lære hvordan du skal bruke arbeidsarket vil vi vise deg hvordan Marie og Per brukte det for å gjøre forandringer for å redusere deres risiko for å dø av hjerteinfarkt og hjerneslag.

Du vil kanskje finne fram arbeidsarket ditt og følge med.

Maries situasjon

Marie er en 55 år gammel kvinne som ikke har hatt hjerteinfarkt eller hjerneslag. Marie har forsøkt å senke kolesterolet sitt ved å følge et kosthold som inneholder lite fett og kolesterol, men etter tre måneder forblir hennes totalkolesterol fremdeles høy (8.0 mmol/l).



Trinn 1: Maries personlige risiko for å dø av hjertesykdom og hjerneslag

	JA	NEI
Unormale kolesterolverdier	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Høyt blodtrykk	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Røyking	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Fravær av regelmessig mosjon	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Overvekt eller fedme	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Diabetes	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hjerteinfarkt eller hjerneslag	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Slik det er identifisert på Trinn 1 på arbeidsarket hennes har Marie 3 risikofaktorer som kan bli forbedret. Hun har usunne kolesterolverdier fordi hennes totalkolesterol er høy, hun har høyt blodtrykk (178/100) og hun røyker også.

Marie har en beregnet risiko for å dø av hjerteinfarkt eller hjerneslag på 7%. Dette vil si at hvis vi fulgte 100 kvinner med samme risiko som Marie i de neste 10 år ville i gjennomsnitt 7 dø av hjerteinfarkt eller hjerneslag og 93 ville ikke.



Maries situasjon

Trinn 2: Mulige fordeler ved livsendringer

Marie kan redusere sin risiko for å dø av hjerteinfarkt eller hjerneslag ved å slutte å røyke, senke blodtrykket sitt og forbedre kolesterolverdien sin.

Livsendringer	Hvor viktig er fordelene (maksimum viktighet er 5 stjerner) * * * * *
× Ingen forandring	
× ↓ Totalkolesterol med livsstilsendring	* * * * *
× ↓ Totalkolesterol med medisiner	* * *
× ↓ Blodtrykket med livsstilsendring	* * * *
× ↓ Blodtrykket med medisiner	* *
× Slutte å røyke	* * * * *
× Forandre alle risikofaktorene	* * * * *

Den andre kolonnen viser hvor viktig Marie synes mulige livsendringer for henne. For eksempel synes hun at å senke kolesterolet og blodtrykket ved å forandre livsstilen sin er mye viktigere enn senke det med medisiner.

Maries situasjon

Dersom 100 personer som Marie forandret alle sine risikofaktorer ville i gjennomsnitt 1 av dem dø av hjerteinfarkt eller hjerneslag i løpet av de neste 10 årene Dette vil si at, som vist i illustrasjonen med 100 ansikter, i gjennomsnitt **1** ville dø av hjerteinfarkt eller hjerneslag og **99** ville ikke.



Maries situasjon

Trinn 3: Maries handlingsplan

Marie diskuterte fordelene og ulempene ved de forskjellige behandlingmulighetene med fastlegen sin. På trinn 3 i arbeidsarket sitt krysset Marie av valgmulighetene hun er interessert i å prøve de neste 6 måneder. Marie bestemmer seg for å prøve livsstilsendringer og medisiner for å forbedre kolesterolverdiene og blodtrykket sitt. Fordi hun allerede driver noe mosjon planlegger hun å øke sin fysiske aktivitet ved å melde seg på bassengtrening. Etter å ha snakket med en farmasøyt på apoteket bestemmer Marie seg for å prøve nikotinplaster for å hjelpe henne til å slutte å røyke.



Trinn 4: Maries framgang

Etter tre måneder kom Marie tilbake til legen for å diskutere framgangen sin. Hun hadde sluttet å røyke. Hennes kolesterol hadde gått ned til 6,3. Blodtrykket var 140 over 83. Hun hadde også gått nesten 1 kg ned i vekt.

Maries risiko for å dø av hjerteinfarkt eller hjerneslag i løpet av de neste 10 årene var redusert til 1 av 100 fra 7 av 100.

Marie er fornøyd med framgangen sin og velger å fortsette med handlingsplanen sin uten noen forandringer.

Pers situasjon

Per er en 65 år gammel mann som har hatt ett hjerteinfarkt.

Per har også høyt blodtrykk

Trinn 1: Pers personlige risiko for hjertesykdom og hjerneslag

	JA	NEI
Unormale kolesterolverdier	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Høyt blodtrykk	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Røyking	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Fravær av regelmessig mosjon	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Overvekt eller fedme	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Diabetes	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hjerteinfarkt eller hjerneslag	<input checked="" type="checkbox"/>	<input type="checkbox"/>



På Trinn 1 i arbeidsarket sitt kan Per se at han har 2 risikofaktorer som kan bli forbedret: Høyt blodtrykk (179 over 92) og overvekt. Per veier 100 kg. Ideelt sett burde han veie mellom 70-80 kg.

Per har en beregnet risiko for å dø av hjerteinfarkt eller hjerneslag på 16 %. Dette vil si at hvis vi fulgte 100 personer som Per i de neste 10 år ville i gjennomsnitt **16** dø av hjerteinfarkt eller hjerneslag og **84** ville ikke.



Pers situasjon

Trinn 2: Mulige fordeler ved livsendringer

Per kunne redusere sin risiko for å dø av hjerteinfarkt eller hjerneslag ved å senke blodtrykket sitt med livsstilsendring og medisiner.

Livsendringer	Hvor viktig er fordelene (maksimum viktighet er 5 stjerner) * * * * *
× Ingen forandring	
<input type="checkbox"/> ↓ Totalkolesterol med livsstilsendring	
<input type="checkbox"/> ↓ Totalkolesterol med medisiner	
× ↓ Blodtrykket med livsstilsendring	* * * * *
× ↓ Blodtrykket med medisiner	* * * * *
<input type="checkbox"/> Slutte å røyke	
× Forandre alle risikofaktorene	* * * * *

Den andre kolonnen viser at Per synes livsstilsendringer er like viktig som å ta medisiner.

Pers situasjon

Dersom 100 personer som Per forandret alle sine risikofaktorer (senket blodtrykket med medisiner og livsstilsendringer) ville i gjennomsnitt **8** av dem dø av hjerteinfarkt eller hjerneslag og **92** ville ikke i løpet av de neste 10 årene



Trinn 3: Pers handlingsplan

Per diskuterte fordelene og ulempene ved de forskjellige behandlingsmulighetene med Fastlegen sin. På trinn 3 i arbeidsarket sitt krysser Per av for valgmulighetene han er interessert i å prøve de neste 6 måneder. Han bestemmer seg for å begynne å ta medisiner for å senke blodtrykket sitt. Han tror også at en økning i mosjonsnivået hans kan forbedre blodtrykket og hjelpe han med å gå ned i vekt. Pers kardiolog henviser han til hjertetrening som er utviklet for pasienter som har hatt hjerteinfarkt.

Pers situasjon

Trinn 4: Pers framgang

Etter tre måneder kommer Per tilbake til legen for å diskutere framgangen sin. Han har begynt å ta medisiner for å senke blodtrykket sitt. Han har vært oppmerksom på kostholdet sitt og har begynt på hjertetrening. Han har gått ned 4,5 kg og blodtrykket hans har gått ned til 158 over 88.

Pers risiko for å dø av hjerteinfarkt eller hjerneslag i løpet av de neste 10 årene er sunket til 11 av 100.

Per ville gjerne redusere sin risiko enda mer.

Han lager en handlingsplan for å lære mer om hvordan meditasjon og avspenningsteknikker kunne redusere stresset i livet hans.



Nå er det tid for at du skal gjøre ferdig ditt personlige arbeidsark.

Lykke til med beslutningstakingen din!

Oppsummeringer i tabell

Se på oppsummeringstabellen som følger som en rask referanseveiviser til informasjonen vi har presentert som valgmuligheter for livsstil

I begge tabellene vil ↑ pil mene økning og ↓pil mene senkning.

FORANDRINGER AV LIVSSTIL				
	LDL	HDL	BLODTRYKK	
			SYSTOLISK	DIASTOLISK
Sunt og hjertevennlig kosthold	↓ 5 %		↓ 9 mm Hg	↓ 5 mm Hg
Øke regelmessig mosjon	↓ 4 %	↑ 5 %	↓ 5-7 mm Hg	↓ 5-7 mm Hg
Slutte å røyke		↑ 14 %		
Gå ned i vekt 4,5 kg	↓ 3 %	↑ 4 %	↓ 7-12 mm Hg	↓ 7-12 mm Hg
Redusere stress				
Referanser	7, 25, 28	25, 28, 40-42	8, 20, 26, 29	8, 20, 26, 29

Oppsummeringer i tabell

MEDISINER SOM SENKER KOLESTEROL				
	LDL	HDL	BLODTRYKK	
			SYSTOLISK	DIASTOLISK
Resiner	↓ 15-25 %	↑ 0-5 %		
Nikotinsyre	↓ 20 %	↑ 20-40 %		
Fibrater	↓ 10-20 %	↑ 0-30 %		
Statiner	↓ 20-50%	↑ 5-10 %		
MEDISINER SOM SENKER BLODTRYKK				
Diuretika			↓ 7-15 mm Hg	↓ 5-10 mm Hg
Beta-blokkere			↓ 7-15 mm Hg	↓ 5-10 mm Hg
Angiotensin- converting enzym (ACE) hemmere			↓ 7-15 mm Hg	↓ 5-10 mm Hg
Angiotensin II- blokkere			↓ 7-15 mm Hg	↓ 5-10 mm Hg
Kalsium- blokkere			↓ 7-15 mm Hg	↓ 5-10 mm Hg
Referanser	47, 50-51, 53	45-47, 51, 53, 55	57-61, 63-65	57-61, 63-65

Tabell for risiko

SCORE- Europeisk Risikotabell FOR 10 ÅRS DØD PÅ GRUNN AV HJERTE-KARSYKDOM⁶⁹

		KVINNER					MENN														
		IKKE RØYKER		RØYKER			IKKE RØYKER		RØYKER												
		ALDER																			
Systolis k	180	7	8	9	10	12	13	15	17	19	22	14	16	19	22	26	26	30	35	41	47
	160	5	5	6	7	8	9	10	12	13	16	9	11	13	15	16	18	21	25	29	34
	140	3	3	4	5	6	6	7	8	9	11	6	8	9	11	13	13	15	17	20	24
	120	2	2	3	3	4	4	5	5	6	7	4	5	6	7	9	9	10	12	14	17
Systolis k	180	4	4	5	6	7	8	9	10	11	13	9	11	13	15	18	18	21	24	28	33
	160	3	3	3	4	5	5	6	7	8	9	6	7	9	10	12	12	14	17	20	24
	140	2	2	2	3	3	3	4	5	5	6	4	5	6	7	9	8	10	12	14	17
	120	1	1	2	2	2	2	3	3	4	4	3	3	4	5	6	6	7	8	10	12
Systolis k	180	2	2	3	3	4	4	5	5	6	7	6	7	8	10	12	12	13	16	19	22
	160	1	2	2	2	3	3	3	4	4	5	4	5	6	7	8	8	9	11	13	16
	140	1	1	1	1	2	2	2	2	3	3	3	3	4	5	6	5	6	8	9	11
	120	1	1	1	1	1	1	1	2	2	2	2	2	3	3	4	4	4	5	6	8
Systolis k	180	1	1	1	2	2	2	2	3	3	4	4	4	5	6	7	7	8	10	12	14
	160	1	1	1	1	1	1	2	2	2	3	2	3	3	4	5	5	6	7	8	10
	140	0	1	1	1	1	1	1	1	1	2	2	2	2	3	3	3	4	5	6	7
	120	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	3	3	4	5
Systolis k	180	0	0	0	0	0	0	0	0	1	1	1	1	1	2	2	2	2	3	3	4
	160	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2	2	3
	140	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2
	120	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
		Kolesterol (mmol/L)					Kolesterol (mmol/L)					Kolesterol (mmol/L)					Kolesterol (mmol/L)				

SCORE	
	Risiko uttrykt i prosent for å dø av sykdom som hjerteinfarkt eller hjerneslag over en 10 års periode
	15 % og høyere risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	10-14 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	5-9 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	3-4 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	2 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	1 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år
	Mindre enn 1 % risiko for å dø av hjerteinfarkt eller hjerneslag de neste 10 år

For å finne absolutt 10 års risiko:
 Finn tabellen for kjønn, røykestatus og alder.
 I tabellen finner du ruten nærmest ditt systoliske blodtrykk og total kolesterol.
 Risiko er høyere enn indikert i tabellen for de med:
 Familiær hyperlipidemi, Diabetes,
 Familehistorie med tidlig hjertesykdom, Lav HDL, Høye triglycider over 2 mmol/l, når vedkommende nærmer seg neste alderskategori og de som har utviklet hjertesykdom. Pasienter med hjerte-karsykdom krever intensiv livsstilsendringer og hvis nødvendig medikamentell

Ressurser

Sosial – og helsedirektoratet

www.shdir.no

www.sef.no

Tlf 24 16 30 00

Røyketelefonen 800 400 85

Gratis materiell kan bestilles på www.tobakk.no

Bedre helse på 1-2-30 Sammen om fysisk aktivitet www.1-2-30.no

Landsforeningen for kosthold og helse

www.lkh.no

Tlf 23 27 25 40

Nasjonalforeningen for folkehelsen

www.nasjonalforeningen.no

tlf 23 12 00 00

Nasjonalforeningens Hjertelinje

23 12 00 50

Svarer på spørsmål om hvordan man kan forebygge hjerte- og karsykdom ved hjelp av endring av levevaner

Landsforeningen for Hjerte- og Lungesyke

www.lhl.no

tlf 22 79 93 00

Ressurser

Grete Roede AS

www.greteroede.no/

Tlf: 66 98 32 00

Libra Helse og Kosthold

www.libra-helse.no

Tlf 800 48 148

Dr Fedon Lindbergs

www.drlindbergs.no

Vgs vektklubb

www.vektklubb.no

Tips til deg som vil slutte å røyke:

RING Røyketelefonen 800 400 85

BESTILL gratis Guide til Røykfrihet

SNAKK med fastlegen din

GÅ på apoteket

MELD deg på røykesluttkurs ved å kontakt fylkesmannen i ditt fylke

<http://fylkesmannen.no>

Nett adresser som ellers kan hjelpe deg:

Opptur. Et tilbud til deg som vil bli uavhengig av røyken

www.slutta.no

www.roykstopp.no

www.happyending.no

Ordbok for faguttrykk

Akupunktur: Tynne nåler som blir stukket gjennom huden inn i energipunkter som finnes i spesifikke områder av kroppen for å balansere energinivå. Nålene kan også bli varsomt vridd eller varmet.

Angina: Brystmerter forårsaket av mangel på surstoff (oksygen) til hjertet.

Angiotensins-converting enzyme (ACE) hemmere: Medisiner som reduserer blodtrykket ved å redusere sammensnøringen av blodårer og tillater blodet å strømme lettere i årene.

Angiotensin II - blokkere: Reduserer sammensnøringen av blodkar, noe som gjør det lettere for blodet å strømme gjennom dem, reduserer **blodtrykk** og øker utskillelsen av vann og salter i nyrene.

Avspenning: En metode for bevisst å frigjøre spenninger i musklene for å hjelpe en person til å bli roligere.

Beta-blokkere: Medisiner som senker blodtrykk ved å sette ned pulsen og redusere kraften i sammentrekningene i hjertemuskelen.

Biofeedback: En teknikk hvor personer lærer å kontrollere kroppsfunksjoner, slik som **blodtrykk**, noe som normalt ikke er under en persons kontroll.

Blodtrykk: Et mål for hvor kraftig hjertet ditt må arbeide for å pumpe blodet rundt i kroppen din. Det er målt i millimeter (mm) kvikksølv (Hg) og blir framstilt med to tall, slik som "135 over 85". Det høyeste tallet er det **systoliske** blodtrykket ditt, og det laveste tallet er det **diastoliske** blodtrykket ditt.

Diastolisk blodtrykk: Det laveste tallet i avlesning av **blodtrykket** ditt. Dette er trykket i blodårene når hjertet ditt er i hvile (mellom hjerteslagene)

Diuretika: En gruppe medisiner som kan hjelpe til å fjerne ekstra vann fra kroppen ved å stimulere nyrene til å bli kvitt mer urin.

Fibrater: Medisiner brukt som et supplement til livsstilsendringer for å redusere **triglycerider** og øke **HDL-kolesterol**.

HDL-kolesterol: High-density lipoprotein, eller HDL-kolesterol er kjent som det "gode" kolesterolet fordi det fremmer fjerning av kolesterol fra blodet noe som forårsaker at årene blir videre. Personer med lave verdier av HDL eller det "gode" kolesterolet har høyere risiko for **hjertesykdom** og **hjerneslag**.

Hjerneslag: Skade i en del av hjernen forårsaket av en avbrytelse av blodforsyningen eller en lekkasje av blod gjennom åreveggene. Sansefølelse, bevegelse eller funksjon som blir styrt av det skadede området i hjernen er svekket. Hjerneslag kan være dødelig.

Hjerteinfarkt: Alvorlig og kraftige brystmerter forårsaket av plutselig innsettende celledød i deler av hjertemuskelen.

Hjertesykdom: En forsnævring av arteriene i hjertet som kan resultere i **angina** og **hjerteinfarkt**.

Kalsium-blokkere: Medisiner som virker på hjertemuskelen. De reduserer hjertets arbeid med å pumpe blod, senker trykket av blodstrømmen gjennom kroppen og forbedrer blodsirkulasjonen gjennom hjertemuskelen.

Kolesterol i blodet: En absolutt nødvendig bestanddel i kroppen. Det blir fraktet rundt i kroppen av **lipoproteiner**. Det er tre typer kolesterol i blodet: **LDL-kolesterol**, **HDL-kolesterol** og **triglycerider**

Kroppsmasseindeks (KMI). For å vurdere vekt brukes i dag oftest kroppsmasseindeks (KMI) som er et uttrykk for vekt i forhold til høyde. $KMI = \text{vekt (kg)} / \text{høyde} \times \text{høyde (m}^2\text{)}$.

Verdens helseorganisasjon (WHO) har gjort følgende vurdering av sammenheng mellom KMI og helse for voksne uansett alder:

Klassifisering	KMI, kg/m ²	Sykdomsrisiko
Undervekt	Under 18,50	Lav risiko for diabetes, økt risiko for andre helseproblemer
Normalvekt	18,50-24,99	Lav risiko
Overvekt	Over 24,99	
• forstadium til fedme	25,00-29,99	Økt risiko for diabetes
• moderat fedme	30,00-34,99	Økt risiko for diabetes. Økt dødelighet
• alvorlig fedme	35,00-39,99	Høy risiko for flere helseproblemer. Økt dødelighet
• svært alvorlig fedme	Over 39,99	Ytterligere økt helserisiko

LDL-kolesterol: Low-density lipoprotein, eller LDL-kolesterol er kjent som det ”dårlige” kolesterolet fordi det fremmer avleiring av kolesterol i åreveggene og forårsaker at de blir trange. Personer med høye verdier av LDL eller det ”dårlige” kolesterolet har høyere risiko for å utvikle **hjertesykdom** og **hjerneslag**.

Lipoproteiner: Partiklene som transporterer **kolesterol** og fett rundt i kroppen.

Meditasjon: En teknikk hvor personer konsentrerer seg om et objekt, et ord eller en ide i den hensikt å endre sinnstilstanden sin.

Niacin: En medisin brukt som supplement til livsstilsendringer for å øke **HDL-kolesterol** eller senke **triglycerider**. Kan bli brukt alene eller i kombinasjon med andre medisiner.

Personlig veiledning: For eksempel, det å møte en profesjonell veileder regelmessig for å hjelpe deg å snakke om årsaker til ditt stress, forbedre ferdighetene dine i kommunikasjon for å styre stress, lære hvordan en kan løse problemer og styre de negative følelsene dine ved bruk av avspenning og øvelser.

Resiner: Medisiner brukt som supplement til livsstilsendringer for å senke **LDL-kolesterol**. Mest brukt sammen med andre **kolesterolsenkende** medisiner.

Statiner: Medisiner brukt sammen med livsstilsendringer for å senke **LDL-kolesterol**. Kan bli brukt alene eller sammen med andre **kolesterolsenkende** medisiner.

Systolisk blodtrykk: Det høyeste tallet i avlesningen av **blodtrykket** ditt. Det er trykket i blodårene dine når hjertet ditt slår.

Transitorisk Ischemisk Attakk: En kort avbrytelse av blodforsyningen til deler av hjernen som resulterer i en midlertidig svekkelse av syn, tale, sanseførmelse eller bevegelse.

Triglycerider: Kjemisk form av fett som finnes i blodet. Representerer en veldig viktig beholdning av fettsyrer.

Veiledning: Råd og psykologisk støtte gitt av helsepersonell som har som mål å hjelpe deg i å klare et spesifikt problem.

Referanser

1. Hjerterinfarkt-fakta om infarkt og annen iskemisk hjertesykdom. Folkehelseinstituttet. Faglig revidert 19. Oktober 2007. [http:// www.fhi.no](http://www.fhi.no)
2. Russell D, Dahl A, Lund C. Primærprofylakse mot hjerneslag. Tidsskrift for Den norske Lægeforening 6 ;127: 754-758 2007.
3. National Institutes of Health. National Heart, Lung, and Blood Institute. National Cholesterol Education program. Second report of the expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult treatment panel II). NIH publication No. 93-3095, p. 1-166, September, 1993.
4. National Institutes of Health. National Heart, Lung, and Blood Institute, National High Blood Pressure Education Program. The sixth report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. NIH publication. No. 98-4080, p. 1-70, November 1997.
5. Haynes RB, Lacourcière Y, Rabkin SW, Leenen FHH, Logan AG, Wright N, Evans CE. Report of the Canadian hypertension society consensus conference: 2. Diagnosis of hypertension in adults. CMAJ 149[4], 409-418. 1993.
6. The Joint National Committee on Detection Evaluation and Treatment of High Blood Pressure. The fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC V). Arch Intern Med 153, 154-183. 1993.
7. Howell WH, McNamara DJ, Tosca MA, Smith BT, Gaines JA. Plasma lipid and lipoprotein responses to dietary fat and cholesterol: a metaanalysis. Am J Clin Nutr 65, 1747-1764. 1997.
8. Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the dietary approaches to stop hypertension (DASH) diet. N Engl J Med 344[1], 3-10. 2001.
9. Hu FB, Rimm EB, Stampfer MJ, Ascherio A, Spiegelman D, Willett WC. Prospective study of major dietary patterns and risk of coronary heart disease in men. Am J Clin Nutr 72, 912-921. 2000.
10. Stampfer MJ, Hu FB, Manson JE, Rimm EB, Willett WC. Primary prevention of coronary heart disease in women through diet and lifestyle. N Engl J Med 343[1], 16-22. 2000.
11. Hu FB, Stampfer MJ, Manson JE, et al. Trends in the incidence of coronary heart disease and changes in diet and lifestyle in women. N Engl J Med 343[8], 530-537. 2000.
12. Liu S, Manson JE, Lee IM, Cole SR, Hennekens CH, Willett WC, Buring JE. Fruit and vegetable intake and risk of cardiovascular disease: the Women's Health Study. Am J Clin Nutr 72, 922-928. 2000.
13. Liu S, Manson JE, Stampfer MJ, Rexrode KM, Hu FB, Rimm EB, Willett WC. Whole grain consumption and risk of ischemic stroke in women. A prospective study. JAMA 284[12], 1534-1540. 2000.
14. Campbell NRC, Ashley MJ, Carruthers SG, Lacourcière Y, McKay DW. 3 Recommendations on alcohol consumption. CMAJ; 160(9Suppl); S13-S20. 1999.
15. National Institutes on Health, National Heart, Lung and Blood Institute in cooperation with The National Institute of Diabetes and Digestive and Kidney Diseases. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. Executive summary. NIH publication No. 98-4083, p. VII-XXVI September, 1998.
16. Gaziano JM, Buring JE, Breslow JL, et al. Moderate alcohol intake, increased levels of high-density lipoprotein and its subfractions, and decreased risk of myocardial infarction. N Engl J Med 329, 1829-1834. 1993.

17. Valmadrid CT, Klein R, Moss SE, Klein BEK, Cruickshanks KJ. Alcohol intake and the risk of coronary heart disease mortality in persons with older-onset diabetes mellitus. *JAMA* 282[3], 239-246. 1999.
18. Nanchahal K, Ashton WD, Wood DA. Alcohol consumption, metabolic cardiovascular risk factors and hypertension in women. *Int J Epidemiol* 29, 57-64. 2000.
19. Rimm EB, Giovannucci EL, Willett WC, Colditz GA, Ascherio A, Rosner B Stampfer MJ. Prospective study of alcohol consumption and risk of coronary disease in men. *Lancet* 338, 464-468. 1991.
20. Elmer PJ, Grimm R, Laing B, et al. Lifestyle intervention: Results of the Treatment of Mild Hypertension Study (TOMHS). *Prev Med* 2[4], 378-388. 1995.
21. Hypertension Prevention Trial Research Group. The hypertension prevention trial: three-year effects of dietary changes on blood pressure. *Arch Int Med* 150[1], 153-162. 1990.
22. Stamler R, Stamler J, Grimm R, et al. Nutritional therapy for high blood pressure. Final report of a four-year randomized controlled trial – The hypertension control program. *JAMA* 257[11], 1484-1491. 1987.
23. Canadian Task Force on Development of The Healthy Heart Kit. The Healthy Heart Kit: Helping your patients reduce their risk, Ottawa, February 1999.
24. Fodor J, Frohlich J, Genest JG, McPherson R, for the Working Group on Hypercholesterolemia and Other Dyslipidemias. Recommendations for the management and treatment of dyslipidemia. *CMAJ* 162[10], 1441- 1447. 2000.
25. Douketis JD, Feightner JW, Attia J, Feldman WF, with the Canadian Task Force on Preventive Health Care. Periodic health examination, 1999 update: 1. Detection, prevention and treatment of obesity. *CMAJ* 160, 513-525. 1999.
26. Dattilo AM, Kris-Etherton PM. Effects of weight reduction on blood lipids and lipoproteins: a meta-analysis. *Am J Clin Nutr* 56, 320-328. 1992.
27. Leiter LA, Abbott D, Campbell NRC, Mendelson R, Ogilvie RI, Chockalingam A. 2. Recommendations on obesity and weight loss. *CMAJ* 160[9Suppl], S7-S12. 1999.
28. Wassertheil-Smoller S, Blaufox MD, Oberman AS, Langford HG, Davis BR, Wylie-Rosett J. The trial of antihypertensive interventions and management (TAIM) study. Adequate weight loss, alone and combined with drug therapy in the treatment of mild hypertension. *Arch Int Med* 152, 131-136. 1992.
29. Lowensteyn I, Coupal L, Zowall H, Grover SA. The cost-effectiveness of exercise training for the primary and secondary prevention of cardiovascular disease. *J Cardiopulmonay Rehabil* 20, 147-155. 2000.
30. Cléroux J, Feldman RD, Petrella RJ. 4. Recommendations on physical exercise training. *CMAJ* 160[9 Suppl], S21-S28. 1999.
31. Arroll B, Beaglehole R. Does physical activity lower blood pressure: A critical review of the clinical trials. *J Clin Epidemiol* 45[5], 439-447. 1992.
32. Fagard RH. Physical fitness and blood pressure. *J Hypertension* 11 (suppl 5), S47-S52. 1993.
33. Manson JE, Hu FB, Rich-Edwards JW, et al. A prospective study of walking as compared with vigorous exercise in the prevention of coronary heart disease in women. *N Engl J Med* 341[9], 650-658. 1999.
34. Manson JE, Nathan DM, Krolewski AS, Stampfer MJ, Willett WC, Hennekens CH. A prospective study of exercise and incidence of diabetes among US male physicians. *JAMA* 268[1], 63-67. 1992.
35. Berlin JA, Colditz GA. A meta-analysis of physical activity in the prevention of coronary heart disease. *Am J Epidemiol* 132[4], 612-628. 1990.
36. Hu FB, Stampfer MJ, Colditz GA, Ascherio A, Rexrode KM, Willett WC, Manson JE. Physical activity and risk of stroke in women. *JAMA* 283[22], 2961-2967. 2000.

37. Blair SN, Kohl III HW, Barlow CE, Paffenbarger RS, Gibbons LW, Macera CA. Changes in physical fitness and all-cause mortality. A prospective study of healthy and unhealthy men. *JAMA* 273[14], 1093-1098. 1995.
38. Lee I-M, Hsieh C-C, Paffenbarger RS. Exercise intensity and longevity in men. The Harvard Alumni Health Study. *JAMA* 273[15], 1179-1184. 1995.
39. <http://www.phac-aspc.gc.ca/>
40. The Smoking Cessation Clinical Practice Guideline Panel and Staff. The agency for health care policy and research smoking cessation clinical practice guideline. *JAMA* 275[16], 1270-1280. 1996.
41. Hughes JR, Keely J, Naud, S. Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction*, 99,29-38. 2004.
42. Huges, JR, Shiffman S, Callas, P, Zhang J. A meta-analysis of the efficacy of over-the-counter-nicotine replacement. *Tobacco Control* 12, 21-27 2003.
43. Etter JF, Stapleton JA. Nicotine replacement therapy for long-term smoking cessation: a meta-analysis. *Tobacco Control* 15(4), 280-285. 2006
44. Jorenby DE, Hays JT, Rigotti NA, Azoulay S, Watsky EJ et al. Efficacy of Varenicline, an $\alpha 4\beta 2$ Nicotinic Acetylcholine receptor partial agonist, vs placebo or sustained-release Bupropion for smoking cessation. *JAMA* 296(1) 56-63. 2006.
45. Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation. I: The Cochran Library, Issue 4. 2003.
46. Spence JD, Barnett PA, Linden W, Ramsden V, Taenzer P. 7. Recommendations on stress management. *CMAJ* 160[(9 Suppl)], S46-S50. 1999.
47. Jones P, Kafonek S, Laurora I, Hunninghake D, for the CURVES Investigators. Comparative dose efficacy study of Atorvastatin versus Simvastatin, Pravastatin, Lovastatin, and Fluvastatin in patients with hypercholesterolemia (The CURVES Study). *Am J Cardiol* 81, 582-587. 1998.
48. Schectman G, Hiatt J. Dose-response characteristics of cholesterol-lowering drug therapies: implications for treatment. *Ann Intern Med* 125[12], 990-1000. 1996.
49. Hebert PR, Gaziano JM, Chan KS, Hennekens CH. Cholesterol lowering with statin drugs, risk of stroke, and total mortality. An overview of randomized trials. *JAMA* 278[4], 313-321. 1997.
50. Bucher HC, Griffith LE, Guyatt GH. Effect of HMGcoA reductase inhibitors on stroke. A meta-analysis of randomized, controlled trials. *Ann Intern Med* 128, 89-95. 1998.
51. Frick MH, Elo O, Haapa K, Heinonen OP, Heinsalmi P, Helo P et al. Helsinki Heart Study: primary-prevention trial with gemfibrozil in middle-aged men with dyslipidemia. *N Engl J Med* 317, 1237-1245. 1987.
52. Paradiso-Hardy FL. Dyslipidemia update: Part II. Pharmacy practice [November], 1-8. 1998.
53. Perreault S, Hamilton VH, Lavoie F, Grover S. A head-to-head comparison of the cost-effectiveness of HMG-CoA reductase inhibitors and fibrates in different types of primary hyperlipidemia. *Cardiovasc Drugs Ther* 10[6], 787-794. 1996.
54. Illingworth D, Stein EA, Mitchel YB, et al. Comparative effects of lovastatin and niacin in primary hypercholesterolemia. *Arch Int Med* 154, 1586-1595. 1994.
55. The Coronary Drug Project Research Group. Clofibrate and niacin in coronary heart disease. *JAMA* 231[4], 360-381. 1975.
56. Lipid Research Clinics Program. The Lipid Research Clinics Coronary Primary Prevention Trials results. I. Reduction in incidence of coronary heart disease. *JAMA* 251[3], :351-364. 1984.

57. Martin MJ, Hulley SB, Browner WS, Kuller LH, Wentworth DW. Serum cholesterol, blood pressure, and mortality: implications from a cohort of 361 662 men. *Lancet* 2, 933-939. 1986.
58. Neaton JD, Grimm RH, Prineas RJ, et al. Treatment of mild hypertension study. Final results. *JAMA* 270[6], 713-724. 1993.
59. Materson BJ, Reda DJ, Cushman WC, et al. Single-drug therapy for hypertension in men. A comparison of six antihypertensive agents with placebo. *N Engl J Med* 328, 914-921. 1993.
60. Wright J, Lee C.H., Chambers GK. Systematic review of antihypertensive therapies: Does the evidence assist in choosing a first-line drug? *CMAJ* 161[1], 25-32. 1999.
61. Wright J. Choosing a first-line drug in the management of elevated blood pressure: What is the evidence? 1: Thiazide diuretics. *CMAJ* 163[1], 57-60. 2000.
62. Wright J. Choosing a first-line drug in the management of elevated blood pressure: What is the evidence? 3: Angiotensin-convertingenzyme inhibitors. *CMAJ* 163[6], 293-296. 2000.
63. Wright J. Choosing a first-line drug in the management of elevated blood pressure: What is the evidence? 2: Beta-blockers. *CMAJ* 163[2], 188-92. 2000.
64. Dina R, Jafari M. Angiotensin II-receptor antoagonists: An overview. *Am J Health-Syst Phar* 57, 1231-1241. 2000.
65. Psaty BM, Smith NL, Siscovick DS, et al. Health outcomes associated with antihypertensive therapies used as first-line agents. A systematic review and meta-analysis. *JAMA* 277[9], 739-745. 1997.
66. The Heart Outcomes Prevention Evaluation Study Investigators. Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. *N Engl J Med* 342, 145-153. 2000.
67. Materson BJ, Reda DJ, Cushman WC, et. al. For the Departments of Veterans Affairs Cooperative Study Group on Antihypertensive Agents. Single-drug therapy for hypertension in men. A comparison of six antihypertensive agents with placebo. *N Engl J Med* 1993; 328: 914-21.
68. World Health Organization: http://www.who.int/bmi/index.jsp?introPage=intro_3.html (03.01.08)
69. www.escardio.org/prevention
European Guidelines on Cardiovascular Disease Prevention in Clinical Practice: Fourth Joint European Societies Task Force on Cardiovascular Disease Prevention in Clinical Practice Graham I; Atar, D; Borch-Johnsen, K et al. Executive summary, *European Heart Journal* 2007, 28, 2375-2414 and Full text *European Journal of Cardiovascular Prevention and Rehabilitation* 2007, 14(Suppl 2), S1-S 113
70. Bogers RP, Bemelmans WJ, Hoogenveen RT, Boshuizen HC, Woodward M et al. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: A meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med* 10;167 (16): 1720-1728. 2007.

Gjøre valg: Livsendringer for å redusere din risiko for hjertesykdom og hjerneslag



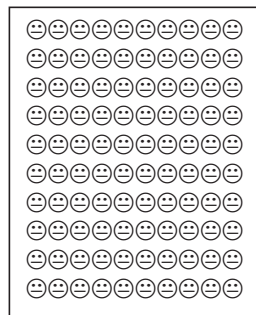
Ditt personlig arbeidsark

Trinn 1: Din personlige risiko for hjertesykdom og hjerneslag

Du har følgende risikofaktorer:

	Ja	Nei
Unormale kolesterolverdier	<input type="checkbox"/>	<input type="checkbox"/>
Høyt blodtrykk	<input type="checkbox"/>	<input type="checkbox"/>
Røyking	<input type="checkbox"/>	<input type="checkbox"/>
Fravær av regelmessig mosjon	<input type="checkbox"/>	<input type="checkbox"/>
Overvekt eller fedme	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
Hjerteinfarkt eller hjerneslag	<input type="checkbox"/>	<input type="checkbox"/>

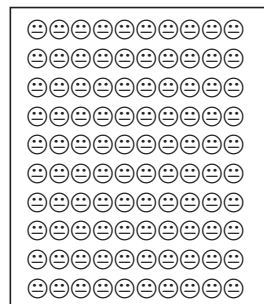
Hvis vi følger 100 personer som deg i de neste 10 årene (se tabell s. 40) ville i gjennomsnitt _____ dø av hjerteinfarkt eller hjerneslag, _____ ville ikke.



Trinn 2: Mulige fordeler ved livsendringer

Livsendringer	Hvor viktig er fordelen for deg? (maksimum viktighet er 5 stjerner) * * * * *
<input type="checkbox"/> Ingen forandring	
<input type="checkbox"/> ↓ Totalkolesterol med livsstilsendring	
<input type="checkbox"/> ↓ Totalkolesterol med medisiner	
<input type="checkbox"/> ↓ Blodtrykket med livsstilsendring	
<input type="checkbox"/> ↓ Blodtrykket med medisiner	
<input type="checkbox"/> Slutte å røyke	
<input type="checkbox"/> Forandre alle risikofaktorer	

Hvis 100 personer som deg forandret alle sine risikofaktorer (se tabell s. 40) i de neste 10 årene ville i gjennomsnitt _____ dø av hjerteinfarkt eller hjerneslag, _____ ville ikke.



Trinn 3: Handlingsplanen din

Kryss av for valgmuligheter du er interessert i å overveie de neste 6 måneder. Vær konkret vedrørende forandringer

VALGMULIGHETER FOR LIVSSTIL				
	Gjør dette allerede	Vil prøve å gjøre dette	Tenker på å gjøre dette	Plan for konkret forandring
Sunt og hjertevennlig kosthold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gå ned i vekt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Mosjonere mer regelmessig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Slutte å røyke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Redusere stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Begrense alkoholinntaket	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
VALGMULIGHETER BLANT MEDISINER (hvis det er anbefalt av lege)				
Kolesterol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Blodtrykk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Andre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Trinn 4: Framgangen din

Du kan fullføre denne delen sammen med fastlegen din for å følge framgangen din de neste 6 måneder

	Mål	I dag: Dato:	2 mnd Dato:	4 mnd Dato:	6 mnd: Dato:
LIVSSTILSENDRING	Valgmuligheter	Kryss av for valgmuligheter du følger			
Sunt og hjertevennlig kosthold	<input type="checkbox"/>				
Gå ned i vekt	<input type="checkbox"/>				
Mosjonere mer regelmessig	<input type="checkbox"/>				
Slutte å røyke	<input type="checkbox"/>				
Redusere stress	<input type="checkbox"/>				
Begrense alkoholinntaket	<input type="checkbox"/>				
MEDISINER		Skriv ned navn på medisinen(e)			
For kolesterol	<input type="checkbox"/>				
For blodtrykk	<input type="checkbox"/>				
Andre	<input type="checkbox"/>				
RESULTATENE DINE	Anbefalte verdier	Før opp verdiene dine			
HDL-kolesterolverdi					
LDL-kolesterolverdi					
Total kolesterolverdi					
Blodtrykk	/	/	/	/	/
Risiko for å dø av hjertekarsykdom:					

Appendix B

Decisional Counseling Program (DCP)

Oversikt over intervensjonen "Decisional Counseling Program" (DCP)

TEMA	MÅL/RESULTAT	INNHold	METODER	EVENTUELLE INSTRUMENTER/STIKKORDSLISTER
Innledning	Tema og prosess for veiledningen er identifisert	Beskrive mål/hensikt med veiledningen Oppmerksomhet på at det er ikke er riktige eller gale svar	Samtale	Samtale guide og stikkordliste for innledningssamtalen
TEMA 1.				
Kunnskap, erfaring og forståelse av hjertesykdom	Har samtalt om: Diagnose Prognose Anbefalinger om livsstilsendringer	Kort repetisjon om nødvendig Hjelp til forståelse. Tilpasse informasjonen til personens situasjon og framtid.	Hefte gjennomlest før samtalen Samtale, spørsmål	Heftet: "Gjøre valg. Livsendringer for å redusere din risiko for hjertesykdom og hjerneslag" før veiledningen Samtaleguide og stikkordliste for samtale om tema 1 (Kunnskap/erfaring/forståelse)
TEMA 2.				
Generelle overbevisninger om helse Spesielle overbevisninger om helse	Har samtalt om: Mottagelighet for og alvorlighet ved mulig forverring av deres hjertesykdom	Individuell risikoprofil Hjelp til å forstå mulige risiko	Presentasjon av risikoprofil Samtale	HeartScore European Society of Cardiology http://www.escardio.org/knowledge/decision_tools/heart_score/se/ Samtale guide og stikkordliste for samtale om tema 2 (Generelle og spesielle overbevisninger om helse/individuell risikoprofil)
TEMA 3.				
Fordele og eventuelle ulemper ved livsstilsendringer	Har tro på at: (1) handling er fordeisaktig (redusere mottagelighet og alvorlighet) (2) det ikke finnes noen overveldende ulemper	Rangering viktighet av ulike livsstilsendringer Vurdere individuelle fordeler Vurdere individuelle ulemper	Hjelpear Samtale	"Viktighet av livsstilsendringer" "Livsstilsendringer A-E") Samtale guide og stikkordliste for samtale om tema 3 (Fordele og eventuelle ulemper ved livsstilsendringer).
TEMA 4.				
Beslutning	Har valgt livsstilsendringer Tidfestet endringer Vurdert egeninnsats Vurdert behov for sosial støtte Laget en plan for livsstilsendringer	Hva er best for deg? Utarbeide skriftlig plan Hvem må gjøre hva og når? Hva trengs for å oppnå målet?	Skrive ned valgte beslutninger i en plan	"Min plan for livsstilsending" Samtale guide og stikkordliste for samtale om tema 4 (Beslutning) 1 Minutts Evaluering av hjemmebesøket

SAMTALE GUIDE OG STIKKORDLISTE FOR INNLEDNING (DCP)

INNLEDNING

Innhold:

Beskrive mål/hensikt med veiledningen

Oppmerksomhet på at det er ikke er riktige eller gale svar

Mål/Resultat

Tema og prosess for veiledningen er identifisert

Samtale guide og stikkord:

Det er ikke sikkert at du går rundt og tenker på at du har noen risikofaktorer du kan gjøre noe med....eller at du har ønske om endring av livsstil.....derfor er hensikten med dette besøket å hjelpe deg til å oppdage:

- Hvilke risikofaktorer du eventuelt står over for
- Hvilke livsstilsendringer som er mulig for deg å gjennomføre
- Hvilke endringer du synes er viktig å gjøre
- Fordeler ved og eventuelle ulemper som kan hindre deg i å gjennomføre livsstilsendringer
- En plan for livsstilsendringer som du lager selv

Det er ikke noen gale eller riktige svar

SAMTALE GUIDE OG STIKKORDSLISTE FOR TEMA 1 (DCP)

KUNNSKAP, ERFARING OG FORSTÅELSE AV HJERTESYKDKOM

Innhold:

Kort repetisjon om nødvendig

Hjelp til forståelse.

Tilpasse informasjonen til personens situasjon og framtid.

Mål/resultat:

Har samtalt om:

Diagnose

Prognose

Anbefalinger om livsstilsendringer

Samtale guide og stikkord:

Har du lest heftet: "Gjøre valg: Livsendringer for å redusere din risiko for hjertesykdom og hjerneslag"?

Hvor mange ganger?

Har du noen spørsmål angående det du har lest?

Kan eventuelt konkret spørre om tema som:

- Årsaker til hjertesykdom og hjerneslag?
- Hva kan skje med de som får hjerteinfarkt og slag
- Viktige risikofaktorer
- Valgmuligheter for livsendringer
- Mulige fordeler eller ulemper ved livsstilsendringer

Eventuelt en kort repetisjon ved behov

SAMTALE GUIDE OG STIKKORDSLISTE FOR TEMA 2 (DCP)

GENERELLE OVERBEVISNINGER OM HELSE SPESIELLE OVERBEVISNINGER OM HELSE

Innhold:

Individuell risikoprofil

Hjelp til å forstå mulige risiko

Mål/Resultat:

Har samtalt om:

Mottagelighet for og alvorlighet ved mulig utvikling eller forverring av deres hjertesykdom

Samtale guide og stikkord:

Presentasjon av individuell risikoprofil utarbeidet ved bruk av HeartScore, svensk versjon http://www.escardio.org/knowledge/decision_tools/heartscore/ på grunnlag av data innhentet ved T1.

Når du ser denne risikoprofilen din, hvilke tanker gjør du deg om utvikling/mulig forverring av hjertesykdom?

Hva betyr dette, slik du ser det?

Hva er viktig for deg?

SAMTALE GUIDE OG STIKKORDSLISTE TEMA 3 (DCP)

FORDELER OG EVENTUELLE ULEMPER VED

LIVSSTILSENDRINGER

Innhold:

Rangering viktighet av ulike livsstilsendringer
Vurdere individuelle fordeler
Vurdere individuelle ulemper

Mål/resultat:

Har tro på at:

- (1) Handling er fordelsaktig (reducere mottagelighet og alvorlighet)
- (2) Det ikke finnes noen overveldende ulemper

Samtaleguide og stikkord:

For å gå litt nærmere inn på hva dette kan bety for deg, og hva du synes blir viktig tenker jeg at du kan jobbe litt med hvor viktig enkelte endringer faktisk er for deg nå.

Hva mener du er de viktigste beslutninger om livsstilsendringer for deg? Kan du angi viktigheten av at du gjør livsstilsendringer ved å krysse av på skalaen fra 0 ikke viktig i det hele tatt til 10 svært viktig for meg.

Du skal få noen oppgaver vedrørende forskjellige livsstilsendringer

Vær vennlig å fullfør de påbegynte setningene, skriv ned det som først dukker opp, husk det er ikke noe riktig eller galt svar.

Hva er det du ønsker å unngå skal skje

Hva er de viktigste fordelene og eventuelle ulempene ved livsstilsendringer for deg

Hva ville være lett for deg å gjøre?

Fordeler versus ulemper ved livsstilsendringer slik du ser det

Veie din viktighet av fordeler og ulemper ved livsstilsendringer opp mot hverandre

Hvordan er tyngden lagt på balanse-vektene dine?

Er fordelene viktigere enn ulempene? Eller er ulempene viktigere enn fordelene?

Hva sier dette deg?

Hjelpeark:

"Viktighet av livsstilsendringer"

"Livsstilsendringer A-E"

VIKTIGHET AV LIVSSTILSENDERINGER

Akkurat nå, hva mener du er de viktigste beslutninger om livsstilsendringer for deg?

Vær vennlig å angi viktigheten av at du gjør livsstilsendringer ved å krysse av på skalaen

fra 0 (Ikke viktig i det hele tatt) til 10 (Svært viktig for meg).

(A) Slutte å røyke	(B) Ha et sunt og hjertevennlig kosthold	(C) Oppnå eller beholde en sunn kroppsvekt	(D) Mosjonere regelmessig	(E) Redusere stress
Svært viktig for meg	Svært viktig for meg	Svært viktig for meg	Svært viktig for meg	Svært viktig for meg
10	10	10	10	10
9	9	9	9	9
8	8	8	8	8
7	7	7	7	7
6	6	6	6	6
5	5	5	5	5
4	4	4	4	4
3	3	3	3	3
2	2	2	2	2
1	1	1	1	1
0	0	0	0	0
Ikke viktig i det hele tatt	Ikke viktig i det hele tatt	Ikke viktig i det hele tatt	Ikke viktig i det hele tatt	Ikke viktig i det hele tatt

A. Å slutte å røyke

Vær vennlig fullfør de påbegynte setningene med det første som du tenker på

1. Fokus på "Å slutte å røyke" og hvorfor dette er viktig for deg:

Å slutte å røyke er **viktig** for meg

fordi _____

og fordi _____

og fordi _____

I tillegg er det viktig for meg å slutte å røyke fordi _____

Det viktigste jeg **ønsker å unngå** ved å slutte å røyke

er _____

og _____

og _____

I tillegg ønsker jeg ved å slutte å røyke å unngå _____

De viktigste **fordelene** jeg får ved å slutte å røyke er _____

og _____

I tillegg, en annen fordel er _____

2. Fokus på ulemper ved å slutte å røyke

Hvis det skulle være noen **ulemper** ved å slutte å røyke måtte det være

at _____

og at _____

og kanskje _____

3. Når jeg tenker på å slutte å røyke ville det være lett for meg å slutte å røyke

dersom jeg _____

Og sannsynligvis lett hvis jeg _____

4. Fordeler versus ulemper ved å slutte å røyke.

Vær vennlig kryss av for viktighet

Hvor viktig er fordelene
ved å slutte å røyke?

Hvor viktig er
ulempene ved å slutte
å røyke?

Svært viktige for meg

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

10
9
8
7
6
5
4
3
2
1
0

*Ikke viktige i det
hele tatt*

*Ikke viktige i det
hele tatt*

Viktighet fordeler: _____	Viktighet ulemper: _____
---------------------------------	--------------------------------

Før viktigheten

på

balansevekten

B. Å ha et sunt og hjertevennlig kosthold

Vær vennlig fullfør de påbegynte setningene med det første som du tenker på

1. Fokus på ”å ha et sunt og hjertevennlig kosthold” og hvorfor dette er viktig for deg:

Å ha et sunt og hjertevennlig kosthold er **viktig** for meg fordi _____

og fordi _____

og fordi _____

I tillegg er det viktig for meg å ha et sunt og hjertevennlig kosthold fordi _____

Det viktigste jeg **ønsker å unngå** ved å ha et sunt og hjertevennlig kosthold er _____

og _____

og _____

I tillegg ønsker jeg ved å ha et sunt og hjertevennlig kosthold å unngå _____

De viktigste **fordelene** jeg får ved å ha et sunt og hjertevennlig kosthold er _____

og _____

I tillegg, en annen fordel er _____

2. Fokus på ulemper med å ha et sunt og hjertevennlig kosthold

Hvis det skulle være noen **ulemp**er med et sunt og hjertevennlig kosthold måtte

det være at _____

og at _____

og kanskje _____

3. Når jeg tenker på å ha et sunt og hjertevennlig kosthold ville det være lett

for meg å ha et sunt og hjertevennlig kosthold dersom jeg _____

og sannsynligvis lett hvis jeg _____

4. Fordeler versus ulemper ved å ha et sunt og hjertevennlig kosthold

Vær vennlig kryss av for viktighet

Hvor viktig er fordelene ved å ha et sunt og hjertevennlig kosthold?

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Hvor viktig er ulempene ved å ha et sunt og hjertevennlig kosthold?

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Viktighet fordeler: _____	Viktighet ulemper: _____
------------------------------	-----------------------------

Før viktigheten

på

balansevekten

C. Å oppnå eller beholde en sunn kroppsvekt

Vær vennlig fullfør de påbegynte setningene med det første som du tenker på

1. Fokus på "Å oppnå eller beholde en sunn kroppsvekt" og hvorfor dette er viktig for deg:

Å oppnå eller beholde en sunn kroppsvekt er **viktig** for meg fordi _____

og fordi _____

og fordi _____

I tillegg er det viktig for meg å oppnå eller beholde en sunn kroppsvekt

fordi _____

Den viktigste jeg **ønsker å unngå** ved å oppnå eller beholde en sunn kroppsvekt

er _____

og _____

I tillegg ønsker jeg ved å oppnå eller beholde en sunn kroppsvekt å

unngå _____

De viktigste **fordelene** jeg får ved å oppnå eller beholde en sunn kroppsvekt er ____

og _____

I tillegg, en annen fordel er _____

2. Fokus på ulemper ved å oppnå eller beholde en sunn kroppsvekt

Hvis det skulle være noen **ulemper** ved å oppnå eller beholde en sunn kroppsvekt måtte det være at _____

og at _____

og kanskje _____

3. Når jeg tenker på å oppnå eller beholde en sunn kroppsvekt ville det være

lett for meg å oppnå eller beholde en sunn kroppsvekt dersom jeg _____

Og sannsynligvis lett hvis jeg _____

4. Fordeler versus ulemper ved å oppnå eller beholde en sunn kroppsvekt

Vær vennlig kryss av for viktighet

Hvor viktig er fordelene ved å oppnå eller beholde en sunn kroppsvekt

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Hvor viktig er ulempene ved å oppnå eller beholde en sunn kroppsvekt

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Viktighet fordeler: _____	Viktighet ulemper: _____
------------------------------	-----------------------------

Før viktigheten på

balansevekten

D. Å mosjonere regelmessig

Vær vennlig fullfør de påbegynte setningene med det første som du tenker på

1. Fokus på "Å mosjonere regelmessig" og hvorfor dette er viktig for deg:

Å mosjonere regelmessig er **viktig** for meg fordi _____

og fordi _____

og fordi _____

I tillegg er det viktig for meg å mosjonere regelmessig fordi _____

Det viktigste jeg **ønsker å unngå** ved å mosjonere regelmessig er _____

og _____

I tillegg ønsker jeg ved å mosjonere regelmessig å unngå _____

De viktigste **fordelene** jeg får ved å mosjonere regelmessig er _____

og _____

I tillegg, en annen fordel er _____

2. Fokus på ulemper ved å mosjonere regelmessig

Hvis det skulle være noen **ulemper** ved å mosjonere regelmessig måtte det være at _____

og at _____

og kanskje _____

3. Når jeg tenker på å mosjonere regelmessig ville det være lett for meg å

mosjonere regelmessig dersom jeg _____

Og sannsynligvis lett hvis jeg _____

4. Fordeler versus ulemper ved å mosjonere regelmessig

Vær vennlig kryss av for viktighet

Hvor viktig er fordelene ved å mosjonere regelmessig

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Hvor viktig er ulempene ved å mosjonere regelmessig

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Viktighet fordeler:

Viktighet ulemper:

Før viktigheten

på

balansevekten

E. Å redusere stress

Vær vennlig fullfør de påbegynte setningene med det første som du tenker på

1. Fokus på "Å redusere stress" og hvorfor dette er viktig for deg:

Å redusere stress er **viktig** for meg fordi _____

og fordi _____

og fordi _____

I tillegg er det viktig for meg å redusere stress fordi _____

Det viktigste jeg **ønsker å unngå** ved å redusere stress er _____

og _____

I tillegg ønsker jeg ved å redusere stress å unngå _____

De viktigste **fordelene** jeg får ved å redusere stress er _____

og _____

I tillegg, en annen fordel er _____

2. Fokus på ulemper ved å redusere stress

Hvis det skulle være noen ulemper ved å redusere stress måtte det være at _____

og at _____

og kanskje _____

3. Når jeg tenker på å redusere stress ville det være lett for meg å redusere

stress dersom jeg _____

Og sannsynligvis lett hvis jeg _____

4. Fordeler versus ulemper ved å redusere stress

Vær vennlig kryss av for viktighet

Hvor viktig er fordelene ved å redusere stress?

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Hvor viktig er ulempene ved å redusere stress?

Svært viktige for meg

10
9
8
7
6
5
4
3
2
1
0

Ikke viktige i det hele tatt

Viktighet fordeler:

Viktighet ulemper:

Før viktigheten på balansevekten

SAMTALE GUIDE OG STIKKORDSLISTE TEMA 4 (DCP)

BESLUTNING

Innhold:

Hva er best for deg?

Utarbeide en skriftlig plan

Hvem må gjøre hva og når?

Hva trengs for å oppnå målet?

Mål/Resultat:

Har valgt livsstilsendringer

Har tidfestet endringer

Har vurdert egeninnsats

Har vurdert behov for sosial støtte

Har laget plan for livsstilsendringer

Samtale guide og stikkord:

Ut fra dette du har jobbet med og oppdaget nå, hva vil du bestemme deg for å gjøre de neste 6 måneder? *Kan du krysse av på dette skjemaet for de livsstilsendringer du vil utføre de neste 6 måneder?*

På de neste sidene kan du sette opp konkrete måter å gjøre forskjellig ting på, samtidig som du skriver ned:

Når vil du begynne med dette

Hva må du gjøre for å få dette til

Hva trenger du for å få dette til

Hva må andre gjøre for at du skal få dette til

Fylle ut "Min plan for livsstilsendring"

Min plan for livsstilsendring

Kryss av for de livsstilsendringer du vil utføre de neste 6 månedene

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Slutte å røyke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ha et sunt og hjertevennlig kosthold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oppnå eller beholde en sunn kroppsvekt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mosjonere regelmessig	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Redusere stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ta mine foreskrevne medisiner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (Beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Slutte å røyke

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Slutte på egenhånd uten hjelp	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Akupunktur	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hypnose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Røykeslutt kurs i gruppe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Røykeslutt kurs/veiledning individuelt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nikotin plaster	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nikotin tyggegummi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

Ha et sunt og hjertevennlig kosthold

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Redusere inntak av fett og kolesterol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Redusere inntak av salt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Øke inntak av fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Øke inntak av omega-3 fettsyrer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Redusere alkoholinntaket	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Øke mengden frukt og grønt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

Oppnå eller beholde en sunn kroppsvekt

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Klare dette på egenhånd ved å spise sunt og øke fysisk aktivitet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vektreduksjonskurs som: Grete Roede, Fedon Lindberg, Libra, Vekt-voktere osv	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Treningskurs med kostholdsveiledning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medikamenter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kirurgi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (Beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (Beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

Mosjonere regelmessig

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Starte på kurs I hjerterehabilitering	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lett aktivitet 60 minutter hver dag	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderat aktivitet 50-60 minutter 3-4 ganger I uken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intens aktivitet 20-30 minutter 3 ganger I uken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

Redusere stress

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
En av disse metodene: meditasjon, avspenning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kombinere disse metodene: meditasjon og avspenning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Personlig veiledning for å diskutere og lære om stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

Ta mine foreskrevne medisiner

	Gjør dette allerede	Vil helt sikkert begynne å gjøre dette	Vil tenke over å gjøre dette	Vil ikke gjøre dette
Snakke med legen min om mine medisiner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ta mine foreskrevne medisiner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annet (beskriv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Jeg begynner med dette (dato) _____

For å få til dette må jeg _____

For å få til dette trenger jeg _____

For å få til dette må andre _____

1 MINUTTS EVALUERING AV HJEMMEBESØKET

1. Vær vennlig å vurdere nytten av hjemmebesøket du har hatt med studiens sykepleier ved å sette en ring rundt det alternativet som passer best for deg:

1-----2-----3-----4-----5
Ikke Ganske Svært
særlig nyttig nyttig
nyttig

2. Hva er den viktigste oppdagelsen du tar med deg videre framover fra hjemmebesøket?

3. Hvilke(t) spørsmål står fremdeles ubesvart?

4. Hvordan kan hjemmebesøket bli bedre?

Appendix C

Fidelity strategies

Effects of a Decision Aid with and without additional decisional counseling for patients being examined for coronary artery disease on cardiac risk reduction behavior and health outcomes

Intervention Fidelity Strategies

A. Study design

Goal	Description	Strategies
Same intervention “dose” within intervention group	<p>Description of intervention “dose” described in research proposal and REK protocol</p> <p>The “dose” is measured by a strict comply with the overview of the intervention and the keywords in the interview guide:</p> <ul style="list-style-type: none"> -Introduction -Topic 1: Knowledge, Experience of CAD -Topic 2: General and Specific Health Beliefs -Topic 3: Benefits and Barriers -Topic 4: Decision 	<p>Scripted counseling with manual</p> <p>Intervention monitor</p> <ul style="list-style-type: none"> - interventionist interview guide and keywords <p>Record variations</p> <ul style="list-style-type: none"> - interventionist notations using field notes - site monitoring with feedback from observation <p>Reinforcement of dose requirements</p>
Same intervention “dose” across intervention group	Research design	<p>Intervention design</p> <ul style="list-style-type: none"> - dose is consistent - information is consistence

B. Provider Training**Standardized manual**

<i>Goal</i>	<i>Description</i>	<i>Strategies</i>
Intervention training is uniform	Training constructed in a similar way for all	Interventionist trained together or trained using a similar method Training manuals are standardized Re-training around any problems observed Supervision teaching initial intervention
Skills acquisition	Criteria: teaching the module according to the script and training is consistent	Skills checklist with teaching De-briefing and problem solving Site audit
Minimize drift	Measure skills over time to ensure that skills do not deteriorate	Subject T2 evaluations "Usefulness of DCP" Interventionist boosters Site audit Booster audit
Accommodate differences	In skill level or experience	Professional leader supervision Monitor differentiation in dropout rates Analysis

C. Delivery of Intervention

Goal	Description	Strategies
Control for differences in interventionist over time	Monitor subject assessment of the interventionist across intervention group	Minute evaluations with feedback to the interventionist after counseling session Subject evaluation with perceptions of the interventionist and the counseling session
Minimize differences within the intervention	Delivery of the same intervention	Scripted intervention protocol Assess drift - intervention observation/audit
Adherence to intervention	Intervention delivered as written/intended	Random monitoring for protocol adherence - Intervention observation/audit - analysis
Minimize contamination	Reduce contamination between intervention groups Reduce contamination across treatment groups	Provider training as outlines Supervision Ensure comfort in reporting deviations from the recommended intervention Field notes

D. Receipt of Intervention

Goal	Description	Strategies
Subject comprehension	Understanding of intervention material taught in the intervention	Interventionist <ul style="list-style-type: none"> - review worksheets - summarized what has been taught - provides feedback - reinforces concepts Subject <ul style="list-style-type: none"> - Can discuss use of concepts - Can complete worksheets - Provide feedback - Development of Action Plan Use outcome measures <ul style="list-style-type: none"> - minute evaluations T2 evaluations
Ability to use cognitive skills	Subjects can use what is taught in the intervention	Same as above
Able to perform behavioral skills	Subjects can use what is taught in the intervention	Same as above

E. Enactment of Intervention Skills

What are the active ingredients: Adherence?

Goal	Description	Strategies
The subject demonstrate use of cognitive skills	Has the subject used the cognitive skills that were taught in the intervention in life settings	Intervention specific T2 2 self-report questionnaire: "Usefulness of DCP" Use of printed materials to foster adherence: DA and worksheet Action plan Retest calls about adherence
The subject demonstrates use of behavioral skills	Has the subject used the behavioral skills that were taught in the intervention in life settings	Intervention specific time 2, 3, 4, self-report questionnaires about adherence Use of printed materials to foster adherence: DA and worksheet Action plan Retest calls about adherence

Date: _____ Interventionist: _____ Observer: _____

Effects of a Decision Aid with and without additional decisional counselling for patients being examined for coronary artery disease on cardiac risk reduction behavior and health outcomes

Intervention Fidelity Observation

CRITERIA ASSESSED	YES	NO	COMMENTS
Introduction			
Content: <ul style="list-style-type: none"> ○ Identification of topics ○ Identification of the process 			
Activities: <ul style="list-style-type: none"> ○ Conversation about: <ul style="list-style-type: none"> ○ Goal for counselling ○ Desired participation ○ No right or wrong answers 			
Topic 1 Knowledge and Experience of CAD			
Content <ul style="list-style-type: none"> ○ Diagnosis ○ Prognosis ○ Health Recommendations 			
Activities: <ul style="list-style-type: none"> ○ Interview ○ Questioning ○ Conversation 			
Topic 2 General Health Beliefs, Specific Health Beliefs			
Content <p>The susceptibility and the severity of potential progression of their CAD</p>			
Activities <ul style="list-style-type: none"> ○ Presentation of individual risk profile ○ Help to comprehend the possible risks 			
Topic 3 Benefits and barriers of lifestyle changes			
Content <ul style="list-style-type: none"> ○ Believe that actions is beneficial ○ Believe there is no overwhelming barriers 			
Activities <ul style="list-style-type: none"> ○ Worksheet <ul style="list-style-type: none"> ○ Rating of importance of potential actions ○ Balance scale 			

CRITERIA ASSESSED	YES	NO	COMMENTS
<ul style="list-style-type: none"> ○ Assessment of benefits ○ Assessment of barriers 			
Topic 4 Decision			
Content <ul style="list-style-type: none"> ○ Treatment selection ○ Action items ○ Barriers and resources ○ Social support ○ Plan for cardiac Risk Factor Modification Behavior 			
Activities: <ul style="list-style-type: none"> ○ Rule out the decision in a form: <ul style="list-style-type: none"> ○ Which is best ○ Who needs to do what and when ○ What do you need to achieve this outcome 			
Minute Evaluation			
Overall field assessment			
<ul style="list-style-type: none"> ○ Counselling within recommended timeframe <ul style="list-style-type: none"> ○ Time started: _____ ○ Time ended: _____ ○ Using scripted interview guide ○ Appropriate emphasis on session topics ○ No omission of information ○ No contaminating information 			

Observation feedback with interventionist: Yes No

Comments:

Review of Minute Evaluation with interventionist: Yes No

Comments:

Follow up: