

Cardiac rehabilitation, physical activity and risk factor control after coronary events: Methodological and clinical aspects

A cross-sectional study of a Norwegian coronary population with detailed analyses of cardiac rehabilitation and physical activity

Kari Peersen

Thesis for the degree of Philosophiae Doctor

**Department of Cardiology, Hospital of Vestfold Trust and
Institute of Clinical Medicine, The Faculty of Medicine, University of Oslo**

**In collaboration with
Department of Medicine, Drammen Hospital, Vestre Viken Trust and
Institute of Basic Sciences, Department of Behavioural Sciences in Medicine
The Faculty of Medicine, University of Oslo**



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List of Papers

Paper I

Sverre E, Peersen K, Husebye E, et al. Unfavourable risk factor control after coronary events in routine clinical practice. *BMC Cardiovasc Disord.* 2017;17(1):40.

Paper II

Peersen K, Munkhaugen J, Gullestad L, Liodden T, Moum T, Dammen T, Perk J, Otterstad JE. The role of cardiac rehabilitation in secondary prevention after coronary events. *Eur J Prev Cardiol.* 2017;24(13):1360-68.

Paper III

Peersen K, Otterstad JE, Sverre E, Perk J, Gullestad L, Moum T, Dammen T, Munkhaugen J. Medical and psychosocial factors associated with low physical activity and increasing exercise level after a coronary event. *J Cardiopulm Rehabil Prev.* In press.

Paper IV

Peersen K, Munkhaugen J, Gullestad L, et al. Reproducibility of an extensive self-report questionnaire used in secondary coronary prevention. *Scand J Public Health.* 2017;24(9):981-89.

Summary

Background

Modern treatment of acute coronary syndromes and stable coronary heart disease (CHD) has led to decreasing mortality rates, with far more patients in need of secondary prevention. Optimal coronary risk factor control is essential for coronary prognosis, and cardiac rehabilitation (CR) is a cornerstone of secondary prevention. Large European studies, with patient inclusion mainly from academic centres, have revealed unfavourable risk factor control and varying contents and low participation rate in CR. Norway did not participate in these studies and national data on risk factor control and CR have previously not been available. More data on coronary risk factor control from representative CHD populations, and increased knowledge about content, participation rates and effect of CR programmes implemented in clinical practice is needed to better understand why we fail to succeed with secondary preventive management. In turn, this may contribute to improve current practice and to the development of more effective and sustained interventions.

Aim

This PhD thesis aimed to determine risk factor control after a coronary event, to study the role of CR in risk factor control, clinical and psychosocial factors, as well as to identify socio-demographic, medical and psychosocial factors associated with physical activity (PA). An additional aim was to explore the reproducibility and thereby the applicability of the comprehensive NOR-COR self-report questionnaire.

Methods

A cross-sectional explorative study included 1127 patients 2-36 months after a coronary event. The study was conducted in a routine clinical setting in two neighbouring hospitals, Drammen and Vestfold, which are fairly representative of Norway with respect to socio-demography, morbidity and mortality. Study data were collected from medical hospital records at time of the index event, and from a clinical examination, blood samples and a comprehensive self-reported questionnaire at follow-up. Descriptive statistics, multi-adjusted linear and logistic regression analyses were applied in *Paper I-III*. In a sub-study 99 coronary patients completed a test and retest with four weeks interval in order to calculate reproducibility values of the NOR-COR questionnaire, with the use of intra-class correlation coefficients and kappa-agreement.

Results

Mean age at the index event was 62 (SD 10) years, with 21% of the patients being female. The index coronary event was myocardial infarction in 80% of the patients, whereas 20% had stable/unstable CHD treated with a revascularisation procedure. The proportion with unfavourable risk factor control was high at follow-up on average 17 months after the coronary index event. On average, the patients had three of six risk factors not at target according to current guideline recommendations. Less than 2% had all factors at target, while 62% had three or more unfavourable risk factors. Patients with previous coronary events had the poorest overall risk factor control, while the youngest had the highest prevalence of smoking, obesity and blood sugar.

The CR participation rate in Vestfold was 75% compared to 18% in Drammen. The CR programme in Vestfold had an interdisciplinary, more comprehensive and multifaceted content with a longer duration than the programme in Drammen, which mainly focused on PA. Belonging to the Drammen cohort was associated with less PA, more obesity, and poorer medication adherence in adjusted analyses compared to the Vestfold cohort. Patients who participated in CR in Vestfold had a better coronary risk factor control and perceived a higher sufficiency of risk factor and illness information compared to the CR non-participants (non-CR). In adjusted analyses CR participation in Vestfold was associated with higher proportions of smoking cessation, better drug adherence and lower low-density lipoprotein cholesterol (LDL-C) versus non-CR. No differences were found for PA, obesity, dietary habits or blood pressure (BP) between CR participants and non-CR in Vestfold.

In all, 18% of the patients in the NOR-COR study were categorised as inactive, 42% were less active than recommended, whereas 40% had an adequate level of PA. Low activity was associated with a cluster of other unhealthy lifestyle factors, depression and poor physical quality of life (QoL) in adjusted analyses. High motivation, better QoL, better perceptions of risk and illness and a lower perceived need of help to increase PA were associated with self-reported increase in PA in adjusted analyses.

A good to very good reproducibility was found for all key instruments in the NOR-COR questionnaire. The reproducibility values from the first part did not differ from those in the last part of the questionnaire. The internal consistency values were acceptable to good on almost all scales.

Conclusions

The thesis demonstrated that risk factor control, including PA, in patients from routine clinical practice in two representative Norwegian hospitals, was poor after a coronary event. This is in accordance with the results of studies from Europe. There were large differences in the content and duration, as well as participation rates of the CR programmes in the two hospitals. Patients who participated in CR in Vestfold had a better coronary risk factor control compared to non-CR, but overall risk factor control was still insufficient underlining the need for further improvement. Insufficient PA was associated with a cluster of unhealthy lifestyle factors, depression and poor physical QoL, but not with CR participation. The latter finding was surprising and the reasons may be that the long-term effect of the CR programmes implemented was not good enough or that participation in CR activities outside these hospitals was not reported. It is concerning that secondary prevention in a well-developed country like Norway is far from optimal. The findings strongly underscore the need for better management and follow-up care of the established risk factors in clinical practice and novel measures to increase the participation rate and quality of existing CR programmes. Future studies should test the effect of more comprehensive CR programmes with interventions that target both traditional coronary risk factors and patient factors like depression, motivation, illness and risk perception.

Summary in Norwegian

Hjerterehabilitering, fysisk aktivitet og risikofaktorkontroll etter koronare hendelser: metodologiske og kliniske aspekter

Bakgrunn

Moderne behandling av akutt koronar syndrom og stabil koronar hjertesykdom har ført til nedgang i dødelighet og dermed flere pasienter med behov for sekundær prevensjon. Optimal kontroll av koronare risikofaktorer er viktig for prognosen, og hjerterehabilitering er en hjørnestein i sekundær prevensjon. Store europeiske studier, med pasientinkludering hovedsakelig fra akademiske sentra, har avdekket mangelfull kontroll av risikofaktorer og varierende innhold og lav deltakelse i hjerterehabilitering. Mer kunnskap om risikofaktorkontroll fra representative koronarpopulasjoner er etterspurt og norske data hos koronarkoronarpasienter har manglet. Det er også et behov for økt kunnskap om innhold og effekt av hjerterehabiliteringsprogrammer som er implementert i klinisk praksis og økt forståelse av hvorfor vi ikke lykkes med risikofaktorkontroll slik at sekundærforebyggende behandling og oppfølging kan forbedres.

Mål

Målet med denne ph.d avhandlingen var å kartlegge andelen som oppnår behandlingsmål for risikofaktorer etter en koronar hendelse, studere betydningen av hjerterehabilitering for risikofaktorkontroll, kliniske og psykososiale faktorer og identifisere sosiodemografiske, medisinske og psykososiale faktorer assosiert med fysisk aktivitet. I tillegg vil man undersøke reproduserbarhet og dermed anvendbarhet av studiens omfattende spørreskjema.

Metode

Studien omfattet 1127 pasienter som deltok i en eksplorativ tverrsnittstudie 2 til 36 måneder etter en koronar hendelse. Studien ble gjennomført ved to norske sykehus, Drammen og Vestfold, som er relativt representative for Norge med hensyn til sosiodemografi, morbiditet og mortalitet. Data ble samlet inn fra sykehusjournalene ved tidspunkt for den koronare hendelsen og fra klinisk undersøkelse, blodprøver og et omfattende selvrapportert spørreskjema.

Resultat

Gjennomsnittlig alder ved undersøkelsen var 62 år og det var 21% kvinner. Indeks hendelse var hjerteinfarkt hos 80%, mens 20% hadde hatt stabil/ustabil angina behandlet med koronar revaskularisering (PCI eller by-pass operasjon). Forekomst av ugunstig risikofaktorkontroll var høy gjennomsnittlig 17 måneder etter hendelsen. 21% røykte daglig, 34% hadde fedme, 60% trente mindre enn anbefalt, 46% hadde før høyt blodtrykk, 57% hadde for høyt LDL-kolesterol og 59% av diabetikerne hadde for høyt langtidsblodsukker. Til sammen hadde pasientene gjennomsnittlig 3 av 6 ugunstige faktorer. Pasienter med tidligere koronare hendelser hadde dårligst risikofaktorkontroll, mens de yngste hadde høyest forekomst av røyking, fedme og høyt langtidsblodsukker.

I Vestfold deltok 75% av pasientene på hjerterehabilitering sammenliknet med 18% i Drammen. Hjerterehabiliteringsprogrammet i Vestfold hadde et tverrfaglig og mer omfattende og sammensatt

innhold og en lengre varighet enn programmet i Drammen som var overveiende fokusert på fysisk aktivitet. I justerte analyser var det å tilhøre Drammen kohort assosiert med mindre fysisk aktivitet, mer fedme og dårligere medikament etterlevelse sammenliknet med Vestfold kohort. Pasientene som deltok i hjerterehabilitering i Vestfold hadde bedre risikofaktorkontroll og opplevde i større grad at de hadde fått tilstrekkelig informasjon om sykdoms- og risikofaktorer enn de som ikke deltok. I justerte analyser var deltakelse i hjerterehabilitering i Vestfold assosiert med høyere forekomst av røykeslutt, bedre medikament etterlevelse, samt lavere LDL-kolesterol sammenliknet med de som ikke deltok. Det ble ikke funnet forskjeller i fysisk aktivitet, fedme, kostvaner eller blodtrykk mellom de som deltok i hjerterehabilitering i Vestfold og de som ikke deltok.

I alt ble 18% av pasientene i NOR-COR studien kategorisert som inaktive, 42% var mindre fysisk aktive enn anbefalt, mens 40% hadde et adekvat fysisk aktivitetsnivå. I justerte analyser var lav aktivitet assosiert med en opphopning av andre ugunstige livsstilsfaktorer, depresjon og dårlig livskvalitet. Høy motivasjon, bedre risiko- og sykdomsforståelse, samt lite behov for hjelp til å øke sin fysiske aktivitet var assosiert med selvrappportert økning av fysisk aktivitetsnivå.

Det ble funnet god til meget god reproduserbarhet av alle de viktigste instrumenter i NOR-COR spørreskjemaet. Det var ingen forskjell i reproduserbarhetsverdier fra første del av skjemaet til siste del. Intern konsistens var akseptabel til god i de fleste skalaer.

Konklusjon

Avhandlingen viste at et flertall av pasientene fra daglig praksis ved to norske sykehus hadde dårlig risikofaktorkontroll inkludert for lite fysisk aktivitet etter en koronar hendelse. Våre observasjoner tilsvarende funn fra liknende studier i Europa. Det var store forskjeller i innhold, varighet og deltakerandel på hjerterehabiliteringsprogrammene ved de to sykehusene. Pasientene som deltok i hjerterehabilitering i Vestfold hadde bedre risikofaktorkontroll enn de som ikke deltok, men total risikofaktorkontroll er likevel ikke bra nok, noe som understreker behovet for videre forbedringer. Lav fysisk aktivitet var assosiert med ugunstig livsstil, depresjon og dårlig fysisk livskvalitet, men ikke med hjerterehabilitering. Sistnevnte funn var overraskende og årsaken kan muligens ligge at langtidseffekten av programmene ikke var gode nok eller at deltakelse i ekstern hjerterehabilitering ikke ble rapportert. Våre funn er bekymringsfulle og understreker et behov for bedre håndtering og oppfølging av etablerte risikofaktorer i klinisk praksis. Det er derfor viktig å øke deltakelse og forbedre kvaliteten på eksisterende hjerterehabiliteringstilbud. Det er også behov for videre forskning på effekten av mer omfattende hjerterehabiliteringsprogram med intervensjoner som i større grad er skreddersydd til den enkelte risikofaktor og pasientfaktorer som depresjon, motivasjon, risiko og sykdomsforståelse.

Abbreviations

ACS	Acute coronary syndrome
ANCOVA	Analysis of covariance
BIPQ	Brief Illness Perception Questionnaire
BMI	Body mass index
BP	Blood pressure
CABG	Coronary artery bypass grafting operation
CHD	Coronary heart disease
CI	Confidence interval
CR	Cardiac rehabilitation
CRP	C-reactive protein
CVD	Cardiovascular disease
DALYs	Disease-adjusted life-years
ESC	European Society of Cardiology
EAPC	European Association of Preventive Cardiology
GP	General practitioner
HADS	Hospital Anxiety and Depression Scale
HbA1c	Glycated haemoglobin A1c
ICC	Intraclass correlation coefficients
K	Kappa agreement
LDL-C	Low-density lipoprotein cholesterol
MI	Myocardial infarction
Non-CR	Cardiac rehabilitation non-participants
NOR-COR	Norwegian Coronary Prevention Project
NSTEMI	non-ST-elevation myocardial infarction
OR	Odds ratio
PA	Physical activity
PCI	Percutan coronary intervention
PRP	Perceived Risk Perception Questionnaire
QoL	Quality of life
RCT	Randomized controlled trial
SD	Standard deviation
SES	Socioeconomic status
SF 12	12-item Short-Form Health Survey
STEMI	ST-elevation myocardial infarction

1 Introduction

1.1 Coronary heart disease and secondary prevention

The prevalence of cardiovascular disease is increasing globally due to aging and population growth.¹ However, mortality rates for coronary heart disease (CHD) have been declining substantially during the last few decades due to contemporary management of CHD, particularly in high-income countries.² Nevertheless, CHD is the leading cause of premature death and disability-adjusted life-years (DALY) globally.^{1,3} In Norway, CHD is the leading cause of death and premature death, and the second leading cause of DALY after low back and neck pain.^{1,4} CHD, if left untreated, is a progressive disease and individuals with CHD are at high risk of recurrent events.⁵ The 1-year total mortality rate after acute coronary syndrome (ACS) was found to be 29% in the French MONICA registries.⁶ In a Greek study, the proportion of recurrent events at six and twelve months was 23% and 36%, respectively.⁷ The management of CHD patients represents a major global economic burden for healthcare systems.^{1,8} As a consequence of the progress in pharmacological therapies, diagnostic technology and procedures, a greater number of patients survive acute coronary events and require optimal secondary prevention.^{2,9,10}

Preventive cardiology may be defined as “*comprehensive multidisciplinary interventions aimed at the promotion of cardiovascular health in both primary and secondary prevention*”.⁸ Preventive cardiology is usually categorised into *primary prevention*, i.e. reducing the cardiovascular (CVD) risk in persons with high risk of developing a first CVD event and *secondary prevention*, i.e. reducing disease progression and the risk of recurrent CVD events in patients with established disease.¹¹ The latter includes cardiac rehabilitation (CR) and comprises professional lifestyle interventions on CHD risk factors and selective use of cardio-protective drug therapies to reduce morbidity and mortality. According to the European Society of Cardiology (ESC) Textbook of Preventive Cardiology, preventive cardiology equates to cardiac rehabilitation (CR) in secondary prevention.¹² Thus, it is essential to promote effective secondary prevention in order to improve the prognosis of these patients.

CHD includes stable and unstable angina pectoris, myocardial infarction (MI) and sudden coronary death. ACS comprises ST elevation MI (STEMI) or non-ST elevation MI (NSTEMI) and unstable angina pectoris.¹³ Patients suffering ACS in Norway are usually examined with angiography in a tertiary hospital, and are treated with acute or sub-acute revascularisation as according to European guidelines.^{14,15} About 13000 MIs are diagnosed annually in Norway^{16,17} and about one third suffer from a recurrent MI. The vast majority of angiographically verified coronary stenoses are revascularised, with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).^{16,17}

1.2 A brief history of CHD prevention

“*An ounce of prevention is worth a pound of cure*” Benjamin Franklin

Historically, the care of patients who have experienced a coronary event has evolved and advanced dramatically over the last century,¹⁸ and the achievements in prevention of CHD have been

impressive.^{19,20} From the nineteen forties onwards epidemiological data emerged highlighting the associations between a numerous risk factors and CHD, including high blood pressure (BP), smoking, unhealthy diet, obesity and high levels of cholesterol.^{19,21,22} Along with better understanding of the preventive effect of lifestyle changes and medical treatment of risk factors, including statins, the first guidelines on CHD prevention were presented in 1994.²³

Exercise has been advocated for better health dating back to 600^{BC}.²⁴ In 1772, Heberden documented that physical activity (PA), in the form of chopping wood, was effective at reducing symptoms of angina pectoris.²⁵ Despite this, strict bed rest was recommended up to six weeks after myocardial infarction as late as 1940.^{18,19,25-28} Physical activities, while sitting in a chair, were introduced by Levine and Lown in 1951,²⁰ and were still recommended in Norwegian physiotherapy education in 1980. (i.e personal experience, Statens Fysioterapiskole, Bergen 1980) In the fifties, Morris et al²⁹ published the first scientific research offering evidence that PA was preventive of development of CHD in primary care, while Hellerstein and Ford²⁷ showed the same to be true after established CHD. Contemporary multi-disciplinary CR has its origin in the sixties where Hellerstein and Ford linked exercise benefits to CHD outcomes.^{18,25,27} Initially, CR was largely based on exercise, but subsequently more comprehensive, multi-faceted, multi-disciplinary CR was evolved to incorporate physical exercise with a healthy lifestyle, management of coronary risk factors, enhancement of psychosocial wellbeing and reduction of disability.^{8,30-33}

1.3 Coronary risk factors and psychosocial factors

The traditional modifiable coronary risk factors encompass smoking, physical inactivity, unhealthy diet, obesity, hypertension, elevated low-density lipoprotein cholesterol (LDL-C), unfavourable blood sugar control and diabetes.³¹ The association between the coronary risk factors and CHD is well documented,³⁴ as is the benefit of achieving risk factor control in order to prevent subsequent events.³⁵⁻³⁸ Changes in modifiable coronary risk factors were found to account for 66% of the decline in the incidence of CHD in a large population-based cohort study from Norway,³⁹ with cholesterol the largest contributor followed by blood pressure, smoking and PA. Risk factor control in the present thesis is defined as achieving the following treatment targets according to the 2012 ESC prevention guidelines prevailing at the time of patient inclusion:¹¹

- Non-smoking
- Moderate to vigorous intensity PA for ≥ 30 minutes ≥ 3 times weekly
- A healthy diet with fruits, vegetables, fish, whole grains, low intake of saturated fat
- BMI < 25 kg/m²
- BP $< 140/90$ mmHg ($< 140/80$ in diabetes patients)
- LDL-C < 1.8 mmol/l (or a $\geq 50\%$ reduction when the target cannot be reached)
- HbA1c $< 7.0\%$ (in diabetes patients)

Even though potentially unexplained risk factors exist, modifiable risk factors account for more than 90% of the risk of acute coronary events worldwide.³⁴ Despite the existence of evidence-based secondary preventive guidelines since 1994,^{11,23,31} a high prevalence of unfavourable risk factor control has been demonstrated in several observational studies,^{40,41,42-45} including the EuroAspire

studies III and IV.⁴⁶⁻⁴⁸ The prevalence and control of major risk factors in stable CHD patients varies geographically.^{49,50} The reasons for poor risk factor control are complex and involve factors related to the condition, its treatment, the patient and the healthcare system.³¹ Socio-demographic, medical, and psychosocial factors may act as barriers to lifestyle changes and treatment adherence, and may mitigate the effect of cardiac rehabilitation.³²

The lifestyle risk factors in CHD patients may have synergetic and multiplicative health effects, rather than additive effects, and they tend to cluster.⁵¹ For example, patients who smoke are more prone to inactivity and unhealthy diet.³⁵ This may have consequences for secondary prevention interventions where it seems important to reach multiple factors simultaneously. The phenomenon of clustering, or co-existence of more unhealthy behavioural risk factors, has also been found in population studies.⁵²⁻⁵⁴ An improvement in healthy lifestyle profile was found in the study of Steca et al six months after ACS, and furthermore that patients with multiple unhealthy behaviours experienced more difficulties in maintaining a healthier lifestyle over time.⁵¹

Smoking is a strong predictor of recurrent events,⁵⁵ and the impact of quitting smoking is overwhelming and is considered the single most effective way to decrease future risk of morbidity and mortality following an acute coronary event.^{11,35,56} Overweight and obesity are highly prevalent conditions in CHD patients, with more than 80% being overweight and almost 40% being obese in the EuroAspire IV study.⁴⁶ Several researchers have described the phenomenon of “obesity paradox”, whereby higher body mass index (BMI), has been associated with lower mortality,⁵⁷⁻⁶⁰ although the concept is controversial and has been criticised because of possible bias and reversed causality.⁶¹ Weight loss has been associated with worse outcome in CHD patients.^{62,63} This was confirmed in a recent observational study from Norway, although only in normal-weighted,⁶⁴ while studies of purposeful intentional weight loss have reported beneficial effects for patients with CHD.^{62,65,66}

Hypertension is the most important modifiable risk factor for mortality and morbidity globally, and plays an essential role for the development and progression of CHD.^{31,67} The prevalence of unfavourable BP control in CHD patients was high for both men and women in the EuroAspire IV study,⁴⁶ in a Norwegian study from Tromsø,⁶⁸ and in our NOR-COR study,⁶⁹ ranging from 42% to 54%. Treatment of high BP is comprised of antihypertensive drugs and lifestyle changes, including PA, weight reduction and a salt-reduced diet.³¹ High levels of LDL-C have a pivotal role in development and progression of CHD.^{34,70} LDL-C levels above target were found in the EuroAspire study (81%),⁴⁶ and in the Reach registry (83%).³⁶ The most regularly used LDL-C lowering treatment is statins,⁷¹⁻⁷³ also documented as effective to reduce coronary events.⁷⁴ Type 2 diabetes is associated with increased risk of mortality after CHD,⁷⁵ and the prevalence is increasing with the obesity epidemic.⁷⁶ Treatment of diabetes and prediabetes includes lifestyle changes and use of antidiabetic drugs.^{77,78}

A recent position paper from the European Association of Preventive Cardiology (EAPC) defined categories related to the social environment, personality traits, and negative affect as psychosocial factors that may have impact on CHD prognosis.³² These factors included low socioeconomic status (SES), low social support, work stress, anger and hostility, type D personality, depression and

anxiety. High levels of psychosocial distress and psychiatric disorders are prevalent among patients with CHD and may negatively affect prognosis.⁷⁹ Psychosocial stress is a strong predictor of MI in patients without previous CHD.³⁴ Elevated levels of stress are associated with greater risk of mortality and non-fatal cardiac events in CHD patients,⁸⁰ and psychosocial and behavioural risk factors may be interrelated.⁸¹ This was found in the EuroAspire IV study, where anxiety and depression were associated with lower levels of PA, and depression with more smoking, obesity and diabetes.⁸² A recent review revealed that psychological intervention in patients with CHD may improve depression, anxiety and stress, as well as reduce cardiac mortality; the findings were, however, hampered by low quality evidence.⁸³ Multimodal behavioural interventions, integrating health education, PA and psychological intervention are recommended for patients with established CHD and psychological symptoms in order to improve psychological health.^{31,84}

Medication treatment and adherence are important elements of secondary prevention.⁸⁵ A high prevalence of non-adherence to cardio-protective drugs has been reported,^{72,86} along with suboptimal medical treatment of coronary risk factors, including elevated blood pressure,⁶⁹ LDL-C⁷² and blood sugar.⁷⁸ A poor adherence is a major barrier to achieving the full potential of efficacious medications.⁸⁶

1.4 Cardiac rehabilitation

The World Health Organization has defined CR as:

*“The sum of activities required to influence favourably the underlying cause of disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve, or resume when lost as normal a place as possible in the community”.*⁸⁷

The aim of CR is to slow or reverse the progression of CHD and to reduce the risk of recurrent cardiovascular events and premature disability, by means of:^{8,31}

- Motivating patients to achieve long-lasting changes of lifestyle including non-smoking, PA, healthy diet habits and weight management
- Optimised medical treatment and management of BP, LDL-C and blood glucose
- Achievement of safety and confidence, better quality of life, function and disease management
- Reduction of anxiety, fears and psychosocial distress

The core components of multifaceted, comprehensive CR today are patient assessment, PA and PA counselling, smoking cessation, nutritional counselling, management of coronary risk factors (i.e. overweight, hypertension, hypercholesterolemia, blood sugar, and diabetes), appropriate prescription and adherence to cardio-protective drugs, psychosocial support in order to enhance psychosocial wellbeing, stress management and vocational management.^{8,11,20,31-33,88} Various methods are recommended to achieve lifestyle changes and risk factor control, including educational group discussions and individual consultations to enhance motivation, illness and risk

understanding, motivational interviewing and self-regulating techniques such as goal setting, evaluation and social and psychological feedback.^{8,30,31,89,90}

CR is recommended at the highest level of evidence and general agreement, IA, in European guidelines for all patients following ACS and heart failure, and IB for stable coronary patients.^{11,31} A recent systematic review suggested that CR is cost-effective, especially with exercise as a core component, even in the modern era of CHD treatment.⁹¹ The researchers underlined that all included studies used life-years as the outcome, and thus might ignore one of the key goals of CR, which is to reduce cardiovascular morbidity. Thus, the results may potentially underestimate the benefits of CR intervention.

1.4.1 CR and mortality

Since the prognostic effect of multi-component CR in the modern era of statins and acute revascularisations still remains controversial, it is worthwhile scrutinising fatal outcomes in meta-analyses and reviews of both randomised clinical trials (RCT) and observational studies on patients with CHD from the present millennium.

In 2004, Taylor et al⁹² included 48 RCTs of 8940 patients with ≥ 6 months follow-up. CR was exercise-based and controls had usual care and not receiving any form of structured training or advice. CR was associated with reduced total and cardiac mortality. Janssen et al³⁰ included 23 RCTs (involving 11085 patients) to determine the efficacy of lifestyle modification programmes. Control condition content was either usual care or standard CR. Lifestyle modification programmes were associated with a significant reduction in all-cause and cardiac mortality. The large GROS study⁹³ evaluated the effect of multi-component CR on total mortality in 25 studies including 219702 patients. The majority of studies were observational (7 prospective controlled cohort studies, pCCSs, and 17 retrospective, rCCSs), whereas only one was a RCT. Control groups represented usual care, which also included participation in non-structured exercise programmes outside of a CR programme. Heterogeneity in design, biometrical assessment of results and potential confounders was evident. Both pCCSs and rCCSs showed highly significant mortality reduction for CR participants. The single RCT, the RAMIT study,⁹⁴ showed neutral results, but a high risk of under-powering was assumed. Anderson et al⁹⁵ included 63 RCTs with 14 486 participants comparing exercise-based CR with a comparator including standard medical care and psychosocial and/or educational interventions, but not any structured exercise training. Overall CR led to a reduction in cardiovascular, but not total mortality. Van Halewijn et al⁹⁶ undertook a meta-analysis of contemporary RCTs including 18 trials with 7691 patients randomised to CVD prevention and rehabilitation (either exercise or lifestyle intervention) or usual care. CVD mortality, but not total mortality, was significantly reduced. In summary, all 4 meta-analyses on RCTs demonstrated a reduction of either cardiac or CVD mortality, whereas the effect on total mortality was neutral in two. Interestingly, there was a highly significant mortality reduction in the only and very large meta-analysis on observational studies. These data confirm a substantial mortality benefit associated with exercise-based and multi-component CR.

1.4.2 CR and other clinical outcomes

In addition to the mortality outcomes, meta-analyses and systematic reviews of CR have revealed reduction in hospitalisations,^{92,95,97} recurrent events,^{30,96,98,99} coronary risk factors,^{30,92,98} and better health-related quality of life (QoL).^{30,93,95,97,100} Both randomised and observational trials have reported favourable associations between CR and lifestyle modifications,¹⁰¹⁻¹⁰⁵ biological coronary risk factors,^{104,105} number of risk factors on target,^{104,105} anxiety and depression,¹⁰³ QoL^{95,100,105} and medication adherence.^{102,103} The Vestfold Heart Care Study,¹⁰¹ a Norwegian RCT exploring the effect of comprehensive CR, found significant improvements in dietary, smoking and exercise habits, better physical QoL and higher 5-year risk reductions for CR participants compared to the usual care group. The interdisciplinary CR program used in clinical practice in Vestfold today is based on the evidence from that study.

1.4.3 CR participation rate

CR may be provided as inpatient or outpatient programmes in hospitals or institutions with various durations, as well as home- or community-based. In a recent report from the Norwegian NOR-STENT trial 52% of the patients reported to have participated in a CR programme lasting less than one week, whereas 48% had participated at least one week.¹⁰⁶ In the same study, only 28% of patients reported having participated in a CR program following their PCI treatment.¹⁰⁶ There are large variations in the participation rates of CR, less than half of eligible coronary patients participate in CR in Europe,^{46,93,103,107} and even less in the USA.¹⁰⁸ The participation rate is dependent on the availability and provision of CR, referral routines, the physicians' endorsement of the effectiveness of such a programme and how well it is implemented in daily routine of the hospital.¹⁰⁹⁻¹¹⁶ Inpatient referral has been shown to be a very strong predictor of CR participation.¹¹⁷⁻¹¹⁹ Underserved groups, that might possibly benefit most from CR participation, are less likely to be referred to and participate in CR.¹¹⁵ These vulnerable groups include older patients, women and patients with a low education level, previous coronary events or comorbidities.^{103,116,117,120} A recent report stated that only about 50% of patients referred to CR actually participated in CR,¹²¹ with references to several studies.^{118,122,123} High levels of participant adherence to CR sessions have been associated with reduction in mortality,^{99,124-128} lifestyle changes¹²⁹ and higher drug adherence.^{124,129}

1.5 Physical activity

PA in medicine is known to have an impact on a variety of diseases, such as metabolic, cardiovascular, lung, muscle-skeletal and mental disorders, as well as cancer.¹³⁰ According to the World Health Organization, 80 % of men and 73% of women worldwide may be considered as insufficiently physically active.¹³¹ Inactivity is responsible for 3.2 million deaths annually worldwide, and accounted for 69.3 million DALYs in 2010. This corresponds to 2.8% of the total volume of DALYs.¹³² It has been estimated that inactivity is responsible for 6% of the disease-burden of CHD.^{133,134}

The previous guidelines on CVD prevention from 2012 stated an IA recommendation in coronary secondary prevention for PA at least 3 times a week for 30 minutes.¹¹ The most recent guidelines did not include any particular PA recommendation for patients with established CHD,³¹ but a

general IA recommendation to perform regular PA at least 150 minutes of moderate or 75 minutes of vigorous intensity a week, or a combination thereof.³¹ Only 37% (50-64 years) and 32% (65+ years) were sufficiently active according to the latter guidelines in a representative general population of adults in Norway.¹³⁵ In Sweden, the SWEDEHEART registry includes participation in a PA programme as one of 11 quality indicators in patient care and secondary prevention after MI.¹³⁶ It has been discussed whether a minimum amount of PA exists for reduced mortality, or if a dose-response relationship without a threshold is present.^{137,138} In primary prevention, 15 min a day or 92 min a week of moderate intensity exercise, even for individuals at risk of cardiovascular disease, was associated with a 14% reduction in all-cause mortality.^{137,139} This has also been suggested in secondary prevention,¹⁴⁰ and as little as 10 min/day of brisk walking was associated with a 33% risk reduction for all-cause mortality in the STABILITY study.¹⁴¹ Despite the benefits of PA on general and cardiovascular health, sixty percent of the CHD patients in Europe,^{35,46,55,142,143} and 80% of those in USA are less active than recommended.¹⁴⁴ An expert group on PA prescription in the EAPC has advocated that health-professionals should prescribe PA to all their CHD patients, in an individual approach, preferable after a careful examination.¹⁴⁵ PA has been shown as effective as most medically prescribed drugs,¹⁴⁶ and the "exercise pill" has been called a wonder drug that has the power to benefit the entire bodily system.¹⁴⁵

Since a modern comprehensive CR programme comprises a lot more than solely PA, it may be difficult to estimate the isolated effect of exercise per se after a coronary event.^{99,147} Abell and co-workers have explored the contribution of individual exercise characteristics in CR through meta-regression and subgroup meta-analysis.⁹⁹ The authors concluded that exercise-based CR was effective at reducing total mortality, cardiovascular mortality and MI, with an observed association between higher exercise adherence and improved outcomes. A recent meta-analysis and review explored the impact of CR on PA levels, and found moderate evidence for CR participation to be associated with increase in PA compared to control.¹⁴⁸ These researchers did not observe any difference in PA outcomes in studies including comprehensive CR compared to exercise-only CR, with a suggestion that improvements in PA with CR are results of exercise training rather than the other components of CR. Both randomised and observational studies have reported a beneficial effect of PA on mortality in CHD patients,^{35,64,127,141,147,149-152} and moreover, physical fitness has been shown to reduce mortality in secondary coronary prevention.¹⁵³⁻¹⁵⁵ Regular PA may have beneficial effects on recurrent events, stent thrombosis, exercise capacity, endothelial function, lifestyle and coronary risk factors, QoL, depression and psychosocial stress.^{105,147,149,156-158} Furthermore, an increasing PA level has been found to be associated with reduced all-cause and CHD mortality risk.^{64,159}

1.5.1 Adherence to physical activity

One of the largest problems with exercise is nonadherence.¹⁴⁷ Schuler and colleagues have described the challenge of adherence to PA in CHD patients with a credible approach: *"Most patients entering secondary prevention programs are beyond the age of 50 years; they have not participated in anything that deserves the term physical exercise for decades since leaving school. To assume that any form of counselling will significantly and permanently change this behaviour is totally unwarranted and without precedence in medicine."* Self-reported reasons for PA non-

adherence are diverse and include lack of time, no energy, other time priorities and poor physical condition,¹³⁵ with barriers to PA reported to be low health literacy, low socioeconomic status, low education, depression, anxiety and lack of motivation or interest.^{82,103,160,161} It is observed that compliance rates are decreasing with time in CHD-patients.^{160,162} Suggested methods for enhancing PA adherence include motivational interviewing⁸⁹ and trans-theoretical models of behavioural change,¹⁶³ or a combination of these,¹⁶⁰ although the effectiveness of these methods in coronary secondary prevention has been modest.¹⁶⁴⁻¹⁶⁷

1.6 Reproducibility of self-reported questionnaires

Self-report questionnaires are applied in epidemiological studies, they are widely used in health research due to feasibility, easy utilisation, and they are cheap to apply.^{22,168} A self-report questionnaire is a valid and appropriate first-line approach to obtain information about patients' lifestyle habits,¹⁶⁰ and is frequently used in medication adherence studies^{169,170} and in studies on QoL and on psychosocial issues.¹⁷¹⁻¹⁷⁶

A test-retest study may provide reliability measures when the same study sample responds to an identical questionnaire at two or more points in time. A reproducibility test will assess the random measurement as well as the stability of the construct measured, but cannot in itself distinguish between the two.¹⁷⁷ Thus, one must take into consideration that any real change in the phenomenon of interest, which may have occurred during the intervening period between tests, will result in seemingly low levels of reliability. Information by self-report questionnaires may be distorted by systematic errors such as the patient giving socially desirable responding to providers, using scales and response options in idiosyncratic ways, as well as recall bias.^{160,178} There are no standards for the ideal time span between the initial test and the retest in reproducibility studies. However, the interval should be long enough to prevent memory effects and short enough to ensure that no real clinical change has occurred among participants.¹⁷⁹ Intervals between two weeks,¹⁸⁰ four weeks,^{181,182} and eight weeks¹⁸³ have been suggested as appropriate intervals between the two measurements.

Even though self-reported information from questionnaires is frequently used in clinical studies, few studies have provided information on the reproducibility of comprehensive questionnaires applied in secondary coronary prevention. Those available are limited by addressing single instruments with a moderate range of items.

1.7 Summary of introduction and motivation for the thesis

As a result of contemporary management of CHD, increasing proportions of patients survive and require optimal secondary prevention.² A high prevalence of unhealthy lifestyle and poor risk factor control is found in CHD patients.⁴⁶ Data on coronary risk factor control in CHD patients have not been available for the Norwegian population. Even though exercise-based multi-component CR is recommended with the highest level of evidence in clinical guidelines, the content, duration and referral rates to CR programmes across Europe is far from optimal. More knowledge about the content and participation rates of CR programmes that are already implemented in clinical practice

and its association with clinical and psychosocial factors is requested. Furthermore, greater insights into the complex interactions of patient and healthcare factors that are associated with control of established risk factors in terms of insufficient level of PA are needed.

The NORwegian CORonary (NOR-COR) Prevention Project was designed to identify socio-demographic, medical and psychosocial factors associated with risk factor control and prognosis after a coronary event, in a cohort representing routine clinical practice (phase I).¹⁸⁴ The project hereby aims to target the modifiable factors of importance for risk factor control and prognosis, in order to develop future tailored interventions.¹⁸⁴ The present PhD thesis will focus on control of coronary risk factors in the NOR-COR population, with an emphasis on insufficient PA, the role of CR in risk factor control, in addition to the reproducibility of the comprehensive questionnaire applied in the study.

2 Aims of the thesis

The main objectives of the present PhD thesis are:

1. Determine the control of the six major coronary risk factors, smoking, insufficient physical activity, obesity, BP, LDL-C and blood glucose according to target recommendation in current guidelines 2-36 months after a coronary event, and to identify the influence of age, gender, number of coronary events and time since index event.
2. Explore differences in patient characteristics, risk factor control, and medication adherence between the two cohorts, Vestfold and Drammen, with one comparison including both CR participants and non-participants, and the second between CR participants and non-participants in the two cohorts.
3. Identify the socio-demographic, medical and psychosocial factors associated with physical inactivity and insufficient activity, in addition to increases in PA after a coronary event.
4. Evaluate the test-retest reliability of the extensive self-report questionnaire assembled and created to be used in the NOR-COR study.

2.1 Hypotheses

The following hypotheses will be explored in the present PhD thesis:

1. The prevalence of unfavourable risk factor control in routine clinical practice in Norway is higher than reported in European studies with patient recruitment mainly from academic centres.
2. The more comprehensive multidisciplinary CR programme offered to the Vestfold cohort will be associated with better risk factor control than the shorter, mainly exercise-based programme in Drammen.
3. By using the comprehensive NOR-COR data set, it is possible to identify potentially modifiable medical and psychosocial factors associated with physical inactivity, insufficient activity and increases in PA.
4. The NOR-COR questionnaire has a good reproducibility and internal consistency.

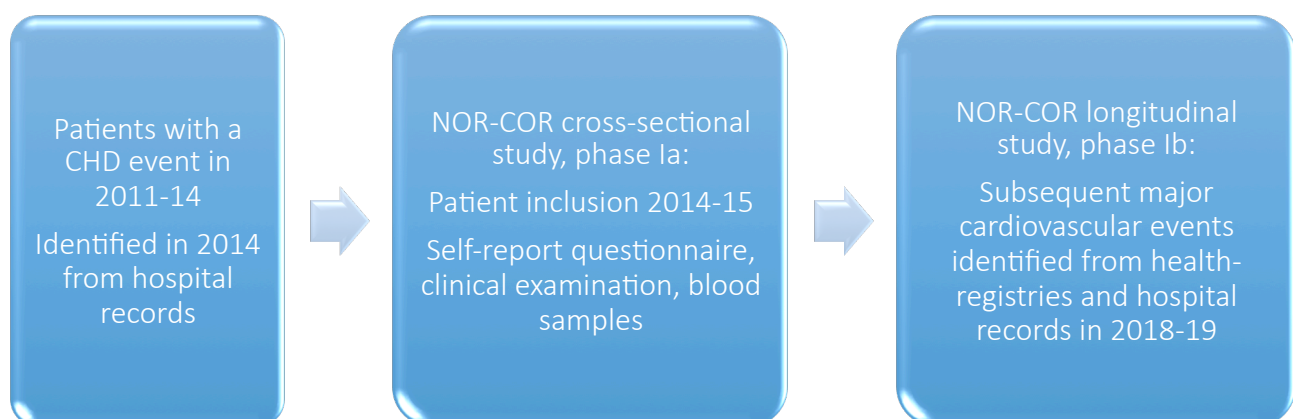
3 Methods

3.1 Design

Epidemiology is defined as “*the study of the occurrence and distribution of health-related states or events in specific populations, including the study of the determinants influencing such states, and the application of this knowledge to the health problems*”.^{185,186} With this definition in mind, a dual-centre, explorative cross-sectional study with a retrospective component was chosen to determine coronary risk factor control after a coronary event, and to identify socio-demographic, medical and psychosocial study factors influencing these risk factors.¹⁸⁴ The advantages of cross-sectional studies include resource efficiency of time and cost, feasibility, the ability to explore a great deal of common variables in prolonged conditions, and the possibility of generating hypotheses.^{185,187} This design may also be suitable to investigate issues where a randomised study would be ethically unjustifiable, like smoking and alcohol. The disadvantages, however, are numerous, including the lack of time dimension, risk of systematic errors including survival bias, and not being able to address causality, since we do not know when exposure occurred relative to outcome.^{185,188} Nevertheless, in order to explore and identify a large variety of study factors associated with unfavourable coronary risk factor control in a sizable CHD population, and within the time frame for a PhD project, this design was considered appropriate and therefore a conscious choice.

The present PhD is based on phase Ia of this NOR-COR prevention project,¹⁸⁴ an observational study conducted in a routine, clinical practice cohort as illustrated in *Figure 1*. We chose study design and inclusion criteria similar to the EuroAspire IV study for comparisons.⁴⁶ Phase Ib of this study will be conducted in late 2018 and 2019, and include an evaluation of the association between risk factor control and 5-years incidence of subsequent major cardiovascular events identified from health registries and hospital records.

Figure 1. The design of the NOR-COR study



3.2 Study population

The study was conducted at two representative, general Norwegian hospitals (Drammen and Vestfold) with a total catchment of 380 000 inhabitants corresponding to 7.4 % of the Norwegian population. The area has a representative blend of urban and rural districts and is broadly representative of Norwegian geography, economy, age distribution, morbidity, and mortality.¹⁸⁹

The study inclusion criteria were:

- a. Age of 18-80 years
- b. Patients hospitalised for a coronary event, defined as a first or recurrent acute MI, and/or a revascularisation procedure with elective or emergency PCI or CABG
- c. The coronary index event was defined as the last event prior to the time of study inclusion
- d. The index event should be 2-36 months prior to study inclusion

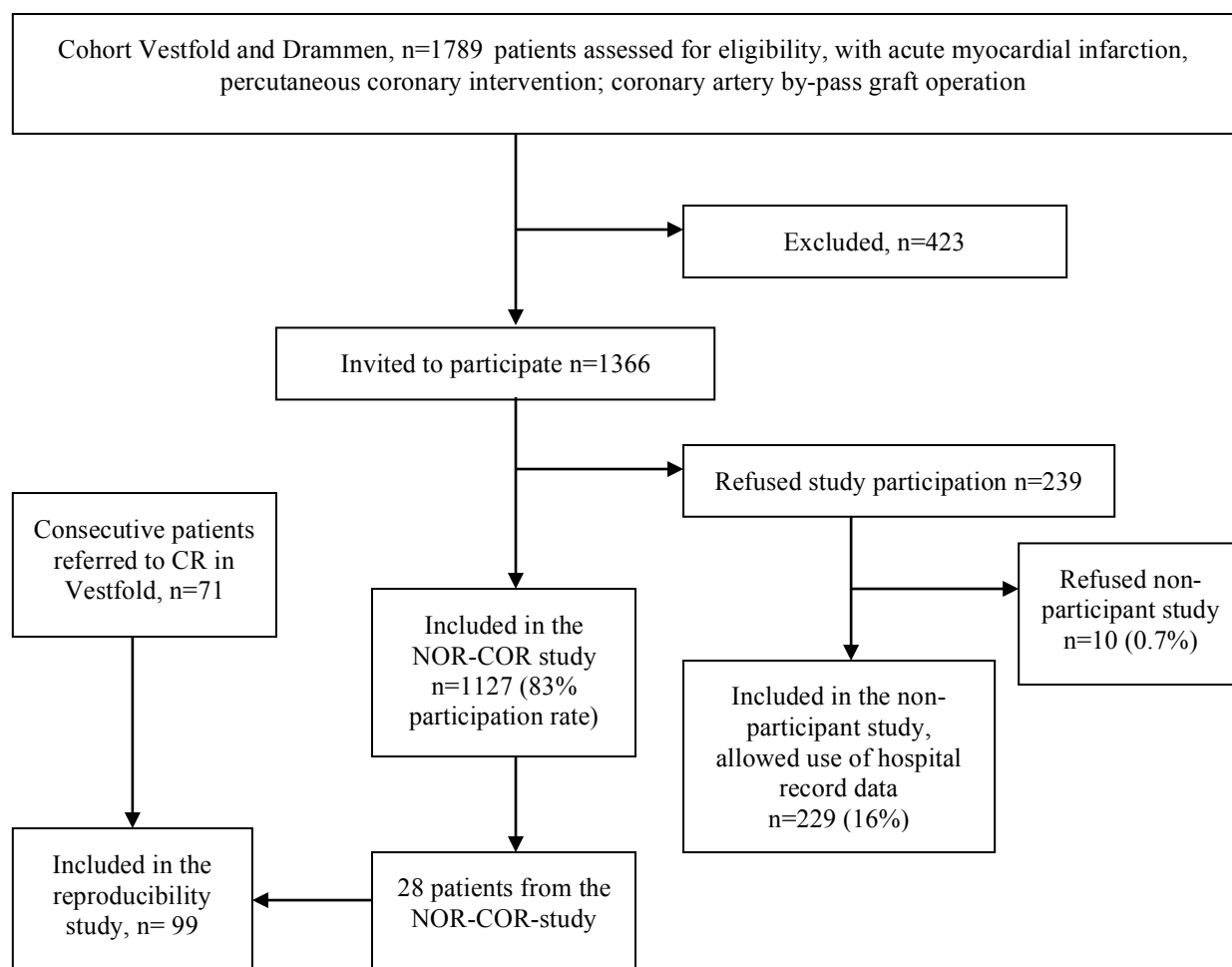
Study exclusion criteria were:

- a. Inability to understand the Norwegian language
- b. Cognitive impairment including living in nursing homes
- c. Psychosis
- d. Active alcohol and/or drug abuse
- e. Short life expectancy due to terminal heart (NYHA class 4), lung, liver- or kidney disease (stage 5), or malignant disease

3.3 Inclusion procedure

The study patients were identified from hospital discharge lists in the last three years prior to study inclusion (2011-2014). The study flow-chart is presented in *Figure 2*. In Drammen all the patients from the discharge lists were screened, while in Vestfold about 90% of the eligible patients were screened. In Vestfold, the order of the discharge lists were randomised within four time groups: 2-6 months, 6-12 months, 12-24 months, and 24-36 months. The reason for this procedure was that the study needed about 550 participants from Vestfold, partitioned into the four time groups, in order to equal the numbers in Drammen. We screened chronologically for the diagnosis of MI (ICD-10 diagnosis I21 and I22), angina pectoris (ICD-10 I20), or CHD (ICD-10 I25.1). Patients with no coronary event or revascularisation in the actual time period, with diagnosis of Type 2 MI, older than 80 years, or not resident in Drammen or Vestfold were excluded from the lists. We identified 1789 patients from both hospitals being eligible for inclusion. In all, 423 patients were excluded due to inability to understand Norwegian (n=44), cognitive impairment (n=28), psychosis (n=18), active alcohol/drug abuse (n=10), short life expectancy (n=136), dead (n=160), and other (n=27) (i.e. inter-current disease, participation in a second study, or travelling abroad). The remaining 1366 patients were either first contacted by phone or directly mailed a letter with study information, an informed consent application form, a comprehensive self-report questionnaire and an appointment for the clinical examination and collection of the venous blood samples.

Figure 2. Flow-chart of the NOR-COR study



Most of the blood samples were analysed at the laboratory at Drammen Hospital to avoid inter-laboratory bias. A total of 1127 participants gave informed consent, attended a clinical visit including blood samples, and completed the questionnaire 2-36 (median 16) months after the index event.¹⁸⁴ Two cardiologists retrospectively registered hospital medical record data from the index event in the two hospitals. The total participation rate was 83% (n=585 from Drammen; 81%, and n=542 from Vestfold; 84%). Only patients who had been hospitalised for their coronary event or for other reasons, but had a coronary event during the relevant period of time, were included in the study. The usual track for a patient with STEMI in our area is to go directly to a tertiary centre for primary PCI, and subsequently return to the local hospitals in Drammen or Vestfold for further treatment. Patients with NSTEMI will largely be hospitalised at the local hospital before and after early PCI at a tertiary centre. Therefore, the likelihood of being missed for patients with MI is small. The majority of patients with elective PCI have, however, a large likelihood of being overlooked in our study, since only a small number have been locally hospitalised before or after the revascularisation procedure. A small number of elective PCI patients have been hospitalised for other reasons and have thus been identified through discharge lists.

Of the patients who refused study participation (n=239), only ten patients actively refused the use of hospital record data, *Figure 2*. The remaining 229 patients were included in a non-participant study.¹⁹⁰ The hospital record data on lifestyle measures are usually insufficient, especially on physical activity and diet.¹⁹¹ Therefore information on these factors is missing in the non-participant study, as well as data on follow-up. We did not have a permission to analyse the excluded patients further, so we only registered information from hospital records.

In the reproducibility study (*Paper IV*), 28 of the NOR-COR participants recruited from the Hospital of Vestfold completed a retest after 4 weeks. In order to increase the number of participants to approximately one hundred to get more robust results, 71 consecutive patients referred to cardiac rehabilitation in Vestfold performed an identical retest, *Figure 2*, left side. These patients were considered stable with respect to their CHD, and the inclusion criteria were the same as for the main study in order to compare the two samples and to generalize the results to the NOR-COR population.

3.4 Study assessment

3.4.1 Development of the study questionnaire

The NOR-COR questionnaire contains 249 questions in 27 pages derived from a number of medical and psychosocial instruments that have been demonstrated previously, to some extent, to be associated with coronary risk factors, adherence to medication and prognosis in cardiac patients.^{169,172,175,184,192-195} Most of the instruments included are widely used in health research and previously validated, and were selected based on knowledge and expertise.¹⁸⁴ As there were no validated instruments for revealing the patient's needs and preferences, a number of questions/items were created *de novo* following an extensive process.⁴⁵ The NOR-COR questionnaire was prepared and revised by the interdisciplinary research group. After two revisions, the questionnaire was pilot-tested with two cardiac nurses and two CHD patients in order to incorporate the patients' perspective, and was subsequently tested with 20 randomly selected eligible CHD patients in order to establish relevance, acceptance and feasibility. The development of the questionnaire is described in detail in the design and method paper.¹⁸⁴

3.4.2 The major coronary risk factors

- a. Physical activity: We used a questionnaire from HUNT 1 to assess self-reported PA status by average frequency (never, <1 time weekly, 1 time weekly, 2-3 times weekly and almost every day), intensity (light, moderate and vigorous), and duration (<15 min, 15-29 min, 30-60 min and >60 min).¹⁹⁶ The self-reported PA questionnaire has previously been validated against direct measurements of VO_{2max} and registration of total activity, in a younger population without CHD.²⁴ The validity for PA-index to VO_{2max} and total vigorous activity was acceptable, but poor for registration of low and moderate activity. In *Paper II*, favourable PA was defined as frequency ≥ 2 -3 times/week. In *Paper I and III* PA status was categorised as: inactive (PA <once/week), low activity (PA \geq once/week and <2-3 times/week moderate intensity 30 min), and adequate activity (PA \geq moderate intensity of

≥ 30 min ≥ 2 -3 times/week). This definition of adequate PA is close to the recommendation in the European Society of Cardiology 2012 prevention guidelines that were prevailing at the time of patient inclusion.¹¹ In *Paper III and Paper IV* we applied a continuous PA-index score; based on the product of frequency in times per week, intensity and duration in hours per session, according to the validation study.¹⁹⁶ The participants were asked to report “how much have you increased your PA level since your index coronary event” measured on a 0-10 Likert Scale (0=nothing, 10=very much), and this variable was applied in *Paper III and IV*.

- b. Smoking: Smoking status at index event was obtained from hospital records. Smoking status at follow-up was recorded from the self-report questionnaire (never smoker, previous smoker, quitter since the index event, current smoker). The primary outcome variables were smoking status at follow-up and smoking cessation since the coronary event.¹⁹⁷
- c. Overweight and obesity: Overweight and obesity was measured with body weight (nearest 0.5 kg) in light clothes and no shoes (SECA 813, DE) and body height (nearest 0.5 cm) using a wall-fixated rod (SECA 264, DE) at the follow-up visit. Overweight was defined as BMI $>25\text{kg/m}^2$, and obesity as BMI $>30\text{kg/m}^2$. Waist circumference was measured (nearest 0.1 cm) using a non-stretchable tape (SECA 201, UK), and a waist circumference >102 cm in men and >88 cm in women was defined as central obesity.
- d. Blood pressure: BP was measured (nearest 1.0 mmHg) with a validated digital sphygmomanometer (Welch Allyn WA) after sitting for >4 minutes.⁶⁹ Unfavourable BP control was defined as $\geq 140/90$ mmHg ($\geq 140/80$ mmHg in diabetics).
- e. LDL-C: LDL-C was analysed (Architect ci16200) in non-fasting venous blood.⁷² Continuous LDL-C was used in *Paper II and III*, favourable LDL-C defined as <1.8 mmol/l in *Paper II*, and unfavourable LDL-C as ≥ 1.8 mmol/l in *Paper I*.
- f. Blood sugar: Blood sugar was assessed by glycated haemoglobin A1c (HbA1c) in non-fasting venous blood and unfavourable blood sugar control was defined as $\geq 6.1\%$ in non-diabetes and $>7.0\%$ in diabetes patients.

3.4.3 Cardiac rehabilitation

In Drammen CR included a multi-disciplinary one-day “heart school” and exercise training twice a week for 6 weeks according to the Ullevål model.¹⁹⁸ In Vestfold a comprehensive, multi-disciplinary CR is provided twice a week for 5 weeks with individual and group approaches, motivational interviewing, education and exercise up to 6 months.¹⁰¹ In Vestfold, all eligible patients after a coronary event were systematically referred to CR when hospitalised. In Drammen, referral was less complete and at random. Participation in the CR program in Vestfold was obtained from hospital records, and defined as an adherence to the programme measuring at least 50%, not including earlier CR. There was no registration of the multi-disciplinary one-day “heart school” in Drammen, whereas exercise participation was obtained from physiotherapy registration lists, however, the registration was not complete. The consequence of this incompleteness was that the Drammen cohort was excluded in further analyses of the role of CR in risk factor control, leaving the analyses to a smaller sample size. Some patients from both cohorts may also have participated in CR programmes outside the two hospitals, but information about participation rates to these programmes was not available.

3.4.4 NOR-COR study factors

Variables obtained from hospital medical records, retrospectively registered from the time of the index event:

Socio-demographic variables:

- a. Patient's age in 1.0 years
- b. Gender, male/female
- c. Ethnicity, 1st and 2nd generation patients born in Asia, Africa, and South America
- d. Time since the index event to the time of inclusion in months (2-36 months)

Medical factors

- a. Coronary aetiology defined as acute myocardial infarction (STEMI or NSTEMI), stable or unstable angina pectoris.
- b. Angiographic findings (open vessel, atherosclerosis without significant stenosis, single and multi-vessel disease) and type of intervention (no intervention, PCI, CABG)
- c. Somatic medication registered in the hospital discharge letter: Anti-platelets, statins, BP lowering agents, nitrates, diabetes medication, and oral anticoagulants.
- d. Somatic comorbidity including the number of coronary events (1 vs. >1), heart failure, atrial fibrillation, stroke or transitory ischemic attack, peripheral artery disease, chronic obstructive pulmonary disorder, kidney- or liver failure, stomach ulcers and inflammatory and rheumatic conditions. Somatic comorbidity was also calculated using the Charlson comorbidity index.¹⁹⁹

Variables obtained from the self-report NOR-COR questionnaire at inclusion:

Socio-demographic factors:

- a. Marital status (in a relationship or living alone)
- b. Level of education (low education defined as completion of primary- or secondary school only)
- c. Employment status (employed or age retired vs. unemployed or receiving disability benefits)

Medical factors:

- a. Drug adherence (8-item Morisky Medication Scale), cut-off for acceptable adherence was set at ≥ 6 ¹⁷⁰
- b. Diet measured by the frequency of intake of fish, vegetables and fruits²⁰⁰
- c. The number of follow-up visits in primary healthcare, categorised as no current follow-up today, follow-up by my general practitioner (GP) < once a year, 1-2 times a year or ≥ 3 times a year

Psychosocial factors

- a. Quality of life, 12-item Short-Form Health Survey (SF-12): a 12-item measure of generic QoL with a physical health component PCS12 and mental health component MCS12.¹⁷¹
- b. Anxiety and depression (Hospital Anxiety and Depression Scale, HADS), a 14-item instrument measuring symptoms of anxiety (HADS-A) and depression (HADS-D). HADS scores < 8 were considered as normal.²⁰¹

- c. Type D personality (distressed personality type, DS-14): a 14-item instrument with seven items each on the subscales of negative affectivity (NA) and social inhibition (SI).²⁰² A score of ≥ 10 points on each subscale is required to be categorised with type D personality.
- d. Illness perception (Brief Illness Perception Questionnaire, BIPQ): an 8-item measure of illness identity, personal and treatment ability to control the illness, consequences, understanding and concern about the illness rated on 11-point Likert scales from 0 to 10, and one item about what caused the patient's illness.²⁰³
- e. Perceived risk perception (PRP): a 3-item measure on 11-point Likert scales; probability for a new event within 12 months, own ability to reduce coronary risk, and to what degree the disease will limit future activities.¹⁹⁵

Beliefs about causes, motivation, perceptions of information, treatment desires (de novo created questions)

- a. Perceptions of the cause of the patient's coronary disease, ranking known CHD risk factors to what extent the patient believed that each risk factor had caused the disease to develop on 11-point Likert scales (0=to no extent, 10=to a very large extent).
- b. Self-reported motivation to increase PA on 0-10 Likert scale (0=no motivation, 10=very high).
- c. Perception of the information provided by health care workers with four assertions: I am cured, but have to change my lifestyle; I am cured and do not need to change my lifestyle; I still have heart disease and need to change my lifestyle, I still have heart disease, but do not need to change my lifestyle.⁴⁵
- d. Perceptions of the health information given about illness and risk factors; perceived sufficiency on 0-10 Likert scales and further need for information.

The socio-demographic variables and somatic comorbidity including coronary history and treatment are descriptive variables. The remaining medical and psychosocial variables are regarded as potentially modifiable.¹⁸⁴

3.5 Statistics

All statistical analyses were conducted with the SPSS version 21 (SPSS Inc.US). The overall significance level was set at $P < 0.05$.

3.5.1 Sample size calculations

The sample size in the NOR-COR study was estimated primarily to reach sufficient subsequent composite events (MI, CV mortality, need of revascularization) after 5 years follow-up.¹⁸⁴ The calculations were based on the REACH study where the incidence of the composite cardiovascular endpoint was 35% after four years follow-up,²⁰⁴ and indicated an expected size of 400 cases with subsequent events. Thus, 1100 participants were considered to be sufficient in the present study. Differences within the participant group with respect to psychosocial risk factors such as HADS (assuming a 20% rate of positives) would be detected with 90% power if the binary outcome has a between-group difference of 10% and the overall level is 15% (even with continuity correction). In the EuroAspire IV Study the prevalence of coronary risk factors ranged between 16% and 80%.⁴⁶

Given an equal distribution of risk factors in our study a sample size of 1000 patients would allow for the inclusion of a considerable number of covariates ($k \sim 15$) when the least prevalent risk factor ($n=160$) was used as a dichotomous outcome variable.

Sample size calculations in reproducibility studies may be a challenging task.²⁰⁵ In the present reproducibility study (*Paper IV*), the sample size was first arbitrary chosen to be 30 of the NOR-COR participants. With a qualitative argumentation of “the more the better”, it was decided to increase the number of participants to approximately 100. This sample size was expected to give sufficient statistical power, sufficient precision and robust results.²⁰⁵ Of that reason 71 consecutive patients referred to CR performed an identical retest as the participants from NOR-COR. This sample size of 99 may be considered acceptable with two replicates in a reproducibility study, according to Giraudeau and Mary.²⁰⁶

3.5.2 Descriptive statistics

Descriptive statistics were applied in all four papers. Descriptive data are presented as means with standard deviations (SD) for continuous variables and frequencies with numbers and percentages for categorical variables. Differences between groups (i.e. cohort Vestfold vs. cohort Drammen, and CR participants vs. CR non-participants (non-CR) in *Paper II*, and reproducibility sample vs. total NOR-COR population in *Paper IV*) were assessed with independent two-sample t-tests for continuous variables and chi-square tests for proportions. In *Paper III*, we applied chi-square tests to compare proportions and analysis of covariance (ANCOVA) to compare mean differences between the three groups of PA status for continuous variables, further described and accounted for below.

3.5.3 Correlations

We applied bivariate correlations with Pearson’s correlation coefficient to calculate associations between perceived sufficiency of information and number of risk factors at target in *Paper II*. Pearson’s / point-biserial correlations were used to calculate linear trend for continuous variables in *Paper I* and in *Paper III*.

3.5.4 Logistic regression analysis

Logistic regression analyses are widely applied in epidemiological studies.²⁰⁷ Binary logistic regression analyses are usually applied when you wish to explore associations between a dichotomous outcome variable and covariates, adjusted for confounders.¹⁸⁵ In *Paper I* a binary logistic regression analysis was applied to calculate odds ratios (OR) and 95% confidence intervals (CI) for unfavourable risk factor control adjusted for age, gender, events prior to index event and time since the index coronary event. In *Paper II* binary logistic regression analyses were used to calculate OR and 95% CI for favourable risk factor control based on CR or cohort affiliation, adjusted for age, gender, education, diagnosis, events prior to index event, diabetes, comorbidity and time since the index coronary event. The same set of variables were used to estimate ORs for all the risk factors and were not removed from the model, even though they might not have been

neither a confounder variable nor a significant variable for the specific risk factor. In *Paper I* and *II*, no variable selection method was applied on the assumption that all variables in the analyses were putative exposures or confounders. We applied the Hosmer and Lemeshow test for goodness of fit analyses, variance inflation factors to check for multicollinearity, and analyses of statistical interactions to check for effect modifiers.

3.5.5 Linear regression analysis

Multiple linear regression analyses are used to explore associations between a continuous outcome variable and covariates.¹⁸⁵ We applied a multiple linear regression analysis in *Paper II* in order to explore the association between CR and continuous LDL-C, adjusted for the same set of variables as in the logistic regression analyses described above. In *Paper III*, multiple linear regression analyses were applied to explore the relative contribution of the various study factors on PA-index and self-reported PA increase. A backwards-stepwise elimination procedure was used to fit a multivariable linear regression model starting with all covariates showing bivariate associations with a p-value <0.10 in crude analyses. The p-value for removal was set at 0.1. The backwards elimination procedures were used to avoid overlooking the effects of the possible suppressor variables.²⁰⁸ Age and sex were forced into the final models on the assumption that these variables could be putative confounders and p-values <0.05 were considered significant. We treated all study factors, including the other risk factors, as potential exposures or confounders, although some of them might be considered as mediators or even colliders. Analyses of interactions were performed to check for effect modification. A further discussion of the possible confounders, mediators, and effect modifiers will be presented in the chapters of discussion. We observed and tested for outliers and deviations from linearity with satisfactory results in all analyses.

3.5.6 General Linear Models

In *Paper I*, we used ANCOVA to estimate marginal means for the number of unfavourable risk factors (smoking, BMI, low PA, BP, LDL-C, and HbA1c) by age, gender and prior coronary events with all independents controlled as dummies simultaneously, and with time since event entered as a linear covariate. The method was chosen because it yields a straightforward and easy presentation of stratified data with several groups or levels. The model was adjusted for time in order to control for differences between groups deriving from differentials in time since the coronary event. As mentioned earlier, ANCOVA was applied in *Paper III* to estimate the differences between the three PA groups, after Bonferroni corrections. The ANCOVA method was selected in order to facilitate the inclusion of several nominal level predictors. In *Paper IV*, ANCOVA was used to examine potential differences in reproducibility across age, gender or education.

3.5.7 Reliability

Reliability may be described as “*The extent to which a measure yields the same number or score each time it is administered when the construct being measured has not changed*”.²⁰⁹

Reproducibility calculations

Reliability studies based on test-retests are essential elements when it comes to establishing the quality of self-report data, with reliability a necessary precondition for test validity, albeit this is obviously no guarantee.²¹⁰ Thus, establishing low reliability in a test in the sense of high levels of random error or noise by definition would detract from the validity of such a test. Highly acceptable reliability values may reassure the reader that the risk of committing type II errors because of random error or noise in the test appears rather negligible.²¹⁰

In *Paper IV*, the test-retest reproducibility after four weeks was calculated by comparing the data obtained at test sessions 1 and 2 using Intraclass Correlation Coefficients (ICC) for continuous data and ordinal variables with at least five response categories,¹⁷⁷ and Kappa (κ) for nominal and ordinal variables.²¹¹ ICC was calculated for each individual question in the NOR-COR questionnaire, as well as for summarised scores when available, as for PA, drug adherence, sleep apnoea, and the psychosocial questionnaires. ICC was calculated based on a two-way mixed effect analysis of variance with 95 % confidence intervals. An acceptable reproducibility was set at the often-recommended level of $\text{ICC} \geq 0.70$ and kappa values were defined as acceptable if above 0.5. The guidelines for interpreting kappa with strength of agreement based on Landis and Koch suggest that values are fair between 0.21 and 0.4, moderate between 0.41 and 0.6, good between 0.61 and 0.8 and very good above 0.81.²¹¹ These guidelines for kappa agreement were also applied to continuous data using ICC.

Internal consistency

Internal consistency provides information about the associations among different items in a multi-item scale.²⁰⁹ In *Paper IV*, internal consistency was calculated with standardized Cronbach's alpha for each set of items or scales. A score of ≥ 0.7 is usually considered satisfactory.^{209,212,213}

3.5.8 Missing data

The amount of missing data in the questionnaires was low, within the range of 0 to 10%. In *Paper IV* the amount of missing data was 1.1% in the first test session and 3.0% in the retest, and at the same level throughout the questionnaire.

3.6 Ethics and approvals

The Regional Committee of Ethics in Medical Research (REK Sør-Øst) has approved the NOR-COR study, with an additional approval for the reproducibility study on October 17th, 2014 (2013/1885). All participants signed an informed consent form prior to study participation. The study has been conducted according to the ethical principals in the Declaration of Helsinki.²¹⁴ The NOR-COR study is registered at www.ClinicalTrials.gov (ID NCT02309255).

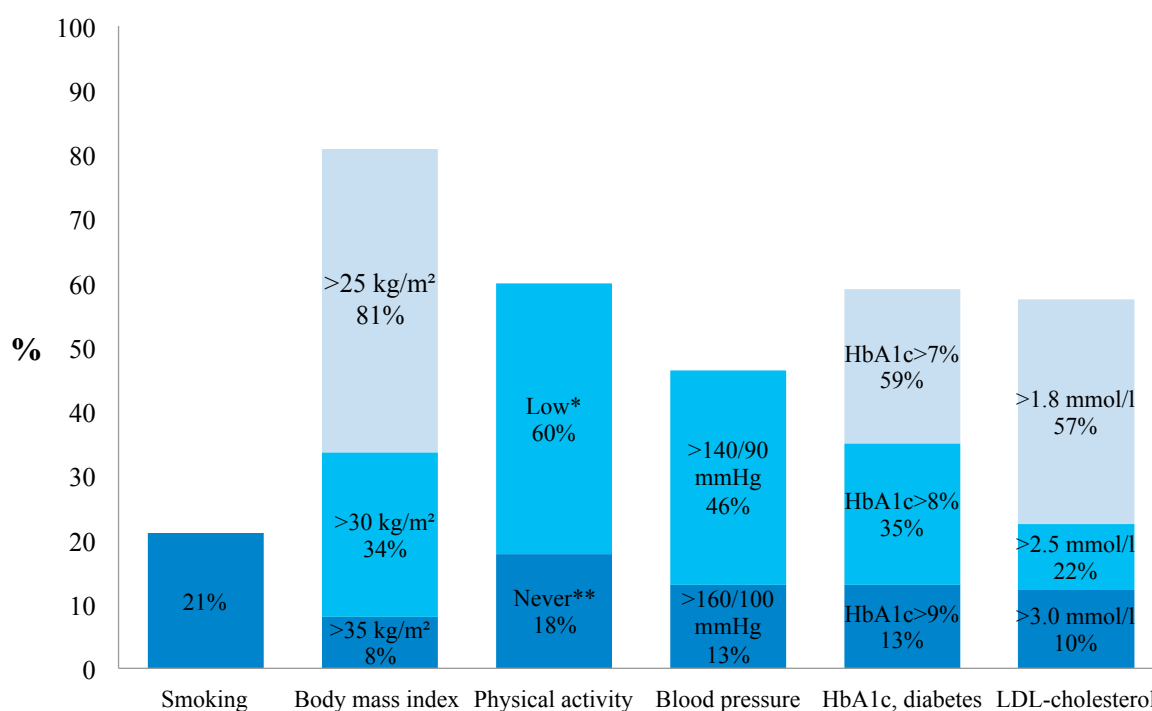
4 Summary of results

4.1 Paper I

In this study, we determined the control of the six major coronary risk factors, smoking, insufficient PA, obesity, BP, LDL-C and blood glucose according to target recommendation in current guidelines 2-36 months after a coronary event. In addition, we identified the influence of age, gender, number of coronary events, and time since index event. Mean age was 62 (SD 10) years at the time of the index coronary event, with 21% of the patients being female. The index coronary event was MI in 80% of the patients and stable or unstable angina with revascularisation in 20%. In all, 30% of the patients had suffered previous events and hypertension was the most prevalent comorbidity at the time of the index event followed by diabetes.

The main findings were that risk factor control at follow-up after an average of 17 months overall was rather poor, as is seen in *Figure 3*. As many as 21% were still smokers and only 44% of those smoking at the index event had quit. Further, 60% reported inadequate levels of PA, and 18% less than once weekly PA. Overweight was found in 81%, obesity in 34%, while 60% had central obesity. High blood pressure was prevalent in 46% and high LDL-C in 57%, although the use of cardio-protective medication was high. Diabetic patients had poor blood sugar control, with 59% having elevated HbA1c levels. Forty percent and 62% of participants ate fruit or vegetables less than once or twice daily, respectively, while almost half of the patients ate fish less than 3 times weekly.

Figure 3. Proportion of coronary risk factors 2-36 months after the index coronary event



*less than moderate activity for 30 minutes 2-3 times/week, **never or less than once a week

More than 60% of the patients had at least three risk factors with inadequate control, according to current guidelines, and only 2% achieved goals for control of all 6 risk factors. In multi-adjusted analyses (*Additional file, attached immediately after Paper I in the Appendix I*), we observed that current smoking ($p<0.001$), obesity ($p<0.001$), and unfavourable HbA1c ($p<0.01$) were more prevalent in younger patients, whereas inadequate BP ($p<0.001$) control was more frequent with increasing age. Current smoking ($p<0.001$) and low PA ($p<0.001$) were more frequent in patients with lower education levels. Those with previous coronary events had the poorest overall risk factor control ($p<0.001$). Women had higher odds of current smoking ($p<0.05$), low PA ($p<0.001$), and elevated LDL-C ($p<0.001$) compared to men. A linear trend for increase in smoking ($p<0.01$) and obesity ($p<0.05$) was observed with increasing time since the coronary event.

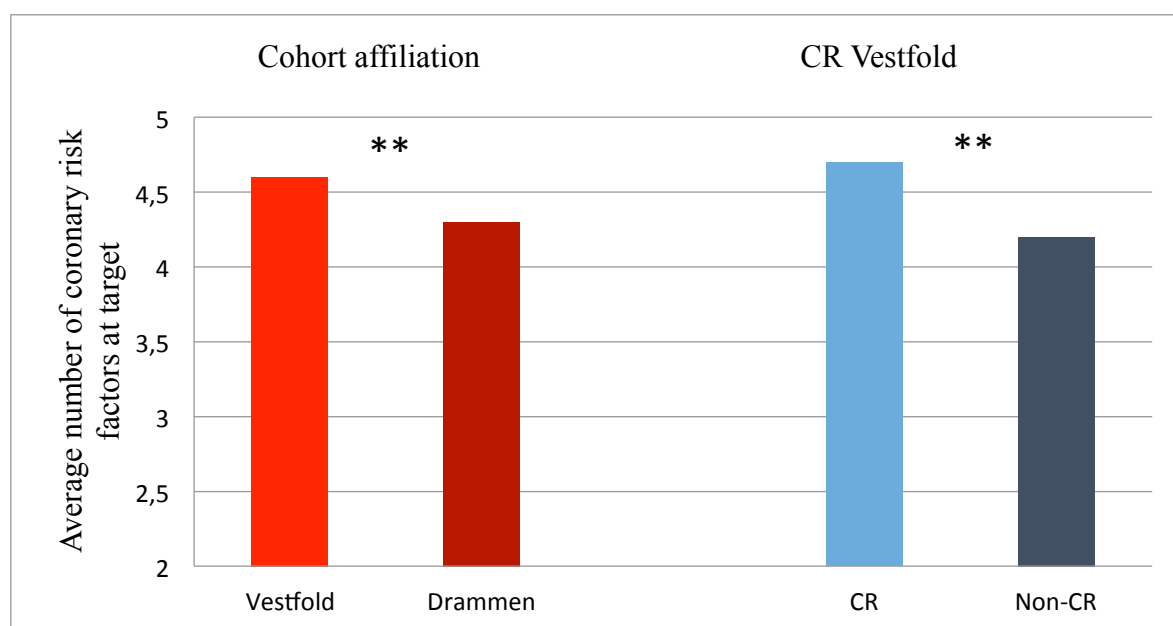
4.2 Paper II

In this study, we explored the role of CR in risk factor control after coronary events. We studied differences in patient characteristics, medication adherence, psychosocial factors, and risk factor control between the two NOR-COR cohorts, Drammen and Vestfold, and between those in Vestfold who participated in CR versus those who did not (non-CR). The CR participation rate was remarkably higher in Vestfold (75%) than in Drammen (18%). In addition, there were large differences between the content and duration of the CR programmes in the two cohorts, with Vestfold having a more comprehensive, multi-faceted and interdisciplinary content and a longer duration than Drammen. The CR participation registration in Drammen was not complete, and although initially stated in the protocol, it was therefore decided to abstain from comparisons of risk factor control between CR participants and non-CR in Drammen, and focus on the planned comparisons in Vestfold only, comprising 542 patients.

The patients from cohort Drammen had lower education ($p<0.01$) and a higher prevalence of previous coronary events ($p<0.01$) than the patients from cohort Vestfold. In adjusted analyses, the prevalence of favourable risk factor control appeared to be better in Vestfold than in Drammen, with more patients having adequate PA, favourable BMI and better medication adherence, all ($p<0.05$). Patients from Vestfold had better overall risk factor control than those in Drammen, with 4.6 risk factors at target vs. 4.3 ($p=0.008$), *Figure 4*.

The CR participants in Vestfold had fewer previous coronary events than their non-CR counterparts ($p<0.001$). However, more than one third of those with prior events had previously participated in CR. CR participation, compared to non-CR, was associated with higher prevalence of smoking cessation ($p<0.01$) and acceptable medication adherence ($p<0.05$), in addition to lower LDL-C levels ($p<0.05$) in adjusted analyses. No intergroup differences were observed for the other risk factors. The CR participants had better risk factor control than non-CR, with 4.7 risk factors at target vs. 4.2 ($p=0.001$), *Figure 4*.

Figure 4. Average number of coronary risk factors at target between Vestfold and Drammen, and between CR and non-CR in Vestfold



CR, cardiac rehabilitation participation, Non-CR, CR non-participation, ** $p < 0.01$

7 factors in the equation: non-smoking, PA ≥ 2 -3 times/week, intake of fruits/vegetables ≥ 2 times/day, BMI $< 30 \text{ kg m}^2$, BP $< 140/90 \text{ mmHg}$, LDL-C $< 1.8 \text{ mmol/l}$, acceptable drug adherence

In the total sample of patients in Drammen and Vestfold combined there were significant correlations between risk factors at target and perceived sufficiency of illness and risk information ($p < 0.001$), in addition to perceived need of additional follow-up ($p < 0.01$).

4.3 Paper III

In *Paper III* we explored the socio-demographic, medical and psychosocial factors associated with low PA. Data on PA was missing in 26 patients, thus a total of 1101 (98%) patients were included in this study. In all, 18% of the patients reported to be inactive, 42% to be insufficiently active and 40% to be adequately active defined as moderate or vigorous intensity of at least 30 min ≥ 2 -3 times per week. In the three groups, the self-reported increase in PA since the index event was 1.8, 3.6, and 4.5, respectively, on a Likert scale from 0=nothing to 10=very much. Only 28% in the inactive group had participated in CR, by contrast to 48 and 50%, respectively, in the more active groups. Compared to the adequately active group, the inactive group was comprised of more patients of female gender ($p < 0.01$), low education ($p < 0.001$), diabetes ($p < 0.001$), unhealthy lifestyle (most factors $p < 0.001$), C-reactive protein (CRP) > 2 ($p < 0.001$) and psychosocial distress (most factors $p < 0.001$) than the adequately active group.

The continuous PA-index variable (i.e. a product of frequency in times weekly, intensity, and duration in minutes per session) correlated highly with the trichotomised PA status variable

(Pearson's correlation 0.77, $p < 0.001$). In adjusted linear regression analyses with PA-index as outcome variable, low PA tended to cluster with other unhealthy lifestyle factors including smoking, unhealthy diet, and obesity, depression and lower scores on the physical component of QoL, *Table 1*. Female gender, low levels of education, MI as index coronary event and previous coronary events were also associated with low activity, however, CR participation was not associated with PA.

Table 1. Association of PA-index calculated from linear regression analysis

	Multi-adjusted Estimate*		
	B (standard error)	Standardized β	P value
Age at index event per 1.0 year	-.015 (.010)	-.050	.123
Male gender	.489 (.221)	.069	.027
Low education ^a	-.506 (.187)	-.085	.007
Acute myocardial infarction as index diagnosis	-.700 (.229)	-.099	.002
≥ 1 previous coronary event prior to the index event	-.411 (.207)	-.066	.048
Current smoking	-1.218 (.223)	-.173	<.001
Fruit and/or vegetables < 2 times/day	-.374 (.183)	-.064	.041
Body Mass Index > 30 kg/m ²	-.463 (.190)	-.076	.015
Quality of life SF-12, physical component per 1.0 point	.075 (.014)	.179	<.001
HADS depression score ≥ 8 ^b	-.869 (.252)	-.107	.001

*Adjusted for all variables with $p \leq .05$ retained in backward elimination linear regression analysis with PA-index as dependent variable and with age and sex forced into the final model. Crude estimates are not shown.

Abbreviations; B, unstandardized regression coefficient, β , standardized regression coefficient, PA-index, product of physical activity frequency, intensity and duration. ^aLow education was defined as completion of primary or secondary school only, ^bHADS, Hospital Anxiety and Depression Scale

In adjusted analyses, a higher motivation ($p < 0.001$), higher scores on the physical component of QoL ($p < 0.001$), perceived own ability to reduce coronary risk ($p < 0.001$), attribution of their coronary disease to lack of PA ($p < 0.001$), reported sufficient risk information ($p < 0.01$) and a lower reported need of help to increase PA ($p < 0.001$) were associated with patients increasing their PA level after the coronary event.

4.4 Paper IV

This paper analysed the reproducibility of the extensive self-report questionnaire used in the NOR-COR study. A total of 99 patients completed the test and retest within 33 (± 6.4) days (range 25 to 50). There were no significant differences between the reproducibility sample and the total NOR-COR study population regarding age, gender, diagnosis, education or employment status, *Table 2*. The mean time interval between index hospitalisation and first time completion of the questionnaire

was 9 months, in contrast to 17 months in the main study. The amount of missing data was 1.1% in the first test session and 3.0% in the second. The reproducibility scores remained high for items throughout the rather sizable questionnaire.

Table 2: Demographic and medical characteristics of the NOR-COR sample and the reproducibility sample

	NOR-COR n = 1127	Reproducibility n = 99	P-value
Age, mean (SD)	61.6 (9.6)	63.2 (8.8)	n.s.
Female gender, %	21	17	n.s.
Living alone, %	26	24	n.s.
Low education^a, %	62	55	n.s.
Coronary diagnosis			n.s.
Non-ST elevation MI, n %	561 (50)	44 (44)	n.s.
ST elevation MI, n %	335 (30)	38 (38)	n.s.
Stable/unstable CHD, n %	231 (21)	17 (17)	n.s.

n, sample size; SD, standard deviations; n.s, non-significant; MI, myocardial infarction; CHD, coronary heart disease,

^aLow education was defined as completion of primary or secondary school only

The reproducibility values for the PA questions were very good, with values ranging between ICC 0.80 to 0.90 for the items frequency, duration, intensity, PA-index and self-reported increase in PA. The values for smoking ranged from kappa 1.0 for current smoking to 0.87 for never smoked. The values for diet were moderate, and good for drug adherence. The test-retest calculations demonstrated good to very good reproducibility values for all the psychosocial instruments including SF12 QoL (ICC 0.77 for the physical component and ICC 0.89 for the mental component) and HADS anxiety (ICC 0.92) and depression (ICC 0.94). All the instruments that were previously validated by others, showed good to very good reproducibility. Furthermore, the self-constructed questions regarding treatment desires had slightly lower test-retest results, but the questions about motivation, attribution of their CHD to lack of PA, and information were good to very good (ICC 0.73-0.94). Calculations of internal consistency revealed good to very good values (Cronbach's alpha from 0.69 to 0.95) in almost all scales and instruments included.

5 Discussion

5.1 Discussion of results

The main results of the study indicate that risk factor control in Norway is poor, a finding which is in accordance with European studies. The results also suggest that the role of CR in risk factor control is essential, although deficient, and that insufficient PA is prevalent after a coronary event, with low PA associated with a cluster of unhealthy lifestyle, depression and poor physical QoL. In addition, the comprehensive self-report questionnaire used in the study showed a good to very good reproducibility and thereby applicability.

5.1.1 Prevalence of risk factor control

Our findings in *Paper I* revealing a high prevalence of unfavourable risk factor control are worrying, considering that the subsequent risk of cardiovascular events has been found to be inversely related to risk factor control.^{35,36} A high prevalence of unhealthy risk factor control was also found in the EuroAspire study.⁴⁶ We found comparable prevalence of elevated BP (46% vs. 43%), obesity (34% vs. 38%) and insufficient PA (both 60%). LDL-C ≥ 1.8 mmol/l was observed in 57% in our patients vs. 81% in EuroAspire IV. However, this was still not good enough, with more than half of the patients having too high a level of LDL-C. The number of daily smokers was higher in our study (21% vs. 16%), although Norway has a lower prevalence of daily smokers than the average in Europe (16% vs. 23% in 2012).²¹⁵ This disparity may tentatively be explained by methodological differences, since the EuroAspire study had a very low participation rate of 49%, and the patients were recruited mostly from academic centres probably making the European figures rather conservative. By contrast, our patients were recruited in a routine, clinical setting with a high participation rate. Moreover, we expected that Norway had a better risk factor control based on the fact that Norway is a high income country with a well-developed health system and a healthy population,²¹⁶ thus being in a better position to offer adequate secondary prevention interventions, including CR, with a higher availability to the patients than many of the countries in the EuroAspire study. Compared with other Nordic countries included in the EuroAspire IV study, Sweden and Finland, we had a poorer risk factor control, except for control of elevated LDL-C.⁴⁶ Furthermore, since 17% of the total population in the present study were non-responders,¹⁹⁰ our results may be better than in reality. The notion of a poorer risk factor control in that group was observed in a recent retrospective study of data obtained from the hospital medical records from both groups.¹⁹⁰ Compared with responders, non-responders had a higher prevalence of depression and anxiety as well as somatic comorbidity, diabetes, and hypertension along with a lower CR participation. We did, however, not have any follow-up information from the non-responders, and thus comparisons of risk factor control were not achievable.

Matters of concern are that the prevalence of unfavourable risk factor control was highest among patients with previous events. Since unfavourable risk factor control is associated with recurrent events,^{35,152} risk factor control would have been especially important in these patients who had already suffered prior events. The poor risk factor control may potentially explain why these patients have suffered several events. The CR participation rate was much lower among those with

prior events, and even though one third had engaged in CR in connection with a previous event, this group of patients should have been more encouraged to participate in CR again.

5.1.2 The role of cardiac rehabilitation

Paper II showed that there were large differences in the CR programmes provided in two neighbouring hospitals regarding referral, content, duration and participation rate. Vestfold had a high CR participation rate with 75% when compared with the average rates from a Norwegian study (28%),¹⁰⁶ a large European survey (range 3-90%, the majority below 50%)¹⁰⁷ and the EuroAspire IV Study (41%).⁴⁶ There may be several reasons for this observation. First, Vestfold hospital has provided well-documented CR for 20 years,¹⁰¹ the programme is implemented in the daily routine in the hospital and consequently the entire personnel are aware of its importance. Second, CR in Vestfold has a start-up within 2 weeks after the coronary event, and thus patients still have their coronary incident at the forefront of their mind and may utilise their sick leave period. Finally, CR is offered to all qualifying patients when hospitalised after a coronary event. Such a systematic, inpatient referral of has been found to be a strong predictor of attendance.¹¹⁷ The low 18% participation rate in Drammen may be due to a suboptimal availability and capacity of the programme to include all eligible patients, to deficient referral routines, as well as that many patients may have participated in other external CR programmes, institutional or community based, and therefore outside our registration and control.

There was no significant difference between CR participants and non-CR in Vestfold in smoking at index event, but a clinically important difference in smoking cessation between the groups was observed at follow-up. CR was associated with smoking cessation to a similar degree as that in the recently published results from the EuroAspire IV study.¹⁰³ The impact of our finding of more than 3 times greater odds of quitting smoking when participating in CR is of great importance for the patients' coronary prognosis.^{11,35,56} However, these results are not good enough, since 17% continued smoking in the CR group. The work of Sverre et al from the NOR-COR study revealed a rather high self-reported motivation for smoking cessation, whereby 68% wanted help to quit smoking and that only 42% had been offered nicotine replacement therapy or any other form of cessation help.¹⁹⁷ This may be a result of too little attention to smoking cessation in secondary prevention, but it may also reflect smokers' attribution of persistent smoking to lack of help or that they have no sincere intention to quit. A review demonstrated that a history of smoking was associated with an increased likelihood of referral to CR, but continued smoking also predicted non-participation in CR and was a strong predictor of CR dropout.²¹⁷ If the difference in smoking cessation that we observed is an effect of CR participation or not is difficult to decide, since it may be that those who quit smoking were more likely to participate in CR than those who continued smoking. We may argue likewise regarding favourable differences in drug adherence and LDL-C between CR participants and non-CR. Nevertheless, our findings of associations between CR and high drug adherence confirms recent results from the EuroAspire IV study,¹⁰³ and the favourable impact of drug adherence on clinical outcomes in CHD patients has been stated in a recent meta-analysis.⁸⁵ Optimal drug treatment and adherence may be essential in management and control of biological risk factors such as LDL-C, BP and blood sugar. We found an impact of CR on the continuous LDL-C variable, although not in terms of the dichotomous target of < 1.8 mmol/l. In the

EuroAspire IV,¹⁰³ a similar missing association between CR and LDL-C on target was observed, but in that study only 20% of CR participants reached the LDL-C target compared to 46% in the present study. A better drug adherence could tentatively be a mediator for the association between CR and LDL-C; CR participation is associated with a better drug adherence, which in turn causes a lower LDL-C. It may be discussed if the difference in LDL-C of 0.23 mmol/l between CR and non-CR is a clinically relevant difference; nevertheless, a strong linear relationship between LDL-C levels and CVD events is suggested in a recent review.²¹⁸

In adjusted analyses we did not find any significant differences between CR participants and non-CR in PA, BP control, BMI or dietary habits in Vestfold. The reasons why CR participation seems to have effect on some risk factors and not all may be complex. The CR programme has provided a lot of information over a long period and thus may have resulted in a high participant information sufficiency and understanding. Motivational interviewing and likewise techniques for behavioural change may have increased smoking cessation and drug adherence. Weight reduction may be challenging and take time, thus it may be more difficult to see results even in CR participants. The missing effect on BP control, which is in line with the findings in the EuroAspire IV study,¹⁰³ may tentatively be explained by insufficient attention being directed to biological risk factors in our CR programme and in the follow-up by cardiologists or GPs.⁷² Thus, a greater awareness and management of all lifestyle and biological risk factors should be emphasised in CR, besides a better transferral of guideline target information to GPs. All risk factors including PA, BP, BMI and dietary habits were, however, in favour of the CR participants, and the combined effect of these small differences may be of clinical importance.

Some patients may be adherers “per se” or healthy adherers; that is, those patients who participate in CR, are also those who are more likely to stop smoking, perform other healthy lifestyle changes, and take their prescribed medication.^{35,99,124,129,219} Adherence to CR may act as a surrogate marker for an overall healthier behaviour, and CR may thereby be seen as a mediator for this healthy adherer effect.

According to Alm-Roijer et al, knowing your risk factors for CHD improves adherence to advice on lifestyle changes and medication.²²⁰ In our study we observed that self-reported sufficiency of illness and risk information correlated with the number of risk factors at target. This may have been a result of CR participation, since knowledge dissemination is one of the elements of CR. In Vestfold, CR participants reported the perception of information sufficiency to a higher degree and had more risk factors at target than non-CR. The importance of information was recently discussed in a qualitative study from the CONCARD investigators in Bergen,²²¹ where patients post PCI experienced not receiving adequate information on how to integrate health information. Thus our results are in accordance with those reported in other studies and emphasises the importance of illness and risk information as a crucial component of CR programmes.

Paper II also calculated differences between the Vestfold and Drammen cohorts, and associations in risk factor control with cohort affiliation. There were several differences between the cohorts in socio-demographic and medical factors, although they are neighbouring counties. Even though we did adjust for all these factors, we found favourable differences in PA, BMI and drug adherence,

with all factors in favour of Vestfold, and with more risk factors at target. Some of these differences may be results of CR, while others may be due to real differences between the cohorts not accounted for in the analyses.

The association between cardiac rehabilitation and physical activity

Adjusted analyses in *Paper II* showed that the CR participants in Vestfold had 43% higher odds of reaching adequate activity than non-CR, although admittedly this was not significant. As already described, we used the same set of covariates for all risk factors in the logistic regression analyses independent of significance. If we omit the non-significant variables, one by one, except for age and gender from the equation, only education and CR remain significantly associated with PA in the final model. When thus reduced to four independents, CR participation is significantly associated with adequate PA in Vestfold (OR 1.57, 1.02-2.43, $p=0.041$). These results are comparable to those of the EuroAspire IV study¹⁰³ where the regression analyses were adjusted for age, gender and education, resulting in a significant association between CR participation and adequate PA being found. In many other studies, CR is associated with adequate PA.^{142,143,148} Based on the analyses above; the reason for our observations could indicatively be adjustment of some variables not being confounders.

Linear regression analyses in *Paper III* confirmed the missing association between CR participation and PA. These estimates, however, were calculated using the whole population with the limitation of incomplete registrations of CR in cohort Drammen, as well as the missing registration of CR activities outside the two hospitals. Other reasons for this rather surprising finding of no association between CR and PA could be that the long-term effect of the CR programmes was not good enough. Furthermore, the non-CR group in Vestfold was diluted because it comprised patients who either had participated in CR earlier or had participated in less than 50% of the programme.

5.1.3 Physical activity

In *Paper III*, we found that 18% were physically inactive. Some of these patients may have been inactive their entire life, and may not have had any ambition to become active. Our proportion of inactive patients was higher than the 12% observed in the general Norwegian population.²²² This may be due to an older population in our study (62 years versus 48 years), to established CHD and comorbidity, or to other socio-graphic or methodological factors. Our questionnaire did not distinguish between PA variations in length or intensity along the week. Therefore, our data cannot easily be converted into the national recommendations of 150 minutes of moderate PA per week, 75 minutes of vigorous exercise, or a combination thereof. We found that 40% were adequately active, defined as at least 30 minutes of moderate activity 2-3 times/week. Thus, our proportion of participants performing adequate activity may be lower than 40% if related to the national recommendations, and thus in accordance with the 37% as observed in the general Norwegian population of 50-64 years,¹³⁵ and comparable to 40% in EuroAspire IV, 41% in the Blitz-4 Registry, and 46% in both ICAROS and OASIS studies.^{35,46,55,102} In spite of some methodological dissimilarity in the studies referred to, our estimate of adequate activity seems realistic, although it

is known that overestimation of PA is prevalent in self-reported data and may be present in all the studies.^{187,196}

We observed associations between insufficient PA levels and current smoking, obesity, and low intake of fruit and vegetables, all factors that may reflect a generally unfavourable lifestyle and poor health behaviour in these patients. We found that unhealthy behaviours tended to cluster, as inactive patients were more prone to smoke, have unhealthy diet and be obese, thus confirming previous findings.^{35,51,142,223} The impact of these clusters may be similar to that of the findings of the OASIS study, where persistent smokers who did not exercise or have a healthy diet had a 4 times higher risk of recurrent events compared to never smokers who modified their diet and were physically active.³⁵ We also found associations between low levels of PA and both depression and poor physical QoL, indicating that these patients have challenges with depression and physical QoL in combination with clusters of unhealthy lifestyle. The complexity of these conditions indicates a need for interdisciplinary approaches in order to improve PA levels, with individualised interventions besides multidimensional CR targeting both unhealthy lifestyle and psychosocial distress. A recent Norwegian observational study by Olsen and co-workers did show that depression levels were not affected by CR participation after PCI,²²⁴ an observation in some contrast to results from a meta-analysis by Rutledge et al²²⁵ and a review by Lavie et al.²²⁶ Consequently, a specific component to target psychological function such as stress management, psychological intervention or PA seems to be an important part of CR as psychological distress, especially depression may be a barrier to lifestyle changes such as to increase PA.³²

Our findings of such factors as unhealthy lifestyle, depression, physical QoL, female gender, low education, having a MI as index event and previous CHD events being associated with inactivity have been reported in other studies. Minges et al reported that female gender, smoking, obesity, and poor self-perceived health were correlated to low PA in CHD patients,²²⁷ while in the Tromsø study, age, high body mass index, smoking and low perceived health were all associated with low PA in a general population.²²⁸ The latter also reported that low SES correlated with low PA. We found an association between low PA and education, whereas no association with marital status or high age was found. It has been reported that MI patients treated with PCI, more often have a sedentary behaviour than patients with elective PCI,²²⁹ confirming our observations of MI patients being less active than those with elective PCI or CABG.

We observed that the patients with previous coronary events were less active than the patients who had suffered their first event. The Charlson comorbidity score was significantly higher for those with previous events (4.5 vs 4.1, $p < 0.001$). Therefore, these patients may be more seriously ill and have more comorbid disorders and thus are not sufficiently fit enough to exercise. Since regular PA could have reduced their coronary risk, suffering several coronary events may indicatively be a result of insufficient PA. This was found in a cohort study from USA where the inactive group was 2-times more likely to have had recurrent events.¹⁵² These findings contradict a study from PCI-patients in China where no association between low PA and recurrent events was found.^{95,230}

The inactive patients reported a very low increase in PA level. Low increase in PA was associated with low motivation, low physical QoL, poor perceived risk control, low information sufficiency,

and a reported need for help to increase PA. Interventions like motivational interviewing and illness and risk understanding may be strategies to reach a higher increase in PA level in these inactive patients. The impact of even a small increase in PA from inactivity to light activity has been reported to be associated with improved risk factor control and mortality reductions.^{64,140,159} This may suggest that a clinically relevant intervention would be to increase the level of PA for inactive patients, even with PA volumes lower than recommended.¹⁴¹ The inactive patients in the present study were less likely to have attended CR, although CR participation did not reach significance in multi-adjusted analyses. Even so, a comprehensive approach with CR seems to be a reasonable option in order to reach acceptable levels for all lifestyle factors, including PA, as well as a interventions of psychological factors as is suggested in several studies.^{30,102}

A concerning finding was that 41% of the inactive patients in our study reported no current follow-up in primary care, although primary healthcare should be responsible for the long-term secondary preventive management in the majority of CHD patients in Europe.^{31,231} Encouragements to secure follow-up appointments in primary healthcare and its cooperation with hospitals, along with applications of new and expansion of available PA programmes, might be viable options for increasing PA in CHD patients²³²

5.1.4 Reproducibility of the NOR-COR study questionnaire

The reproducibility values and internal consistency measures found in *Paper IV* were good to very good for almost all items and scales. The most important implication of these findings is that such robust results support the application of the NOR-COR questionnaire in further and previous analyses.

We had expected a tendency towards lower reproducibility scores at the end of the extensive questionnaire, possible due to tiredness, restlessness, or unfocused participants. This did not, turn out to be the case, however, the values retained good throughout the questionnaire. This finding is somewhat supported from a diet study of Subar et al where the length of the questionnaire had little impact on the response rate or data quality.²³³ The researchers indicated that clarity and ease of questionnaire administration might have compensated for questionnaire length. Thus, our findings of quite acceptable reproducibility data may possibly be explained from the extensive process with developing and pilot testing the NOR-COR questionnaire, which in turn may have resulted in a questionnaire clear and easy to respond. Moreover, many of the included questionnaires have previously been validated and found to have acceptable reliability and reproducibility, including HUNT 1 PA,¹⁹⁶ Morisky Medication Scale,²³⁴ HADS,²³⁵ and SF-12.²³⁶

The reproducibility sample comprised NOR-COR patients (n=28) and consecutive patients referred to CR in Vestfold (n=71). Both groups included both CR participants and non-CR. We did not find any socio-demographic differences between the reproducibility sample and the NOR-COR sample, and this may be important for the application of the questionnaire and interpretation of the results.

The reproducibility values for the variables used in *Paper I-III* were predominantly very good, including PA, smoking, drug adherence, QoL, depression and anxiety, motivation and information. These findings are in accordance to previous studies on PA,¹⁹⁶ smoking,³⁴ drug adherence,^{234,237} anxiety and depression²³⁵ and QoL.²³⁶ Reproducibility values for PA questionnaires have been shown to decline with a longer interval between tests,^{196,238} possibly because the risk of real changes in exercise behaviour may be present. We found, however, very good values for both PA frequency and PA-index with four weeks interval, which is considered to be a relatively long interval.

We observed significant differences in the reproducibility values across gender, age, and education in a small proportion of the variables; however, there was no consistency regarding which subgroup showed the highest level of reproducibility across the different variables. Based on the relatively small sample size in this paper, such a subgroup analysis must be interpreted with caution.

5.1.5 Discussion across papers

Risk factor control, including PA, from a routine clinical practice was poor 2-36 months after a coronary event. This may be interrelated to low participation rate in CR, and that the CR programmes mainly address lifestyle changes and to a lesser extent biological risk factors. Strategies to ensure a high CR participation rate and some adjustments of existing content and focus should be implemented. A special attention may be addressing smoking and depression, since these factors were associated with insufficient PA. Another important attention may be targeting motivation, through motivational interviewing, and to boost the patients' illness and risk perception, since these factors were associated with low increase in PA.

5.2 Discussion of methods

5.2.1 Random error

Random error is variability in the precision of any data sampling technique or health measurement instrument that we cannot easily explain.^{207,239} Random error or noise may attenuate study results be they positive or negative, thus obscuring real differences.^{239,240} As the study sample size increases, however, the effect of random error or chance decreases.^{207,239} Thus, the large sample size of the present study should be large enough to obtain accurate estimates of the prevalence of risk factors control and the effects of most covariates.

We have used a 95% CI, which will cover the true unknown effect measure by a 95% probability, and a p-value of 0.05 in all analyses, which means that the risk by chance is less than 5% of rejecting the null hypothesis given no true association. The risk of finding significant p-values increases with the number of comparisons. Therefore, in *Paper III* we used Bonferroni corrections to counteract the problem of multiple comparisons. The number of cases within each outcome variable should at least be ten times the number of covariates that are included in the final model.¹⁸⁵ Given a prevalence of the least frequent risk factor “smoking” in *Paper I* of 21%, the number of patients included (1100) will allow us to include 23 covariates in the model. In *Paper II*, however, only half of the sample was used to estimate the role of CR versus non-CR. With a larger sample size, more outcome variables could possibly have reached significance, illustrated by wide confidence intervals. Even a 43% higher odds of being adequately active among CR participants was not statistically significant. Thus, the lower sample size may have led to a Type II error of not rejecting the null-hypothesis even though a true difference was present.

Experienced and specially trained study personnel collected and recorded all data and this may have reduced the chance of random error in data processing. Information obtained by self-report questionnaires may introduce random error or noise, such as patients being distorted by a poor or oscillating understanding of the underlying meaning of a question, being distracted or confused, or responding based upon current mood. Highly acceptable reproducibility values may, however, tentatively reassure that the risk of random error or noise in the test is rather small.²¹⁰

5.2.2 Systematic error

Internal validity implies that there is no bias in the way the data is collected, analysed, and interpreted, and refers to the ability to measure what the study is supposed to measure.^{185, 240} Systematic errors may bias results of a study in any direction, and a common classification of systematic errors is selection bias, information bias and confounding.^{185,240}

Selection bias

Selection bias refers to the study participants’ representativeness of the entire population.¹⁸⁵ The representativeness of the NOR-COR sample should be boosted by the recruitment from a routine, clinical practice, with almost all consecutive patients in the actual time interval considered eligible, a rather large sample size and a high participation rate. In addition, our study hospitals have a sizeable catchment area including a representative blend of urban and rural areas in Norway in

terms of geography, economy, age distribution, CHD morbidity and mortality.¹⁸⁹ Nevertheless, the NOR-COR sample may be influenced by selection bias, since our exclusion criteria may have resulted in a somewhat healthier study sample than a total CHD population after CHD events. Patients from ethnic minorities who did not understand Norwegian were excluded from the study, as were patients with severe psychiatric and somatic morbidities, those with high age and non-survivors. Further, a potential problem may be that the non-responders (17 %) were different from the responders. In the study of non-responders¹⁹⁰ we observed that they represented a higher prevalence of females, ethnic minorities, living alone, hypertension, diabetes, CR non-participation, comorbidity, depression, anxiety and psychotropic drugs than the NOR-COR responders. Thus, it is reasonable to suggest that the prevalence of unfavorable risk factor control in these patients might have been even higher than in the NOR-COR sample.

We anticipated that the likelihood of having missed MI patients to be small, due to hospitalizations at our local hospitals. Nevertheless, an unknown number of patients may have had their MI abroad, have moved, or left the tertiary hospital without returning to the local hospital. The majority of patients with elective PCI, however, may have had a greater likelihood of being missed in our study, since only a small proportion were hospitalised locally before or after the revascularisation procedure. A few of these patients have been hospitalised for other reasons, and thus were identified through our discharge lists. The NORSTENT study included patients who were treated with PCI, with 42,5% of patients having either stable or unstable angina, as opposed to 6% in our study. This observation may corroborate that we have missed a substantial number of angina patients in NOR-COR. Furthermore, this may to some extent have biased our results in Paper III, since we found a difference between MI and stable/unstable angina in association with adequate PA.

Patients > 80 years were not included, and only 3% of patients had ethnic minority background, as opposed to an average of 9% in Norway.²⁴¹ In addition, patient characteristics of the non-participants differed considerably from participants,¹⁹⁰ thus caution must be taken when generalising to these groups. The proportion of women is rather low (21%), most probably reflecting the upper age limit of 80 years, since the majority of women suffer their heart disease at an older age. However, there were more women in the non-participant sample, suggesting some gender skewness. With these selection criteria in mind, caution must be taken when extrapolating our findings as representative of a general CHD population after a coronary event.

Information bias

Information or measurement bias is a systematic distortion of the exposure or outcome, a consequence of dependence between exposure and effect variables, and includes recall bias, patients giving socially desirable answers and misclassification.^{188,239,240} Differential misclassification may occur when patients are categorized erroneously with regard to exposure or endpoint. In the NOR-COR study this may have happened if patients deliberately have given socially desirable answers, including over-reporting of PA,¹⁹⁶ medication adherence²⁴² and the sufficiency of treatment or information, and likewise underreported current smoking, unhealthy diet, and alcohol intake.¹⁸⁷ Furthermore, recall bias is a potential problem in all self-report questionnaires,²⁴³ and may occur when groups of patients with a certain condition are able to recall their habits or states more

correctly than patients without these conditions. For example, in patients for whom PA is very important, it is likely that the PA information will be more accurate than in an inactive patient who does not bother to exercise. The medical information from the index hospitalisation was retrospectively retrieved from hospital records by two cardiologists, and may therefore be influenced by reporting bias. The clinical examinations were made according to strict procedures, thus minimising the risk of random or systematic error.

Confounders, mediators, and effect-modifiers

A confounder is a variable that is associated to both the exposure and the outcome, but as a cause and not as an effect of either.^{185,187} Observational study group comparisons are hampered by differences in baseline patient characteristics, and therefore require adjustments. In this study, the large pool of eligible predictors largely consisted of variables for which establishing a univocal causal direction was difficult. Thus, whether a bivariate effect was retained as statistically significant in the trimmed model because it was a confounder or a mediator would be hard to establish. For the same reason, analyses specifically focusing on pairs of predictors to identify which of them acted as a confounder or a mediator in relation to the other were not systematically carried out. The sample size would seem to hedge against lacking robustness, not least because the independents showed very modest correlations between themselves, i.e. no multicollinearity. Searches for effect modifiers were carried out separately in *Paper I, II, and III*, and here the distinction between a confounder and a mediator is hardly relevant. There were, however, no significant interactions between relevant variables in either of the *Papers I-III*. Of that reason no further discussion on effect-modifiers is carried on.

In analyses of factors associated with a given coronary risk factor, PA, in *Paper III*, the other coronary risk factors were included in the analyses as study factors. The rationale for allowing inclusion of risk factors was the exploratory approach of the entire project. Thus, the status of an eligible predictor as a confounder, an isolated causal factor or a mediator was not considered particularly relevant when a risk factor was evaluated as a possible candidate.²⁰⁸

All the factors adjusted for in *Paper I and II* may be considered as putative confounders. Age and gender may influence both risk factors and CR, although these were not significant in crude analyses. It is known that education may influence both CR participation and the risk factors.¹⁰³ Coronary diagnosis might be a possible confounder because the severity of the event may influence the likelihood of being advised to and actual participation in a CR, as well as the patient's perception of the importance of changing lifestyle. The number of previous events may be a confounder and influence both CR participation and the risk factors; in the sense that earlier CR participation may cause non-CR the second time and that recurrent events may result in a more difficult achievement of risk factor control. On the other hand, previous events may also be seen as a collider, a consequence of both non-CR and poor risk factor control. Comorbidity and diabetes may be seen as confounders as they may influence both CR participation and risk factor control.^{36,109} The analysis in *Paper III* may be seen as a predictive model for low PA, and in such models causality is not a typical concern.²⁰⁸

5.2.3 External validity

External validity refers to the generalizability of the study results to subjects outside the study sample; if the results may be extrapolated to all patients with the same disease.^{185,240} The results of this study may, to some extent, be generalised to the Norwegian population of CHD patients after a coronary event, but with caution as already pinpointed during the paragraph on selection bias. In addition, caution is needed when generalising our findings to international populations, since both risk factors and covariates differ between countries and regions.^{38,46,49,82}

5.2.4 Ethical considerations

The Regional Committee of Ethics in Medical Research approved the NOR-COR study. It was considered that study participation would not cause any harm or disadvantages to the patients. Patients with findings that required further medical attention, including high BP, high LDL-C and high blood sugar were recommended to contact their GP's for intensified treatment. The GP's were informed in a separate letter. With BP >180/100 mmHg a study cardiologist intensified BP lowering treatment at the hospital outpatient clinic.

6 Strengths and Limitations

6.1 Strengths

The study is conducted from an unselected CHD population in routine clinical practice. The participation rate was high at 83%. We have some information about the non-participants, since the majority agreed to let us have access to their hospital medical records, although no follow-up information is available for comparison with the participants. The population studied is thought to be broadly representative for the Norwegian population in general. The reproducibility of the self-report questionnaire was highly acceptable for all key items and instruments, while the internal consistency was good for most instruments.

6.2 Limitations

With a cross-sectional design the study factors were measured at one point in time with the possibility of biases based on selective memory and cognitive interpretation. Patients participating in the study are more likely to be those who are more interested in their own health than the non-participants, a bias that may overestimate risk factor control. This design is subject to the risk of reversed causality, since we can establish associations with the major risk factors, but not establish whether each risk factor is an effect or a cause.^{185,188} We are aware of the possible impact of known and potentially unknown confounding factors such as cognitive ability and health-literacy.

In *Paper II*, the analyses of CR in Drammen could not be performed due to incomplete registrations, and this represents an important limitation to this article. The estimate of CR participation in Drammen in the other articles must, for the same reason, be interpreted with caution.

A self-report questionnaire from the HUNT 1 study was chosen to measure PA because of feasibility, though with a risk of bias. Objective monitoring of PA might have been more accurate, but also more complicated to carry out. The questionnaire has previously been validated against direct measurements of VO_{2max} and registration of total activity, but in a younger study population without established CHD than in our study.¹⁹⁶ The validity for PA-index to VO_{2max} and total vigorous activity was acceptable in that study, but poor for registration of low and moderate activity.¹⁹⁶ Patients may overestimate their PA levels in self-report questionnaires due to subjective interpretations or a wish to give socially desirable answers.^{147,196} This may result in weaker associations between PA and the other factors, and the presented associations are likely to be underestimated.

7 Clinical implications and proposals for future research

7.1 Implications for clinical practice

The poor risk factor control found in the present study ought to give rise to implications for clinical practice. The results may partly be due to a low participation rate in CR or to suboptimal quality of the existing CR programmes. Since both referral rate and adherence to exercise-based CR is far from optimal, strategies to increase the proportion of patients referred to, enrolled in and motivated to participate in CR seem essential. Proposals to enhance the referral to, the use of, and the effect of CR have been to refer all eligible patients, to include home-based exercise, and to thoroughly discuss the need for lifestyle changes and medication with patients.²⁴⁴ Providing flexible, coordinated, individualised and menu-based models of CR and PA interventions tailored to the individual patients' needs and the failures of risk factor control may be action points for the future.^{99,245,246} In *Paper II* and *III* we suggested more effective, prolonged, and developed CR programmes, as well as community- or home-based programs in the primary care setting. Such programmes have been found effective, particularly in the control of smoking and physical activity,^{105,232,247,248} but also with neutral or controversial results.²⁴⁹⁻²⁵¹ We observed that CR was very different in the two hospitals in terms of provision, referral, content and participation rate. The Hospital of Drammen has now made specific plans to develop and increase their CR programme to be more comprehensive and multidisciplinary, and in addition they plan new interventions in order to make secondary prevention even more effective and extended into primary care. The Hospital of Vestfold has scrutinised their CR programme to improve the quality, especially concerning management of biological risk factors. Addressing patient factors like depression, low QoL, motivation, illness and risk perception in CR programmes through motivational interviewing, illness and risk information and psychological support may be strategies to increase PA.

In Denmark, the quality of CR may have been increased, at least in hospitals, after the implementation of national guidelines for cardiac rehabilitation.²⁵² In Norway we do not have national guidelines for CR. It seems useful and beneficial to have common standards and directions in order to implement CR of high quality for as many CHD patients as possible. Another tool to improve not only the availability, but also the quality of CR may be a CR register, as established in Denmark some years ago.²⁵³ Organised PA has been included as one of 11 quality indicators of MI treatment in the Swedeheart registry.¹³⁶ Over the last few years an improved risk factor control in Sweden has been observed through the registry, perhaps due to the monitoring of each hospital and active feedback. The Norwegian Society of Cardiology has started promising attempts to improve the quality of secondary prevention by way of questionnaires on smoking habits and QoL linked to the MI registry.¹⁷ The future challenge may be to extend the registry to include data on BP, LDL-C, PA and CR as in Sweden.

Tele-health medicine is rapidly being taken into use and should be considered as a promising tool to improve risk factor control.^{41,254-257} These interventions make use of short-messages or smartphone Apps for lifestyle improvement,^{41,255,258-262} or internet based programmes.¹⁰⁵ A Cochrane review of internet-based interventions, however, concluded that the results are controversial given small sample sizes and limiting heterogeneity.²⁶³

Better discharge routines and information transfer from hospital to primary care are some of our suggestions for future practice. GP's, who conduct more than 90% of all preventive consultations, play a key, but under-studied, role in the continuing care after coronary events.²⁴⁵ We have made a SWOT-analysis (i.e. strengths, weaknesses, options and threats) in cooperation with primary health care and patients to search for deficiencies and shortages in information flow and knowledge.¹⁹¹ These discussions revealed a gap in transition of information, consultancy and knowledge of guidelines, along with a desire for obligatory CR for all coronary patients after an event. We have also re-examined the hospital records to find information about risk factors and risk factor control.¹⁹¹ A review of 200 discharge letters from the NOR-COR participants revealed that lifestyle and risk factor control were hardly mentioned, except for smoking and BP, and a call for action was required. It should not be too difficult to change these deficiencies and make a better description of the patients' risk factor profile in discharge letters with advice on targets or follow-up guidance, along with better collaboration between the different health care providers in order to improve the continuity of care.

The NOR-COR study group has in addition to the present work explored socio-demographic, medical and psychosocial factors associated with persistent smoking,¹⁹⁷ LDL-C,⁷² BP,⁶⁹ diabetes⁷⁸ and CRP.²⁶⁴

7.2 Implications for future research

In the phase Ib of the NOR-COR study, which will be conducted in late 2018 and 2019, the 5-years incidence of subsequent major cardiovascular events will be identified from health registries and hospital records. Moreover, we plan to evaluate the relative importance of CR, coronary risk factors and psychosocial factors for prognosis.

Suggestions for future research may be proof of concept studies to explore if treatment of depression or illness and risk perception may contribute to increase in PA levels, along with intervention studies to test out more comprehensive CR programmes based on the findings from NOR-COR Ia and Ib. These studies may attempt to address all risk factors including titrating of drugs to optimise LDL-C⁷² and BP,⁶⁹ drug adherence (*Paper II*),⁷² smoking (*Paper I, II, and III*),¹⁹⁷ as well as depression, motivation, illness and risk perception (*Paper III*), along with a better transformation of health information to primary care.¹⁹¹

8 Conclusions

Risk factor control in a representative CHD population from routine clinical practice in Norway was far from optimal. The most unfavourable control, including insufficient PA, was found in the patients with previous coronary events. Risk factor control in Norwegian clinical practice is comparable to risk factor control in Europe, even though the latter was mostly recorded in academic centres, and the fact that Norway is a high-income country with a well-developed health system and service.

There were large differences in provision, content, duration and participation rates in the CR programmes in Vestfold and Drammen. Participation in CR Vestfold was associated with smoking cessation, achievement of high drug adherence and optimising LDL-C levels. All risk factors were superior among CR participants compared to non-CR, although not significant for all of them, including PA, in adjusted analyses. Reasons for this may be adjustment of some variables not being confounders, that the implemented CR programme was not good enough, or that the non-CR group was diluted with earlier or external CR participation. More risk factors at target, and even modest risk factor improvements may influence prognosis, morbidity and mortality in the long term. A high CR participation rate may give more patients the possibility of achieving these improvements.

Insufficient PA was prevalent after a coronary event and clustered with other unfavourable risk factors such as smoking, unhealthy diet and obesity, as well as psychosocial factors including depression and low physical QoL. Even a small increase in PA may improve prognosis. Low increase in PA was associated with low motivation, poor perceived risk control, low information sufficiency and a reported need for help to increase PA. Whether more support from healthcare providers and interventions that target patients' depression, motivation (e.g. motivational interviewing) or illness and risk perception may improve PA level should be investigated.

The reproducibility of the comprehensive NOR-COR questionnaire is, overall, good to very good, thus reducing the risk of random error and supporting both future and previous applications.

It is concerning that secondary prevention in a well-developed country like Norway is far from optimal. The findings strongly underscore the need for better management and follow-up care of the established risk factors in clinical practice and novel measures to increase the participation rate and quality of existing CR programmes. Future studies should test the effect of more comprehensive CR programmes with interventions that target both traditional coronary risk factors and patient factors like depression, motivation, illness and risk perception.

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Appendix 1

Paper I-IV

RESEARCH ARTICLE

Open Access



Unfavourable risk factor control after coronary events in routine clinical practice

Elise Sverre^{1*}, Kari Peersen², Einar Husebye¹, Erik Gjertsen¹, Lars Gullestad³, Torbjørn Moum⁴, Jan Erik Otterstad², Toril Dammen⁴ and John Munkhaugen¹

Abstract

Background: Risk factor control after a coronary event in a recent European multi-centre study was inadequate. Patient selection from academic centres and low participation rate, however, may underscore failing risk factor control in routine clinical practice. Improved understanding of the patient factors that influence risk factor control is needed to improve secondary preventive strategies. The objective of the present paper was to determine control of the major risk factors in a coronary population from routine clinical practice, and how risk factor control was influenced by the study factors age, gender, number of coronary events, and time since the index event.

Methods: A cross-sectional study determined risk factor control and its association with study factors in 1127 patients (83% participated) aged 18–80 years with acute myocardial infarction and/or revascularization identified from medical records. Study data were collected from a self-report questionnaire, clinical examination, and blood samples after 2–36 months (median 16) follow-up.

Results: Twenty-one percent were current smokers at follow-up. Of those smoking at the index event 56% continued smoking. Obesity was found in 34%, and 60% were physically inactive. Although 93% were taking blood-pressure lowering agents and statins, 46% were still hypertensive and 57% had LDL cholesterol >1.8 mmol/L at follow-up. Suboptimal control of diabetes was found in 59%. The patients failed on average to control three of the six major risk factors, and patients with >1 coronary events ($p < 0.001$) showed the poorest overall control. A linear increase in smoking ($p < 0.01$) and obesity ($p < 0.05$) with increasing time since the event was observed.

Conclusions: The majority of coronary patients in a representative Norwegian population did not achieve risk factor control, and the poorest overall control was found in patients with several coronary events. New strategies for secondary prevention are clearly needed to improve risk factor control. Even modest advances will provide major health benefits.

Trial registration: Registered at ClinicalTrials.gov (ID NCT02309255).

Keywords: Secondary prevention, Coronary heart disease, Risk factors, Guidelines

Background

Over the recent years, there has been a decline in mortality rates worldwide [1] leaving a large number of coronary heart disease (CHD) patients in need of optimal secondary prevention. A positive trend in acute myocardial event rates and recurrences from 1994–2009 were also found in Norway [2]. The association between modifiable risk factors and CHD is overwhelmingly documented [3], likewise the benefit of achieving risk factor

control to reduce the risk of subsequent events [3, 4]. Despite evidence-based guidelines [5] and cardiac rehabilitation programs for more than 20 years, the EuroAspire studies revealed that the implementation of secondary prevention is far from optimal, with increasing prevalence of smoking in patients <50 years, physical inactivity, obesity and diabetes [6, 7]. In the European cohort of the REACH Study (2003–2004), 40% of symptomatic cardiovascular disease patients had poor control of at least three of the five risk factors assessed [8]. In the Clarify study conducted a decade later, some

* Correspondence: elisbj@vestreviken.no

¹Department of Medicine, Drammen Hospital, 3004 Drammen, Norway
Full list of author information is available at the end of the article



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improvements were found, but even in Europe, the best region, 50% did not achieve risk factor control [9].

Even though the abovementioned studies provide valuable data on the quality of secondary prevention, patient selection could potentially be a matter of concern. In EuroAspire IV [6] patient inclusion was conducted mainly from academic centres, with potentially better secondary prevention than general cardiac practice. Furthermore, the average interview rate was 49%, and the remaining non-participants were probably more likely to have an even poorer risk factor control. In other multinational studies [9–11], patient identification and inclusion has been conducted at outpatient clinics, often specialist centres, and patients attending them may be more concerned about their health. Previous prevalence estimates thus most likely overestimate adherence to guidelines in the general population of CHD patients. Estimates based on studies of everyday clinical practice are clearly needed.

The reasons for unhealthy lifestyle and low risk factor control are complex and poorly understood and the identification of patient and healthcare factors of importance for coronary risk profile remains a public health priority [5]. The overall aim of the The NORwegian CORonary (NOR-COR) Prevention Study is to identify medical, and psychosocial factors associated with unfavourable risk factor control after a cardiovascular event. The present paper determines control of the six major coronary risk factors based in routine clinical practice, and identifies the influence of age, gender, number of coronary events, and time since the index event.

Methods

Design and population

The design, methods, and baseline characteristics of the NOR-COR Study have been described elsewhere [12]. Briefly, 1789 consecutive patients aged 18–80 years with a first or recurrent coronary event defined as acute myocardial infarction, coronary artery by-pass graft operation, or percutaneous coronary intervention (PCI) were identified from hospital discharge lists from 2011–14. In patients with recurrent coronary events, the index event was defined as the last event recorded prior to the time of study inclusion. Of these patients, 423 were excluded due to cognitive impairment ($n = 28$), psychosis ($n = 18$), drug abuse ($n = 10$), short life expectancy ($n = 136$), dead ($n = 160$), not able to understand Norwegian ($n = 44$), and other ($n = 27$). Of the remaining 1366 invited patients, 1127 (83%) participated in attending a clinical visit and completing a comprehensive questionnaire [12] after 2–36 months (median 16) follow-up. The frequency of missing values for the questionnaire based data was low, within the range from 0–10%.

The study was conducted at two Norwegian hospitals (Drammen and Vestfold) with a total catchment of 380,000 inhabitants corresponding to 7.4% of the Norwegian population. The catchment area has a representative blend of city and rural districts and is representative of Norwegian geography, economy, age distribution, morbidity, and mortality [13]. The cardiac rehabilitation program at Drammen Hospital includes a multi-disciplinary one day “heart school”, and exercise training twice per week for 6 weeks. The Hospital of Vestfold provides comprehensive lifestyle intervention described elsewhere [14].

Ethics, consent and permission

The study was approved by the Regional Committee of Ethics in Medical Research. All patients signed a written informed consent prior to study participation.

Study assessments

Medication and co-morbidity at the index event were registered from the hospital medical records. Cardiovascular medication, risk factors and study factors at follow-up were obtained from the self-report questionnaire, the clinical examination and blood-samples. All blood samples were analysed at Drammen hospital. Diet was assessed by a brief diet questionnaire including seven selected quantitative questions (the frequency of intake of different types of foods and beverages). These questions have been validated against intake of matching food groups [15]. Time since the index coronary event was calculated from index event to the date of study inclusion. Low education was defined by completion of primary- and secondary school only.

Major coronary risk factors

- *Smoking*: categorized as current, former or never.
- *Overweight and obesity*: Body weight was measured in light clothes without shoes (SECA 813, DE). Height was measured using a wall fixed mechanical measuring rod (SECA 264, DE). Overweight and obesity was defined as body mass index (BMI) $>25 \text{ kg/m}^2$ and $>30 \text{ kg/m}^2$, respectively. Waist circumference was measured with a non-stretchable tape (SECA 201, DE). A waist circumference above 94 cm and 102 cm in men and above 80 cm and 88 cm in women was defined as central overweight and obesity, respectively.
- *Physical activity*: assessed by frequency (never, <1 time weekly, 1 time weekly, 2–3 times weekly and almost every day), intensity (light, medium and vigorous), and duration (<15 min, 15–29 min, 30–60 min and >60 min). Low physical activity was defined

as less than moderate activity level for 30 min of 2-3 times a week.

- **Blood Pressure (BP) control:** BP was measured after standard procedures using a Welch Allyn digital sphygmomanometer. Unfavourable BP control was defined as BP > 140/90 mmHg (>140/80 mmHg in diabetics).
- **Blood-sugar control:** assessed by HbA1c analysed - Tosoh G8, Ca, US. Unfavourable blood sugar control was defined as HbA1c \geq 6.1% (non-diabetics) and >7.0% (diabetics) [5].
- **Low density lipoprotein (LDL) cholesterol:** analysed - Architect ci16200, Ca, US. Elevated LDL cholesterol was defined > 1.8 mmol/l [5].

Statistics

Statistical analyses have been performed using SPSS version 21. Parametric descriptive statistics were applied. Binary logistic regression analysis was used to calculate odds ratios (ORs) for unfavourable risk factor control and adjusted for age, gender, number of coronary events, and time since the index event.

General Linear Model (ANCOVA) was used to estimate marginal means for number of unfavourable risk factors (smoking, BMI, physical inactivity, BP, LDL cholesterol, and HbA1c) by age, gender and number of coronary events with all independents controlled as dummies simultaneously, and with time since event entered as a linear covariate.

Results

Baseline characteristics are presented in Table 1. Myocardial infarction and stable CHD was the index event in 80% and 20% of the patients, respectively. Angiography was performed in all patients but one, and 90% were revascularized. Patients with >1 coronary event amounted to 30% with a median number of events of 2 (range 2-11). In this group, the proportion of patients with diabetes was more than twice that seen among those with one event only (28% vs. 12%, $p < 0.001$).

The prescription rate of recommended preventive drugs [5] was high at discharge. All the patients treated with PCI were prescribed dual anti-platelet treatment. At follow-up, there was a small reduction in the use of beta-blockers (from 85 to 72%) and angiotensin converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) (from 56 to 50%), while the proportions that used at least one statin (93%) and anti-platelet agent (97%) were almost identical. At the time of follow-up, 50% of the patients had attended cardiac rehabilitation.

The proportion of unfavourable risk factors at follow-up was high (Fig. 1). Of those who smoked at baseline, 56% continued to do so. The majority of patients (84%)

Table 1 Characteristics of the patients ($n = 1127$) at the time of the index coronary event

Mean age at index event (Standard Deviation)	61.6 (9.6)
Women (%)	21
Smoking (%)	35
Diagnoses	
ST-elevation infarction (%)	30
Non ST-elevation infarction (%)	50
Stable or unstable angina (%)	20
More than 1 coronary event (%)	30
Angiographic findings	
No significant stenoses (%)	6
Singel vessel disease (%)	55
Multi-vessels disease (%)	39
Intervention	
PCI ^a with stent (%)	75
PCI ^a without stent (%)	2
Coronary artery bypass graft operation (%)	13
No intervention (%)	10
Previous or ongoing participation in cardiac rehabilitation (%)	50
Co-morbidity	
Hypertension (%)	43
Diabetes type I or II (%)	17
Heart failure (%)	13
Atrial fibrillation (%)	9
Stroke or transitory ischemic attack (%)	7
Peripheral artery disease (%)	9
Medication at discharge after the index event	
Aspirin (%)	99
Other antiplatelets (%)	88
Statins (%)	96
Beta blockers (%)	85
ACE inhibitors or ARB ^b (%)	56
Calcium channel blockers (%)	16
Diuretics (%)	22
Antidiabetic (%)	11
Insulin (%)	4
Warfarin or NOAC ^c (%)	7

All information was obtained from the hospital medical records

^aPercutaneous coronary intervention, ^bACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker. ^cNOAC, new oral anticoagulants

had an increased waist circumference, and 60% had central obesity. Ninety-three per cent of the patients used at least one BP lowering drug at discharge after the index event (Table 1), and the same percentage reported use of statin at follow-up. However, the frequency of elevated BP and LDL cholesterol at follow-up were still high. Of the diabetic patients 59% had HbA1c >7% although 79%

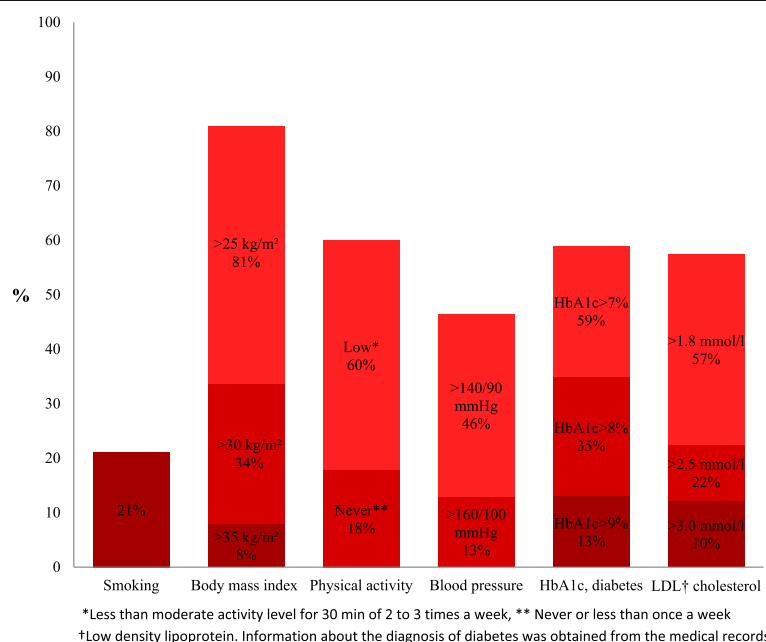


Fig. 1 Proportion of coronary risk factors 2-36 months after the index coronary event

used blood sugar lowering medication. In patients without known diabetes, 21% had an HbA1c value $\geq 6.1\%$ and of these patients 8% had HbA1c $\geq 6.5\%$ indicating diabetes [16]. The proportion that reported to eat fish less than 3 times a week was 46%, while 62% ate fruits or vegetables less than two times daily, and 40% less than once daily.

Current smoking (25% vs. 12%, $p < 0.001$) and physical inactivity (64% vs 34%, $p < 0.001$) were significantly more frequent in patients with low vs. high education, while overweight, unfavorably blood pressure, blood glucose and LDL cholesterol control were not.

The estimated marginal means for number of unfavourable risk factors [5] by gender, age and number of coronary events are shown in Fig. 2. On average, the patients had three of the six measured risk factors not at target according to guideline recommendations [5]. Less than 2% achieved control for all risk factors, while 62% had three or more unfavourable risk factors. Patients with more than one coronary event (β 0.43, $p < 0.001$) had the poorest overall risk factor control.

Multi-adjusted odds ratios (OR) for unfavourable coronary risk factors at follow-up by age, gender, number of coronary events, and time since the index event are shown in Additional file 1. Current smoking ($p < 0.001$), obesity ($p < 0.001$) and elevated HbA1c ($p < 0.01$) were significantly more frequent in the younger patients, while inadequate BP control ($p < 0.001$) was more frequent with increasing age. ORs for current smoking, low physical activity, and LDL > 1.8 mmol/l were significantly higher in women compared to men. ORs for low

physical activity, obesity, and elevated LDL cholesterol were significantly higher in patients with several coronary events. There were no significant differences in ORs between the four time groups since the index event, but for smoking ($p < 0.01$) and obesity ($p < 0.05$) the test for linear trend was statistically significant with reduction in risk factor control with increasing time since the event.

Discussion

Of the CHD patients included from a high income country with a well-developed health care system [17], the majority had a poor risk factor control and thus did not achieve adequate secondary prevention. There were high proportions of current smoking, obesity and physical inactivity. Blood pressure, cholesterol and blood sugar control were inadequate despite the high reported use of medications. Only a minority of patients ($< 2\%$) fulfilled the guidelines recommendations [5] for all coronary risk factors, and more than half of them had inadequate control of three or more risk factors. The measured study factors influenced risk factor control with the poorest overall lifestyle control in the youngest patients. Patients with several previous CHD events had the poorest overall coronary risk factor control. There was a higher prevalence of smoking and obesity with increasing time since the coronary event.

There are certain limitations of the study. First, the coronary risk factors and study factors were measured at one point in time and thus are prone to measurement and recall bias. Moreover, diet is calculated by a semi-quantitative measure, only. Our questions about physical activity have

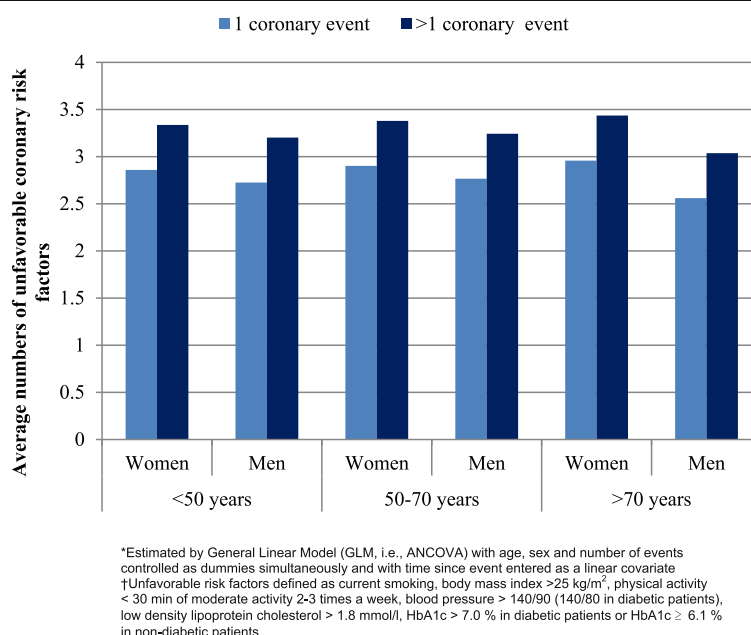


Fig. 2 Estimated marginal means* of number of coronary risk factor†

been validated [18], and we have chosen cut off values as close as possible to guidelines recommendations. Information about the number and the different types of antiplatelet agents at follow-up is not available. The routine clinical setting and the high participation rate (83%) are important strengths of the study. The time span from the index event to follow-up was 2-36 months allowing us to assess how time influences risk factor control. This might impose a selection bias by survival effect. The contribution of excluded patients due to death and short life expectancy is, however, quite similar among the groups with an index event within one year (33%), two years (34%), and three years (33%), respectively, prior to inclusion. Thus, the risk for bias by survival should be minor.

The latest EuroAspire Study [6] had similar inclusion criteria and age distribution as the NOR-COR Study, and in comparison they found a higher proportion of LDL cholesterol >1.8 mmol/l (81% vs. 57%) and diabetes (27% vs. 17%), but fewer diabetic patients had HbA1c >7% (48% vs. 59%). Low physical activity was defined differently, but both studies showed that low physical activity was predominant (60% vs. 60%). The frequencies of hypertension (43% vs. 46%), obesity (38% vs. 34%), and central obesity (58% vs. 60%) were quite similar. The proportion of current smoking was significantly higher (21%) in our CHD population compared to both EuroAspire IV [6] (16%), and other international studies [9–11, 19] (12–18%). Statistics from OECD indicate a lower prevalence in Norway versus average EU regarding smoking (19% vs. 23% [average EU]) [20]

and obesity (10% vs. 18% [OECD average]) [21]. It is therefore a paradox that a higher rate of smoking was found among CHD patients in Norway compared to Europe, while the rate of obesity was quite similar. This paradox can be explained by the aforementioned risk of selection bias [6, 7] and by the contribution of non-responders. In the present study with high participation rate from routine clinical practice, these factors are to a higher degree accounted for. There is an ample risk that previous studies [6, 7] have underestimated the prevalence of smoking and obesity in CHD patients.

We found a higher use of anti-platelets (97% vs. 94%), and statins (93% vs. 86%), but lower use of beta-blockers (72% vs. 83%) and ACEI/ARBs (50% vs. 75%) compared with EuroAspire IV [6]. However, there were significant differences in the use of these drugs in various European countries [6].

Large studies from different regions worldwide have also demonstrated that 30–80% of CHD patients had diabetes, were obese, and had LDL cholesterol and BP above the recommended targets [9–11]. In the REACH Registry, one-year risk of subsequent cardiovascular events was inversely related to risk factor control [22], emphasizing the importance of reaching these treatment goals.

The reasons for the low adherence to secondary prevention are complex and multi-factorial [5, 23]. Low socioeconomic status is known to affect both risk factor control and the course of CHD negatively [24, 25], and we confirmed the well-known association between low

education and unfavourable lifestyle. Psychosocial factors such as anxiety, depression, type-d personality and lack of social support may affect both etiological factors, lifestyle and adherence, and are associated with adverse outcomes in CHD patients [26]. Furthermore many revascularized patients have no symptoms. In a recent post PCI study, many patients perceived that they were cured from their CHD [27]. Few reported lifestyle-style factors as being causal, and almost 40% perceived no need for lifestyle changes. Patients' understanding of CHD and CHD risk factors have been shown to be insufficient [28]. Furthermore, many patients attribute their disease to factors they cannot influence [27] like age and family history, that may partly explain lack of motivation to change lifestyle and adhere to their medical regimen. Despite overwhelming documentation of the benefits of secondary preventive drug [5], a meta-analysis revealed that only 60% of CHD patients had good adherence to cardiovascular medication [29]. Poor adherence with medication may in part explain why many patients do not reach treatment targets for BP, cholesterol and blood sugar. When the vast majority of patients were prescribed cholesterol and BP lowering drugs, and only 40-55% reached treatment targets, it is possible that the drugs chosen were not the optimal, the dosages applied were too low, the patients were not compliant or a combination. The clinical significance of long-term dual anti-platelet therapy after coronary stent procedures was recently documented in CHD [30], reflecting the need for improved secondary prevention programs that also address drug-adherence reliability and over time (>12 months).

The youngest patients had the highest proportion of unfavourable lifestyle factors, and this might have contributed to an early onset of CHD. The positive trend in acute myocardial infarction event rates and recurrences from 1994-2009 in Norway were mostly seen among patients older than 65 years, whereas less favourable trends were observed among younger patients, in particular women [2]. This is concerning, and may be due to the particular poor risk factor control in this sub-group as demonstrated in the present study. Correspondingly, the poor risk factor control in patients with more than one coronary event might be why they suffer repeated events. It is concerning that the success of secondary prevention in these high-risk patients is that poor. The effect of lifestyle intervention programs on risk factor control and subsequent events is well documented [14, 31]. In the present study, only half of the patients attended the available programs. The participation rates in cardiac rehabilitation programs range between 30-60% in Europe, lowest among the oldest patients, and those with co-morbidity [7, 32]. Underutilization of effective preventive programs or

implementation of programs that do not result in adherence in routine clinical practice, may contribute to poor risk factor control. The higher proportion of current smokers and obese patients with increasing time since the coronary event underline the need for more long-lasting secondary preventive programs [33].

Medical and psychosocial factors may act as barriers to lifestyle changes, treatment adherence and may moderate the effects of cardiac rehabilitation [26]. The predictors of good adherence to risk factor control are likely to differ by patient characteristics and risk factors, indicating a need for more tailored interventions [34]. Accordingly, we found different impact of age, gender, education, time since the event, and the number of events on the major risk factors. In the further studies, we aim to explore the relative importance of a number of potentially modifiable factors on risk factor control [12].

Conclusion

The majority of CHD patients from a routine clinical practice in a representative Norwegian population did not achieve control of the major coronary risk factors. The measured non-modifiable study factors had different impact on the risk factors, and the poorest overall control was found in patients with several coronary events. It is concerning that secondary prevention of CHD fails in a country with a well-developed health care system. Further knowledge about factors associated with poor risk factor control and strategies for implementation of these factors are strongly needed to improve secondary prevention. Even modest advances will provide major health benefits.

Additional file

Additional file 1: Multi-adjusted odds ratio for unfavourable coronary risk factors 2-36 months after the index coronary event. (DOCX 16 kb)

Abbreviations

ACE: Angiotensin converting enzyme; ARB: Angiotensin receptor blocker; BMI: Body mass index; BP: Blood pressure; CHD: Coronary heart disease; CI: Confidence interval; LDL: Low density lipoprotein; NOAC: New oral anticoagulant; OR: Odds ratio; PCI: Percutaneous coronary intervention

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Availability of data and materials

According to Norwegian legislation, the Norwegian Data Protection Authority, and the Committee of Ethics, we are not allowed to share original study data publicly. However, except for anthropometric data, the other

essential data in which the conclusions in the article are based on will be provided upon request.

Authors' contributions

ES performed the statistical analyses and was responsible for interpretation of data. Furthermore, she drafted the manuscript. KP helped with data interpretation and helped to draft the manuscript. EH participated in the design of the study, helped with interpretation of data, and helped to draft the manuscript. EG participated in the design of the study, helped with interpretation of data, and helped to draft the manuscript. LG participated in the design of the study, helped with interpretation of data, and helped to draft the manuscript. TM helped to perform the statistical analyses, helped with interpretation of data, and helped to draft the manuscript. JEO participated in the design of the study, helped with interpretation of data, and helped to draft the manuscript. TD participated in the design of the study, helped with interpretation of data, and helped to draft the manuscript. JM participated in the design of the study, helped to perform the statistical analyses, helped with interpretation of data, and helped to draft the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

All participants gave informed consent before study participation. The NOR-COR study was approved by the Regional Committee of Ethics (REK Sør-Øst) 12. February, 2014 (2013/1885).

Author details

¹Department of Medicine, Drammen Hospital, 3004 Drammen, Norway.

²Department of Medicine, Vestfold Hospital, Tonsberg, Norway. ³Department of Cardiology, Oslo University Hospital Rikshospitalet, Medical Faculty, University of Oslo, Oslo, Norway. ⁴Department of Behavioural Sciences in Medicine, University of Oslo, Oslo, Norway.

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Additional file 1: Multi-adjusted odds ratio for unfavourable coronary risk factors 2-36 months after the index coronary event

	Current smoking (n=230)		Body Mass Index >30 kg/m ² (n=340)		Low physical activity** (n=665)		Blood Pressure† >140/90 mmHg (n=470)		HbA1c†† >7.0% (n=108)		LDL cholesterol††† >1,8 mmol/l (n=628)	
	%	OR (CI)*	%	OR (CI)*	%	OR (CI)*	%	OR (CI)*	%	OR (CI)*	%	OR (CI)*
Age												
< 50 years (n=151)	26	1.00	47	1.00	55	1.00	31	1.00	76	1.00	61	1.00
50-69 years (n=730)	23	0.82 (0.54- 1.24)	34	0.56 (0.38- 0.82)	58	1.06 (0.74- 1.51)	48	1.99 (1.33- 2.99)	59	0.36 (0.13- 1.01)	58	0.82 (0.56- 1.18)
≥ 70 years (n=246)	14	0.44 (0.26- 0.75)	23	0.32 (0.20- 0.52)	70	1.72 (1.11- 2.65)	53	2.43 (1.53- 3.89)	51	0.29 (0.09- 0.93)	54	0.66 (0.43- 1.02)
Gender												
Women (n=237)	25	1.00	36	1.00	69	1.00	41	1.00	51	1.00	66	1.00
Men (n=890)	20	0.68 (0.48- 0.97)	33	0.80 (0.58- 1.11)	58	0.60 (0.44- 0.82)	48	1.29 (0.95- 1.77)	62	1.91 (0.91- 4.01)	55	0.57 (0.42- 0.78)
Time since the index event												
2-6 months (n=233)	19	1.00 ⁺	29	1.00 ⁺	61	1.00	48	1.00	59	1.00	53	1.00
6-12 months (n=242)	18	0.91 (0.56- 1.46)	32	1.20 (0.79- 1.81)	58	0.81 (0.56- 1.19)	48	0.98 (0.67- 1.44)	61	1.05 (0.40- 2.78)	58	1.22 (0.84- 1.77)
12-24 months (n=347)	21	1.12 (0.73- 1.72)	34	1.37 (0.93- 2.00)	60	0.96 (0.67- 1.36)	48	0.99 (0.69- 1.41)	65	1.35 (0.55- 3.29)	61	1.44 (1.02- 2.03)
24-36 months (n=305)	26	1.48 (0.97- 2.28)	37	1.46 (0.99- 2.16)	60	1.03 (0.72- 1.48)	42	0.80 (0.55- 1.16)	52	0.69 (0.27- 1.75)	57	1.23 (0.86- 1.75)
Numbers of coronary events												
1 event (n=790)	20	1.00	32	1.00	56	1.00	44	1.00	62	1.00	55	1.00
> 1 event (n=337)	23	1.36 (0.99- 1.87)	37	1.34 (1.01- 1.80)	69	1.77 (1.34- 2.34)	52	1.31 (1.00- 1.73)	57	0.75 (0.40- 1.42)	64	1.58 (1.20- 2.08)

*CI=95% confidence interval, **Less than 30 minutes of moderate activity 2-3 times a week, †Blood pressure > 140/90 (140/80 in diabetic patients), †† in diabetic patients, †††LDL, low density lipoprotein cholesterol, *Significant linear test for trend in current smoking and BMI <30 kg/m², respectively, using time since the coronary event as continuous variable. All estimates are adjusted for age, gender, time since the index event and number of coronary event.

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ORIGINAL ARTICLE

Reproducibility of an extensive self-report questionnaire used in secondary coronary prevention

KARI PEERSEN^{1,2}, JOHN MUNKHAUGEN^{3,4}, LARS GULLESTAD^{2,5},
TORIL DAMMEN⁴, TORBJORN MOUM⁴ & JAN ERIK OTTERSTAD¹

¹Department of Medicine, Hospital of Vestfold, Norway, ²Faculty of Medicine, University of Oslo, Norway, ³Department of Medicine, Drammen Hospital, Norway, ⁴Department of Behavioural Sciences in Medicine, Faculty of Medicine, University of Oslo, Norway, and ⁵Department of Cardiology, Oslo University Hospital, Norway

Abstract

Aims: Self-reported information from questionnaires is frequently used in clinical epidemiological studies, but few provide information on the reproducibility of instruments applied in secondary coronary prevention studies. This study aims to assess the test–retest reproducibility of the questionnaire applied in the cross-sectional NORwegian CORonary (NOR-COR) Prevention Study. **Methods:** In the NOR-COR study 1127 coronary heart disease (CHD) patients completed a self-report questionnaire consisting of 249 questions, of which there are both validated instruments and de novo questions. Test–retest reliability of the instrument was estimated after four weeks in 99 consecutive coronary patients. Intraclass Correlation Coefficient (ICC) and Kappa (κ) were calculated. **Results:** The mean interval between test and retest was 33 (± 6.4) days. Reproducibility values for questions in the first part of the questionnaire did not differ from those in the latter. A good to very good reproducibility was found for lifestyle factors (smoking: $\kappa = 1.0$; exercise: ICC = 0.90), medical factors (drug adherence: ICC = 0.74; sleep apnoea: ICC = 0.87), and psychosocial factors (anxiety and depression: ICC = 0.95; quality of life 12-Item Short-Form Health Survey (SF12): ICC = 0.89), as well as for the majority of de-novo-created variables covering the patient's perceptions, motivation, needs, and preferences. **Conclusions:** The present questionnaire demonstrates a highly acceptable reproducibility for all key items and instruments. It thus emerges as a valuable tool for evaluating patient factors associated with coronary risk factor control in CHD patients.

Key Words: Secondary prevention, coronary heart disease, questionnaires, reproducibility, coronary risk factors

Introduction

As a result of the contemporary management of coronary heart disease (CHD), an increasing proportion of patients survive and require optimal secondary prevention [1]. A high prevalence of unhealthy lifestyle and poor risk factor control in CHD patients was demonstrated in a large European multicentre study [2]. The reasons for these findings are complex and somewhat poorly understood, and the identification of optimal patient management and healthcare factors of importance for an improved coronary risk profile remains a public health priority [3]. The aims

of an ongoing cross-sectional study, the NORwegian CORonary (NOR-COR) Prevention Study [4], are to identify medical and psychosocial factors associated with unfavourable risk factor control after a coronary event. Most of the data to be explored has been collected through a comprehensive self-report questionnaire.

Self-report questionnaires are frequently used in health research because they are easy to utilize, feasible, and cheap to apply. In order to ensure reproducibility and reliability, a test–retest study is of great

Correspondence: Kari Peersen, Department of Medicine, Hospital of Vestfold, 3103 Tønsberg, Norway.
Email: kari.peersen@siv.no

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importance. The reliability of such a test is assessed by measuring the responses of the same study sample to an identical questionnaire at two or more points in time. A reproducibility test will assess random measurement errors as well as the stability of the construct measured, but cannot in itself distinguish between the two [5]. Thus, one must take into consideration that any real change in the phenomenon of interest that may have occurred during the intervening period between tests will result in seemingly low levels of reliability.

There are no standards for the ideal time span between the initial test and the retest in reproducibility studies. The interval should be long enough to prevent memory effects and short enough to ensure that no real clinical change has occurred among participants [6]. Intervals of one to two weeks [7] and one month [8] have been suggested.

Self-reported information from questionnaires is frequently used in clinical epidemiological studies, but few provide information on the reproducibility of instruments applied in secondary coronary prevention studies. Those available are limited by only addressing single questionnaires with a moderate range of items. So far, few studies have explored whether reproducibility remains satisfactory in a comprehensive questionnaire applied in clinical patient studies. The purpose of this study was to evaluate the test-retest reliability of an extensive self-report questionnaire assembled and created to be used in the NOR-COR study [4]. Given acceptable reproducibility results, such a questionnaire could be valuable in future studies on risk factor control and lifestyle measures in long-term secondary coronary prevention.

Materials and methods

A complete description of the design and methodology applied in the NOR-COR study is published elsewhere [4]. In the present study, the self-report questionnaire used in NOR-COR was completed twice by 99 stable patients with an interval of four weeks.

Design of the NOR-COR questionnaire

The NOR-COR questionnaire contains 249 questions derived from a number of medical and psychosocial instruments that have previously, to some extent, been demonstrated to be associated with coronary risk factors, adherence to medication, and prognosis in cardiac patients [9–15]. As there were no validated instruments for revealing the patient's needs and preferences, a number of questions/items were created de novo following an extensive process

[16], described in detail previously [4]. The NOR-COR questionnaire was pilot-tested in two CHD patients in order to incorporate the patients' perspective, and subsequently tested in 20 randomly selected eligible CHD patients in order to establish relevance, acceptance, and feasibility.

The following descriptive variables have been obtained from the questionnaire:

- *Socio-demographic factors:*
 - Marital status;
 - Level of education.
- *Behaviour/lifestyle risk factors:*
 - Smoking status (never, previous, or current smoking);
 - Physical activity (frequency, duration, intensity, and a sum-score) [17];
 - Diet (the frequency of intake of fish, vegetables, and fruits);
 - Alcohol consumption (the past four weeks).
- *Medical factors:*
 - Drug adherence (the 8-item Morisky Medication Adherence Scale) [18];
 - Obstructive sleep apnoea (Berlin Questionnaire) [19].
- *Psychosocial factors*
 - Quality of life (12-Item Short-Form Health Survey (SF12)): a 12-item measure of generic quality of life with a physical health sub-scale Physical Component Summary (PCS12) and mental health sub-scale Mental Component Summary (MCS12) [20];
 - Anxiety and depression (Hospital Anxiety and Depression Scale, HADS) [21];
 - Rumination (Ruminative Response Scale, RRS): a 22-item self-report inventory designed to assess the tendency to ruminate in response to a depressed mood [15];
 - Worry (Penn State Worry Questionnaire, PSWQ): a 16-item measure of pathological worry [22];
 - Type D personality (distressed personality type, Type D Scale, DS-14): a 14-item instrument with seven items each on the sub-scales of negative affectivity (NA) and social inhibition (SI) [23];
 - Illness perception (Brief Illness Perception Questionnaire, BIPQ): an 8-item measure of illness identity, personal and treatment ability to control the illness, consequences, understanding and concern about the illness rated on a Likert scale from 0 to 10, and one item about what caused the patient's illness [24];
 - Perceived risk perception (PRP): a 3-item measure on a Likert scale from 0 to 10; probability for a new event within 12 months,

- your own ability to reduce coronary risk, and to what degree the disease will limit your activities [13];
- Insomnia (Bergen Insomnia Scale): a 7-item measure of on an 11-point Likert scale from 0 to 10 [25].
- *Treatment desires, perceived needs, beliefs about causes, motivation (de-novo-created questions)*
 - Beliefs regarding what caused the patient's CHD, ranking known CHD risk factors from 0 to 10 on a Likert scale indicating to what extent the patient believed that each risk factor had caused the disease to develop;
 - Motivation for further lifestyle changes and changes already achieved in these lifestyle factors;
 - Perceived needs of sufficient health information about CHD and the risk factors;
 - Participation in healthcare follow-up (cardiac rehabilitation, follow-up visits in primary healthcare);
 - Perception of the information provided by healthcare workers [16] with four assertions: I am cured, but have to change my lifestyle; I am cured and do not need to change my lifestyle; I still have heart disease and need to change my lifestyle; and I still have heart disease, but do not need to change my lifestyle;
 - Perceived needs for further secondary preventive follow-up today in order to meet the goal of prevention (email/telephone, nurse, cardiac rehabilitation, physiotherapist, nutritionist, psychiatrist/psychologist, Internet, and/or mobile app).

Study population

A total of 1127 (83% participation rate) patients aged 31–80 (mean 62) with first or recurrent diagnosis or treatment for CHD (acute myocardial infarction, coronary artery bypass graft operation, and/or elective or emergency Percutaneous Coronary Intervention (PCI)) within the time period from eight weeks to three years previously, participated in the NOR-COR study, and completed the questionnaire. The study was conducted at two Norwegian hospitals, Drammen and Vestfold. Initially, 28 of the participants recruited from Vestfold Hospital completed the NOR-COR questionnaire a second time after four weeks. It was decided to increase the number of participants to approximately 100 in order to obtain sufficient statistical power in this reproducibility study. Accordingly, 71 consecutive patients referred to cardiac rehabilitation in Vestfold Hospital performed an identical retest, with inclusion criteria

identical to those in the NOR-COR study [3]. The participants in this reproducibility study were considered as having been stable with respect to their CHD, and none had been re-hospitalized during the interval between test and retest. The same observer conducted all tests and retests, and was very alert for possible changes in the patients' physical or psychological condition that might affect retest results. In order to evaluate possible group differences, patient characteristics in the reproducibility sample and the entire NOR-COR population were compared.

Statistics

Descriptive data are presented as means \pm standard deviations (SDs), while reproducibility results are presented with 95% confidence intervals (CIs). Differences between the reproducibility sample and the NOR-COR population regarding age, sex, education, and type of event were assessed with independent two-sample *t*-tests and chi-square tests. Test-retest reliability was calculated by comparing the data obtained at test sessions 1 and 2 using Intraclass Correlation Coefficients (ICCs) for continuous data and for ordinal variables with at least five response categories [5], and Kappa (κ) for nominal and ordinal variables [26] for each individual question in the NOR-COR questionnaire, as well as for summarized scores when available, such as for exercise, drug adherence, sleep apnoea, and the psychosocial questionnaires. ICC was calculated based on a two-way mixed-effect analysis of variance with 95% CIs. An acceptable reproducibility was set at the often-recommended level of ICC ≥ 0.70 and κ values were defined as acceptable if above 0.5. The guidelines for interpreting κ with strength of agreement based on Landis and Koch [26] suggest that values are fair between 0.21 and 0.4, moderate between 0.41 and 0.6, good between 0.61 and 0.8, and very good above 0.81. These guidelines for κ agreement will also be applied to continuous data using ICC. Internal consistency was calculated with standardized Cronbach's alpha for each set of items or scales. Analyses of covariance were used to examine potential differentials in reproducibility across age, gender, or education. Statistical analyses were conducted with the SPSS version 21 (SPSS Inc., US). The significance level was set at $p < 0.05$.

Ethics

This study was approved by the Regional Committee of Ethics in Medical Research, approval number 2013/1885. Written informed consent was obtained

from all included participants. The study is registered at www.clinicaltrials.gov (ID NCT02309255).

Results

A total of 99 patients completed the retest within an interval of 33 (± 6.4) days. One patient who broke his leg and a woman who lost her son within the interval between tests were excluded from the reproducibility study. The mean time interval between index hospitalization and first-time completion of the questionnaire was 34 weeks (range 8–83). The amount of missing data was 1.1% in the first test session and 3.0% in the retest, at the same level throughout the questionnaire. Participant feedback revealed that the time used to fill out the questionnaire was 30 to 45 minutes. Reproducibility figures obtained from the first part of the questionnaire did not differ from those of the last part.

There were no significant differences between patient characteristics among the NOR-COR population and the reproducibility study sample (Table I). The reproducibility values were very good for exercise and smoking (Table II), good for the use of alcohol, and moderate for diet. The reproducibility coefficients for drug adherence were acceptable, and very good for obstructive sleep apnoea.

The test–retest reliability calculations of the psychosocial factors presented in Table III show good reproducibility for quality of life (PCS12) and very good for all other psychosocial instruments. The majority of the questions covering the patient's perceptions, needs, preferences, and motivation were above the limits for acceptable reproducibility (Table IV). The participants were asked about their preferences for follow-up to meet their present needs of optimal prevention. The reproducibility level for these replies was fair to good.

Fair internal consistency was found for sleep apnoea Berlin Category 1 sum (Cronbach's $\alpha = 0.45$ in test 1 and 0.35 in retest); however, the values improved to good (Cronbach's $\alpha = 0.68$ in test 1 and 0.66 in retest) if item 4 ("does your snoring bother others") was deleted from computation. Moderate internal consistency was found for the 8-item Morisky Medication Adherence Scale (Cronbach's $\alpha = 0.54$ in both tests) and SF12 (Cronbach's $\alpha = 0.65$ in test 1, 0.61 in retest). All other scales showed good to very good internal consistency and Cronbach's α ranged from 0.69 to 0.95, with slightly higher values in the second test.

Significant differences in the level of reproducibility across gender, age, or education level were found in a small proportion of the variables; however, there was no consistency regarding which subgroup showed the highest level of reproducibility.

Table I. Demographic and medical characteristics of the NOR-COR sample and the reproducibility sample.

	NOR-COR <i>n</i> = 1127	Reproducibility <i>n</i> = 99	<i>p</i> -value
Age, mean (SD)	61.6 (9.6)	63.2 (8.8)	ns
Female gender, %	21	17	ns
Living alone, %	26	24	ns
Low education,^a %	62	55	ns
Coronary diagnosis			ns
Non-ST elevation MI, <i>n</i> %	561 (50)	44 (44)	ns
ST elevation MI, <i>n</i> %	335 (30)	38 (38)	ns
Stable/unstable CHD, <i>n</i> %	231 (21)	17 (17)	ns

NOR-COR: NORwegian CORonary Prevention Study; *n*: sample size; SD: standard deviation; ns: non-significant; MI: myocardial infarction; CHD: coronary heart disease; ST: ST-segment.

^aLow education was defined as completion of primary or secondary school only.

Discussion

The present study analysed the reproducibility of the questionnaire applied in the NOR-COR study. Our findings demonstrated acceptable to excellent values for almost all of the variables explored. This level of reproducibility in data from the NOR-COR questionnaire will be valuable in performing further analyses, findings, and, indeed, conclusions of the project.

There were few missing data in both tests, and the reproducibility remained high throughout the rather extensive questionnaire. The test–retest sample had similar patient characteristics to those of the total NOR-COR population. Information obtained by self-report questionnaires may be distorted by systematic errors such as the patient giving socially desirable answers, using scales and response options in idiosyncratic ways, as well as recall bias. Systematic errors and biases are hard to assess and control, and would in fact tend to boost test–retest correlations. On the other hand, poor or oscillating understanding of the underlying meaning of a question, being distracted or confused, or responding based on current mood will introduce random error or noise in measurements, thereby reducing statistical associations of substantive interest, as well as test–retest correlations. Test–retest correlations allow for estimates of random measurement errors to be established, given that the underlying construct is stable [5]. Thus, acceptable intra-individual reproducibility is reassuring in the sense that one has apparently minimized the risk of committing type II errors because of random error or noise. Conversely, reliability estimates typically based on internal consistency within a set of items tend to be boosted by systematic errors such as response scale effects and thus may yield misleadingly favourable results [27].

Table II. Test–retest reliability of lifestyle risk factors and medical factors.

	Test 1 Mean (SD)	Test 2 Mean (SD)	ICC, 95% CI	κ, 95% CI
Exercise				
Frequency, times per week	3.0 (1.5)	2.9 (1.4)	0.85 (0.78–0.90)	
Exercise sum score ^a	9.2 (1.2)	9.0 (1.1)	0.90 (0.85–0.94)	
Smoking				
Current smoking, <i>n</i> (%)	15 (15)	15 (15)		1.0
Previous smoking, <i>n</i> (%)	66 (67)	69 (70)		0.94 (0.87–1.02)
Never smoked, <i>n</i> (%)	28 (28)	25 (25)		0.87 (0.76–0.98)
Diet				
Fish >3 times/week, <i>n</i> (%)	51 (53)	53 (55)		0.49 (0.32–0.66)
Fruit/veg ≥ 2 times/day, ^b <i>n</i> (%)	41 (43)	39 (40)		0.44 (0.26–0.62)
Alcohol last 4 weeks, <i>n</i> (%)	81 (84)	84 (86)		0.75 (0.56–0.94)
Drug adherence				
Morisky scale sum score	7.4 (0.9)	7.3 (1.0)	0.74 (0.61–0.83)	
Obstructive sleep apnoea				
Berlin category 1 sum ^c	1.59 (1.2)	1.55 (1.2)	0.87 (0.80–0.91)	
Berlin category 2 sum	0.45 (0.8)	0.41 (0.8)	0.89 (0.83–0.93)	

ICC: intraclass correlation coefficient; κ: Kappa agreement; CI: confidence interval; SD: standard deviation.

^aExercise sum score, sum of frequency, duration, and intensity.

^bFruit and/or vegetables at least twice a day.

^cBerlin category 1 sum, snoring, and sleep apnoea; Berlin category 2 sum, tired or exhausted.

Table III. Test–retest reliability of psychosocial factors.

	Test session 1 Mean (SD)	Test session 2 Mean (SD)	ICC (95% CI)
Quality of life, SF12			
Physical health sub-scale sum score	41.89 (5.5)	41.44 (5.4)	0.77 (0.65–0.85)
Mental health sub-scale sum score	50.83 (8.5)	50.83 (9.6)	0.89 (0.84–0.93)
Hospital Anxiety and Depression Scale (HADS)			
HADS-A sum; anxiety	3.63 (3.7)	3.30 (3.9)	0.92 (0.88–0.95)
HADS-D sum; depression	2.96 (2.9)	3.01 (3.5)	0.94 (0.91–0.96)
HADS-T sum; total score	6.59 (6.1)	6.32 (6.8)	0.95 (0.93–0.97)
Ruminative Response Scale (RRS)			
RRS sum score	29.47 (9.3)	29.29 (11.2)	0.88 (0.81–0.92)
Penn State Worry Questionnaire (PSWQ)			
PSWQ sum score	35.0 (12.2)	34.6 (12.8)	0.91 (0.86–0.94)
Type D personality (DS-14)			
Social inhibition sum score	7.55 (5.5)	7.32 (5.5)	0.90 (0.85–0.94)
Negative affectivity sum score	5.76 (5.5)	5.40 (5.7)	0.91 (0.86–0.94)
Brief Illness Perception Questionnaire (BIPQ)			
BIPQ sum score	25.9 (12.3)	25.8 (13.1)	0.91 (0.86–0.94)
Perceived risk perception (PRP), Likert scale 0–10			
PRP 1	2.1 (2.1)	2.7 (2.4)	0.59 (0.39–0.73)
PRP 2	6.9 (2.5)	6.9 (2.6)	0.67 (0.50–0.78)
PRP 3	2.3 (2.3)	2.6 (2.5)	0.74 (0.60–0.82)
Bergen insomnia scale			
Insomnia sum score	11.2 (10.3)	10.7 (10.5)	0.92 (0.88–0.95)

SD: standard deviation; CI: confidence interval; ICC: intraclass correlation coefficient; CI: confidence interval.

The mean time interval between index hospitalization and first-time completion of the questionnaire was eight months. After this relatively long period the majority had completed the rehabilitation process in our hospital. Possible early problems with medication habituation, anxiety, and depression were considered sufficiently diminished, and the patients' physical activity level was restored. It is, however, not possible

to guarantee total stability (i.e. lack of “true” change) over four weeks, but the abovementioned should have reduced the risk of clinically important improvements or deteriorations that might have influenced reproducibility in the data presented. Test–retest correlations tend to be higher when the time interval between the two points of measurement is short, because few changes have occurred, but there is also a risk of

Table IV. Test–retest reliability of beliefs about disease causes, motivation, perceived needs, and treatment desires.

	Test session 1 Mean (SD) Likert scale 0–10	Test session 2 Mean (SD) Likert scale 0–10	ICC (95% CI)
Beliefs regarding what caused CHD			
Smoking	3.84 (4.0)	3.80 (4.0)	0.78–0.95
Lack of exercise	4.47 (3.0)	4.91 (3.0)	0.94 (0.91–0.96)
Motivation for lifestyle changes and already applied changes			
Motivation to quit smoking	7.83 (3.6)	8.48 (2.5)	0.87 (0.69–0.95)
Motivation to improve diet	5.26 (2.9)	5.39 (2.9)	0.85 (0.78–0.90)
Motivation to increase exercise	5.06 (3.0)	5.52 (2.8)	0.75 (0.62–0.83)
Have changed diet	5.62 (2.6)	5.43 (2.8)	0.84 (0.76–0.89)
Have increased exercise	4.78 (3.1)	4.93 (2.8)	0.89 (0.84–0.93)
Perceived needs of additional information			
Sufficient information about disease	8.19 (2.2)	8.23 (2.0)	0.73 (0.60–0.82)
Sufficient information about risk factors	8.58 (1.8)	8.20 (1.9)	0.80 (0.70–0.86)
	Test session 1 n (%)	Test session 2 n (%)	κ (95% CI)
Healthcare follow-up			
Participated in cardiac rehabilitation	92 (93)	92 (93)	0.69 (0.41–0.98)
Current follow-up general practitioner ≥ 3 times/year	48 (49)	44 (44)	0.72 (0.58–0.86)
Perception of the information provided			
Cured from CHD	68 (69)	67 (68)	0.55 (0.38–0.74)
No need to change lifestyle	28 (28)	27 (27)	0.63 (0.46–0.81)
Treatment desires			
Email, SMS, telephone	50 (52)	45 (47)	0.56 (0.39–0.73)
Cardiac nurse	66 (68)	61 (63)	0.34 (0.15–0.53)
Multidisciplinary cardiac rehabilitation	32 (33)	26 (28)	0.54 (0.36–0.72)
Physiotherapist	31 (32)	31 (32)	0.71 (0.56–0.86)
Dietician	32 (33)	31 (32)	0.69 (0.54–0.84)
Psychiatrist/psychologist	14 (14)	7 (7)	0.57 (0.44–0.70)
Internet	27 (28)	23 (25)	0.47 (0.28–0.67)
Mobile app	17 (18)	15 (16)	0.70 (0.50–0.90)
No need for follow-up	32 (36)	31 (33)	0.63 (0.46–0.81)

ICC, intraclass correlation coefficient; κ, Kappa agreement; CI, confidence interval; CHD, coronary heart disease.

memory effects; that is, respondents recalling their response on the first occasion and choosing the same option on the second occasion in order to appear “consistent”. In order to avoid influence of memory effects and to reduce the possibility of significant events and real changes between the two tests, four to eight weeks has been suggested as the ideal time between the two measurements [28,29].

In post-Myocardial infarction (MI) patients, the assessment of type D personality has been shown to be very stable over 18 months [30] and comparable to the good reproducibility of frequency of exercise per week in stable coronary patients when measured with one week interval between the two tests, whereas reproducibility for exercise diminishes with a longer interval between tests [31–33]. In the present context, the majority of our study participants clearly belonged to the category of stable CHD.

We had expected a tendency towards lower reproducibility in questions from the last part of the questionnaire due to tiredness or fatigue. This did

not turn out to be the case, as was also observed in a diet study where the length of the questionnaire had only a minor impact on the response rate and data quality [34].

In the INTERHEART study [35] structured questionnaires were administered to obtain information about socio-demographic factors and cardiovascular risk factors. Repeat measures of risk factors were made in 279 controls at a median interval of 409 days. Except from a nearly identical, and very good agreement rate for smoking in INTERHEART and the present study (κ = 0.94 vs. 1.0, respectively), the respective reproducibility values in INTERHEART and our study differed for depression (κ = 0.44 vs. ICC = 0.94), regular physical activity (κ = 0.56 vs. ICC = 0.85 for frequency), and alcohol (κ = 0.52 vs. ICC = 0.75). Different questionnaires and time interval that had elapsed between test and retest may explain these divergences.

The reproducibility of drug adherence, sleep apnoea, and psychosocial factors based upon widely

used questionnaires in the present study was high and in line with most other studies [18–25,36].

Our findings of quite acceptable reproducibility data with only few exceptions can be explained by the extensive process used to develop de novo questions and inclusion of questionnaires that have previously been validated and found to have acceptable reproducibility [17–25,36].

These robust reproducibility data will have practical implications for future analysis of the association between potentially modifiable patient factors and unfavourable risk factor control. Since most of the data to be used in this context is derived from the questionnaire, the present findings are reassuring for further NOR-COR projects and for its application in future clinical studies of secondary CHD prevention.

Study limitations

The participants of the reproducibility study exclusively represented Vestfold Hospital where nearly 80% attend cardiac rehabilitation. Since only half of the NOR-COR study participants attended such a programme, a selection bias cannot be excluded. However, no socio-demographic differences were observed between the entire NOR-COR population and the reproducibility study sample.

True change in the underlying phenomenon will of course result in low or at least reduced test–retest correlations, thus giving the impression of relatively poor measurement reliability (if no true change is assumed). Weak test–retest correlations, therefore, must be viewed with caution since we may in fact be underestimating reliability. However, in the present study this seems to be a rather unnecessary concern since we have consistently found very high test–retest correlations, also for measures for which one might suspect some true change to have occurred in the time period between test and retest (e.g. the reproducibility for physical activity frequency was found to be ICC 0.85). The risk of overestimating measurement reliability because of artificially boosted test–retest correlations (caused by memory effects, stable biases and/or response styles, mode of administration, etc.) can only be assessed by applying alternative research designs, such as having access to a gold standard, systematically altering instrument style and formatting, switching modes of administration etc., which is clearly outside the scope of the present paper.

Conclusion

Reliability studies based on test–retests are essential elements when it comes to establishing the quality of self-report data. A good to very good reproducibility

was found for almost all of the items and scales used in the comprehensive NOR-COR questionnaire. Thus, this instrument emerges as a valuable tool for evaluating risk factor control in CHD patients in general, laying the foundation not only for further analyses, findings, and conclusions in the NOR-COR project, but also for similar comprehensive questionnaires applied in future clinical patient studies.

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Supplemental material

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Appendix 2

The NOR-COR study questionnaire

Spørreskjema NOR-COR Studien

Rnd.....

Kjære NOR-COR deltager. Takk for at du vil delta i denne studien. Vi håper du vil svare på alle spørsmålene nedenfor så nøye som mulig. Noen spørsmål vil være mer relevante for enkelte deltakere, men ikke for andre. Noen spørsmål kan være vanskelige å svare på. Prøv likevel å svare etter beste skjønn, og legg vekt på det som er vanlig eller gjennomsnittlig for deg. Dersom det er spørsmål du ikke forstår kan du ta med deg spørreskjemaet når du kommer på hjertepoliklinikken så vil vi hjelpe deg.

1. BOSITUASJONEN OG SIVILSTATUS

Bor du alene eller sammen med andre?

Sett ett eller flere kryss.

- | | |
|---|--------------------------|
| Bor alene..... | <input type="checkbox"/> |
| Ektefelle eller samboer..... | <input type="checkbox"/> |
| Separert/skilt..... | <input type="checkbox"/> |
| Bor for tiden på sykehjem, aldershjem eller liknende..... | <input type="checkbox"/> |

2. UTDANNING

Hvilken utdanning er den høyeste du har fullført?

Sett ett kryss

- | | |
|--|--------------------------|
| Grunnskole 7-10 år, framhaldsskole, folkehøgskole..... | <input type="checkbox"/> |
| Realskole, middelskole, yrkesskole, 1-2 årig videregående skole..... | <input type="checkbox"/> |
| Artium, øk. gymnas, allmennfaglig retning i videregående skole..... | <input type="checkbox"/> |
| Høgskole/universitet, mindre enn 4 år..... | <input type="checkbox"/> |
| Høgskole/universitet, mer enn 4 år..... | <input type="checkbox"/> |

3. ARBEID/TRYGD

Hva slags arbeidssituasjon har du nå?

Ett eller flere kryss

- | | |
|---|--------------------------|
| Lønnet arbeid i 100 % stilling..... | <input type="checkbox"/> |
| Lønnet arbeid i redusert stilling..... | <input type="checkbox"/> |
| Pensjonist | <input type="checkbox"/> |
| Under utdanning..... | <input type="checkbox"/> |
| Arbeidsledig, permittert..... | <input type="checkbox"/> |
| Sykemeldt eller arbeidsavklaringspenger | <input type="checkbox"/> |
| Midlertidig eller varig uføretrygdet..... | <input type="checkbox"/> |

4. INTERNETT OG MOBILBRUK

- 4.1 Har du internett hjemme?..... Ja ☐ Nei ☐
- 4.2 Bruker du internett til vanlig?..... Ja ☐ Nei ☐
- 4.3 Har du en mobiltelefon med internettilgang?..... Ja ☐ Nei ☐
- 4.4 Søker du regelmessig helseinformasjon på nett?... Ja ☐ Nei ☐
- 4.5 Søker noen av dine nærmeste regelmessig helseinformasjon på nett?..... Ja ☐ Nei ☐

5. MEDISINER

5.1 Kryss av dersom du bruker en eller flere av de følgende hjertemedisiner fast:

Sett ett eller flere kryss

Blodfortynnende (f.eks. Albyl E, Marevan, Plavix, Brilique, Efient, Xarelto, Eliquis, eller Pradaxa)..... ☐

Kolesterolsenkende (f.eks. Simvastatin, Lipitor, Lescol, Pravachol, Zocor, Pravastatin Lovastatin, Atorvastatin, Crestor) ☐

Betablokker (f.eks. Selo-zok, Emconcor, Metoprolol, Carvedilol, Atenolol, Tenormin, Bisprolol, Unilock, Sotalol, Inderal eller Pranolol) ☐

ACE-hemmer/ARB (f.eks. Triatec, Ramipiril, Enalapril, Zestril, Renitec, Captopril, Zanioress, Zestoretic, Losartan, Diovan, Valsartan, Aprovel, CoAprovel, Micardis, Atacand, Cozaar eller Exforge)..... ☐

5.2 Vennligst oppgi navn og styrke på din(-e) kolesterolsenkende medisin (-er):

Navn: Styrke: mg.

Navn: Styrke: mg.

Sett ett kryss her dersom du ikke tar noen kolesterolsenkende medisiner: ☐

5.3 Har du opplevd bivirkninger når du tar dine hjertemedisiner?

Nei ☐ Kanskje ☐ Ja ☐ I så fall hvilke?

5.4 Har du opplevd seksuelle problemer (impotens etc.) når du tar hjertemedisiner?

Nei ☐ Ja ☐ Jeg husker ikke ☐

5.5 Har du noen gang fått informasjon av lege om at seksuelle problemer kan forekomme ved behandling med hjertemedisiner?

Nei ☐ Jeg husker ikke ☐ Ja ☐ I så fall hvilke?

5.6 Hvor ofte tok du dine kolesterolsenkende medisiner som forskrevet sist uke?

Sett ett kryss

☐ ☐ ☐ ☐ ☐ ☐

Hver dag 6 av 7 dager 5 av 7 dager 4 av 7 dager < 4 av 7 dager Jeg tar de ikke

5.7 Hvor ofte tok du dine blodfortynnende medisiner som forskrevet sist uke?

Sett ett kryss

☐ ☐ ☐ ☐ ☐ ☐

Hver dag 6 av 7 dager 5 av 7 dager 4 av 7 dager < 4 av 7 dager Jeg tar de ikke

5.8 Hvor ofte tok du dine medisiner som forskrevet av lege den siste måneden?

Sett ett kryss

Hele tiden (100 %)..... ☐

Nesten hele tiden (ca. 90 %)..... ☐

Det meste av tiden (ca. 75 %)..... ☐

Omtrent halvparten av tiden (ca. 50 %)..... ☐

Mindre enn 50 % av tiden..... ☐

5.9 Hvor ofte glemte du å ta 1 eller fler av dine reseptbelagte medisiner den siste måneden?

Sett ett kryss

Aldri..... ☐

En gang i løpet av siste måned..... ☐

2-3 ganger i løpet av siste måned..... ☐

En gang per uke..... ☐

Flere ganger per uke..... ☐

Omtrent hver dag..... ☐

5.10 Hvor ofte bestemte du deg for å la være å ta 1 eller fler av dine reseptbelagte medisiner i løpet av den siste måneden?

Sett ett kryss

Aldri..... ☐

En gang i løpet av siste måned..... ☐

2-3 ganger i løpet av siste måned..... ☐

En gang per uke..... ☐

Flere ganger per uke..... ☐

Omtrent hver dag..... ☐

6 Ett kort spørreskjema om medisinbruk

Sett ett kryss

Hender det at du av og til glemmer å ta dine medisiner?..... Ja ☐ Nei ☐

Enkelte glemmer å ta sine medisiner av andre grunner enn forglemmelse. Hvis du tenker på de siste 2 ukene, var det noen dager du ikke tok dine medisiner?..... Ja ☐ Nei ☐

Har du noen gang kuttet ned eller stoppet å ta dine medisiner uten å informere din lege fordi du følte deg verre når du tok de?... Ja ☐ Nei ☐

Når du er på reise eller drar hjemme fra, hender det at du av og til glemmer å ta med medisinene dine?..... Ja ☐ Nei ☐

Tok du alle dine medisiner i går?..... Ja ☐ Nei ☐

Når du føler at symptomene dine er under kontroll, hender det at du slutter å ta dine medisiner?..... Ja ☐ Nei ☐

Det å ta medisiner hver dag oppleves som ubeleilig for enkelte. Har du noen ganger følt at det er vanskelig å ta dine medisiner som forskrevet av lege?..... Ja ☐ Nei ☐

Hvor ofte har du problemer med å huske å ta alle dine medisiner?

Aldri/sjelden..... ☐

En gang i blant..... ☐

Noen ganger..... ☐

Vanligvis..... ☐

Hele tiden..... ☐

7. FYSISK AKTIVITET

Sett ett kryss

7.1 Hvor ofte driver du med fysisk aktivitet?

(Ta et gjennomsnitt)

Aldri..... ☐

Sjeldnere enn 1 gang i uka..... ☐

En gang i uka..... ☐

2-3 ganger i uka..... ☐

Omtrent hver dag..... ☐

7.2 Dersom du driver fysisk aktivitet så ofte som en eller flere ganger i uka:

Hvor hardt tar du i?

(Ta et gjennomsnitt)

Tar det rolig uten å bli andpusten eller svett..... ☐

Tar det så hardt at jeg blir andpusten og svett ☐

Tar meg nesten helt ut..... ☐

7.3 Hvor lenge holder du på hver gang?

(Ta et gjennomsnitt)

Mindre enn 15 minutter ☐

16-30 minutter..... ☐

30 minutter – 1 time..... ☐

Mer enn 1 time..... ☐

8. RØYKING

Sett ett eller flere kryss

8.1 Røyker du selv?

Sigaretter daglig..... Ja ☐ Nei ☐

Sigarer/sigarillos daglig..... Ja ☐ Nei ☐

Pipe daglig..... Ja ☐ Nei ☐

8.2 Jeg har aldri røkt daglig (sett kryss)..... ☐

8.3 Har du noen gang røkt daglig?..... Ja ☐ Nei ☐

8.4 Hvor mange sigaretter røyker eller røykte du vanligvis daglig?

(angi antall sigaretter).....

8.5 Hvor mange år har du til sammen røykt daglig? (angi antall år).....

8.6 Bruker du daglig snus?..... Ja ☐ Nei ☐

8.7 Omtrent hvor mange bokser snus bruker du per uke?

9. Kosthold

9.1 Hvor mange ganger per uke inntar du følgende matvarer?

Sett ett kryss på hver rad

	Mer enn 2ganger/dag	Ca.1 gang/dag	4-6 ganger/uke	Mindre enn 3 ganger/uke
Fisk som pålegg/middag.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grønnsaker.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frukt/bær.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pølser/hamburger og tilsvarende...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Brus/saft med sukker.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pasta/ris.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Poteter.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sjokolade/smågodt.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. HØYDE/VEKT

10.1 Hvor mye veier du uten klær?..... kg.

10.2 Hvor høy er du? cm.

10.3 Hva stemmer om din vekt?

Sett ett kryss

Ikke overvektig ☐ Litt overvektig ☐ Svært overvektig ☐

De neste spørsmålene omfatter hjertesykdommen din. Med hjertesykdom mener vi at du enten har hatt et hjerteinfarkt, hatt behov for ny utblokking av hjertets kransårer eller har blitt hjerteoperert.

11. DIN OPPFATNING AV HJERTESYKDOMMEN OG RISIKOFAKTORER

11.1 Hvilke av de følgende utsagn føler du stemmer for deg?

Sett ett kryss

Jeg er nå frisk igjen av hjertesykdommen, men må endre min livsstil (dvs. omlegging av kosthold, økt fysisk aktivitet og/eller røykestopp) ☐

Jeg er nå frisk igjen av hjertesykdommen og behøver ikke å endre livsstil... ☐


Jeg har fortsatt hjertesykdom og må endre min livsstil..... ☐

Jeg har fortsatt hjertesykdom, men behøver ikke endre min livsstil..... ☐

12.5 Hvor mye har du økt ditt fysiske aktivitetsnivå etter at du fikk påvist hjertesykdommen?

Sett ring rundt ett tall


Ingen ting 0 1 2 3 4 5 6 7 8 9 10 Svært mye



12.6 Har du lyst til å øke ditt fysiske aktivitetsnivå ytterligere?

Sett ring rundt ett tall


Har ikke lyst 0 1 2 3 4 5 6 7 8 9 10 Har veldig lyst



12.7 Hvor mye mer sunt (hjerterevennlig) spiser du etter at du fikk påvist hjertesykdommen?

Sett ring rundt ett tall


Ingen ting 0 1 2 3 4 5 6 7 8 9 10 Svært mye



12.8 Har du lyst til å gjøre kostholdet enda sunnere/hjerterevennlig?

Sett ring rundt ett tall

Har ikke lyst 0 1 2 3 4 5 6 7 8 9 10 Har veldig lyst



13. INFORMASJON OM HJERTESYKDOMMEN OG RISIKOFAKTORER

13.1 Var det noen til stede på sykehuset den dagen du fikk informasjon om hjertesykdommen?

Sett ett eller flere kryss

Ektefelle/samboer eller nær familie..... ☐

Venner eller bekjente..... ☐

Jeg var alene..... ☐

Jeg husker ikke fordi det er lenge siden jeg fikk diagnose..... ☐

13.2 Fikk du råd og veiledning om hvordan du skal forebygge nye hjertehendelser (dvs. ett nytt hjerteinfarkt, behov for ny utblokking eller ny hjerteroperasjon) før du ble skrevet ut fra sykehuset?

Sett ett kryss

Ja ☐ Nei ☐ Husker ikke/vet ikke ☐

13.3 Har du fått informasjon fra sykehuset om at dine barn eller andre i din nære familie bør undersøkes for hjertesykdom?

Ja ☐ Nei ☐ Husker ikke/vet ikke ☐

13.4 Hvor har du fått informasjon om hjertesykdommen og/eller risikofaktorer etter at du ble utskrevet fra sykehus?

Sett ett eller flere kryss

Gjennom familie og venner..... ☐

Internett..... ☐

Fra brosjyrer, aviser, bøker eller blader..... ☐

Fra fastlegen ☐

Fra interesseorganisasjoner som f.eks. Landsforeningen for hjertesyke (LHL).... ☐

Informasjon fra apoteket..... ☐

Fra annet helsepersonell (fysioterapeut, sykepleier el.lign.)..... ☐

Fra Hjerterehabiliteringen på sykehuset..... ☐

Angi dersom du har fått informasjon fra ett annet sted

Jeg har ikke fått informasjon om hjertesykdommen og/eller risikofaktorer etter at jeg ble utskrevet fra sykehus..... ☐

13.5 I hvilken grad opplever du at du har fått tilstrekkelig informasjon om hjertesykdommen og hvordan du kan forebygge nye tilfeller (dvs. ett nytt hjerteinfarkt, behov for ny utblokking eller ny hjerteroperasjon)?

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I stor grad

←-----→

13.6 Skulle du ønske du hadde fått mer informasjon om hjertesykdommen?

Sett ett kryss

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

13.7 I hvilken grad opplever du at du har fått tilstrekkelig informasjon om hjertervennlig kosthold, fysisk aktivitet, blodtrykk, kolesterol og tobakk?

Sett ring rundt ett tall

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I stor grad

←-----→

13.8 Skulle du ønske du hadde fått mer informasjon om risikofaktorer for hjertesykdom?

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

14. OPPFØLGING FRA HELSEVESENET ETTER AT DU SIST VAR INNLAGT PÅ SYKEHUS MED HJERTESYKDOMMEN

14.1 Hvilken oppfølging ble du anbefalt og/eller tilbudt de første ukene/månedene etter at du var innlagt på sykehus med hjerteinfarkt, utblokking eller hjerteroperasjon?

Sett ett eller flere kryss

Jeg har aldri blitt anbefalt/tilbudt noen spesiell oppfølging..... ☐

Jeg ble tilbudt hjertescole i regi av sykehuset med bl.a. sykepleier..... ☐

Jeg ble anbefalt/tilbudt videre oppfølging hos min fastlege..... ☐

Jeg ble anbefalt/tilbudt fysisk aktivitet i regi av fysioterapeut på sykehuset. ☐

Jeg ble anbefalt/tilbudt fysisk aktivitet i regi av fysioterapeut i kommunen... ☐

Jeg ble anbefalt/tilbudt hjerterehabilitering på et rehabiliteringssenter..... ☐

14.2 Fulgte du opp den denne anbefalingen Ja ☐ Nei ☐ Jeg husker ikke ☐

14.3 Dersom du svarte nei på spørsmål 14.2, hva var de viktigste årsakene til det?

Sett ett eller flere kryss

Jeg visste ikke om disse tilbudene..... ☐

Tilbud (-ene) lå for langt unna der jeg bor..... ☐

Tidspunktene passet ikke..... ☐

Jeg hadde ikke tid..... ☐

Jeg så ikke behovet for disse tilbudene..... ☐

Jeg deltok på en annen oppfølging av hjertesykdommen enn de nevnt i 14.1.. ☐

Andre årsaker.....

14.4 Ble noen av dine nærmeste pårørende tilbudt å delta på deler av sykehusets hjertescole?

Ja ☐ Nei ☐ Jeg husker ikke ☐

Rnd....

15.1 Hvordan følges din hjertesykdom opp av helsevesenet i dag?

Jeg deltar jevnlig på et privat tilbud (som betales helt av egne midler) der fysisk aktivitet og/eller hjelp til livsstilsendringer er viktig..... ☐

.....


Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Sett ring rundt ett tall

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 | svært stor grad


For lite fysisk aktivitet

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Røyking

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Overvekt

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Stress i hverdagen

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Tretthet eller dårlig søvn

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Depresjon/tristhet

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Høyt blodtrykk

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Sukkersyke (diabetes)

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad




Høyt nivå av kolesterol i blodet (lipider)?

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad



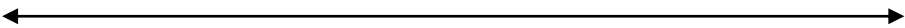
Alderen?

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad



Tilfeldigheter/uflaks

Ingen grad 0 1 2 3 4 5 6 7 8 9 10 I svært stor grad



Annen årsak.....

16.2 Siden du fikk en påvist hjertesykdom har du kanskje gjort enkelte endringer av din livsstil. Kan du i dag tenke deg å gjøre ytterligere endringer av din livsstil?

Ja ☐ Nei ☐ Kanskje hvis jeg fikk hjelp og støtte fra helsepersonell ☐

16.3 Hvilke av de følgende tiltakene kunne du tenke deg å gjøre dersom du fikk hjelp og støtte fra f.eks. en lege eller sykepleier?

Sett ett eller flere kryss

Få et mer «hjertervennlig» kosthold (mindre mettett fett, sukker, salt)?.....	<input type="checkbox"/>
Øke mitt fysiske aktivitetsnivå.....	<input type="checkbox"/>
Slutte å røyke.....	<input type="checkbox"/>
Ta hjertemedisinene mine som forskrevet.....	<input type="checkbox"/>
Leve mindre hektisk (mindre stressende).....	<input type="checkbox"/>
Gå ned i vekt.....	<input type="checkbox"/>
Jeg ønsker ikke å gjøre noen tiltak.....	<input type="checkbox"/>
Jeg har allerede gjort de tiltakene jeg mener er nødvendige	<input type="checkbox"/>

17. DINE BEHOV FOR OPPFØLGING AV DIN HJERTESYKDOM

17.1 Hvilke tilbud kan helsevesenet bidra med for at du skal få best mulig oppfølging av din hjertesykdom?

Skriv ned inntil 4 tilbud i prioritert rekkefølge

1.
2.
3.
4.

17.2 Hvilke av tilbudene nedenfor kunne du tenke deg dersom de var tilgjengelig i dag?

Sett ett kryss

A. Oppfølging via telefon, e-post, SMS

Mulighet for og bli kontaktet eller selv kontakte helsepersonell (f.eks. en erfaren hjertesyrkepleier) på telefon, e-post eller SMS når jeg trenger det.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette til budet?

B. Oppfølging av en hjertesyrkepleier

Mulighet for oppfølging av en hjerte-syrkepleier på poliklinikken på sykehuset. Et slikt tilbud vil omfatte både en samtale, en klinisk undersøkelse og justering av mine hjertemedisiner ved behov

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette til budet?

Mulighet for besøk av en erfaren hjertesyrkepleier i mitt eget hjem. Et slikt tilbud vil omfatte både samtale, en klinisk undersøkelse og justering av mine hjertemedisiner ved behov

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette til budet?

C. Gruppesamling med medpasienter

Mulighet for samlinger på sykehuset der jeg kan møte medpasienter og diskutere felles utfordringer ved hjertesyrdommen. Ulike tema som motivasjon, psykiske utfordringer, kosthold, trening, medisiner osv. kan diskuteres. Timene ledes av en hjertesyrkepleier.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette tilbudet?

D. Oppfølging av fysioterapeut

Mulighet for oppfølging av en fysioterapeut for veiledning og hjelp til å øke mitt fysiske aktivitetsnivå.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette tilbudet?

E. Oppfølging av ernæringsfysiolog

Mulighet for oppfølging av en ernæringsfysiolog for veiledning og råd for å bedre mitt kunnskapsnivå om et sunt og «hjerterennlig» kosthold.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette tilbudet?

F. Oppfølging av psykolog eller psykiater

Mulighet for oppfølging av en psykolog eller psykiater for å lære strategier som kan hjelpe meg å oppnå ønskede livsstilsendringer, samt hjelpe meg å mestre psykiske utfordringer relatert til sykdommen/stressmestring.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette tilbudet?

G. Tverrfaglig oppfølging

Mulighet for tverrfaglig oppfølging av både hjertesyrkepleier, psykolog/psykiater, fysioterapeut, ernæringsfysiolog og lege. Innholdet i tilbudet vil være en blanding av det som er beskrevet ovenfor.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

Dersom du svarer ja, hvor mange ganger per år kan du tenke deg dette tilbudet?

H. Oppfølging via internett

Jeg kunne tenke meg å få tilgang til en passord-beskyttet internettside med følgende innhold:

1. Kvalitetssikret kunnskap og gode råd for meg og mine pårørende om livsstilsendringer og oppfølgingen av sykdommen.
2. Mulighet for registrering av oppdatert medisinske og helseatferd (kosthold, fysisk aktivitet etc.).
3. Ett forum der man kommuniserer med helsepersonell og eventuelt medpasienter dersom hvis ønskelig.

Ja, absolutt ☐ Ja ☐ Kanskje ☐ Nei ☐

I. Oppfølging ved bruk av en mobil applikasjon (APP)

Jeg kunne tenke meg at helsevesenet utviklet en mobil applikasjon (APP) med bl.a. følgende innhold:

1. Hjelp til å holde oversikt over mine medisiner og minne meg på og ta de til rett tid.
2. Hjelp til og enten endre kosthold, økt mitt fysiske aktivitetsnivå, gå ned i vekt eller slutte å røyke (dersom dette er ett behov).
3. Eventuelt mulighet for å kommunisere med min behandler eller medpasienter.

Ja, absolutt ☐

Ja ☐

Kanskje ☐

Nei ☐

Jeg ser ikke behovet for noe ytterligere oppfølgingstilbud fra helsevesenet for min hjertesykdom

Enig ☐

Uenig ☐

Jeg kunne tenke meg ett tilbud fra helsevesenet over internett

Ja, absolutt ☐

Ja ☐

Kanskje ☐

Nei ☐

17.3 Hvilke av tilbudene angitt i spørsmål 17.2 kunne du tenke deg å delta på i dag på dersom de var tilgjengelige?

Skriv ned 4 tilbud i prioritert rekkefølge

1.

2.

3.

4.

18 ALKOHOLBRUK

18.1 Omtrent hvor ofte har du i løpet av de siste 12 måneder drukket alkohol? (Regn ikke med lettøl)

Sett ett kryss

4-7 ganger pr. uke ☐

Ca. 1 gang pr. måned ☐

2-3 ganger pr. uke ☐

Noen få ganger pr. år ☐

Ca. 1 gang pr. uke ☐

Ingen ganger siste år ☐

2-3 ganger pr. måned ☐

Aldri drukket alkohol ☐

18.2 Har du drukket alkohol i løpet av de siste 4 uker? Ja ☐ Nei ☐

Hvis ja:

Har du drukket så mye at du har kjent deg sterkt beruset (full)?

Nei ☐ Ja, 1-2 ganger ☐ Ja, 3 ganger eller mer ☐

18.3 Hvor mange glass øl, vin eller brennevin drikker du vanligvis i løpet av 2 uker?
(Regn ikke med lettøl)

Sett 0 hvis du ikke drikker alkohol

	Øl	Vin	Brennevin
Antall glass	<input type="text"/>	<input type="text"/>	<input type="text"/>

18.4 Hvor ofte drikker du 5 glass eller mer av øl, vin eller brennevin ved samme anledning?

Sett ett kryss

Aldri.....	<input type="checkbox"/>	Ukentlig	<input type="checkbox"/>
Månedlig	<input type="checkbox"/>	Daglig.....	<input type="checkbox"/>

19.1 Har noen av dine foreldre eller søsken fått påvist koronar hjertesykdom (hjerteinfarkt, behov for utblokking eller hjerteroperasjon) før 65 (kvinner) og 55 (menn) års alder?

Ja ☐ Nei ☐ Vet ikke/husker ikke ☐

19.2 Har du fått informasjon fra sykehuset om at dine barn eller andre i din nære familie bør undersøkes for hvorvidt de også er disponert for hjertesykdom?

Ja ☐ Nei ☐ Vet ikke/husker ikke ☐

20. LIVSKVALITET, HUMØR, MESTRING OG SØVN

Nedenfor kommer en del spørsmål om livskvalitet, humør, psykiske helseplager og søvn. Dette er svært relevante problemstillinger for mange hjertepasienter. Enkelte av spørsmålene kan ligne på hverandre, men dette er meningen.

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

Sett ett kryss

Utmerket ☐ Meget god ☐ God ☐ Nokså god ☐ Dårlig ☐

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

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

Ja, begrenser meg mye ☐ Ja, begrenser meg litt ☐ Nei, begrenser meg ikke i det hele tatt ☐

3. Gå opp trappen flere etasjer

Ja, begrenser meg mye ☐ Ja, begrenser meg litt ☐ Nei, begrenser meg ikke i det hele tatt ☐

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

4. Du har utrettet mindre enn du hadde ønsket Ja ☐ Nei ☐

5. Du har vært hindret i å utføre visse typer arbeid eller gjøremål Ja ☐ Nei ☐

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

6. Du har utrettet mindre enn du hadde ønsket Ja ☐ Nei ☐

7. Du har utført arbeidet eller andre gjøremål mindre grundig enn vanlig Ja ☐ Nei ☐

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

Ikke i det hele tatt ☐ Litt ☐ En del ☐ Mye ☐ Svært mye ☐

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

9. Følt deg rolig og harmonisk?

Hele tiden ☐ Nesten hele tiden ☐ Mye av tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i det hele tatt ☐

10. Hatt mye overskudd?

Hele tiden ☐ Nesten hele tiden ☐ Mye av tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i det hele tatt ☐

11. Følt deg nederfor og trist?

Hele tiden ☐ Nesten hele tiden ☐ Mye av tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i det hele tatt ☐

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

Hele tiden ☐ Nesten hele tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i det hele tatt ☐

Her er en liste med ting folk noen ganger gjør eller tenker når de føler seg nedtrykt, trist eller deprimert. Les hver av dem og kryss av for hvor ofte du gjør eller tenker det som beskrives når du føler deg slik. NB: det vi er interessert i er hva du faktisk gjør/tenker, ikke hva du synes du bør gjøre/tenke

	Nesten aldri	Noen ganger	Ofte	Nesten alltid
	1	2	3	4
1. Tenker på hvor ensom du føler deg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Tenker "Hvis jeg ikke klarer å komme meg ut av dette, får jeg ikke gjort jobben min"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Tenker på dine følelser av utmattethet og smerte	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Tenker på hvor vanskelig det er å konsentrere seg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Tenker "Hva er det jeg gjør for å fortjene dette"?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Tenker på hvor passiv og umotivert du føler deg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Analyserer nylige hendelser for å prøve å forstå hvorfor du er deprimert.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Tenker på hvorfor det virker som om du ikke føler noe lenger.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Tenker "Hvorfor kommer jeg meg ikke i gang?".	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Tenker "Hvorfor reagerer jeg alltid på denne måten?".	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Er for deg selv og tenker på hvorfor du føler som du gjør. ☐ ☐ ☐ ☐
12. Skriver ned hva du tenker på og analyserer dette. ☐ ☐ ☐ ☐
13. Tenker på en nylig situasjon og ønsker at det hadde gått bedre. ☐ ☐ ☐ ☐
14. Tenker "Hvis jeg fortsetter å føle meg på denne måten, kommer jeg ikke til å kunne konsentrere meg". ☐ ☐ ☐ ☐
15. Tenker "Hvorfor har jeg problemer som andre mennesker ikke har?" . ☐ ☐ ☐ ☐
16. Tenker "*Hvorfor takler jeg ikke ting bedre?*". ☐ ☐ ☐ ☐
17. Tenker på hvor trist du føler deg. ☐ ☐ ☐ ☐
18. Tenker på alle dine mangler, svakheter og feil. ☐ ☐ ☐ ☐
19. Tenker på hvorfor du ikke føler deg i stand til å gjøre noen ting. ☐ ☐ ☐ ☐
20. Analyserer personligheten din for å prøve å forstå hvorfor du er deprimeret. ☐ ☐ ☐ ☐
21. Drar et sted alene for å tenke over dine følelser. ☐ ☐ ☐ ☐
22. Tenker på hvor sint du er på deg selv. ☐ ☐ ☐ ☐

Nedenfor følger en rekke påstander som man ofte bruker for å beskrive seg selv. Vær vennlig å lese hver påstand og kryss av for det svaret som passer. Det finnes ingen riktige eller gale svar, din egen vurdering er den som teller.

Uriktig	Ganske uriktig	Verken riktig eller uriktig	Ganske riktig	Riktig
0	1	2	3	4

1. Jeg oppnår lett kontakt når jeg møter mennesker.

☐ ☐ ☐ ☐ ☐

- | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 2. Jeg lager ofte oppstyr rundt uviktige ting. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Jeg snakker ofte med fremmede. . | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Jeg føler meg ofte ulykkelig. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Jeg er ofte irritert. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Jeg føler meg ofte hemmet i sosialt samvær. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Jeg har et negativt/pessimistisk syn på ting. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Jeg finner det vanskelig å starte en samtale. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Jeg er ofte i dårlig humør. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Jeg er en lukket person. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Jeg foretrekker å holde andre mennesker på avstand. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Jeg bekymrer meg ofte for noe. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Jeg er ofte "nede i grøfta". | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Når jeg snakker med andre, finner jeg ikke de rette tingene å snakke om. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter de kryss for ett av de fire svarene som best beskriver dine følelser **den siste uken**. Ikke tenk for lenge på svaret – de spontane svarene er best.

1. Jeg er nervøs eller anspent	8. Jeg føler meg som om alt går langsommere
<input type="checkbox"/> For det meste <input type="checkbox"/> Ofte <input type="checkbox"/> Noen ganger <input type="checkbox"/> Ikke i det hele tatt	<input type="checkbox"/> Nesten hele tiden <input type="checkbox"/> Svært ofte <input type="checkbox"/> Fra tid til annen <input type="checkbox"/> Ikke i det hele tatt

2. Jeg gleder meg fortsatt over ting jeg pleide å glede meg over	9. Jeg føler meg urolig liksom jeg har sommerfugler i magen
<input type="checkbox"/> Avgjort like mye <input type="checkbox"/> Ikke fullt så mye <input type="checkbox"/> Bare lite grann <input type="checkbox"/> Ikke i det hele tatt	<input type="checkbox"/> Ikke i det hele tatt <input type="checkbox"/> Fra tid til annen <input type="checkbox"/> Ganske ofte <input type="checkbox"/> Svært ofte
3. Jeg har en urofølelse som om noe forferdelig kommer til å skje	10. Jeg har sluttet å bry meg om hvordan jeg ser ut
<input type="checkbox"/> Helt sikkert og svært ille <input type="checkbox"/> Ja, men ikke så veldig ille <input type="checkbox"/> Litt ille, men det bekymrer meg ikke så mye <input type="checkbox"/> Ikke i det hele tatt	<input type="checkbox"/> Ja, helt klart <input type="checkbox"/> Jeg bryr meg ikke så mye som jeg burde <input type="checkbox"/> Det kan nok hende jeg ikke bryr meg nok <input type="checkbox"/> Jeg bryr meg utseendet like mye som jeg alltid har gjort
4. Jeg kan le og se det morsomme i situasjoner	11. Jeg føler meg rastløs som om jeg stadig må være i aktivitet
<input type="checkbox"/> Like mye som jeg alltid har gjort <input type="checkbox"/> Ikke like mye nå som før <input type="checkbox"/> Avgjort ikke så mye nå som før <input type="checkbox"/> Ikke i det hele tatt	<input type="checkbox"/> Uten tvil svært mye <input type="checkbox"/> Ganske mye <input type="checkbox"/> Ikke så veldig mye <input type="checkbox"/> Ikke i det hele tatt
5. Jeg har hodet fullt av bekymringer	12. Jeg ser med glede frem til hendelser og ting
<input type="checkbox"/> Veldig ofte <input type="checkbox"/> Ganske ofte <input type="checkbox"/> Av og til <input type="checkbox"/> En gang i blant	<input type="checkbox"/> Like mye som jeg alltid har gjort <input type="checkbox"/> Heller mindre enn jeg pleier <input type="checkbox"/> Avgjort mindre enn jeg pleier <input type="checkbox"/> Nesten ikke i det hele tatt
6. Jeg er i godt humør	13. Jeg kan plutselig få en følelse av panikk
<input type="checkbox"/> Aldri <input type="checkbox"/> Noen ganger <input type="checkbox"/> Ganske ofte <input type="checkbox"/> For det meste	<input type="checkbox"/> Uten tvil svært ofte <input type="checkbox"/> Svært ofte <input type="checkbox"/> Ikke så veldig ofte <input type="checkbox"/> Ikke i det hele tatt
7. Jeg kan sitte i fred og ro og kjenne meg avslappet	14. Jeg kan glede meg over en god bok eller et radio- eller et TV program
<input type="checkbox"/> Ja, helt klart <input type="checkbox"/> Vanligvis <input type="checkbox"/> Ikke så ofte <input type="checkbox"/> Ikke i det hele tatt	<input type="checkbox"/> Ofte <input type="checkbox"/> Fra tid til annen <input type="checkbox"/> Ikke så ofte <input type="checkbox"/> Svært sjelden

For hvert av utsagnene nedenfor krysser du av for det svaralternativet som beskriver deg best, eller som er mest typisk for deg.

	Ikke be- skrivende		Noe be- skrivende		Veldig be- skrivende	
	1	2	3	4	5	
1. Jeg blir ikke bekymret selv om jeg ikke har tid å gjøre alt.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Jeg blir overveldet av mine bekymringer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Jeg pleier ikke å bekymre meg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Jeg blir bekymret i mange situasjoner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Jeg vet jeg ikke burde bekymre meg, men jeg klarer ikke la være.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Jeg bekymrer meg mye når jeg blir stresset.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Jeg bekymrer meg alltid for noe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Jeg synes det er lett å se bort fra bekymringer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Straks jeg er ferdig med en oppgave begynner jeg å bekymre meg for alt annet jeg må gjøre.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Jeg bekymrer meg aldri for noe som helst.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Når det ikke er noe jeg kan gjøre med et problem, slutter jeg å bekymre meg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Jeg har vært en som bekymrer seg hele mitt liv.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Jeg har merket meg at jeg har bekymringer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. Har jeg først begynt å bekymre meg, kan jeg ikke slutte.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Jeg bekymrer meg hele tiden.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Jeg bekymrer meg for oppgaver inntil de alle er gjennomførte.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Instruksjon. På spørreskjemaet under er det 6 spørsmål knyttet til søvn og tretthet. Vær vennlig og sett ring rundt det alternativet (antall dager pr uke) som passer best for deg. 0 er ingen dager i løpet av en uke, 7 er alle dager i løpet av en uke.

Eksempel

Hvis du 3 dager i løpet av en uke har brukt mer enn 30 minutter på å sovne etter at du har slukket lyset, setter du ring rundt alternativ 3.

I løpet av den siste måneden, hvor mange dager pr. uke har du brukt mer enn 30 minutter for å sovne inn etter at lysene ble slukket?

0 1 2 **3** 4 5 6 7

Antall dager pr. uke

1. I løpet av den siste måneden, hvor mange dager pr. uke har du brukt mer enn 30 minutter for å sovne inn etter at lysene ble slukket?

0 1 2 3 4 5 6 7

2. I løpet av den siste måneden, hvor mange dager pr. uke har du vært våken mer enn 30 minutter innimellom søvnen?

0 1 2 3 4 5 6 7

3. I løpet av den siste måneden, hvor mange dager pr. uke har du våknet mer enn 30 minutter tidligere enn du har ønsket uten å få sove igjen?

0 1 2 3 4 5 6 7

4. I løpet av den siste måneden hvor mange dager pr. uke har du følt deg for lite uthvilt etter å ha sovet?

0 1 2 3 4 5 6 7

5. I løpet av den siste måneden, hvor mange dager pr. uke har du vært så søvnig/trett at det har gått ut over skole/jobb eller privatlivet?

0 1 2 3 4 5 6 7

6. I løpet av den siste måneden, hvor mange dager pr. uke har du vært misfornøyd med søvnen din?

0 1 2 3 4 5 6 7

Har du brukt sovemedisiner siste uke? (sett kryss)

Ja ____ Nei ____

Dersom du har svart JA:

Navn _____ Styrke (mg) _____

Antall dager siste uke: _____

Nedenfor følger noen spørsmål om dine søvnvaner

1. Snorker du?

- ☐ a. Ja
- ☐ b. Nei
- ☐ c. Vet ikke.

Hvis du snorker:

2. Er din snorking:

- ☐ a. Litt høyere enn lyden av pusten din
- ☐ b. Like høy som tale/snakking
- ☐ c. Høyere enn tale/snakking
- ☐ d. Veldig høy – kan høres i tilstøtende rom

3. Hvor ofte snorker du

- ☐ a. Nesten hver dag
- ☐ b. 3-4 netter i uken
- ☐ c. 1-2 netter i uken
- ☐ d. 1-2 netter i måneden
- ☐ e. Aldri eller nesten aldri

4. Har snorkingen din plaget andre?

- ☐ a. Ja
- ☐ b. Nei
- ☐ c. Vet ikke

5. Har noen lagt merke til at du stopper å puste i søvne?

- ☐ a. Nesten hver dag
- ☐ b. 3-4 ganger i uken
- ☐ c. 1-2 ganger i uken
- ☐ d. 1-2 ganger i måneden
- ☐ e. Aldri eller nesten aldri

6. Hvor ofte føler du deg trett eller utslitt etter at du har sovet?

- ☐ a. Nesten hver dag
- ☐ b. 3-4 ganger i uken
- ☐ c. 1-2 ganger i uken
- ☐ d. 1-2 ganger i måneden
- ☐ e. Aldri eller nesten aldri

7. I løpet av tiden du er våken, føler du deg trett, utslitt eller ikke helt på topp

- ☐ a. Nesten hver dag
- ☐ b. 3-4 dager i uken
- ☐ c. 1-2 dager i uken
- ☐ d. 1-2 dager i måneden
- ☐ e. Aldri eller nesten aldri

8. Har du noen gang duppet av eller sovnet mens du har vært fører av et kjøretøy?

- ☐ a. Ja
- ☐ b. Nei

Hvis ja:

9. Hvor ofte skjer dette?

- ☐ a. Nesten hver dag
- ☐ b. 3-4 ganger i uken
- ☐ c. 1-2 ganger i uken
- ☐ d. 1-2 ganger i måneden
- ☐ e. Aldri eller nesten aldri

Her følger noen spørsmål om hvordan hjertesykdommen påvirker deg.
Vennligst sett en ring rundt det tallet som best samsvarer med din mening.

1. Hvor mye påvirker sykdommen livet ditt?

Ingen påvirkning 0 1 2 3 4 5 6 7 8 9 10 Voldsom påvirkning

2. Hvor lenge tror du at sykdommen din vil vare?

Svært kort tid 0 1 2 3 4 5 6 7 8 9 10 For alltid

3. Hvor mye kontroll føler du at du har over sykdommen din?

Absolutt ingen kontroll 0 1 2 3 4 5 6 7 8 9 10 Svært stor kontroll

4. Hvor mye mener du at behandlingen din kan hjelpe mot sykdommen din?

Ikke i det hele tatt 0 1 2 3 4 5 6 7 8 9 10 Svært hjelpsom

5. Hvor mye opplever du symptomer fra sykdommen din?

Ingen symptomer i
det hele tatt 0 1 2 3 4 5 6 7 8 9 10 Mange alvorlige
symptomer

6. Hvor bekymret er du angående sykdommen din?

Ikke bekymret i
det hele tatt 0 1 2 3 4 5 6 7 8 9 10 Svært bekymret

7. Hvor godt føler du at du forstår sykdommen din?

Forstår ikke i
det hele tatt 0 1 2 3 4 5 6 7 8 9 10 Forstår svært godt

8. Hvor mye påvirker sykdommen din deg følelsesmessig? (dvs. gjør den deg sint, redd, urolig eller deprimert?)

Ikke påvirket følelses-
messig i det hele tatt 0 1 2 3 4 5 6 7 8 9 10 Svært følelses-
messig påvirket

9. Vennligst skriv ned i rekkefølge de tre viktigste faktorene som du tror forårsaket sykdommen din.

De aller viktigste årsaker for meg:”

1. _____
2. _____
3. _____

21. HVILKE RÅD OG TIPS KUNNE DU TENKE DEG Å GI OSS SOM JOBBER I HELSEVESENET MED HJERTEPASIENTER?

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Vi håper du nå kan legge alle arkene i den vedlagte konvolutten og sende de til oss så snart som mulig. Tusen takk for at du tok deg tid til å svare på disse spørsmålene!