

# BMJ Open Rethinking rehabilitation after percutaneous coronary intervention: a protocol of a multicentre cohort study on continuity of care, health literacy, adherence and costs at all care levels (the CONCARD<sup>PCI</sup>)

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## ABSTRACT

**Introduction** Percutaneous coronary intervention (PCI) aims to provide instant relief of symptoms, and improve functional capacity and prognosis in patients with coronary artery disease. Although patients may experience a quick recovery, continuity of care from hospital to home can be challenging. Within a short time span, patients must adjust their lifestyle, incorporate medications and acquire new support. Thus, CONCARD<sup>PCI</sup> will identify bottlenecks in the patient journey from a patient perspective to lay the groundwork for integrated, coherent pathways with innovative modes of healthcare delivery. The main objective of the CONCARD<sup>PCI</sup> is to investigate (1) continuity of care, (2) health literacy and self-management, (3) adherence to treatment, and (4) healthcare utilisation and costs, and to determine associations with future short and long-term health outcomes in patients after PCI.

**Methods and analysis** This prospective multicentre cohort study organised in four thematic projects plans to include 3000 patients. All patients undergoing PCI at seven large PCI centres based in two Nordic countries are prospectively screened for eligibility and included in a cohort with a 1-year follow-up period including data collection of patient-reported outcomes (PRO) and a further 10-year follow-up for adverse events. In addition to PROs, data are collected from patient medical records and national compulsory registries.

**Ethics and dissemination** Approval has been granted by the Norwegian Regional Committee for Ethics in Medical Research in Western Norway (REK 2015/57), and the Data Protection Agency in the Zealand region (REG-145-2017). Findings will be disseminated widely through peer-reviewed publications and to patients through patient organisations.

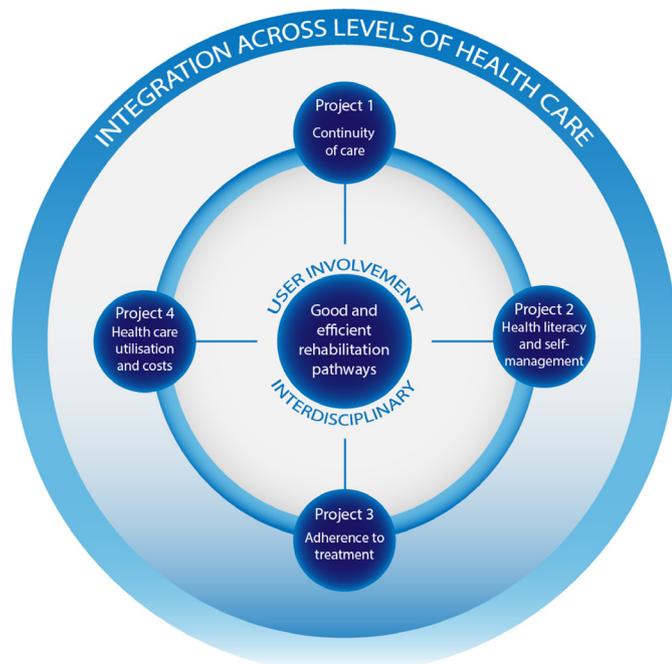
**Trial registration number** NCT03810612.

## Strengths and limitations of this study

- The CONCARD<sup>PCI</sup> is an interdisciplinary, multicentre effort with the unique combination of data from hospital medical records, patient self-report and national registries providing opportunities to identify novel pathways for continuity of care that contribute to outcomes.
- Although the linkage to national registers will ensure complete follow-up of the study population, potential challenges include response rate of patient self-report at follow-up.
- Non-participants will be compared with participants on a limited number of registry variables to account for potential selection bias.

## INTRODUCTION

The widespread commitment to involve patients in planning and service development has become a key element of current healthcare policy. Health literacy, as the ability to access, process and comprehend health information and services, can be used to complement both individual patient care and community-level development. Understanding the varying health literacy of patients, particularly in those who experience poor access and outcomes, is thereby pivotal.<sup>1</sup> The American Heart Association (AHA) recently published a scientific statement<sup>2</sup> addressing health literacy in cardiovascular disease as of fundamental relevance to primary and secondary prevention. European leaders in secondary prevention have called for action



**Figure 1** Projects in CONCARD<sup>PCI</sup> researching bottlenecks for good and efficient patient pathways across levels of healthcare.

in the postacute aftercare of patients with coronary artery disease (CAD).<sup>3</sup> Although CAD is the single most common cause of death in Europe, there has been an encouraging decrease in mortality ascribed to improvements in risk factor management, pharmacological treatment and revascularisation techniques.<sup>4</sup> Since more people need to manage life with CAD as a chronic disease, modern developments in primary healthcare provision have led to increased interest in continuity of care as an essential element.<sup>5–7</sup> Patients' transition from hospital to home is particularly challenging because patients need to adjust their lifestyle, incorporate new medications and acquire additional sources of support.<sup>8</sup> Although there is compelling evidence for secondary prevention following CAD, a large majority fail to achieve lifestyle changes and therapeutic targets set by the European Society of Cardiology guidelines.<sup>9</sup> Therefore, adherence to treatment is also of concern. Non-adherence to medications is common for patients with cardiovascular diseases.<sup>10</sup> Taking prescribed antiplatelet and other secondary preventive medication after percutaneous coronary intervention (PCI) is pivotal; however, it is unknown if non-adherence also applies for patients following PCI.

This paper describes a multicentre cohort study, the CONCARD<sup>PCI</sup>, that seeks to identify bottlenecks and hurdles in the patient journey and suggest the optimal timing of services and alignment with patient preferences for patients with CAD undergoing PCI. Of special interest are challenges with continuity of care, health literacy and self-management, adherence to treatment advice, costs at all care levels and associations with future short and long-term health outcomes.

Uptake to cardiac rehabilitation (CR) is suboptimal,<sup>9 11 12</sup> and few sufficiently powered real-world studies have been undertaken with the explicit purpose of investigating continuity of care and pathways of CR in patients after PCI. In addition to investigating factors associated with low referral, participation, health literacy and adherence rates among CR participants, studies are increasingly needed on evaluating alternative modes of providing CR. Follow-up of healthcare use, costs and predictors of costs following PCI in a non-clinical trial setting have been infrequently investigated.<sup>13 14</sup> Thus, a large cohort of real-world observations that can ascertain interventions for future clinical trials is needed.<sup>15</sup> The CONCARD<sup>PCI</sup> responds to this challenge. In CONCARD<sup>PCI</sup>, we hypothesise that continuity of care, Health literacy and self-management, and adherence to treatment in patients are directly associated to outcomes after PCI.

### AIM OF THE RESEARCH PROGRAMME

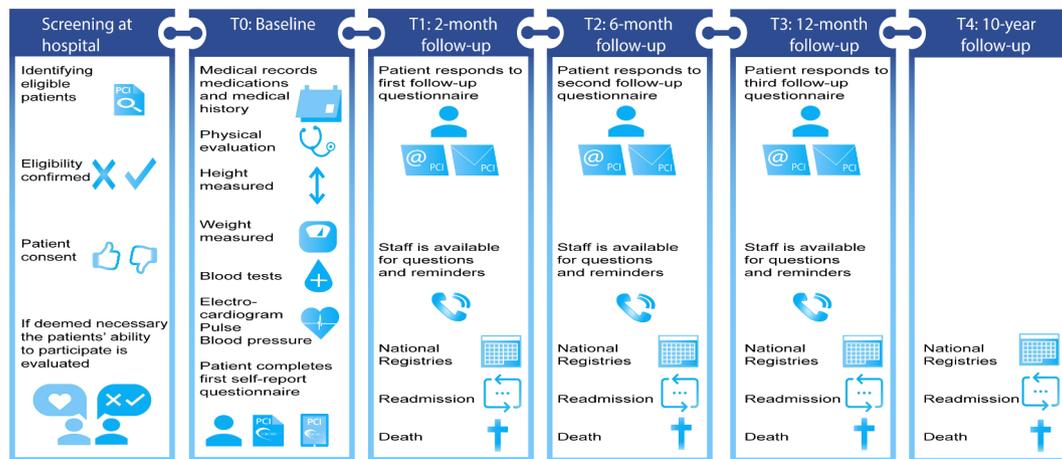
The overall aim of CONCARD<sup>PCI</sup> is to investigate (1) continuity of care, (2) health literacy and self-management, (3) adherence to treatment, and (4) healthcare utilisation and costs, to determine associations with future short and long-term health outcomes in patients after PCI. CONCARD<sup>PCI</sup> is organised into four thematic projects on continuity of care; health literacy and self-management; adherence to treatment; and healthcare use and costs (figure 1).

### METHODS

#### Study design and setting

CONCARD<sup>PCI</sup> is a large-scale multicentre cohort study with serial prospective survey data collection, clinical data and register-based follow-up. We collect data from hospital medical records, patient self-report surveys and national registries (figure 2). Preliminary work has been performed including in-depth interviews on patients' experiences of healthcare delivery to provide a context for the quantitative data and inform the content of the cohort survey questionnaires. Three follow-up surveys over 1 year are undertaken, and a 10-year follow-up for adverse events.

Seven large referral PCI centres in Norway and Denmark were selected based on the following considerations: presence of a committed research team including CONCARD<sup>PCI</sup> study nurses and a local principal investigator, prior research experience including research infrastructure, geographical location and size. The PCI centres perform from 900 to >2000 (mean 1668) PCI procedures annually, are having 629–1400 beds (mean 943) and are referral centres for coronary angiography and PCI for a total of 37 local hospitals (figure 3, table 1). Haukeland University Hospital is the sponsor centre of this investigator-initiated research programme. For study organisation, see online supplementary appendix.



**Figure 2** Measuring time points and data collection in the cohort study in CONCARD<sup>PCI</sup>.

### Study population

All patients undergoing PCI at seven large PCI centres are prospectively screened for eligibility. Screening is performed in the hospital setting by the site coordinator and trained CONCARD<sup>PCI</sup> study nurses. Daily admission records and the operating programme are reviewed to identify potentially eligible patients. Electronic medical records are reviewed to confirm eligibility according to the inclusion and exclusion criteria (table 2). When cognitive impairment is suspected by clinical or study personnel and there is no medical record of the problem, the Confusion Assessment Method<sup>16</sup> and 4AT<sup>17</sup> are used to investigate whether the patient must be excluded. Patients who are delirious or too clinically unstable to participate following PCI, who would otherwise be eligible, are reassessed until discharge. During the in-hospital assessment, participants provide informed consent. Because many of the questionnaires are designed for patient self-assessment, patients who need a complete proxy are ineligible. If participants need assistance in filling out the questionnaires, this is registered in the case report form (CRF). Regarding sample size and study power, see the *Data analysis and sample size determination* section.

### Measurement and data collection

In CONCARD<sup>PCI</sup> a broad range of outcomes are measured and data are collected by physical assessment at baseline, review of the medical records, patient self-reported questionnaires (at baseline, 2, 6 and 12 months) and from national registries (table 3 and figure 2). A comprehensive data dictionary and CRF are provided to ensure standardisation of abstracted data. For the Danish centres, eCRFs are used. Patients included in the study undergo a brief physical assessment and complete the self-report questionnaires at baseline after PCI (T0) (table 3 and figure 2). A follow-up with postal or electronic questionnaires is distributed to all patients included in the study, 2 months after discharge (T1). The time interval ensures time for follow-up care to evaluate early post-discharge continuity of care. A consecutive subgroup of patients (n=100) at the Sponsor Coordinating Centre

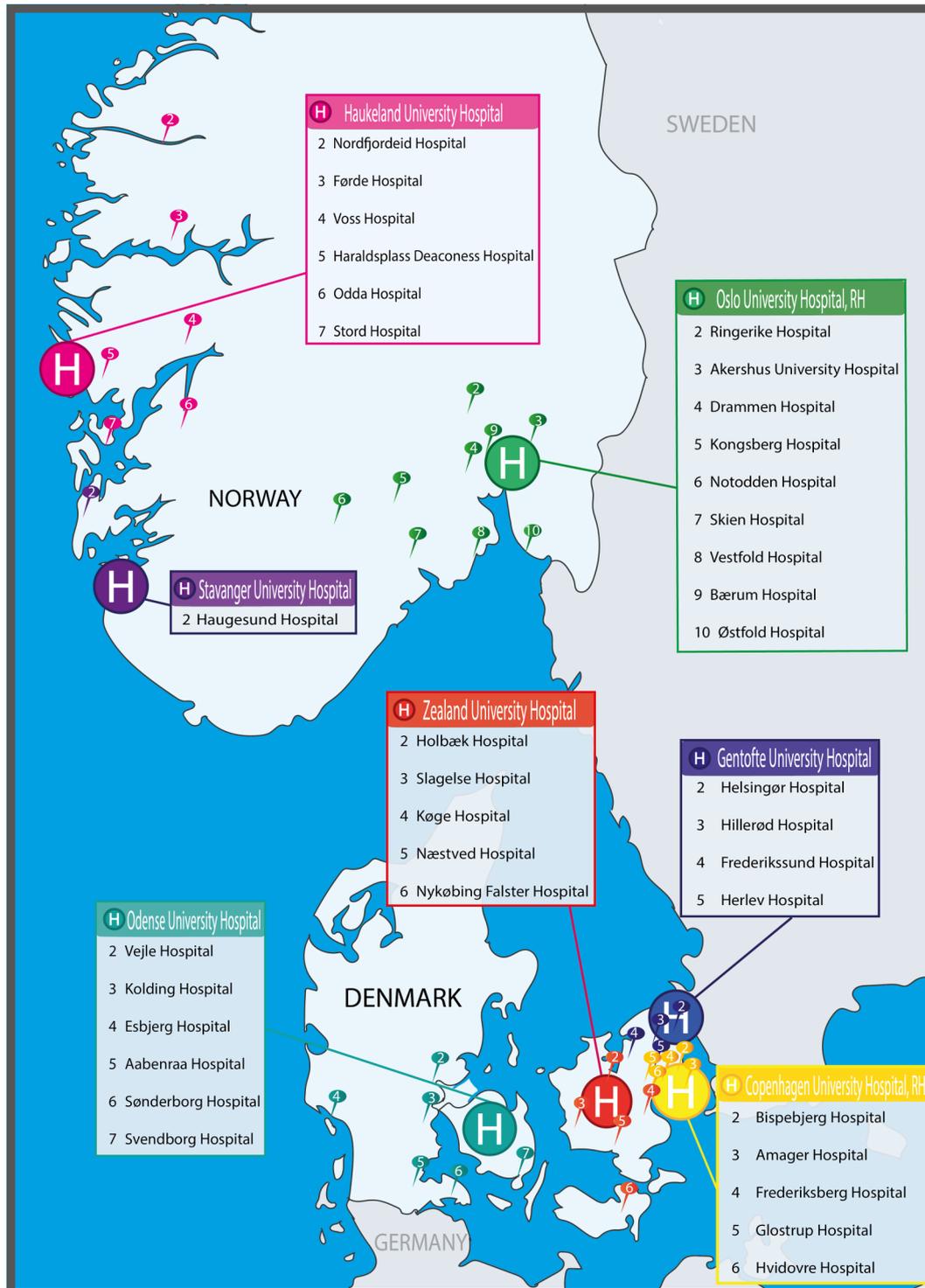
are approached for a retest of the eHealth Literacy Scale (eHEALS)<sup>18</sup> and the Heart Continuity of Care Questionnaire (HCCQ)<sup>19</sup> as part of the validation process of the instruments. All patients are followed up with postal or electronic questionnaires at 2 (T1), 6 (T2) and 12 (T3) months after discharge. Non-responders receive one reminder. Vital status is identified to avoid sending questionnaires to deceased patients or their family. Patient adverse events are followed through national registries for 10 years or until death (T4) (figure 2). Questionnaire packages are discussed with patient representatives and piloted at every measuring time point (T0–T3) before employed in the large-scale cohort study.

To objectively assess adherence to therapy, serum levels of a wide panel of cardiac medications are measured. A consecutive subsample of 500 Norwegian patients from two centres will be invited to give a blood sample 1 year after the index procedure. The time is chosen as it corresponds to collection of patient-reported data on adherence. Moreover, adherence tends to diminish over time<sup>20</sup>; hence, the 1-year contact was chosen. Serum levels are submitted to an accredited clinical pharmacology laboratory, and quantified using liquid chromatography with mass spectrometry. Patients are labelled as non-adherent when serum level of at least one of the evaluated drugs is below the limit of quantification.

### Management of cohort and registry data

For the *Norwegian centres*, baseline (T0) data are transferred to the National Coordinating Centre for data entry and/or review. The forms are reviewed and queries sent to the centre for missing or incomplete items. All follow-up data are collected by postal mail and managed at the National Coordinating Centre. The paper version data are entered into electronic files by trained staff.

For the *Danish centres*, each centre registers patients who are screened, and either included or excluded in separate Microsoft Excel (V.2016) spreadsheets in a shared secure team site server hosted by the National Coordinating Centre. Data from medical records are entered into a shared SurveyXact (V.12.9) database at each study



**Figure 3** H=PCI centres including the local hospitals in their catchment area.

site and managed by the National Coordinating Centre. Patient self-reports at both baseline (T0) and follow-up are collected either electronically using a tablet via a SurveyXact link or by paper as requested by the patient. Paper version data are entered into the SurveyXact database by trained CONCARD<sup>PCI</sup> study nurses. All follow-up data are collected and managed by the National Coordinating Centre.

Every resident in Norway and Denmark has a unique personal identifier that allows data sets from national registries to be merged on an individual level. The data sets will be released in a coded and deidentified form, but with a unique identifier common to the data sets making individual merging possible. The heart registries, prescription registries,<sup>21 22</sup> cause of death registries<sup>23 24</sup> and administrative registries on social security microdata

**Table 1** Description of centres participating in CONCARD<sup>PCI</sup>

	Centre 1 (HUS)	Centre 2 (SUS)	Centre 3 (RH <sup>Os</sup> )	Centre 4 (HGH)	Centre 5 (ZUH)	Centre 6 (RH <sup>Cph</sup> *)	Centre 7 (OUH)
Total hospital beds	1400	482	697	949	629	1377	1064
PCI procedures per year†	1565	905	2124	1290	921	2243	2633
Catchment area of number of local hospitals	7	1	9	4	5	5	6

Centre 1 is the Sponsor Coordinating Centre.

\*RH<sup>Cph</sup> has regional function for all patients with ST-elevation myocardial infarction affiliated to the capital region and Zealand region.

†Figures from 2017.

HGH, Herlev and Gentofte University Hospital, Copenhagen, Denmark; HUS, Haukeland University Hospital, Bergen, Norway; OUH, Odense University Hospital, Odense, Denmark; PCI, percutaneous coronary intervention; RH<sup>Cph</sup>, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark; RH<sup>Os</sup>, Oslo University Hospital, Rikshospitalet, Oslo, Norway; SUS, Stavanger University Hospital, Stavanger, Norway; ZUH, Zealand University Hospital, Roskilde, Denmark.

and healthcare utilisation<sup>25 26</sup> are mandatory, and legally exempted from requirement of obtaining patient consent. Strict rules on how data can be used or linked are followed to secure privacy protection. Although these data are similar in composition, we are interested in contrasting and comparing Denmark with its high CR uptake to Norway with a lower uptake.

### Data analysis and sample size determination

Descriptive statistics of the cohort by nation will be generated using proportions, means and SDs or medians and IQRs as appropriate. Cross-sectional analysis will be used for continuity of care (table 4) using multiple linear regression testing for a random effect for nation. For health literacy, there is a single follow-up and multiple linear regression testing for a random nation effect will be used. The cohort's longitudinal observations over 1 year will be modelled using generalised linear mixed models (GLMM) that account for within-person correlation for adherence to medications, healthcare utilisation and cost (table 4). We will test whether patients clustered within nation is significant. If so, we will include it as a hierarchy

in the GLMMs. For time to readmission, and time to major adverse cardiac event, we will use competing risk models to account for censoring by death. We will construct risk stratification models that predict the probability of each outcome for specific combinations of risk factors. We will establish internal validity by using bootstrapping techniques. We will test whether missing data are at random. If not, we will estimate the probability of missingness and include it as a weight or covariate factor in the models. For psychometric evaluation of translated instruments we evaluate the structural, discriminant and convergent validity, and reliability of the scales. For internal consistency, Cronbach's alpha is used. Test-retest reliability is evaluated by using intraclass correlation coefficients of patients' results obtained at a 2-week retest interval. Confirmatory factor analysis is used for evaluating the factor structure of the original eHEALS<sup>18</sup> and HCCQ<sup>19</sup> instruments.

*Power calculations* for the cohort study are based on time-to-first event outcomes, as these require the most patients. To maintain at family-wise type I error of 0.05% and 80% power using the method of Hsieh and Lavori<sup>27</sup> for adjusted Cox regression models 2550 patients are needed. To adjust for losses to follow-up, we increased this estimate by 18% for a total of 3000 patients. Thus, all outcomes will have ≥80% power with alpha ≤0.05.

### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethical guidelines of the World Medical Association, Declaration of Helsinki and the legislation in Norway and Denmark guide the study (Declaration of Helsinki, 2008). At inclusion, a detailed letter informing the potential participant of the study, and the right to withdraw from the study at any time without any reason is underlined. The identifying key is kept in a separate file from the data. The data are kept in strict confidence in locked files at research servers to protect the participants' privacy. Approval by the Norwegian Regional Committee for Ethics in Medical Research in Western Norway has been granted (REK 2015/57), and from the Data Protection Agency in the Zealand region for the Danish centres (REG-145-2017). Written agreements between the Sponsor Coordinating

**Table 2** Eligibility criteria for CONCARD<sup>PCI</sup>

Inclusion criteria	<ul style="list-style-type: none"> <li>▶ Patients undergoing percutaneous coronary intervention (PCI)</li> <li>▶ ≥18 years of age</li> <li>▶ Living at home at the time of index hospitalisation and inclusion</li> <li>▶ Informed consent</li> </ul>
Exclusion criteria	<ul style="list-style-type: none"> <li>▶ Patients who do not speak Norwegian/Danish</li> <li>▶ Patients who are unable to fill in the questionnaires due to reduced capacities</li> <li>▶ Patients who are institutionalised</li> <li>▶ Patients with expected lifetime less than 1 year</li> <li>▶ Patients undergoing PCI without stent implementation, or related to transcatheter aortic valve implantation (TAVI) or MitraClip examination</li> <li>▶ Previous enrolment in CONCARD<sup>PCI</sup> (readmissions)</li> </ul>

**Table 3** Sociodemographic, clinical and patient-reported measures, and timing of assessments in the CONCARD<sup>PCI</sup> prospective cohort study

Measure	Details	Self-report	Hospital medical records	National registry	Time*	Project†
Sociodemographic data	Marital status, cohabitation status, education, work status, immigration status, income, rehabilitation participation, available support system, readmission to hospital, time of first meeting with general practitioner.	X		X	T0-T3	1-4
Clinical characteristics	Clinical status at admission (blood pressure, heart rate, laboratory results (haemoglobin, creatinine, troponin, total and high/low-density lipoproteins), body weight, height, waist circumference, upper arm circumference, medical history including comorbidity and frailty, and previous hospital admissions, procedural and angiographic findings including completeness of revascularisation, complications during hospital stay, additional procedures, length of hospital stay, death.	X	X	X	T0	1-4
Medication	Medication at discharge (type and dosage), consumption of prescribed medication during follow-up, side effects from medication, polypharmacy, discontinuation, serum levels of cardiac medications (quantified using liquid chromatography with mass spectrometry).	X	X	X	T0-T3	3
Lifestyle	Physical activity (frequency, duration, intensity), sexual activity, tobacco use (current, previous, never), alcohol consumption (frequency, units per week), diet (frequency and amount of intake of different foods, beverages, supplements).	X			T0-T3	1-3
Healthcare utilisation	Patients' use of the healthcare system (community vs hospital-based services, specialist vs general provider, urban vs rural setting).	X		X	T1-T3	4
Internet use	Patients' use of electronic equipment with internet access, use of internet to find health information and use of the web portal <a href="http://helsenorge.no">helsenorge.no</a>	X			T0-T3	2-3
Major life events	Comprises three items assessing major life events.	X			T1-T3	1-3
Beliefs about Medicines Questionnaire (BMQ) <sup>42</sup>	Comprises 11 items (the BMQ-Specific) and assesses the key psychological constructs that underpin the core X beliefs influencing adherence to medicines.	X			T1-T3	3
eHealth Literacy Scale (eHEALS) <sup>18</sup>	Comprises 10 items and assesses patients' combined knowledge, comfort, and perceived skills at finding, evaluating and applying electronic health information to health problems.	X			T0, T3	2
EQ-5D-5L <sup>43</sup>	Comprises five items and is widely used for measuring economic preferences for health states.	X			T0-T3	4
Health Literacy Questionnaire (HLQ) <sup>44</sup>	Comprises 20 items measuring four levels of health literacy: appraisal of health information (5 items); social support for health (5 items); ability to find good information (5 items); and understanding health information (5 items).	X			T0, T3	2
Heart Continuity of Care Questionnaire (HCCQ) <sup>19</sup>	Comprises 33 items covering eight topic areas: heart condition explained, communication among providers, preparation for discharge, posthospital review of treatment, receipt of conflicting information, information on medications and on physical and dietary needs.	X			T1	1
HeartQoI <sup>45</sup>	Comprises 14 items with 10-item physical and 4-item emotional subscales.	X			T3	1-4
Medication Adherence Report Scale (MARS-5) <sup>46</sup>	Comprises five items and measures self-reported adherence to medicines, and assesses both intentional and unintentional non-adherence.	X			T1-T3	3
Minimal Insomnia Symptom Scale (MISS) <sup>47,48</sup>	Comprises three items assessing major features of insomnia, that is, difficulties initiating sleep, waking at night and not feeling refreshed by sleep.	X			T0-T3	1-3
Patient Activation Measure (PAM) <sup>49</sup>	Comprises 13 items assessing patient knowledge, skill and confidence for self-management.	X			T2	2
RAND-12 <sup>50</sup>	Comprises 12 items with 3-5 response levels. It generates two health indices: mental and physical health.	X			T0-T3	1-4
Sleep Sufficient Index (SSI) <sup>48,51</sup>	Comprises two items assessing amount of actual and desired sleep.	X			T0-T3	1-3
Study of Osteoporotic Fractures (SOF index) <sup>52</sup>	Comprises three items and assesses weight loss, inability to rise from a chair five times without using the arms and self-reported poor energy.	X			T0, T3	1-3
Hospital Anxiety and Depression Scale (HADS) <sup>53</sup>	Comprises 14 items and determines the levels of anxiety and depression that a patient is experiencing, and generates two subscales: HADS-D and HADS-A.	X			T0-T3	1-4

Continued

Table 3 Continued

Measure	Details	Self-report	Hospital medical records	National registry	Time*	Project†
Myocardial Infarction Dimensional Assessment Scale (MIDAS) <sup>54</sup>	Comprises 35 items specifically measuring seven different domains of health status and daily life challenges in individuals who have suffered a myocardial infarction: physical activity (12 items), insecurity (9 items), emotional reaction (4 items), dependency (3 items), diet (3 items), concerns over medication (2 items) and side effects (2 items).	X			T1–T3	1–3
Nordic Patient Experiences Questionnaire (NORPEQ) <sup>55</sup>	Comprises eight items and gives a brief measure of patient experiences in evaluation of the quality of healthcare delivery.	X			T1	1
Seattle Angina Questionnaire (SAQ-7) <sup>56</sup>	Comprises seven dimensions of coronary artery disease: physical limitation, angina frequency and quality of life.	X			T0–T3	1–3
WHOOOL-BREF <sup>57</sup>	Comprises one global item on overall quality of life.	X			T0–T3	1–4

\*T0: baseline, T1: 2-month follow-up, T2: 6-month follow-up, T3: 12-month follow-up.

†Project 1: continuity of care, Project 2: health literacy and self-management, Project 3: adherence to treatment, Project 4: healthcare use and costs.

EO-5D-5L, 5-level version of EuroQoL-5 Dimension; RAND-12, RAND-12 Item Health Survey; WHOQOL-BREF, The World Health Organization Quality of Life Instrument Abbreviated.

Centre, and the local principal investigators and directors of the departments in each participating study centre, are signed before initiation of data collection. The study is registered at ClinicalTrials.gov.

### PATIENT AND USER INVOLVEMENT

CONCARD<sup>PCI</sup> involves patients and stakeholders to target aspects of the patient journey to identify bottlenecks and carve out a user-friendly intervention. Patient involvement is carried out in several ways: two patient representatives with a history of CAD, and trained to be patient representatives both in healthcare and research settings,<sup>28</sup> provide input to the planning, implementing and reporting of results from the study. Representatives from all healthcare levels will be end users of knowledge from the project and are actively involved in the project through the CONCARD<sup>PCI</sup> Expert Group (online supplementary appendix). Reporting of patient involvement will follow the GRIPP2 reporting checklists.<sup>29</sup>

### COMMUNICATION OF RESULTS AND TRANSITION OF KNOWLEDGE

The CONCARD<sup>PCI</sup> has a close-to-practice and clinical approach, which will be an advantage in dissemination and communication with end users. Results will be disseminated to patients through patient organisations, and to healthcare professionals in PCI treatment teams and CR teams, as well as in primary care through seminars and scientific meetings. Due to the comprehensiveness of the outcome measures in the thematic projects (table 4), numerous scientific papers are expected. Long-term follow-up will be reported as data become accessible. Authorship on publications from the study will be allocated using the guidelines for authorship defined by the International Committee of Medical Journal Editors and depends on personal involvement.

### DISCUSSION

While medicine has produced large advances in cardiac treatment, there is need for more consistent patient pathways and systematic follow-up care. In order to do so, bottlenecks in the patient journey need to be identified. CONCARD<sup>PCI</sup> aims to close knowledge gaps related to four main areas: (1) continuity of care, (2) health literacy and self-management, (3) adherence to treatment, and (4) healthcare utilisation and costs of care. Although landmark cohort studies have been carried out to describe the aftercare of patients after acute myocardial infarction (MI), less is described of the patient journey, specifically after PCI, and rarely have these included extensive self-report from patients. In the past decade, an increasing number of studies using patient-reported outcomes have been performed, but in a different setting, with shorter follow-up and targeting subgroups of patients with acute MI.<sup>30–34</sup> The US-based SILVER-AMI study focused

**Table 4** Definition of outcomes in CONCARD<sup>PCI</sup>

Outcome	Definition
Continuity of care	As measured by the Heart Continuity of Care Questionnaire (HCCQ). <sup>19</sup>
Health literacy and eHealth literacy	As measured by the Health Literacy Questionnaire (HLQ) <sup>44</sup> and eHealth Literacy Scale (eHEALS) questionnaire. <sup>18</sup>
Adherence to medication	As measured by the Medication Adherence Report Scale (MARS-5), <sup>46</sup> Beliefs about Medicines Questionnaire (BMQ) <sup>42</sup> and data related to consumption of prescribed medication identified through national prescription registries, and serum levels of cardiac medication.
Healthcare utilisation	As measured by patients' use of primary care services (general practitioner visits) and secondary care services (inpatient admissions and outpatient visits).
Healthcare (associated) costs	As measured by the tariffs of national agreements between the professional associations of medical specialists and the National Health Services, and the tariffs of the national case-mix system of the diagnosis-related groupings (DRG) and the Danish Ambulatory Grouping System (DAGS).
Time to readmission	Cardiac and all-cause readmissions.
Time to death	Cardiac and all-cause mortality.
Time to major adverse cardiac events (MACE)	A composite of cardiac mortality and hospitalisation for cardiovascular disease or chest pain.

on older adults,<sup>30</sup> the VIRGO study<sup>31</sup> concentrated on younger women after acute MI, TRIUMPH<sup>32</sup> was designed to examine racial differences after acute MI, Vanderbilt Inpatient Cohort Study<sup>33</sup> included both patients after acute MI and patients with heart failure, and NOR-COR<sup>34</sup> retrospectively surveyed patients below 80 years of age 2–38 months after the index event including also patients with coronary artery bypass surgery or no intervention. Age is of particular concern as it is documented that invasive strategies benefit clinically stable very old patients with non-ST-elevation acute coronary syndrome.<sup>35</sup> In contrast, CONCARD<sup>PCI</sup> has an extended perspective by prospectively including adult patients with no age limit, engaging stakeholders throughout the study, applying a comprehensive interdisciplinary approach and including data from national registries. One great asset of the participating Nordic countries is infrastructure in research with access to demographics and health information through the national registries. The registries include all citizens, and a personal identifying number ensures no loss to follow-up. In addition to national compulsory registries on death (National Death Registry),<sup>23 24</sup> readmission and use of healthcare services (National Patient Registry)<sup>25 26</sup> and prescription and medication consumption (National Prescription Registry),<sup>21 22</sup> the countries have disease-specific national medical quality registries (eg, the Norwegian Registry of Invasive Cardiology). With establishing national registries, opportunities for nationwide comparisons and quality improvement of healthcare service are created.

While the aforementioned studies<sup>30–34</sup> also have detailed data abstracted from medical records and self-report, CONCARD<sup>PCI</sup> has a timely approach in the four thematic projects—one of which concerns health literacy, and specifically eHealth literacy is of particular relevance in information technology-driven societies. The AHA Scientific Statement on health literacy<sup>2</sup> calls for studies examining health literacy and cardiovascular outcomes

beyond 30-day readmission. It is suggested that health literacy can be evaluated as part of programmes aiming to improve secondary prevention in that health literacy influences dropout rates in CR. CONCARD<sup>PCI</sup> responds to this challenge.

Lack of continuity of care and low health literacy are likely to carry increased healthcare utilisation (eg, readmission to hospital) and increased cost.<sup>36</sup> The potential need for rethinking CR based on patient preferences and in-built economic analysis is a relevant path to follow. Moving towards a more patient-centred care aims to maximise patients' self-care abilities. Increased self-care is an overarching goal when healthcare expenditure rises to unaffordable levels. Further, in additional parameters, patient-reported outcomes can potentially identify patients at high risk of adverse outcomes and hospital readmissions,<sup>37 38</sup> which is of importance both to patients and society.

The importance of increased patient involvement and shared decision-making at all levels of healthcare is underlined in policy documents at a governmental and regional level.<sup>39</sup> Patient involvement is a unique feature of CONCARD<sup>PCI</sup> scarcely described in comparable large-scale studies. The use of standardised patient-reported outcome measures may provide information that can assist in this decision-making.<sup>37 38</sup> In CONCARD<sup>PCI</sup>, we include patient-reported outcome measures on a global, generic and disease-specific level,<sup>40</sup> and pose research questions related to patient pathways that concern a large group of patients. We anticipate that treatment outcome (adherence), safe communication (continuity and health literacy) and self-management will prove important to future healthcare.

However, the study has some limitations. We lack participating hospitals from northern Norway. The remoteness and distance to the PCI centre is a feature of that area and therefore of particular concern. However, travel time to the PCI centre from the most remote fjords in western

Norway is also long and this catchment area is included in the study (figure 3). Further, we exclude patients with delirium and dementia due to ethical reasons regarding informed consent and logistical difficulties. Delirious patients and patients too clinically unstable to be included following the PCI procedure, who would otherwise be eligible, are reassessed until discharge. Non-participants will be compared with participants on a limited number of registry variables to account for potential selection bias. Extensive self-report is a feature of CONCARD<sup>PCI</sup>, and we use validated questionnaires and only a few de novo created questions based on patient interviews. Still, the response rate of follow-up (T1–T3) may be a potential limitation. However, previous methodological work in patients with CAD showed high acceptability of comprehensive questionnaires<sup>41</sup> and patient representatives participating in planning of CONCARD<sup>PCI</sup> ensured relevance of the questionnaires.

## STATUS

Data collection for the cohort study commenced on 12 June 2017 and is expected to continue until July 2020, with a 10-year follow-up until July 2029. The inclusion of patients for the blood sampling for objective medication adherence measurement has started.

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