The Effect of Hospital-Based Case Management in Cancer Care Pathways

PhD dissertation

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PhD thesis: The Effect of Hospital-Based Case Management in Cancer Care Pathways

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OUTLINE OF THE THESIS

The pivot of this PhD thesis is a randomised controlled trial of case management which was conducted at Department P, Aarhus University Hospital, from March 2009 to May 2011. The ideas for an evaluation of hospital-based case management in cancer care were initially described in 2006 in the grant application for the umbrella project ‘Coherence in Cancer Care’, which received start-up funding from the Novo Nordisk Foundation and the Danish Cancer Society.

Chapter 1 introduces the concept of case management and provides a general introduction to cancer care and the challenges of healthcare. It also presents the definitions of relevant terms and the aims of the thesis. Chapter 2 offers a description of the methods used. Chapter 3 presents the results, which are presented in more detail in the four papers. Chapters 4 and 5 offer a discussion of the methods and results. Chapter 6 summarises the conclusions relevant to the aims of the project. Chapter 7 raises the perspectives and offer suggestions for future research. Chapter 8 lists the references used in the thesis. Chapters 9 and 10 are the English and Danish summaries. The four papers follow in Chapters 11-14.

Appendices A-G include the CM manual (containing statement of consent, needs assessment checklist, etc.), the questionnaires and cover letters, tables of patients’ characteristics at follow-up, data quality of responses in returned questionnaires, and a review published on the subject ‘care coordination’ in Ugeskrift for Læger.
THE FOUR PAPERS OF THE THESIS

- Wulff CN, Thygesen M, Søndergaard J, Vedsted P; Case management used to optimize cancer care pathways: A systematic review; BMC Health Services Research. 2008;8:227.

- Wulff CN, Vedsted P, Olesen F, Thaysen HV, Laurberg S, Rasmussen PC, Søndergaard J; A randomised controlled trial of hospital-based case management for colorectal cancer patients: Methods and feasibility; Submitted to BMC Health Services Research, 9 Dec 2011.

- Wulff CN, Vedsted P, Søndergaard J; A randomised controlled trial of hospital-based case management to improve colorectal cancer patients’ health-related quality of life and evaluations of care; submitted to British Medical Journal, 7 April 2012.

- Wulff CN, Vedsted P, Søndergaard J; A randomized controlled trial of hospital-based case management in cancer care: A general practitioner perspective; Accepted for publication in Oxford Family Practice, 11 July 2012.
MOTIVATION

Working as a junior doctor and being a man with family and friends, I understand the importance of patients’ preferences being respected and the importance of patients experiencing continuity of care.

While working as a junior doctor, I have experienced that inadequate coordination of diagnostics and treatment has a negative impact on both patients’ well-being and on productivity within healthcare.

The conduct of evidence-based medicine is extremely important, not least due to the limited financial and clinical resources, but also not to waste patients’ valuable time. The delivery of many health services is not evidence-based, either because the evidence has not been sought or because no research exists. Thus, when Jens Søndergaard in February 2007 told me about the ideas for a trial testing case management for cancer patients, I understood that this was my chance to do health services research in an under-investigated healthcare area that I find very important.

“A health system that does not satisfy its consumers, regardless of technical quality, does not optimally serve society.” (1)

“Low-quality care typically does not stem from a lack of effective treatments, but from inadequate systems to carry them out.” (2)
This PhD project was carried out during my past employment as a research fellow in the positive climate that permeates the Research Unit for General Practice, Aarhus University, from May 2007 to April 2012. I would like to express my gratitude to many people.

First of all, I wish express my gratitude to my supervisors. The basis for this present work springs from motivating discussions with my daily supervisors, ‘Skrivebordsgeneralerne’ (‘The Desk Generals’), Professor Jens Søndergaard and Professor Peter Vedsted. You learned me a lot! I also wish to thank my clinical supervisors Professor, Chief Surgeon Søren Laurberg and Chief Surgeon Peter Christian Rasmussen for constructive discussions regarding the organisation and treatment of colorectal cancer.

Professor Frede Olesen, former Director of the Research Unit for General Practice in Aarhus was not formally my supervisor, but vigorously contributed with ideas and enthusiasm.

Clinical Nurse Specialist and PhD Fellow Henriette Vind Thaysen offered invaluable support in all parts of the project, from developing the intervention, engaging the case managers, running the dialogue with the staff at Department P to collecting data and auditing medical records. Henriette, I owe you much gratitude.

My special thanks go to Trine Røge and Mette Søndergaard, registered nurses experienced in colorectal cancer, for resigning your permanent positions and faithfully taking on the fixed-term case manager assignments. Trine and Mette, I could not have found better people to take on these tasks. I hope you also appreciated our case management journey and I wish you all well!

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At Surgical Department P, I wish to thank the following people for discussions and support: Chief Surgeons Henrik Christensen and Anders Tøttrup, Head Nurse Martha Lund, Medical Secretary Liss Lawaetz, Ambulatory Nurse Inga Have and PhD Fellow Mette Bak Nielsen.

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Thank you, to the General Practitioners Kaj Sparle Christensen, Roar Maagaard and Ivar Østergaard (in memory of him) for help with improving questionnaires and teaching the case managers about primary care.

Most importantly, I wish to thank the patients, relatives and primary health professionals who agreed to participate and shared their thoughts by answering the questionnaires. Without you, there would be no thesis.

Finally, I wish to thank my family. First of all, my fantastic wife Anne and our two lively sons Gustav and Andreas, who were born while I was working on this project. Anne, thank you for enduring a lot!
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CM</td>
<td>Case management</td>
</tr>
<tr>
<td>CNW</td>
<td>Christian Nielsen Wulff</td>
</tr>
<tr>
<td>CRC</td>
<td>Colorectal cancer</td>
</tr>
<tr>
<td>EORTC QLQ-C30</td>
<td>The European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire version 3.0</td>
</tr>
<tr>
<td>FACT-G/ -C</td>
<td>The Functional Assessment of Cancer Therapy Scale Generic/ Colorectal version</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-related quality of life</td>
</tr>
<tr>
<td>IQR</td>
<td>Inter-quartile range</td>
</tr>
<tr>
<td>MDT</td>
<td>Multidisciplinary team</td>
</tr>
<tr>
<td>PROs</td>
<td>Patient-reported outcomes</td>
</tr>
<tr>
<td>PPR</td>
<td>Prevalence proportion ratio</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>RN</td>
<td>Recruiting nurse</td>
</tr>
</tbody>
</table>
The Effect of Hospital-Based Case Management in Cancer Care Pathways
CONTENTS

Chapter 1: Introduction ........................................................................................................ 1

GENERAL INTRODUCTION ............................................................................................. 2
1.1.1  Cancer incidence and prevalence in Denmark .............................................. 2
1.1.2  The Danish healthcare system ................................................................. 3
1.1.3  Cancer diagnostics and cancer care in Denmark .................................. 3

CANCER CARE CHALLENGES AND ACTIONS TAKEN .............................................. 4
1.2.1  General challenges of healthcare in developed countries ................. 4
1.2.2  Cancer-related healthcare challenges ....................................................... 4
1.2.3  Actions taken to improve coordination and continuity of care ......... 5
1.2.4  Case management and the case manager ............................................. 6

CONCEPTS AND DEFINITIONS .................................................................................. 8
1.3.1  Quality of care ............................................................................................... 8
1.3.2  Patient evaluations ...................................................................................... 8
1.3.3  Health-related quality of life .................................................................... 8
1.3.4  Continuity of care ....................................................................................... 9
1.3.5  Care coordination ....................................................................................... 9
1.3.6  Shared care .................................................................................................. 9
1.3.7  Integrated care ..............................................................................................
1.3.8  Disease management and care management ........................................ 10
1.3.9  Healthcare concepts resembling case management ......................... 10

BACKGROUND AT A GLANCE .................................................................................. 11
1.4.1  Problems at a glance ....................................................................................
1.4.2  The case management concept at a glance .......................................... 11

AIMS ............................................................................................................................. 12
1.5.1  Overall aim ....................................................................................................
1.5.2  Specific aims ...................................................................................................

Chapter 2: Material and methods .................................................................................. 13

THE SYSTEMATIC REVIEW ......................................................................................... 14
The Effect of Hospital-Based Case Management in Cancer Care Pathways

2.1.1 Literature search ............................................................... 14
2.1.2 Study selection ............................................................... 14
2.1.3 Data extraction ............................................................... 15

INTERVENTION STUDY DESIGN .................................................. 16
2.2.1 Setting ............................................................................. 16
2.2.2 Participants ...................................................................... 17
2.2.3 Recruitment and randomisation procedures ....................... 17
2.2.4 Blinding ........................................................................... 18

THE INTERVENTIONS ................................................................... 19
2.3.1 The control group ............................................................. 19
2.3.2 The case management intervention ..................................... 19
2.3.3 Development and piloting of the case management intervention 21

QUESTIONNAIRES ..................................................................... 23
2.4.1 Questionnaires in general ................................................ 23
2.4.2 The participant baseline questionnaire ............................... 23
2.4.3 The participant follow-up questionnaire ............................ 23
2.4.4 EORTC QLQ-C30 .............................................................. 24
2.4.5 The GP questionnaire ....................................................... 25
2.4.6 Questionnaire logistics ..................................................... 25

REGISTRY DATA .......................................................................... 27
2.5.1 Danish National Health Service Register ............................ 27
2.5.2 Other registries and other information used .......................... 27

SAMPLE SIZE CALCULATION, STATISTICS, ETHICS AND REGISTRATION ........................................... 28
2.6.1 Sample size calculation .................................................... 28
2.6.2 Statistics ........................................................................... 28
2.6.3 Ethics and registration ...................................................... 28

Chapter 3: The studies ................................................................. 29
PAPER 1 ..................................................................................... 31
3.1.1 Aim ................................................................................. 31
3.1.2 The literature search ....................................................... 31
## Contents

3.1.3 The studies........................................................................................................... 32

PAPER 2.................................................................................................................. 33

3.2.1 Aim ................................................................................................................... 33
3.2.2 Data and analyses ........................................................................................... 33
3.2.3 Feasibility of recruitment and allocation procedure ....................................... 33
3.2.4 Feasibility of the case management intervention ............................................. 36

PAPER 3.................................................................................................................. 37

3.3.1 Aim ................................................................................................................... 37
3.3.2 Methods ............................................................................................................ 37
3.3.3 Results ............................................................................................................. 37

PAPER 4.................................................................................................................. 42

3.4.1 Aim ................................................................................................................... 42
3.4.2 Methods ............................................................................................................ 42
3.4.3 Results ............................................................................................................. 42

Chapter 4: Discussion of methods ............................................................................. 45

METHODS FOR THE SYSTEMATIC REVIEW................................................................. 46

4.1.1 Search strategy .................................................................................................. 46
4.1.2 Summarising the studies .................................................................................. 46

THE RCT: ASPECTS OF INTERNAL AND EXTERNAL VALIDITY................................. 47

4.2.1 Internal and external validity of findings from a RCT .................................. 47

CASE MANAGEMENT IS A COMPLEX INTERVENTION............................................... 48

4.3 Challenges of evaluating complex interventions ................................................. 48

4.3.1 Development of the CM intervention ............................................................... 48
4.3.2 Ensuring feasibility and piloting procedures .................................................. 49
4.3.3 Evaluation of the intervention ......................................................................... 50
4.3.3.1 Assessing effectiveness ............................................................................. 50
4.3.3.2 Fidelity ....................................................................................................... 51

THE OUTCOME MEASURES ..................................................................................... 53

4.4.1 Patient-reported outcomes in general ............................................................ 53
4.4.1.1 Timing of assessments .............................................................................. 53
4.4.1.2 Selection bias caused by attrition .................................................. 53
4.4.1.3 Information bias ........................................................................... 54
4.4.2 Health-related quality of life ............................................................... 54
4.4.2.1 Measurement properties of the EORTC QLQ-C30 ......................... 54
4.4.2.2 Statistical analyses of HRQoL data .................................................. 55
4.4.3 Patient evaluation items ..................................................................... 56
4.4.4 The general practitioner-notable effects ............................................. 57
4.4.4.1 The general practitioners’ evaluations ............................................. 58
4.4.4.2 Contacts to the GPs and the out-of-hours GP services ..................... 59

SUMMARISING VALIDITY ............................................................................. 61
4.5.1 Summarising internal validity ............................................................ 61
4.5.2 External validity ................................................................................. 62
4.5.3 Summarising internal and external validity ....................................... 62

Chapter 5: Discussion of results .................................................................. 63

AIM 1: Establishing the evidence and best practice ....................................... 64
5.1.1 Comparison with existing literature focusing on cancer ..................... 64

AIM 2: Feasibility of the CM intervention ..................................................... 66
5.2.1 Conducted CM activities and patient caseload .................................. 66

AIM 3: Patient-reported outcomes ............................................................... 67
5.3.1 HRQoL ............................................................................................. 67
5.3.1.1 Conceptual model of HRQoL and comparison with the literature 67
5.3.1.2 HRQoL-results in comparison with other research ....................... 68
5.3.1.3 Concluding remarks on effectiveness of CM on HRQoL ............... 68
5.3.2 Patient evaluations ............................................................................. 69

AIM 4: Effects notable to the GPs ................................................................. 70
5.4.1 GP evaluations .................................................................................. 70
5.4.2 Patients’ contacts to GPs at daytime and out-of-hours ..................... 71

Chapter 6: Main conclusions ...................................................................... 73

6.1 Overall aim of the PhD project ............................................................. 74
6.2 What was already known on CM in cancer care? (Aim 1) ................. 74
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3 Methods and feasibility of the RCT testing CM (Aim 2)</td>
<td>74</td>
</tr>
<tr>
<td>6.4 Effectiveness as to patient-reported outcomes (Aim 3)</td>
<td>75</td>
</tr>
<tr>
<td>6.5 GP-notable consequences of the CM intervention (Aim 4)</td>
<td>75</td>
</tr>
<tr>
<td>Chapter 7: Perspectives and future research</td>
<td>77</td>
</tr>
<tr>
<td>7.1 Perspectives and lessons learned</td>
<td>78</td>
</tr>
<tr>
<td>7.2 Proposals for future research</td>
<td>79</td>
</tr>
<tr>
<td>Chapter 8: References</td>
<td>81</td>
</tr>
<tr>
<td>Chapter 9: English summary</td>
<td>99</td>
</tr>
<tr>
<td>Chapter 10: Dansk resumé</td>
<td>103</td>
</tr>
<tr>
<td>Chapter 11: Paper 1</td>
<td>107</td>
</tr>
<tr>
<td>Chapter 12: Paper 2</td>
<td>127</td>
</tr>
<tr>
<td>Chapter 13: Paper 3</td>
<td>153</td>
</tr>
<tr>
<td>Chapter 14: Paper 4</td>
<td>179</td>
</tr>
<tr>
<td>Appendix A: The CM manual</td>
<td>207</td>
</tr>
<tr>
<td>Appendix B: Patient baseline questionnaire</td>
<td>247</td>
</tr>
<tr>
<td>Appendix C: Patient follow-up questionnaire</td>
<td>257</td>
</tr>
<tr>
<td>Appendix D: Data quality of patient responses</td>
<td>271</td>
</tr>
<tr>
<td>Appendix E: GP questionnaire</td>
<td>275</td>
</tr>
<tr>
<td>Appendix F: GP evaluation data quality</td>
<td>283</td>
</tr>
<tr>
<td>Appendix G: Care coordination paper published in Ugeskrift For Læger</td>
<td>287</td>
</tr>
</tbody>
</table>
CHAPTER 1:

INTRODUCTION
Cancer care pathways extend from exposure, over symptoms, through diagnostics and treatment, through survivorship and for roughly half of all cancer patients through a palliative phase. In the past decade, the topics ‘coordination of cancer care pathways’ and ‘continuity of cancer care’ have often been discussed in the media and by policymakers. Unfortunately, in Denmark, these discussions have been driven by research indicating poor relative cancer survival compared with the surrounding countries (3,4), several media case stories about inappropriate delay and coherence in care pathways, and research indicating that many cancer patients experience inadequate information and support (5).

Many different elements in the effort to improve the organisation and continuity of cancer care are being discussed. One proposed element is the implementation of hospital-based case managers (case management, CM), the effects of whose introduction appears to be scientifically poorly studied.

This thesis aims to increase our insight into the effects of hospital-based CM used to improve cancer care. First, however, this chapter gives a brief overview of cancer epidemiology in Denmark, the organisation of cancer care in Denmark, the challenges/ inadequacies of cancer care (apply to most developed countries), Danish steps taken to improve the inadequacies, and the concept of CM.

1.1.1 Cancer incidence and prevalence in Denmark

Roughly every third Dane will develop cancer at some time during his or her life. In 2010, a total of 35,563 new cancer cases were registered (exclusive basal cell skin cancer), and by 31 December 2010, a total of 234,683 Danes (98,504 men and 136,179 women) were living with at least one cancer diagnosis.

Overall, colorectal cancer (CRC) is the most frequent cancer type (4,363 new cases in 2010; 12% of all); for men, prostate cancer, CRC and lung cancer are the most frequent cancer types; for women, the most frequent are breast cancer, lung cancer and CRC. In 2010, persons above 60 years accounted for 75% of all cancers (6). Cancer is the primary cause of death, causing 15,799 (29% of all) deaths in 2010 (7). The overall 5-year relative cancer survival is 51% for men and 56% for women (8).
1.1.2 The Danish healthcare system

The Danish healthcare system is based on the principle of free and equal access for all citizens registered with the National Register of Persons. Thus, the vast majority of health services are tax-financed and free of charge for the users (9).

All general practitioners (GPs) in Denmark are independent contractors with the Regional Health Administrations and are remunerated on a mixed fee for service and capitation basis. Almost all (98%) of the population are assigned to a specific general practice through a list system. People have to consult their specific GP for medical advice, and the GP acts as a gatekeeper as to investigation and treatment in hospitals and as to practising medical specialists other than ophthalmologists and ear-nose-throat office-based specialists (10). In general practice, medical records are fully computerised (but not externally shared), and communication between hospitals and general practice is based on standardised electronic letters. The GPs in turn (rota-system) undertake the out-of-hours GP services which are open on weekdays from 4PM-8AM plus 24 hours in weekends and on bank holidays.

The hospitals are owned and managed by the five Danish regions. The regions must provide free hospital treatment and emergency treatment. Within certain limits, citizens can freely choose the hospital in which they wish to be treated. Anyway, most citizens are treated in their region’s own hospitals, which may refer patients to highly specialised departments in other hospitals, possibly in other regions. Private hospital care is available, but they deliver only 3% of all hospital services and do not normally undertake treatment for cancer (9,10).

Hospital medical records are still specific to each department, but shared and computerised medical records are being developed these years.

1.1.3 Cancer diagnostics and cancer care in Denmark

The Danish gatekeeper system means that for 85% of cancer patients the GP is involved in the pathway to diagnosis (11,12). Normally, the hospital specialists assume responsibility for detailed diagnostics and for coordination and follow-up of cancer care. Usually, the GP is informed about the cancer diagnosis by means of a brief ambulatory note, whereas detailed information about diagnostics tests, the cancer stage, its treatment and planned follow-up is transferred after treatment has ended (e.g. by means of discharge summaries sent after surgery and after completed oncology treatment). Even though, the Danish GP is positioned as an anchor healthcare professional, the GP’s role during cancer treatment and in relation to follow-up and rehabilitation seem poorly defined (13).
CANCER CARE CHALLENGES AND ACTIONS TAKEN

1.2.1 General challenges of healthcare in developed countries

Rapid developments in medical technology and specific treatments have specialised and centralised healthcare during recent decades. Care for patients suffering from chronic disease or cancer (or combinations of these diseases) therefore often takes place across different settings and involves numerous health professionals from different disciplines. Sadly, high-quality multidisciplinary care often seems compromised by inadequate communication and coordination between health professionals and problems with patients’ access to trusted health professionals, for which reason many patients experience inadequate continuity of care and many feel ‘left in limbo’ (14-16).

1.2.2 Cancer-related healthcare challenges

A cancer diagnosis negatively affects the individual’s quality of life both before, during and after treatment (17-20).

Both qualitative and quantitative research has found that many cancer patients and their relatives experience inadequate information about and psychosocial support in relation to diagnosis, treatment, symptom management, aftercare, prognosis and rehabilitation. Many patients experience continuity breaks of which one type is inadequate information transfer to GPs, especially when care involves providers in different settings (5,11,21,22). Many patients also express uncertainty about where to go and who to address in case of questions or problems (5,11,23). A recent Danish survey of 4,346 cancer patients found that they crucially valued if one healthcare professional overlooked and took responsibility for the overall hospital care (11).

Suboptimal patient evaluations are problematic for many reasons. First of all, patient evaluations have gradually become recognised as an important quality of care-element at par with ‘technical quality’ and objective outcomes, and a mismatch may exist between these aspects (24-27). Moreover, suboptimal patient evaluations may negatively affect treatment compliance and concordance (28) and patients’ well-being (29,30).

Parallel to the patient evaluations, qualitative and quantitative Danish research involving GPs has found that many GPs lack timely and thorough information from the hospital to successfully handle patients’ contacts and to initiate rehabilitation (31-33). The consequences of these deficits in communication and information transfer from the hospital to the GPs have not been thoroughly
studied, but the deficits probably have an adverse effect on patients’ safety by causing unnecessary readmissions, lack of appropriate follow-up and medication errors (34). In addition, research from the U.S. has found that cancer patients are less likely to receive the recommended care for chronic conditions and to receive sufficient preventive care even if they have more medical contacts than age-matched non-cancer patients (35). Danish qualitative research has found that GPs generally wish for earlier and more detailed information from the hospital-based health professionals regarding their patients’ medical and non-medical conditions and needs. Some GPs also wish to be more involved in the treatment decision processes (33,36).

Conclusively, evidence exists that both cancer patients and their GPs commonly experience inadequate coordination and continuity of cancer care caused by numerous health professionals involved in each patient’s care and no standardised knowledge transfer, direct communication channels and clearly described responsibilities.

1.2.3 Actions taken to improve coordination and continuity of care

In Denmark, it was decided in 2004 to introduce a so-called ‘contact person’ scheme in general healthcare in order to ease patients’ access to hospital-based health professionals and the scheme was statutorily implemented 1 January 2009 (37,38). A ‘contact person’ therefore has to be appointed for every patient treated within hospitals. Despite good intentions, it is questionable whether the introduction of ‘contact persons’ improves patients’ safety, experience of coherence and access to qualified personalised health care support (39-41). The reasons for this are several, among others, that the contact person’s tasks are generally confined to one specific department; and that alternating working hours and other local conditions afford the staff with poor conditions for duly assuming the role of contact person (39).

Since 2000, three cancer plans have been launched in Denmark. The second Cancer Plan (2005) recommended fast-track ‘cancer packages’ for patients with suspected cancer to speed up and smoothen hospital-based activities from referral to cancer treatment (42). One consequence of the cancer packages was that the hospitals were urged to point out ‘forløbskoordinatorer’ (43). Anyway, the function was not clearly defined and tasks appeared to diverge from a ‘forløbskoordinator’-function previously described within Danish chronic care-publications (please see Section 1.2.4 below for a further discussion).

The third Cancer Plan (2010) recommended that the cancer packages should undergo revision and should embrace the entire care pathway, i.e. go beyond
treatment. Most recommendation was subsequently politically adopted along with a statutory decision that hospitals treating cancer patients were to engage ‘forløbskoordinatorer’ to improve care coordination and patients’ experiences of continuity of care (44,45).

1.2.4 Case management and the case manager

CM has been used for decades in English-speaking healthcare settings (46,47) “based on the assumption that people with complex health problems need assistance in using the healthcare system effectively.” (48) Despite various definitions and specifications of CM models, there seem to be agreement that the pivotal purpose of CM is to link quality and cost-effective care for individual patients requiring numerous or long-term health services (47-51).

The following is a common CM definition (52):

“A collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet the client’s health and human service needs. It is characterized by advocacy, communication, and resource management and promotes quality and cost-effective interventions and outcomes.”

CM is usually conducted by experienced nurses, who are engaged as case managers. Descriptions of CM models vary, but they typically include the framework (i.e. the prominent features of the intervention), the setting (hospital-based, hospital-to-community-based, or community-based/primary care-based) and the target population (e.g. CM for patients suffering from diabetes) (47,49).

CM can be implemented as a ‘tool’ within a disease management program (see Section 1.3.8), as a single intervention or it may be combined with other interventions (53,54). Tasks and responsibilities for the case managers obviously vary. Common tasks are supervision of care plans and services, patient outreach and support, information dissemination, and serving as an easily accessible hospital-based health professional for all those who are involved in the care pathway. Case managers have been described to take on different roles, for instance: manager, facilitator, clinician, consultant (patient advocate) and educator. Case managers are characterised as possessing strong clinical, managerial and communicative skills, as well as possessing the ability to work independently while maintaining their colleagues’ respect (47,55,56).

In line with the purpose of CM, ‘to link and optimise cost-effective care’, research on CM has usually analysed combinations of clinical, patient-reported and cost endpoints. Several reviews have sought to summarise the effectiveness
of community- and hospital-to-community-based CM for patients suffering from chronic disease. Despite variability as to interventions, methodology and outcomes studied, findings indicate that CM promotes cost-effective care (53,57-59). A few reviews have focused on the effects of hospital-based CM for patients suffering from chronic disease, but their findings can be characterised as inconclusive and the methodology deployed in most of these studies has been reported to be poor (60,61). Importantly, we have found no review focusing on the effectiveness of CM within cancer care.

In Denmark, the concept of CM was initially introduced in 2005 as an element of disease management programmes for patients suffering from chronic diseases. The Danish term ‘forløbskoordinator’ was stated as synonym to ‘case manager’. A generic case manager function was described, but publications at the same time articulated a need for gathering experience as to the conduct of CM and to its effectiveness (62-64).

As previously stated, within cancer care, the ‘forløbskoordinator’ was initially mentioned in 2007 in publications on the cancer packages. The function was described “being responsible for monitoring and documenting cancer care pathways and for informing the management about possible bottlenecks and inappropriateness.” (43) Apparently, these publications disregarded that the ‘forløbskoordinator’ had already been defined in the chronic disease reports published by the National Board of Health. As a consequence of the lack of definition and proposed duty list, since 2007, many hospital departments have engaged nurses or medical secretaries as ‘forløbskoordinatorer’ to take on various tasks in relation to cancer patients’ care pathways.

The basis for the present PhD thesis is formed by discussions on several levels about implementation of case managers within Danish cancer care and that the evidence for CM effectiveness is sparsely analysed. The project began before the term ‘forløbskoordinator’ was introduced within Danish cancer care for which reason we decided to use the term ‘forløbskoordinator’ as a synonym for the tested case manager function.
CONCEPTS AND DEFINITIONS

Before proceeding to the detailed description of present study, we believe that a broad introduction to some of the key concepts used in this thesis is in place.

1.3.1 Quality of care

The definition of ‘health care quality’ formulated by the Institute of Medicine seems commonly accepted. It goes: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” (14)

According to Donabedian, who for decades debated ‘quality of medical care’, it is a multidimensional construct, “a remarkably difficult notion to define [...] a reflection of values and goals current in the medical care system and in the larger society of which it is a part.” (1) Donabedian stated that assessment of quality of care relies on three types of information which could be classified as to: “the structure”, “the process”, and “the outcome” (24).

1.3.2 Patient evaluations

In this thesis, ‘patient evaluations’ refer to patients’ assessment of processes of care and their satisfaction with care.

We are well aware that in the literature, ‘patient satisfaction’ and ‘patient evaluations’ often are seen as different entities (25,65). According to Wensing and Elwyn, “‘evaluation’ suggests a cognitive process in which specific aspects of care are assessed, while ‘satisfaction’ refers to an emotional response to the whole experience in health care.” (65)

In research studies, patient evaluations often accompany assessment of traditional clinical outcomes on account of the growing realisation that patient evaluations is one distinct quality of the care aspect (25,66). Thus, the patient is the only person experiencing the entire care pathway and the patient’s preferences, values and evaluation of these processes have been found to differ from those of the health professionals (27,67).

1.3.3 Health-related quality of life

‘Health-related quality of life’ (HRQoL) refers to subjectively assessed quality of life emphasizing aspects related to health and illness (68-70). HRQoL is primarily assessed in research studies using questionnaires; which can generally be characterised as generic measures or disease-/ population-specific measures (69,71). Most HRQoL instruments measure different aspects (often called...
domains) of well-being, for instance symptoms, functional status and overall quality of life (measured on so-called subscales) (72,73).

1.3.4 Continuity of care

According to a synthesis by Haggerty et al, “Continuity is the degree to which a series of discrete healthcare events is experienced as coherent and connected and consistent with the patient’s medical needs and personal context.” (74) Haggerty et al stated that two core elements distinguish continuity from other healthcare attributes. The first is care of the individual patient, the second is care over time. Further, Haggerty et al divided continuity of care into three types: “Informational continuity: The use of information on past events and personal circumstances to make current care appropriate for each individual. Management continuity: A consistent and coherent approach to the management of a health condition that is responsive to a patient’s changing needs. Relational continuity: An ongoing therapeutic relationship between a patient and one or more providers.” (74)

1.3.5 Care coordination

In this thesis, ‘care coordination’ (and ‘coordination of care’) refers to: “the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services.” (75)

Unfortunately, ‘care coordination’ appears esoterically used and, obviously, with different meanings. For instance, some authors have used ‘care coordination’ as a synonym for case management (76), while other have used the term synonymously with continuity of care (77).

1.3.6 Shared care

‘Shared care’ is a concept closely related to CM and care coordination. Generally, shared care is about sharing the responsibility for and the coordination of care between two or more health care providers in different settings or locations using the existing resources (78).

1.3.7 Integrated care

There is no commonly accepted definition of ‘integrated care’ (79). In this thesis, integrated care refers to a feature of care. Its core elements are that care “is organized around the needs and preferences of patients, that patients are actively involved in decisions about their own care (patient-centredness), that
care is given in optimal collaboration between all the professionals involved (multidisciplinary care) and that seamless and continuous care is given with optimal coordination and organization of the total care process (organization of care).” (80)

As a consequence of above definition, ‘integrated care interventions’ refer to different kinds of interventions used to achieve one or more of above elements, e.g. case management (80).

1.3.8 Disease management and care management

One among numerous definitions of ‘disease management’ goes: “an intervention designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple treatment modalities.” (81) Agreement seems to exist that a disease management program focuses on improving the health of populations rather than that of individuals (CM focus on individuals) and that programs vary tremendously because of numerous different elements and variations in comprehensiveness (81-84).

Care management is a term closely related to disease management, and many researchers regard the two terms as being synonyms (85).

1.3.9 Healthcare concepts resembling case management

Various concepts and functions resembling case management and case managers have been introduced to improve continuity and cost-effective health care for individual patients. ‘Cancer care coordinators’ and ‘patient navigators’ are two examples of ‘case manager’-related functions within cancer care.

The ‘cancer care coordinator’ is a function identical to that of the case manager described above introduced within the Australian healthcare sector within the past decade. The ‘cancer care coordinator’ has been defined as: “someone who engages directly with a patient, manages the care process, including the development and communication of the care plan, and secures that all the care needed is arranged and delivered.” (86,87)

In the U.S., many patient navigation programs have been introduced to reduce healthcare disparities for underserved populations’ (ethnic minorities and the poor) care. Most often, the ‘patient navigator’ is a dedicated lay person who offers support and guidance to an individual with abnormal cancer screening test results or helps patients diagnosed with cancer in accessing the healthcare system and overcoming barriers to obtaining optimal cancer care (88-90).
1.4.1 Problems at a glance

- Cancer is common: One in three persons will be struck by cancer and the overall 5-year age-standardised relative cancer survival is 51% for men and 56% for women.
- A diagnosis of cancer has a large impact to the well-being of the sufferer.
- Cancer patients are less likely than other ill persons to receive recommended care for chronic conditions and to receive preventive care.
- Many cancer patients have unfulfilled information and support needs during the period of their cancer treatment.
- Many GPs to cancer patients report that they receive insufficient information from the hospital to support and help manage patients’ medical and non-medical conditions.
- Research on methods to improve coordination and continuity of cancer care is needed.

1.4.2 The case management concept at a glance

- CM is often advocated as a method that may improve coordination and continuity of care for patients having complex care needs.
- Danish policymakers, patients associations and media have argued that the implementation of hospital-based case managers may improve cancer care.
- The policy context is that ‘forløbskoordinatorer’ (a case manager-like function) will be introduced for all Danish cancer patients.
- The effects of CM conducted by hospital-based case managers in cancer care seem sparsely studied.
- There is an urgent need for establishing evidence on effectiveness of CM implemented in cancer care.
AIMS

1.5.1 Overall aim
The overall aim of this thesis was to explore the contents and effectiveness of CM in cancer care.

1.5.2 Specific aims
The specific aims of this thesis were:

1. To compile the contents and effects of CM in cancer care based on a systematic literature review (Paper 1).
2. To develop, implement and present the feasibility of an RCT including a CM intervention customized to the Danish healthcare system, CRC patients and Department P, Aarhus University Hospital (Paper 2)
3. To analyse the effectiveness of above-mentioned CM intervention as to patient-reported outcomes (PROs), i.e. HRQoL and patient evaluations (Paper 3).
4. To analyse the effects of above-mentioned CM intervention as to GPs’ evaluations and patients’ contacts to the GPs and the out-of-hours GP services (Paper 4).
CHAPTER 2:

MATERIAL AND METHODS
The Effect of Hospital-Based Case Management in Cancer Care Pathways

THE SYSTEMATIC REVIEW

The aim of Paper 1 was to compile the contents and effects of CM in cancer care based on a systematic literature review. The methods used in this paper are described below.

2.1.1 Literature search

We performed database searches and concurrent snowball searches with the aim of detecting all published randomised controlled trials (RCTs) in which CM had been applied in the care for people with cancer. The review was restricted to RCTs because they have the most robust design for establishing cause-effect relationship between an intervention and its outcomes (91-93).

The following databases were searched for papers published in English, Norwegian, Swedish or Danish during the years up to August 2008: PubMed, Embase, Web of Science, CINAHL and The Cochrane Central Register of Controlled Trials.

Various combinations of MeSH, key words and text words were used in the searches to accommodate for differences between the databases. The PubMed and Embase databases made it possible to limit searches to publications that used the “randomised controlled trial” design. In the Cinahl, Web of Science and Cochrane databases, RCTs were searched for by adding the terms "randomly" OR "randomised" OR "randomized" (free-text) to the search criteria.

See Paper 1 for keywords searched and the detailed PubMed search.

2.1.2 Study selection

Papers on CM-like interventions were included if they fulfilled all of the following inclusion criteria:

1) The intervention should meet the criteria for CM, which comprise multidisciplinary collaboration and care coordination, and in-person meetings between the patient and the case manager aimed at supporting, informing and educating the patient.

2) The intervention should focus on cancer patients’ care; and if other diseases than cancer were included, the majority of the included patients should be suffering from cancer.

3) The intervention should aim to improve subjective (e.g. patient-, carer- or GP-reported) or objective outcomes, and effects should be reported in the paper.
Excluded were studies that centred on cancer screening or palliative cancer care.

2.1.3 Data extraction

No specific software was used for extraction of data to obtain a descriptive overview of intervention characteristics, outcomes of interest and findings. Elements from the CONSORT guidelines and their checklists (94,95) were used to assess elements influencing internal and external study validity.
INTERVENTION STUDY DESIGN

The rest of this chapter forms the basis for Papers 2-4 by describing the elements and the methods of an RCT analysing the effectiveness of a hospital-based CM intervention.

2.2.1 Setting

The Surgical Department P, Aarhus University Hospital in Aarhus performs surgery for both benign and malignant diseases of the lower intestinal system (colon, rectum and anus). At the time of the present trial, the Department consisted of three bed wards, an endoscopic clinic, an outpatient clinic, a stoma clinic and a surgical section.

The surgeons at Department P are highly specialised in diagnostics and treatment of locally advanced and recurrent CRC. Patients suffering from locally advanced and recurrent CRC are therefore referred from other surgical centres in Denmark to undergo assessment and if possible the advanced treatment conducted in the Department.

Colorectal cancer treatment

Appropriate CRC treatment hangs on meticulous disease staging (96). Most patients suffering from CRC are offered immediate surgery with a curative intent. Patients suffering from locally advanced rectal cancer are typically offered pre-operative chemo-radiotherapy. Some patients are offered post-surgical oncological treatment, and patients suffering from metastatic disease or non-radically treated patients may undergo, e.g. liver resection or radiofrequency ablation.

Rectal cancer treatment is often more extensive than colon cancer treatment, but survival from the two cancer types is almost identical. The overall 1-year CRC survival rate is 73%, and the overall 5-year survival rate is 45% (97).

Usual diagnostics and treatment coordination at Department P

Patients from the local catchment area had their endoscopic investigation performed by a surgeon who entrusted a nurse to coordinate and book further diagnostics. All rectal cancer patients and patients suffering from locally advanced colon cancer had their diagnostic investigations and treatment offer discussed at a multidisciplinary team (MDT) meeting. Patients with localised colon cancer had their treatment offer decided by the surgeon in the outpatient
clinic. The patient and the surgeon agreed on a treatment plan which was coordinated and booked by one of two experienced outpatient nurses.

Patients referred from other CRC centres had their disease stage and treatment discussed at a MDT meeting. A chief surgeon ultimately decided these patients’ treatment offer, and a dedicated secretary coordinated and booked the patients’ contacts.

Patients suffering from locally advanced or recurrent CRC were planned to be seen by the same chief surgeon at all visits. Fast-track surgery was standard care for primary colon cancer. Patients planned to go through fast-track surgery visited the ward before hospitalisation. At this visit, a dedicated nurse provided information on the perioperative procedures including planned discharge at day two after surgery.

As statutorily prescribed for patients treated in hospitals, patients at Department P were informed that one or more named health professionals (ward nurses) functioned as ‘contact persons’ during their diagnostics and treatment.

2.2.2 Participants

During the inclusion period from 11 March 2009 to 29 December 2010, all patients at Department P were assessed for inclusion. We included patients with a diagnosis of CRC or ‘a highly probable diagnosis of CRC’ (according to a Department P surgeon) who were to undergo further investigation or treatment at Department P. We excluded patients with poor Danish language skills or apparent cognitive dysfunction. Moreover, most eligible patients suffering from primary non-metastatic rectal cancer were recruited to another research study which hindered their inclusion into this RCT.

2.2.3 Recruitment and randomisation procedures

The first meeting between the recruiting nurse (RN) and an eligible patient most often took place in the outpatient clinic after the patient’s cancer had been staged and treatment had been booked. All potential participants were asked to participate and were orally informed that the purpose of the trial was to analyse the effects of two differently organised ‘contact person’ functions. Patients interested in participation were handed over an informed consent form for participation in a research project and a baseline questionnaire, which they were allowed to fill in at home. If the patient returned these documents, the RN contacted an independent secretary situated at the Research Unit for General Practice who performed the computerised, concealed allocation procedure.
The SiMin minimisation software (99) was used to randomise participants using a 1:1 allocation ratio. Minimisation is a dynamic allocation method which may be considered instead of stratified block randomisation when several stratification factors are to be used (100). Minimisation seeks to even out predefined stratification factor imbalances between groups. The patient’s stratification characteristics determine to which group the patient will be allocated. Most often, minimisation also incorporates a random factor. One advantage of minimisation is that randomisation lists become unnecessary (100). To ensure comparable groups in terms of baseline characteristics potentially associated with the outcomes, the following stratification factors were used: gender (male / female), cancer type (rectal cancer / colon cancer) and age (< 65 years/ 65-79 years/ > 79 years). A random factor of 1:4 was used (i.e. 80% probability of allocation to the group where the patients’ characteristics were underrepresented).

2.2.4 Blinding

The individual patient’s allocation status was known by the patient and the case managers, but blinded to the researchers. A label in the patients’ medical records informed healthcare professionals at Department P about which patients were allocated to CM. The GPs of the control group patients were informed about the study only when receiving the follow-up questionnaire. The GPs of the CM participants were informed about the CM service in all notes sent by the case managers.
2.3.1 The control group

The control group patients received usual treatment and care at Department P. In the usual procedure, patients were assigned and informed about one or more contact persons at Department P who could be contacted in case of problems or questions. No particular health professional overlooked the patients’ care pathways and they were not pro-actively contacted by telephone.

Control group patients’ GPs were sent information from the Department P surgeons as part of the usual practice in the Department. An ambulatory note was usually sent after the patient’s first visit to the endoscopic section or after the patient’s first visit in the outpatient setting. Detailed information about the patient’s cancer stage, treatment and planned follow-up was usually sent to the GP after the patient had ‘completed’ cancer treatment.

2.3.2 The case management intervention

The CM intervention was conducted as a supplement to usual treatment and care. The case managers’ tasks (including the scheduling of visits), the needs assessments and their areas of responsibility were described in a detailed manual (see Appendix A). The described case manager function corresponded to the description in the Danish Generic Model for Disease Management Programmes (63).

Two experienced nurses were employed especially to work as case managers. They were situated at Department P and worked daytime and weekdays only. Their principal task was to ensure that the individual patient experienced coherent and meaningful care from the time of randomisation until four weeks after ‘completed’ cancer treatment. We defined treatment as ‘completed’ when the surgeon planned no further treatment.

The CM intervention had four main elements:

- Supervision of the patient’s care pathway with the purpose of anticipatory correction of inadequacies.
- Regular, pro-active, scheduled patient contacts with the purpose of anticipating inconveniences and preventing the patient’s feeling of ‘being left in limbo’.
- Day-time reactive telephone support. The case manager functioned as a CRC knowledgeable, consistent and immediately available hospital-based health professional.
• Provision of scheduled written information to the patient’s GP and other relevant health professionals concerning the patient’s planned treatment, level of information and potential psychosocial concerns.

As early as possible after the patient’s randomisation, the case manager arranged a face-to-face (preferably) or telephone meeting where a systematic needs assessment (see checklist in manual) was conducted and where the patient was informed about the CM service. The assessment focused on the patient’s psychosocial resources / barriers, knowledge and beliefs about CRC, planned treatment and potential complications. After the assessment, an electronic message summarising the planned treatment, the potential barriers for optimal care and patient’s knowledge about his or her situation was sent to the patient’s GP. Both the patient and the patient’s GP were given the case manager’s direct cell phone number and information about availability, which was Monday to Friday from 8.30am to 3pm.

The case manager contacted the patient (at least) every second week by telephone to assess the patient’s health status, psychosocial well-being and awareness of upcoming diagnostics and treatment. The case manager intended to meet the patient at every Department P encounter. If the patient felt uncomfortable or if something unexpected occurred, the case manager repeated and underpinned information, gave advice about things to do and helped establish contact to a surgeon, a home nurse, the GP, etc. If such ‘disturbances’ were encountered, the case manager temporarily intensified proactive contacts.

Needs assessments similar to the one performed initially were performed at every transition between care settings. At any transitions between care settings where Department P was involved, the case manager sent the patient’s GP an electronic summary message about the treatment status and about potential barriers for optimal care. When relevant, the case manager informed health professionals at other institutions about the patient’s health status.

The case managers were introduced as members of the MDT and joined the bi-weekly MDT meetings at Department P. The case managers had access to all hospital-based computerised patient administration systems.

The case managers kept paper records of all contacts in relation to their patients. For the purpose of the feasibility assessment, the case managers noted the number of minutes spent having contact with the patients, their relatives and other health professionals. They characterised these contacts according to four documentation categories (information, support, coordination and involvement) already being used by other Danish nurses (101).
A PaT-plot (102) of the control group intervention, the CM group intervention and the time of patient questionnaires can be seen in Figure 2.1.

2.3.3 Development and piloting of the case management intervention

The CM intervention and manual were developed in close cooperation with Clinical Nurse Specialist Henriette Vind Thaysen, Department P, and based on a thorough review of the CM literature, any literature describing problems experienced by cancer patients in relation to their disease, their treatment and their meetings with the healthcare system. Furthermore, the intervention was informed by other interventions focused on improving psychosocial support, information and health care continuity.

Before recruitment of trial participants began, the case managers spent more than two months studying and training CM. The formal introductory programme encompassed personalised education and training provided by key health care professionals: healthcare system (Professor Frede Olesen and Professor Peter Vedsted), CRC diagnostics and treatment (chief surgeons at Department P), use of computerised patient administration systems (Information Officer Lis Lund) and communication with cancer patients (Psychologist Mai-Britt Guldin). The case managers made day visits to the surgery ward, two different GP surgeries, the local oncology department and the local radiological department, and they attended a one-week residential cancer rehabilitation course together with cancer patients at Dallund Rehabilitation Centre (run by the Danish Cancer Society).

The inclusion procedures and the intervention were piloted on ten patients. During the pilot test, the research team and the case managers cooperated on improving the intervention and on revising the manual.

During the pilot test, all doctors and nurses at Department P had oral and written information about CM, the case managers’ tasks and the trial.

Considerations regarding the development of the CM intervention are described in Chapter 4.
Figure 2.1 Overview of the interventions.

<table>
<thead>
<tr>
<th>Time 0</th>
<th>Consecutive colorectal cancer patients at Department P, Aarhus University Hospital were assessed according to the inclusion and exclusion criteria. Patients who met the criteria were informed about the project. Patients who returned the statement of consent and the baseline questionnaire were randomised.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CM GROUP*</td>
<td>CONTROL GROUP</td>
</tr>
<tr>
<td>Time 0</td>
<td>a</td>
</tr>
<tr>
<td>Week 0-8</td>
<td>1</td>
</tr>
<tr>
<td>Week 8</td>
<td>HRQoL and patient evaluation questionnaire</td>
</tr>
<tr>
<td>Week 9-30</td>
<td>1</td>
</tr>
<tr>
<td>Week 30</td>
<td>HRQoL and patient evaluation questionnaire</td>
</tr>
<tr>
<td>Week 31-52</td>
<td>1</td>
</tr>
<tr>
<td>Week 52</td>
<td>HRQoL and patient evaluation questionnaire</td>
</tr>
</tbody>
</table>

Explanations:

| a | First contact between the case manager and the patient: Information about CM service and needs assessment. |
| b | Electronic summary message from the case manager to the patient’s GP and other relevant persons: Information about CM, planned treatment and care, needs assessment and shared care. |
| c | The case manager meets the patient in Department P and regularly contacts the patient by phone to assess bio-psycho-social well-being and information level (contacts end four weeks after the end of cancer treatment). |
| d | Change in care setting and/ or treatment plan: Electronic summary message from the case manager to the GP and if relevant to other involved healthcare professionals. |
| e | Information about the statutory contact person (handover of calling card). |
| 1 | Diagnosing and treatment of colorectal cancer. |
| * | Only planned CM activities are illustrated. In-going calls, etc. are not depicted. |

GP: general practitioner; CM: case management; HRQoL: health-related quality of life
QUESTIONNAIRES

2.4.1 Questionnaires in general

Two participant questionnaires, one used at baseline and one used at each of the three follow-up time points, plus a GP questionnaire were designed. Below follows a description of the baseline questionnaire (Appendix B), the follow-up questionnaire (Appendix C) and the GP questionnaire (Appendix E).

2.4.2 The participant baseline questionnaire

The baseline questionnaire included 30 items of a validated HRQoL measure, the European Organisation for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30) (described below) and 24 items assessing participants’ characteristics for the purpose of investigating whether potential confounders had been evenly distributed. Items clarified through this questionnaire were: self-rated health prior to the cancer, co-morbidity, evaluation of preceding cancer diagnostics and care, evaluation of the GP, locus of control-related issues, structural network and anticipated social support, as well as socio-demographics. Most items were adapted from items used in previous Danish healthcare surveys (103-105).

Around 40 patients assisted in the face validity- and pilot-testing, which was conducted in several steps. Moreover, colleagues at the Research Unit familiar with designing questionnaires scrutinised and commented on the questionnaire.

2.4.3 The participant follow-up questionnaire

The patient evaluation questionnaire included the 30 items of the EORTC QLQ-C30 (see below) and 60 ad hoc piloted patient evaluation items, which were supposed to tap aspects related to information, support, continuity of care and overall quality of care. The first 57 items of the questionnaire were answered using the categories ‘Completely agree’, ‘Agree’, ‘Do not agree’, ‘Completely disagree’ and ‘Don’t know/ Not applicable’. The last three items asked participants for their overall impression of care using the categories: ‘Excellent’, ‘Very good’, ‘Good’, ‘Less good’ and ‘Bad’.

During the pilot test, eight items were chosen as the primary patient evaluation endpoints; six of these items were supposed to tap information and support from health professionals, and continuity of care; two items asked for patients’ assessment of the overall quality of care. Based on the responses from the pilot
test, we decided to dichotomise the answers into very positive responses and less than very positive responses (i.e. ‘Completely agree’ vs ‘Agree’/’Do not agree’/’Completely disagree’; and ‘Excellent’/’Very good’ vs ‘Good’/’Less good’/’Bad’). ‘Don’t know/Not applicable’ and missing answers would be omitted if comparable between groups.

An extensive literature search in PubMed and in the Patient-Reported Outcome and Quality of life Instruments Database (106) revealed no across-the-continuum patient evaluation measure relevant for cancer care (107). Validated measures appeared to focus on either the in-patient setting or the out-patient setting. Ad hoc items were developed based on an extensive review of the literature on ‘quality of health care’ (24,65), ‘continuity of care’ (74) and ‘determinants for cancer patient satisfaction’ (29,108-110). Moreover, findings from Danish health care surveys (5), and items used in Danish and English questionnaires (5,27,111-114) inspired the development of the items.

The questionnaire was piloted and improved in several rounds. First, it was sent to colleagues at the Research Unit and it was face validity-tested in the out-patient clinic at Department P. Next, it was sent to 37 CRC patients who had been treated at Department P within the past six months. Twenty-four patients returned a filled-in questionnaire. Their answers were used to inspect the distribution of responses and to assess time used to fill in the questionnaire. Five of the 24 patients were contacted by telephone and systematically asked for wording, interpretation and acceptability of particular items using ‘think-aloud’ and ‘verbal probing’ approaches (115). Based on the piloting, some items were rephrased to avoid floor and ceiling effects.

2.4.4 EORTC QLQ-C30

The EORTC QLQ-C30 is a validated cancer-population specific, 30-item questionnaire available in a Danish version (116,117). The EORTC QLQ-C30 measures HRQoL on one global health status scale, five functioning scales (physical, role, emotional, cognitive and social functioning) and nine symptom scales. The first 28 items are scored on a 4-point Likert scale ranging from 1 (not at all) to 4 (very much). The last two items which measure the global health status scale are scored on a modified 7-point linear analogue scale.

A continuous scale score ranging from 0 to 100 was calculated if the patient had answered at least half of the items of the scale. A score of 100 indicated the highest functioning (118).
The primary endpoint of this study was the global health status scale. The functioning scales were secondary endpoints. The symptom scales were not analysed as we did not anticipate that CM would impact these aspects of well-being.

The first two pages of both patient questionnaires contained the items from the EORTC QLQ-C30.

2.4.5 The GP questionnaire

The GPs' evaluations of care were explored using an ad hoc piloted 20-item questionnaire. The first 18 items addressed three aspects: patient-specific information from the hospital, the course of treatment and deficiencies in patient-specific information. Moreover, the GP was asked whether he or she had contacted the hospital on his or her own initiative; if 'yes', the GP was asked to respond to two items evaluating these contact(s).

Items were answered using two four-point Likert scales; ‘To a great extent’, ‘To some extent’, ‘To a small extent’, ‘Not at all’, and ‘Don’t know/N.A.’; or ‘Strongly agree’, ‘Agree’, ‘Disagree’, ‘Strongly disagree’ plus ‘Don’t know/N.A.’.

The development of the questionnaire was based on a search in various databases (PubMed, Bibliotek.dk, DanMedBul plus Google) for established measures to be filled in by the GP, but neither validated nor commonly used GP measures were identified. Eventually, ad hoc items relevant for present study were developed inspired by items in questionnaires developed by colleagues at the Research Unit. The GP questionnaire was piloted and validated in a two-step procedure: First, it was sent to GP colleagues at the Research Unit; second, it was sent to a group of experienced GPs who were asked to respond to the items while reflecting on the care pathway of their most recent cancer patient. The GPs were asked to add comments and to note any disregarded aspects.

2.4.6 Questionnaire logistics

The participant follow-up questionnaire, enclosed a one-page cover letter and a pre-stamped envelope, was posted to participants alive at eight, 30 and 52 weeks after inclusion (-/+1 week). Non-response after three weeks prompted a posted reminder. Non-response after six weeks prompted a reminder phone contact.

The GP questionnaire was posted 30 weeks after the patient’s recruitment (whether the patient was alive or dead), if necessary with a posted reminder three weeks later. The GP letter consisted of a one-page cover letter, the questionnaire and a pre-stamped envelope for the return of the questionnaire.
An Access database was created for the purpose of managing questionnaire logistics. Each questionnaire was assigned a unique ID number enabling questionnaires to be non-referable to the patient, but allowing merging of questionnaire data into each patient’s Access database file.

All questionnaires were designed and optically scanned using the computer programme Teleform Enterprise Version 8 (Cardiff software inc., San Marcos, CA, USA). CNW and three student workers performed the optical scanning process and verified the scanning results. A coding manual describing the handling of inadequately filled-in items was developed prior to questionnaire dispatch. The data processing procedures described above were well-known at the Research Unit and their validity has been documented (119). Verified Teleform questionnaire data were transferred to the statistical program Stata version 11.2 (StataCorp, College Station, Tex, USA) using StatTransfer and they were further checked for errors.
Chapter 2:
Material and methods

REGISTRY DATA

All residents of Denmark have a personal identification number, a unique 10-digit number assigned to them by the Central Population Register, which permits accurate linkage of personal information from different databases and registries.

2.5.1 Danish National Health Service Register

The Danish National Health Service Register holds information about the activities of health professionals contracted with the tax-funded Danish public healthcare system. Professionals’ notification of patient contacts and any provided procedures to the registry is connected with reimbursement from the Regional Health Administrations. The data completeness of the register is therefore assumed to be very high (120).

Using the participants’ personal identification numbers, we retrieved data from the Danish National Health Service Register on 30 December 2011. The retrieval contained data on patients’ contacts to their GPs and the out-of-hours GP services in the time span from three months before to nine months after the day of the individual patient’s inclusion.

2.5.2 Other registries and other information used

The Danish Colorectal Cancer Group (DCCG) holds a register which includes information on all primary CRC patients (97). In December 2011, this register was used to gather information on primary CRC patients’ types of cancer and any surgical interventions performed. Information not found in this database was sought in a local database and by scrutinising medical records from Department P.

On the day of scheduled follow-up, each patient was checked with regard to vital status and address in the database of the Central Office of Civil Registration (121).
2.6.1 Sample size calculation
The global health status subscale of the EORTC QLQ-C30 formed the basis for the sample size calculation which indicated a need to include at minimum 140 patients in each group. The calculation was based on the following premises: 10 units as the minimal clinically relevant difference (122), the average score of the control group patients should be similar to reference data on CRC patients (mean 60.7; SD 23.4) (123), 90% power, two-sided significance level of 5% and 15% drop-out.

2.6.2 Statistics
All data were analysed using Stata version 11.2 (Stata Corporation, Texas, US) and analysed according to ‘intention-to-treat’ principle, i.e. patients were kept in the analyses regardless of their final diagnosis and degree of CM exposure. Statistical significance was set to 0.05 or less (two-sided).

2.6.3 Ethics and registration
The Danish Data Protection Agency approved the creation of a research database (file number: 2008-41-2932), and the RCT was indexed at www.clinicaltrials.gov (registration ID number: NCT00845247).

According to the Danish Research Ethics Committee System (124), the trial was not a biomedical intervention and did not need the ethics committee’s approval. This was confirmed by correspondence with the chair of the regional ethics committee. We deemed that the project was ethically acceptable to all participants as we did not know whether CM entailed better care than usual care, and we did not anticipate that CM and usual care would differ in terms of specific treatment offered, adverse effects and complications.
CHAPTER 3:

THE STUDIES
This chapter summarises each of the four papers.

**Paper 1** is a systematic review of intervention studies on effectiveness of CM within cancer care. This review was conducted in the planning phase of the RCT to develop our intervention on best practice.

**Paper 2** reports the development, methods and feasibility of the RCT.

**Papers 3-4** go through its results.
3.1.1 Aim
The paper “Case management used to optimize cancer care pathways: A systematic review” sought to identify all previously conducted CM-like RCTs and to summarise common features of the studies and their results.

3.1.2 The literature search
The search identified 654 unique papers possibly describing an intervention fulfilling our criteria for a CM-like intervention (see Chapter 2). Figure 3.1 shows that we found only seven papers reporting on the effectiveness of CM within cancer care while using an RCT design.

**Figure 3.1: Study inclusion**

654 potentially relevant RCTs identified in PubMed, Cinahl, Web of Science, Embase, Cochrane Register of Controlled Trials, and by snowball search.

629 promptly rejected by "scanning" headings or abstract.

25 RCTs retrieved for scrutiny by MT, PV and CW.

- Not CM: 15
- Not cancer: 1
- Not RCT: 2
- Other reasons: 2*

Seven RCTs included in the review, i.e. fulfilling inclusion and exclusion criteria.

* Two articles were excluded for more than one reason

** Two articles reported on already included articles or components hereof
3.1.3 The studies

The seven studies diverged much in terms of target patients, settings, intervention contents/activities and outcomes measures (See Paper 1, Table 1).

Two studies (125,126) included breast cancer patients only, two studies lung cancer patients only (127,128) and three studies included different cancer types (129-131). Three studies were targeted at subgroups of patients within the cancer type(-s); inclusion in two trials was delimited by patient age (125,131) and in one trial by cancer stage (127).

Six of the trials were conducted in the U.S. (125-127,129-131) and one in the U.K. (128). Two studies named the intervention CM (125,129), but the other studies still fulfilled the criteria set for CM.

Regarding effectiveness (Paper 1, Table 2), the methods used to measure effects were all different in terms of the instruments used and the timing of the assessment timing, and the validity of many of the instruments was not specified. All three RCTs analysing patient evaluations reported statistically significantly better care evaluations (some aspects) among CM patients than among non-CM patients (125,128,130). Two (126,128) of three (126,128,129) studies which analysed HRQoL reported better scores on some subscales among CM patients than among non-CM patients.

In addition to the above diversities which made it difficult to summarise the studies, we found the reporting of the studies to be generally poor (Paper 1, Table 3).
3.2.1 Aim
The paper “A randomised controlled trial of hospital-based case management for colorectal cancer patients: Methods and feasibility” describes the development, the methods and the feasibility of the RCT. The rationale for describing these elements in a specific paper is that CM is a complex intervention that may be difficult to satisfactorily report in a paper whose focus is on the results.

Chapter 2 reported the research methodology and the CM intervention for which reason only feasibility of recruitment, allocation and the CM intervention are reported below.

3.2.2 Data and analyses
Information on participants was gathered at baseline by means of the baseline questionnaire; information on disease characteristics was gathered 11 months after inclusion by a combination of registry retrievals and an audit of medical records (see 2.5.2).

Contacts and activities conducted by the case managers were analysed based on case notes in the CM medical records for the first 61 consecutively included patients. Contacts within 12 months from each patient’s day of inclusion were included in the calculations.

3.2.3 Feasibility of recruitment and allocation procedure
The recruitment period began on 11 March 2009 and ended 29 December 2010 when the a priori calculated sample size was reached. During this period, 532 patients were eligible for the trial of whom 280 (53%) were included. Reasons for non-participation appear from Figure 3.2. The 252 non-participants differed statistically significantly from the participants with regard to cancer type and age, but not gender. Thus, 83% (210 of 252) of the non-participants versus 46% (130 of 280) of the participants suffered from rectal cancer. The non-participants’ mean age was 68.6 (12.40) years versus the participants’ 66.3 (11.4) years.

Table 3.1 shows that the randomisation established two similar groups at baseline. Of the 280 participants, 186 (66.4%) were male, 142 (51%) suffered from colon cancer and 130 (46%) from rectal cancer.
Figure 3.2 Flow diagram of the trial.

**Patients with a diagnosis or a 'highly-probable diagnosis' of colorectal cancer at Department P (11 March 2009 – 29 December 2010)**

N= 532

- Exclusion criteria assessment and information about the project
- Patient consent, baseline questionnaire and randomisation (Week 0; n=280)
- NON-PARTICIPATION (N=252):
  - Another research project (n=116)
  - Excluded (n=56)
  - No care pathway at Dep P (n=24)
  - Cognitive dysfunction (n=12)
  - Poor Danish language skills (n=20)
  - Not asked due to ethical considerations (n=8)
  - Did not want to participate (n=67)
  - Missed (n=5)

---

**THE CONTROL GROUP** (n=140)

- Questionnaires were sent to patients at 8, 30 and 52 weeks after inclusion.
- Questionnaires were sent to GPs at 30 weeks.
- Information on all GP services from the Danish National Health Service Register in the period -3 to 9 months from baseline

**THE CM GROUP** (n=140)

- Questionnaires were sent to patients at 8, 30 and 52 weeks after inclusion.
- Questionnaires were sent to GPs at 30 weeks.
- Information on all GP services from the Danish National Health Service Register in the period -3 to 9 months from baseline

CM: case management
GP: general practitioner

Follow-up data and data for analyses are not shown (Figure 3.4 shows the data for Paper 3; Figure 3.5 shows the data for Paper 4.)
Table 3.1 *Patient characteristics at baseline by group assignment.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group N=140</th>
<th>CM group N=140</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>66.2 (11.7)</td>
<td>66.3 (11.1)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>47 (33.6%)</td>
<td>47 (33.6%)</td>
</tr>
<tr>
<td>Male</td>
<td>93 (66.4%)</td>
<td>93 (66.4%)</td>
</tr>
<tr>
<td>Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>62</td>
<td>58</td>
</tr>
<tr>
<td>Recurrent</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Rectal cancer</td>
<td>64 (45.7%)</td>
<td>66 (47.1%)</td>
</tr>
<tr>
<td>Primary</td>
<td>47</td>
<td>48</td>
</tr>
<tr>
<td>Recurrent</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Other cancer*</td>
<td>2 (1.4%)</td>
<td>2 (1.4%)</td>
</tr>
<tr>
<td>Not cancer*</td>
<td>2 (1.4%)</td>
<td>2 (1.4%)</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>16 (11.4%)</td>
<td>17 (12.1%)</td>
</tr>
<tr>
<td>Yes</td>
<td>124 (88.6%)</td>
<td>123 (87.9%)</td>
</tr>
<tr>
<td>Endoscopic surgery</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Laparoscopic surgery</td>
<td>20</td>
<td>24</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td>One or more chronic diseases*</td>
<td>73 (52.1%)</td>
<td>74 (52.9%)</td>
</tr>
<tr>
<td>Co-morbid diseases*:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>41 (29.3%)</td>
<td>53 (37.9%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>19 (13.6%)</td>
<td>20 (14.3%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>16 (11.4%)</td>
<td>6 (4.3%)</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>21 (15.0%)</td>
<td>21 (15.0%)</td>
</tr>
<tr>
<td>Negative self-rated health status prior to cancer diagnosis**</td>
<td>8 (5.8%)</td>
<td>11 (8.0%)</td>
</tr>
<tr>
<td>Negative evaluation of preceding diagnostics and care pathway**</td>
<td>12 (8.7%)</td>
<td>13 (9.6%)</td>
</tr>
<tr>
<td>Cohabiting or married**</td>
<td>99 (72.3%)</td>
<td>103 (73.6%)</td>
</tr>
<tr>
<td>Income &lt; 33,500 EUR/year**</td>
<td>56 (41.2%)</td>
<td>51 (37.0%)</td>
</tr>
<tr>
<td>Education for 3 years or longer**</td>
<td>34 (24.2%)</td>
<td>41 (30.4%)</td>
</tr>
<tr>
<td>Unemployed (senior citizen, unemployed etc.)**</td>
<td>90 (67.2%)</td>
<td>93 (67.9%)</td>
</tr>
</tbody>
</table>

Data are means (SD) or numbers (%).
CM: case management
* Eight patients were falsely thought to suffer from colorectal cancer at the time of inclusion.
** Reported by patients in the baseline questionnaire.
# Percentage of patients answering the item.
3.2.4 Feasibility of the case management intervention

On average, the case managers handled 9.7 (median 8, IQR: 5-13) contacts and spent 205 (median 150, IQR: 100-260) minutes in contact with the patient, his or her relatives and health care professionals. When contacts to professionals were excluded, the average number of minutes was 170 (median: 130; IQR interval: 85-215).

On average, 2.3 (median 2, IQR: 2-3) electronic summary messages were sent to the patients’ GPs.

A percentage-wise categorisation of the case managers’ contacts is shown in Figure 3.3. As can be seen, the case manager spent most of their time in contact with the patients, and ‘provision of support’ was their most time-consuming activity.

The research group met with the case managers on a regular basis to ensure that the CM intervention was being conducted in accordance with the manual. Halfway through the trial, each case manager was caring for 10-15 patients (caseload) who were undergoing CRC diagnostics or treatment. Throughout the trial, at least one of the two case managers was accessible on weekdays, except for two weeks during the midsummer of 2009 and 2010.

Figure 3.3 Bar charts illustrating case manager contacts.

Description of activities:
Support: Conversation with the patient about the disease and care pathway, pain and colorectal function. Repetition of already provided information.
Information: Guidance and counselling.
Coordination: Dissemination of information and contacts to other health professionals. Request of diagnostics test, etc.
Involvement: Encouraging the patient or the relatives to take certain actions.
3.3.1 Aim
The paper “A randomised controlled trial of hospital-based case management to improve colorectal cancer patients’ health-related quality of life and evaluations of care” analysed the effect of CM on patients’ HRQoL and their evaluations of care.

3.3.2 Methods
The patient questionnaire was sent to all patients alive at week 8, 30 and 52 after inclusion. The data analysed in this paper were the HRQoL scales and the dichotomised answers on eight patient evaluation items (identified during the questionnaire pilot test). Each follow-up data set was analysed separately. The primary endpoints were the global health status scale of the EORTC QLQ-C30 and the eight patient evaluation items. The secondary endpoints were scores on the functioning scales of the EORTC QLQ-C30. Patients’ HRQoL scores from the baseline questionnaire were a prerequisite for analysing the follow-up HRQoL.

The EORTC QLQ-C30 scores were analysed using analysis of covariance (ANCOVA) which, in effect, ‘adjusts each patient’s follow-up score for his or her baseline score’ (132). Complimentary to the formal statistical tests, the HRQoL subscales were plotted stratified by the time of the individual’s last response and by group. These plots present the data in an easily interpretable way and illustrate potential complexity of the data (which might be caused by non-random drop-out) (133).

The dichotomised patient evaluations were analysed using a generalised linear model (GLM) with log link for the binomial family and robust variance. Differences are presented as prevalence proportion ratios (PPRs) (134,135).

Non-response analyses were conducted to determine whether attrition had caused groups to be different in terms of the variables used in the minimisation procedure (gender, cancer type and age group). The primary endpoints were tested for subgroup-treatment effect interaction to detect possible subgroup benefits related to cancer type, gender and age using the same categories as used in the minimisation procedure (136).

3.3.3 Results
Figure 3.4, which is a continuation of Figure 3.2, shows that response rates were almost similar in each group (89% or higher) at all three time points. In addition,
the number of filled-in patient evaluation items and the number of calculated HRQoL scales appeared not to differ between the groups (Appendix D, Tables D3-D4).

Figure 3.4 Flow diagram (Paper 3).

The first part of the flow diagram is shown in Figure 3.2. Analysis boxes show the number of patients in calculations of scores/proportions and in the analysis of differences (Tables 3.2 and 3.3) and the number of patients in the profiles (See Paper 3, Figure 3).

CM: case management
Diff.: differences
* Wish of withdrawal stated in previously returned questionnaire.
No statistically significant group differences were found on any of the HRQoL subscales at eight, 30 or 52 weeks (see Table 3.2). The 95% confidence intervals (CIs) of the point difference estimates were all within +/- 10 units (after round of), which has been proposed as the minimal clinically important difference (122). The plots stratifying patients by length of follow-up and by group confirmed that positive effects were not overlooked (see Paper 3, Figure 3).

As to the patient evaluations, 27 of 28 difference point estimates favoured CM; five, three and zero of eight items were statistically significantly more positively answered by CM patients than by non-CM patients at week eight, 30, and 52, respectively (see Table 3.3).

Mortality 52 weeks after inclusion was higher in the CM group (31 patients) than in the control group (20 patients), but this difference was not statistically significant, and the two groups appeared almost similar in terms of the patients’ remaining characteristics (See Appendix D, Tables D1-D2). Anyway, to investigate the impact of potential attrition bias, analyses were conducted both with and without adjustment for gender, cancer type and age group. Difference between findings as to statistical significance appeared on a few patient evaluation items (Table 3.3, shown with asterisks), but not on HRQoL.

We found no statistical indication that any subgroup (gender, age, or cancer type) benefited differently from CM.
Table 3.2 Mean baseline and mean follow-up scale scores and ANCOVA-calculated group differences.

<table>
<thead>
<tr>
<th></th>
<th>8 weeks (if baseline scale)</th>
<th>30 weeks (if baseline and 8 weeks scale)</th>
<th>52 weeks (if baseline, 8 and 30 weeks scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n-control group: 116-119</td>
<td>n-control group: 101-104</td>
<td>n-control group: 96-99</td>
</tr>
<tr>
<td></td>
<td>n-CM group: 120-123</td>
<td>n-CM group: 102-107</td>
<td>n-CM group: 92-94</td>
</tr>
<tr>
<td><strong>Baseline Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global quality of life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>61.02 (25.90)</td>
<td>64.94 (23.68)</td>
<td>65.73 (22.19)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>64.38 (22.04)</td>
<td>66.09 (21.02)</td>
<td>67.21 (21.07)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global quality of life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>61.58 (21.43)</td>
<td>71.15 (20.57)</td>
<td>74.06 (21.17)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>64.48 (20.41)</td>
<td>71.24 (21.58)</td>
<td>70.56 (26.07)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global quality of life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>1.34 (-3.41 to 6.08)</td>
<td>-0.91 (-5.91 to 4.09)</td>
<td>-4.18 (-10.38 to 2.06)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>0.579</td>
<td>0.720</td>
<td>0.189</td>
</tr>
<tr>
<td>Physical functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>84.16 (18.54)</td>
<td>85.69 (17.05)</td>
<td>86.53 (15.96)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>84.88 (18.45)</td>
<td>86.29 (16.09)</td>
<td>86.03 (16.30)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>73.69 (23.17)</td>
<td>70.94 (23.14)</td>
<td>74.38 (20.10)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>74.40 (21.63)</td>
<td>71.23 (23.68)</td>
<td>78.14 (27.47)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>0.27 (-4.65 to 5.18)</td>
<td>-3.42 (-8.17 to 1.33)</td>
<td>-2.04 (-6.46 to 2.38)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>0.915</td>
<td>0.157</td>
<td>0.363</td>
</tr>
<tr>
<td>Role functioning</td>
<td></td>
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<td></td>
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<tr>
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<td>70.26 (32.95)</td>
<td>73.10 (31.36)</td>
<td>74.38 (30.10)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>71.14 (33.61)</td>
<td>74.37 (31.22)</td>
<td>78.14 (31.04)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Role functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>53.30 (35.11)</td>
<td>72.94 (31.34)</td>
<td>80.03 (28.76)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>55.56 (35.37)</td>
<td>71.23 (29.68)</td>
<td>81.49 (19.68)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Role functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>1.91 (-6.47 to 10.29)</td>
<td>-3.19 (-10.46 to 4.08)</td>
<td>-2.29 (-9.97 to 5.40)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>0.654</td>
<td>0.388</td>
<td>0.558</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>73.00 (23.18)</td>
<td>74.87 (21.69)</td>
<td>75.82 (21.23)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>73.75 (22.43)</td>
<td>75.05 (20.65)</td>
<td>84.04 (21.01)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>76.18 (22.91)</td>
<td>85.36 (18.94)</td>
<td>86.22 (19.22)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>79.94 (22.13)</td>
<td>82.34 (20.94)</td>
<td>84.04 (21.01)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>3.35 (-1.41 to 8.11)</td>
<td>-4.19 (-8.75 to 0.36)</td>
<td>-2.08 (-7.56 to 3.40)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>0.167</td>
<td>0.071</td>
<td>0.455</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>87.11 (18.73)</td>
<td>88.46 (16.38)</td>
<td>88.46 (15.89)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>87.98 (18.34)</td>
<td>85.38 (18.36)</td>
<td>85.38 (19.84)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>85.29 (19.58)</td>
<td>85.42 (17.84)</td>
<td>86.22 (16.84)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>85.93 (20.67)</td>
<td>85.38 (18.36)</td>
<td>87.59 (17.44)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
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<td></td>
</tr>
<tr>
<td>Cognitive functioning</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>0.14 (-4.28 to 4.55)</td>
<td>-0.36 (-4.47 to 3.76)</td>
<td>-0.78 (-4.95 to 3.38)</td>
</tr>
<tr>
<td>CM GROUP</td>
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<td>0.864</td>
<td>0.711</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>83.05 (23.77)</td>
<td>85.92 (20.71)</td>
<td>86.73 (20.30)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>84.44 (22.44)</td>
<td>82.22 (23.14)</td>
<td>86.39 (22.49)</td>
</tr>
<tr>
<td><strong>Follow-up Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>73.31 (25.89)</td>
<td>83.17 (23.40)</td>
<td>86.39 (22.49)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>76.48 (26.59)</td>
<td>82.22 (23.14)</td>
<td>85.48 (22.42)</td>
</tr>
<tr>
<td><strong>Group difference (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>2.34 (-3.48 to 8.12)</td>
<td>-2.86 (-8.24 to 2.52)</td>
<td>-1.06 (-7.62 to 4.90)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>0.425</td>
<td>0.295</td>
<td>0.726</td>
</tr>
</tbody>
</table>

Patients included in week 30 analyses were all included in week 8 analyses. Patients included in week 52 analyses were all included in week 8 and 30 analyses.
CM: Case management.
Table 3.3 Numbers and proportions (%) of patients taking a very positive or less positive stand, and the group differences.

<table>
<thead>
<tr>
<th>Patient evaluation item:</th>
<th>WEEK 8 AFTER INCLUSION</th>
<th>WEEK 30 AFTER INCLUSION</th>
<th>WEEK 52 AFTER INCLUSION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual care N=121</td>
<td>CM N=124</td>
<td>PPR</td>
</tr>
<tr>
<td>Overall, the information was satisfactory</td>
<td>50 (0.43)/67 (0.57)</td>
<td>58 (0.45)/63 (0.52)</td>
<td>1.12 (0.85 to 1.45) p=0.423</td>
</tr>
<tr>
<td>Doctors and nurses have overall been good at offering my family guidance, counselling, support and help</td>
<td>25 (0.20)/63 (0.64)</td>
<td>40 (0.32)/64 (0.62)</td>
<td>1.08 (0.75 to 1.55) p=0.687</td>
</tr>
<tr>
<td>At no time have I ever in doubt who to contact if I needed guidance, counselling, support and help</td>
<td>55 (0.47)/63 (0.54)</td>
<td>78 (0.63)/45 (0.67)</td>
<td>1.84 (1.00 to 1.65) p=0.051*</td>
</tr>
<tr>
<td>In my experience, a doctor or a nurse from the hospital has been there for me through my entire treatment course</td>
<td>51 (0.45)/63 (0.55)</td>
<td>73 (0.60)/49 (0.40)</td>
<td>1.34 (1.04 to 1.72) p=0.223*</td>
</tr>
<tr>
<td>When I was discharged after surgery, I felt confident about going home</td>
<td>34 (0.36)/61 (0.64)</td>
<td>53 (0.54)/46 (0.46)</td>
<td>1.50 (1.00 to 2.67) p=0.016*</td>
</tr>
<tr>
<td>In my experience, my treatment course has been coherent</td>
<td>41 (0.36)/74 (0.64)</td>
<td>57 (0.48)/61 (0.52)</td>
<td>1.85 (0.99 to 1.85) p=0.054</td>
</tr>
<tr>
<td>How do you assess the quality of your investigation and treatment at Department P so far?</td>
<td>89 (0.79)/28 (0.24)</td>
<td>105 (0.88)/15 (0.12)</td>
<td>1.15 (1.02 to 1.28) p=0.025*</td>
</tr>
<tr>
<td>How do you assess the quality of your overall diagnostics and treatment so far?</td>
<td>85 (0.71)/35 (0.29)</td>
<td>95 (0.77)/28 (0.23)</td>
<td>1.09 (0.54 to 2.17) p=0.258</td>
</tr>
</tbody>
</table>

Table shows absolute numbers and proportions (%). PPR = prevalence proportion ratio (95% CI) adjusted for age-group, gender and cancer type. A PPR > 1 indicates that more CM patients than control group patients concurred with the item. "Don't know/ Not applicable" and missing answers were almost comparable and have been omitted. * p < 0.05 in adjusted analyses.
3.4.1 Aim
The paper “A randomised clinical trial of hospital-based case management in cancer care: A general practitioner perspective” analysed partly the GPs’ evaluation of information from the hospital and the collaboration with hospital specialists, partly the patients’ contacts to GPs during daytime and out-of-hours.

3.4.2 Methods
The ad hoc piloted 20-item questionnaire was sent to all patients’ GPs 30 weeks after the patients’ recruitment. The GPs’ answers to the items were dichotomised and differences between the groups were analysed using a generalised linear model (GLM) with log link for the binomial family taking into account the potential cluster effect due to the fact that some GPs answered questionnaires on more than one patient. Group differences in responses are presented as prevalence proportion ratios (PPR) (134,135).

Data on the patients’ contacts to GP-led services in the period from three months before recruitment to nine months after recruitment were retrieved from the Danish National Health Service Register. The following daytime GP contacts were included in the analyses: Normal consultation, planned preventive consultation, conversational therapy, telephone consultation, e-mail consultation, home visit and outreach visit. The following out-of-hours GP services contacts were included in the analyses: Consultation, home visit and telephone consultation not followed by a consultation/ home visit. The patients’ contacts with their GPs and out-of-hours GP services were divided into periods of 90 days. These periods and the total follow-up period were analysed using two methods: 1) The numbers of contacts were compared using a negative binomial regression model which handles the dependent structure of contacts at the individual level (137); censoring caused by patient death was included in the model. 2) The proportions of patients with at least one contact were compared using a GLM with log link for the binomial family with robust variance (135).

3.4.3 Results
Figure 3.5 shows the number of patients with follow-up data. All 280 patients’ GPs were identified and sent a questionnaire. In both groups, 114 (81%) GPs returned a completed questionnaire.
Figure 3.5 Follow-up data (Paper 4).

We found a tendency of better GP evaluations in the CM group; three items regarding information from the hospital (psychological effects of the cancer, social effects of the cancer and information given to the patient by the specialists) and one summary measure of information deficiencies differed statistically significantly and favoured the CM group (Paper 4, Table 2 and 3). Fewer GPs of CM patients than GPs of non-CM patients reported contacting the hospital (11 vs 27; PPR=0.41 (95% CI: 0.22 to 0.78; p=0.007), but no differences were observed for the two items in relation to the 'quality' of these contacts.

Table 3.4 shows that no differences were observed between the groups as to daytime GP contacts. The analyses of out-of-hours GP contacts indicated more contacts among CM patients than among non-CM patients. In the period between day 181 and 270, the ratio of proportions of at least one contact with the out-of-hours services was 2.34 (95% CI: 1.16 to 4.71; p=0.018), and the corresponding result in the period from day 1-270 was 1.49 (95% CI: 1.07 to 2.07; 0.019).

Because of the tendency of CM to increase out-of-hours GP contacts, exploratory post hoc subgroup-treatment effect interaction analysis (136) was conducted to investigate whether certain patient characteristics were associated with increased contacts (only data on the entire follow-up period were analysed). None of the interaction analyses including the variables and categories from the minimisation reached a level of statistical significance.
Table 3.4 Patient contacts with GPs during daytime and out-of-hours in 90 days periods.

<table>
<thead>
<tr>
<th>Daytime:</th>
<th>Incidence rates*</th>
<th>IRR*</th>
<th>Proportion with contact*</th>
<th>Proportion ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>CM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90 days pre-</td>
<td>4.99</td>
<td>5.12</td>
<td>1.03 (0.83 to 1.26)</td>
<td>0.95 (0.87 to 1.03)</td>
</tr>
<tr>
<td>recruitment</td>
<td>(4.31 to 5.79)</td>
<td>(4.42 to 5.94)</td>
<td>p=0.812</td>
<td>p=0.185</td>
</tr>
<tr>
<td>1-90 days post</td>
<td>5.26</td>
<td>5.23</td>
<td>0.99 (0.80 to 1.23)</td>
<td>0.94 (0.86 to 1.03)</td>
</tr>
<tr>
<td>inclusion</td>
<td>(4.52 to 6.13)</td>
<td>(4.49 to 6.09)</td>
<td>p=0.949</td>
<td>p=0.208</td>
</tr>
<tr>
<td>91-180 days</td>
<td>5.08</td>
<td>4.76</td>
<td>0.94 (0.74 to 1.19)</td>
<td>0.99 (0.89 to 1.09)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(4.29 to 6.01)</td>
<td>(4.01 to 5.66)</td>
<td>p=0.602</td>
<td>p=0.783</td>
</tr>
<tr>
<td>181-270 days</td>
<td>4.14</td>
<td>4.42</td>
<td>1.07 (0.82 to 1.39)</td>
<td>1.05 (0.94 to 1.16)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(3.43 to 4.99)</td>
<td>(3.67 to 5.33)</td>
<td>p=0.624</td>
<td>p=0.403</td>
</tr>
<tr>
<td>1-270 days</td>
<td>14.61</td>
<td>14.76</td>
<td>1.01 (0.84 to 1.22)</td>
<td>0.98 (0.94 to 1.02)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(12.82 to 16.66)</td>
<td>(12.94 to 16.84)</td>
<td>p=0.914</td>
<td>p=0.253</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Out-of-hours:</th>
<th>Incidence rates*</th>
<th>IRR*</th>
<th>Proportion with contact*</th>
<th>Proportion ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>CM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90 days pre-</td>
<td>0.31</td>
<td>0.31</td>
<td>1.02 (0.85 to 1.91)</td>
<td>0.89 (0.54 to 1.46)</td>
</tr>
<tr>
<td>recruitment</td>
<td>(0.20 to 0.48)</td>
<td>(0.20 to 0.49)</td>
<td>p=0.943</td>
<td>p=0.643</td>
</tr>
<tr>
<td>1-90 days post</td>
<td>0.24</td>
<td>0.40</td>
<td>1.69 (0.91 to 3.14)</td>
<td>1.65 (1.00 to 2.73)</td>
</tr>
<tr>
<td>inclusion</td>
<td>(0.15 to 0.37)</td>
<td>(0.27 to 0.60)</td>
<td>p=0.094</td>
<td>p=0.052</td>
</tr>
<tr>
<td>91-180 days</td>
<td>0.39</td>
<td>0.42</td>
<td>1.08 (0.52 to 2.25)</td>
<td>1.49 (0.89 to 2.51)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(0.23 to 0.64)</td>
<td>(0.25 to 0.72)</td>
<td>p=0.832</td>
<td>p=0.128</td>
</tr>
<tr>
<td>181-270 days</td>
<td>0.18</td>
<td>0.40</td>
<td>2.24 (0.87 to 5.75)</td>
<td>2.34 (1.16 to 4.71)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(0.09 to 0.37)</td>
<td>(0.22 to 0.73)</td>
<td>p=0.094</td>
<td>p=0.018</td>
</tr>
<tr>
<td>1-270 days</td>
<td>0.83</td>
<td>1.29</td>
<td>1.56 (0.93 to 2.61)</td>
<td>1.49 (1.07 to 2.07)</td>
</tr>
<tr>
<td>post inclusion</td>
<td>(0.57 to 1.20)</td>
<td>(0.90 to 1.85)</td>
<td>p=0.093</td>
<td>p=0.019</td>
</tr>
</tbody>
</table>

*Incidence rates (adjusted for different length of follow-up) and incidence rate ratios (IRRs) were calculated using a negative binomial regression model.

# Proportions of patients alive at the beginning of the period.
The confidence intervals of all estimates are shown in brackets.
An IRR or a proportion ratio >1 indicates more contacts among CM patients.
CHAPTER 4:

DISCUSSION OF METHODS
4.1.1 Search strategy

Prior to initiating the systematic review we found much confusion in the use of terms and definitions related to CM (49,86). Our ‘working definition’ of CM was that of an intervention that included “multidisciplinary collaboration, care coordination, and in-person meetings between the patient and the case manager aimed at supporting, informing and educating the patient.” (138) The systematic review was based on extensive literature searches including many more terms than just ‘case management’ and ‘case manager’ because previous database searches had shown that a wider choice of search term was more productive in identifying literature on CM than a search confined to above two terms. On the other hand, the ‘widened search’ blurred the convenient, clear-cut distinction between which interventions to include and which to exclude.

Numerous non-intervention articles on CM and related concepts were found, but we were surprised to find only seven RCTs. This scarcity of research papers might be influenced by publication bias, i.e. more studies have been conducted than eventually published due to “null, negative or disappointing results” (139). According to Easterbrook et al, the tendency of publication bias to positively skew the conclusions of a systematic review is minimised if the review is limited to RCTs and possibly even further reduced after prospective registration of trials in databases has become mandatory in healthcare science (140). A search in the database www.clinicaltrials.gov (2012 February 26) for ‘case management’ AND cancer’ showed that only one RCT (141) besides ours had been registered prior to 2008. As a consequence, we do not believe that publication bias was a problem in relation to our review.

4.1.2 Summarising the studies

Before conducting our literature search, we had planned to summarise the studies based on their settings (tax- or private-paid healthcare system and the case managers’ placement) and possibly on cancer type. Moreover, we had planned to score the quality of the individual studies (142) and possibly do meta-analysis statistics (143). The small number of trials and the diversity of the nature of their settings, interventions and outcome methodologies precluded such meta-analyses and it was deemed sufficient to deploy CONSORT checklist criteria to establish the quality of the papers (94).
4.2.1 Internal and external validity of findings from a RCT

The usefulness of a scientific study depends on both its internal validity and its external validity. ‘Internal validity’ can be defined as: “The degree to which a study is free from bias or systematic error.” (144) Internally valid inferences from a study depend on “the soundness of the study design, conduct, and analysis in answering the question that it posed for the study participants.” (144) Important issues in this context are, among others, subject-matter knowledge regarding causality and/or theory, assessment of intervention fidelity and procedures for assessment of outcomes (144-146).

The principal internal validity elements of the present study are discussed in this chapter. First by using a model regarding ‘complex interventions’, we discuss aspects of the study design and the CM intervention. Second, the outcomes measures are discussed in detail. Finally, the chapter offers a summary of aspects of internal validity and raises the issue of external validity, i.e. whether the results can be generalized to other patients in other context (144,146,147).
4.3 Challenges of evaluating complex interventions

Any intervention can be characterised in the spectrum simple to complex, though no sharp boundary exists. “Complex interventions are usually described as interventions that contain several interacting components.” (148) According to the 2006 guideline from the Medical Research Council (MRC) on the development and evaluation of complex interventions, they may be characterised in terms of (148):

- The number of and interactions between the components within the experimental and control interventions.
- The number and difficulty of behaviours required by those delivering or receiving the intervention.
- The number of groups or organisational levels targeted by the intervention.
- The number and variability of outcomes.
- The degree of flexibility or tailoring of the intervention permitted.

For optimal interpretation and usefulness of a complex intervention, the MRC guideline proposes that the following four process stages and appertaining activities be considered when designing the study. The stages are: 1. Development, 2. Feasibility/piloting, 3. Evaluation, and 4. Implementation (148).

The below sections discuss the present CM trial in relation to the MRC-proposed activities within stages 1-3.

4.3.1 Development of the CM intervention

The MRC-proposed activities at this stage are: ‘identifying the evidence base’, ‘identifying/developing appropriate theory’ and ‘modelling process and outcomes’ (148).

The apparent scarcity of CM research studies within cancer care motivated the systematic review which served the purpose of ‘identifying the evidence base’. For ‘identifying/developing appropriate theory’, the literature was searched for descriptions of problems experienced by cancer patients and by professionals within the healthcare system and for interventions designed to target these problems. The Danish description of the case manager function within chronic care (62-64) was scrutinized.

For ‘modelling process and outcomes’, a working collaboration was established with surgeons and nurses at Department P. CRC was identified as an cancer type for which hospital-based CM was likely to be particularly useful for two reasons.
Chapter 4: Discussion of methods

First, CRC treatment often involves several departments; second, the typical CRC patient is 71 years or older and often suffers from comorbidity, which may complicate treatment and care (97). Colon cancer and rectal cancer patients have similar problems and needs as to psychosocial well-being, information and support (29,149). Inversely, patients suffering from pseudomyxoma or cancer of the anus appeared to differ from CRC patients with regard to the complexity of their treatment and their needs and they were therefore excluded from the study.

Based on the above characteristics, we developed the CM manual (see Appendix A) and a ‘working model’ regarding main CM components, their hypothesized consequences and the hypothesized direction of measurable outcomes (see Figure 4.2).

![Figure 4.2](image_url)

Figure 4.2 Model depicting elements of the CM intervention, hypothesized processes and measured outcomes with hypothesized directions.
Blue boxes in red rectangle: patient-perceived continuity of care elements.

4.3.2 Ensuring feasibility and piloting procedures

The MRC-proposed activities at this stage are: ‘testing procedures’, ‘estimating recruitment/retention’ and ‘determining sample size’ (148).

We initially considered targeting the intervention to subgroups of CRC patients with certain needs or characteristics, e.g. patients above 65 years or patients...
living alone. We scrutinized a local research database and found that Department P had treated 355 CRC patients in 2007. Given this number, the calculated sample size (140 patients per group), the expected nurse salaries and our budget it was decided for pragmatic reasons to include CRC patients in general. The inclusion criteria, “patients with a diagnosis of CRC or ‘a highly probable’ diagnosis of CRC”, were a compromise between not ‘wasting’ case manager time on patients who after diagnostics were told that they did not suffer from CRC and initiating CM ‘in time’; we anticipated that CM would be most effective if initiated before the patients began treatment.

To ensure the feasibility of the study, recruitment and intervention procedures were tested and improved in a pilot test involving ten patients. Piloting of separate CM activities and simultaneous qualitative exploratory research could possibly have produced a more focused and effective intervention, but this foundered on budgetary and the time frame constraints.

4.3.3 Evaluation of the intervention
The MRC-proposed activities at this stage are: ‘assessing effectiveness’, ‘understanding change process (process evaluations/fidelity)’ and ‘assessing cost-effectiveness’ (148).

4.3.3.1 Assessing effectiveness
The RCT design in general is regarded superior to non-experimental designs for establishing effectiveness of interventions owing to its ability to minimize selection and information bias and to control for confounding (93,150,151). Even so, different types of RCTs exist. CM, which is based on visibility and communication, could probably have been more validly tested in a cluster-randomised trial with randomisation at treatment unit level. However, for a cluster randomised trial to be unbiased, several departments or hospitals should be included which was not possible given our budget (93). Moreover, facing the premise of no established effectiveness of hospital-based CM, we argue that a cluster-randomised trial covering numerous units would have been ethically irresponsible because of its extremely costly nature compared with the present trial, which was ‘just’ costly. Another benefit of the present set-up was our ability to easily keep track of what happened in both the usual care group and the intervention group. Still, the single-department set-up and randomisation at the patient level had at least three important limitations. These limitations and their possible consequences are discussed below:

First, the CM intervention involved no formal collaboration routines between the case managers and the usual staff, which possibly limited its effectiveness.
Moreover, the CM intervention involved no organisational changes (i.e. no organisational optimisation), which supposedly would be part of ‘routine’ CM. The consequence was that reliable cost-effectiveness analyses could not be conducted.

Second, the patients’ allocation statuses were obvious to the usual staff at Department P. It is possible that the usual staff noticed ‘effective’ CM actions which they tried to ‘copy’ with a view to improving control group patients’ care. We argue that the ‘spill-over effect’ was limited because the usual staff’s option to provide ongoing support and supervision of care would have required organisational restructuring (e.g. revised work plans) or extra manpower neither of which happened. In addition, the control group GPs received no enhanced written information because staff nurses were not authorised to use the electronic patient administration systems, which is used for communication between Danish hospitals and GPs.

Third, patients’ awareness of participating in a research study might have influenced their evaluations (information bias). Patients’ experience of ‘winning’ or ‘losing’ the randomisation and their ‘belief’ or ‘disbelief’ in the intervention might have influenced their evaluations to be either more positive or more negative than if the evaluation had not been connected with participation in an RCT. Information bias was sought reduced by limiting the inclusion procedure to oral information and by asking eligible patients for participation in a randomised research project aiming at ‘improving the organisation of the contact person scheme’. The minimised inclusion procedure was possible because the project was not a biomedical research project (see Section 2.6.3). We believe that patients over time ‘forgot’ that they were taking part in a randomised study for which reason the patient evaluations were unaffected by information bias.

4.3.3.2 Fidelity

To correctly interpret outcomes from a complex intervention, it is of utmost importance to describe both usual care and the intervention, and to assess fidelity, i.e. whether and to which degree the planned interventions were actually conducted (145).

Usual care was described in Chapter 2. The ongoing dialogue with the case managers, clinical supervisors and other staff at Department P convinced us that control group patients’ care remained stable during the trial.
Several steps were taken to induce fidelity towards the CM intervention: The intervention was described in a manual, the case managers went through a special training programme, a preliminary intervention was pilot-tested and improved in collaboration with the case managers (with the purpose of strengthening the case manager’s ‘ownership’ to the manual), patient needs assessment was based on a checklist, and the case managers were requested to take notes of all contacts with patients, relatives and health professionals. The case managers were also instructed to categorise all contacts using a coding system already used by Danish nurses and to note minutes spent on these categories of contacts (101).

Fidelity assessment was undertaken as an element of the feasibility assessment reported in Paper 2. It was based on a calculation of the time the case managers spent on contacts with the patients, relatives and professionals and on a calculation of conducted activities. Because the coding system had just recently been implemented, the case managers reported difficulties categorising their contacts. Regular meetings between the research staff and the case managers were conducted both for fidelity assessment and for supervision of the case managers.

To better understand the ‘active ingredients’ and possible constraints of CM, a qualitative study was initiated by an anthropologist who observed the case managers and interviewed several patients in their homes. The results from this study have not yet been published.
4.4.1 Patient-reported outcomes in general

The patient-reported outcomes (PROs) (152) measured in this thesis were HRQoL and patient evaluations. The below section offers a discussion of elements supposed to affect both HRQoL and patient evaluations.

4.4.1.1 Timing of assessments

The timing of the assessment of PROs is important in pragmatic clinical trials where participants undergo different combinations of treatment modalities (153). Sending out questionnaires at certain time points after the patient’s inclusion is easily interpretable, but responses may suffer from extra variability compared to an event-based dispatch (e.g. four weeks after surgery).

In our trial, an event-based questionnaire dispatch was impossible because patients were not exposed to common events (not all had surgery, radiation or chemotherapy). Efforts were made to reduce response variation in the sense that assessments were planned to take place at time points where fewest patients underwent treatment or were hospitalised. The decision to do assessments at eight, 30 and 52 weeks after the individual’s randomisation was based on: a review of 14 medical records of already treated CRC patients at Department P, our pilot test, the assumption that the typical participant would be suffering from a primary diagnosed cancer, and that recruitment would take place shortly after the day where the surgeon informed the patient about the diagnosis.

For colon cancer patients and for patients suffering from locally-not-advanced rectal cancer who had surgery, the assessment at eight weeks took place approximately four weeks after surgery, whereas for rectal cancer patients with locally advanced disease, the eight-week time window corresponded to a few weeks after cessation of neoadjuvant treatment, i.e. before surgery was performed. The assessment at 30 weeks corresponded to the time at which almost all rectal cancer patients had recovered from their cancer surgery and completed adjuvant treatment, if any. The assessment at 52 weeks was included because at that time point almost all participants had ended treatment.

4.4.1.2 Selection bias caused by attrition

We believe that the minimisation procedure had achieved its purpose of equalizing the groups as to known and unknown confounders at baseline (see Table 3.1). If participants with different characteristics answered items
differently independently of the CM, uneven attrition across allocation groups as to these characteristics could bias the results. An excess number of CM patients had died 52 weeks after their inclusion. To investigate whether this influenced the results, we investigated whether the groups were similar in terms of the remaining and the responding patients’ characteristics (see Appendix D, Tables D1-D2). The groups did appear similar, but sensitivity analyses including adjustment for the variables (and categories) used in the minimisation were, nevertheless, conducted. Importantly, the results from these analyses differed only minimally from the crude results. Moreover, because questionnaire response rates across groups (Figure 3.4) were similar, we conclude that the analyses of PROs did not suffer from selection bias.

4.4.1.3 Information bias

Information bias was discussed in Section 4.3.3.1. To summarise, patient evaluations of both groups might to some degree have been influenced by patients’ awareness of participating in a research study. We do not believe that HRQoL answers were influenced by the patients’ potential awareness of their allocation group.

4.4.2 Health-related quality of life

4.4.2.1 Measurement properties of the EORTC QLQ-C30

Several ‘validated’ generic and disease-specific HRQoL instruments are available for use in Danish (69,154). The purpose of the present study was to evaluate the impact of CM on general well-being and functioning for which reason we searched for cancer-generic measures. The EORTC QLQ-C30 (116) was chosen in favour of another commonly used cancer-generic measure, the Functional Assessment of Cancer Therapy Scale (FACT-G), because it is the most used measure in Europe and in the CRC context (155,156).

Trustworthy results from studies using HRQoL instruments require that the measurement properties (validity, reliability and responsiveness) of the instrument are reasonably known. These properties depend on the context and those who are being measured, and ‘validation’ (i.e. establishing the measurement properties) is therefore an inexhaustible, ongoing process (157,158). The use of a ‘validated’ instrument accordingly very seldom implies that all measurement properties can be established in the exact population and the exact context in which the instrument is used.

Two very important measurement properties are test-retest reliability (“the extent to which a measurement will give the same result on separate
administrations” and responsiveness (“the ability of an instrument to detect important change over time in the construct being measured”) (159). The measurement properties of the EORTC QLQ-C30 had been studied in various cancer populations and settings (116,117,160) before the present trial was designed, but not within the area of CRC care. In 2011, Uwer et al reported test-retest reliability and responsiveness of the EORTC QLQ-C30 in a group of CRC patients undergoing radio- or chemotherapy (161). Patient-experienced ‘change in state of health’ assessed with an ad hoc item served as the ‘anchor item’ in both analyses. Reproducibility was tested in the group undergoing chemotherapy within the subgroup of patients experiencing a stable state of health. Disappointingly, the reproducibility of the global health status appeared to be only ‘fair’. Responsiveness was largely dependent on the context, and responsiveness on most scales was ‘small’ when patients went through radiotherapy. The study analysed similar properties for the FACT-C (which includes the FACT-G). Importantly, the overall FACT-G score appeared superior to the global health status of the EORTC QLQ-C30 in terms of reproducibility; but, overall, the responsiveness of the FACT-G scales appeared to be inferior to that of the EORTC QLQ-C30 scales (161)\(^1\). A paper by Luckett et al underpins Uwer et al’s findings by stating that no psychometric evidence exists for favouring the FACT-G over the EORTC QLQ-C30 or vice versa, but the instruments differ as to item format, scale structure and tone (162).

In conclusion, the measurement properties of the EORTC QLQ-C30 scales had not been established in the present context and in the present, relatively diverse group of CRC patients. We regret that we did not include an ‘anchor item’ (‘Have you experienced any change in state of health since the last assessment?’) in the ad hoc items of the questionnaire which would have allowed analysis of test-retest reliability and responsiveness in the present population and context. On the other hand, if the effect of CM on HRQoL had been substantial, we would undoubtedly have seen some indication of higher EORTC QLQ-C30-scores in the CM group.

4.4.2.2 Statistical analyses of HRQoL data

When HRQoL is assessed repeatedly over time, the choice stands between analysing data from each assessment separately or analysing data within a longitudinal perspective. Cross-sectional analyses answer whether the groups differ at specific assessments, but they typically require that multiple tests be

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\(^1\) Anyway, according to a consensus paper published by experts on PROs, the responsiveness statistics used in the cited paper were inappropriate (157).
done, which raises concern about type I error (‘false positive’ results). On the other hand, longitudinal data analyses answer whether the groups differ over time, and any such variation over time may be a very strong indicator of effect. The statistical significance of a longitudinal measure may be obscured if effect varies in opposite directions over time. Both the cross-sectional and the longitudinal analytical method may be biased in the presence of non-random drop-out due e.g. to patient death or patients being too ill to answer. It should be noted that when non-random drop-out exists, there is no ‘golden standard’ for analysis (133,163).

We decided to do cross-sectional comparisons in order not to miss any effect at any time point and because minimally relevant scale cross-sectional contrasts for the EORTC QLQ-C30 have been reported to guide interpretation of results (122). The analyses were accompanied by graphical presentations of the mean scores in the groups stratified by the patients’ last consecutive questionnaire responses. These plots serve two purposes: They provide an overview of all the data at the same time, and they suggest whether a complexity of the data exists that might have biased the statistical analyses (133). The longitudinal graphical presentations (Paper 3, Figure 3) show that non-random drop-out applied to most scales, i.e. non-responders had lower scores at the assessment before non-response than responders. Importantly, we have no reasons to believe that such drop-out should have biased the outcomes.

Different methods may be applied in the analysis of cross-sectional data. We chose analysis of covariance (ANCOVA), which is generally the method of choice when the outcome is also measured at baseline because it is unaffected by possible baseline imbalances, which analysis of change scores is not, and because it has a greater statistical power than both follow-up score comparison and comparison of change scores (132).

4.4.3 Patient evaluation items

As stated in the methods section, we found no established questionnaire suitable for the purpose of evaluating continuity of care across the continuum analysed in the present study. Ad hoc items were developed based on the literature and inspired by previous questionnaire surveys. The ad hoc items might actually have been advantageous as all items were relevant for the patients. On the other hand, items were not validated or sought grouped in dimensions, so answers from the two groups could only be compared item-by-item.

CNW was contacted by five patients who expressed difficulties in answering some of the items because their care pathway had crossed several departments.
Because the number of such contacts was low and the response rates high, we believe that the patients found the items to be both relevant and easy to respond to.

During the pilot test, a ‘ceiling effect’ occurred if items were naturally dichotomised (i.e. ‘Completely agree’ + ‘Agree’ vs. ‘Do not agree’ + ‘Completely disagree’). To be able to analyse improvements from usual care, we decided to dichotomise the answers as ‘Completely agree’ vs ‘the rest’. This was believed to pose no problem because the aim was to compare the two groups and not to compare findings with those of other surveys.

The proportions of patients in the two groups who ‘completely agreed’ were compared using a generalised linear model (GLM) with log link for the binomial family with robust variance. Associations were presented as PRRs instead of odds ratios, which would have overestimated associations due to the high proportion of positive evaluations (134).

Because of the observed non-random drop-out with regard to HRQoL and the possible correlation between an individual’s HRQoL and ‘satisfaction with care’ (113), it is very likely that those who answered and returned the questionnaires were more ‘satisfied’ than the non-responders. It is also possible that patients who returned the questionnaires but answered ‘Don’t know/ N.A.’ and omitted answering certain items did so because of ‘dissatisfaction’. Importantly, response rates (Table 3.4) and the number of ‘Don’t know/ N.A.’ and non-responded items (Appendix D, Table D4) were almost identical in the two allocation groups, so we have no reason to believe that the results suffered from selection bias.

The ‘halo-effect’ phenomenon (158) might have affected the individual patient’s answering in a way that a positive or negative answer to one item (tapping something which the individual highly valued or disvalued) spread to their answering of other items. That could possibly contribute to the finding that almost all analysed patient evaluation items favoured CM.

4.4.4 The general practitioner-notable effects

In the Danish tax-paid healthcare system, almost all citizens are affiliated with a local GP office, who is remunerated from the Regional Health Administrations, and all contacts to GPs are registered in a central system. This system makes it possible to send a questionnaire to patients’ GPs and it ensures that data regarding patients’ contacts to the GPs and the out-of-hours GP services are nearly complete (120).
4.4.4.1 The general practitioners’ evaluations

The GP questionnaire was sent 30 weeks after the day of each patient’s inclusion to be able to compare GPs’ evaluations of the entire cancer care pathways with and without the involvement of a case manager. Choosing a later time of assessment would potentially have introduced extra recall problems.

We would have preferred to use a validated measure to assess the GP evaluations, but none suited our purposes. A possible strength of the ad hoc developed questionnaire was that it included relatively few items, which possibly encouraged more GPs to respond than would have been the case if there had been more items. On the other hand, several items suffered from a ‘ceiling effect’ (see Paper 3, Table 2), which reduced the possibility to detect differences between the groups. ‘Ceiling effects’ were highly undesirable and should have been prevented through a better pilot test. Moreover, the statistical power was reduced because a similar, relatively high number of GPs in the two groups answered ‘Don’t know/N.A.’ (Appendix F, Table F1) which reduced the chances of establishing differences between groups.

According to the Danish National Health Service Register, five persons who gave informed consent to participation had opted to be on a paid fee-for-service scheme that allowed them to contact any GP or any private practicing physician for health care services. They all stated a name-given GP who was sent a questionnaire. Four of these GPs returned a filled-in questionnaire, and only one stated that he was not familiar with the patient. Three GPs to patients with usual public health insurance coverage noted that they were not able to fill in the questionnaire. In each group, 114 (81% of included patients’) GPs ultimately returned a filled-in questionnaire.

Cluster adjustment was planned a priori because we anticipated that some GPs would care for and fill in questionnaires on more than one patient. Twenty-five of 189 GPs answered more than one questionnaire. This number was higher than anticipated and made us wonder whether answers regarding control group patients could be influenced ‘false negatively’ if the GP had already completed a questionnaire on a CM patient. Post hoc sensitivity analyses were conducted in which responses from GPs of control group patients were excluded if the GPs had already returned a questionnaire on a CM patient (11 questionnaires were excluded). These results were very similar to the crude results, but the adjustment caused generally wider 95% CIs which meant that the summary measure on GP-experienced information deficiencies dropped below the level of statistical significance (PPR=0.77; 95% CI: 0.59 to 1.01; p=0.058). All other
differences fell out to the same ‘side’, and the same items were statistically significant.

4.4.4.2 Contacts to the GPs and the out-of-hours GP services

The data completeness of the Danish National Health Service Register is assumed to be very high, but over-reporting to the register may exist because health professionals are paid for their services by a mix of capitation basis and fee-for-service (120). Still, we have no reason to believe that over-reporting, if present, should differ between the allocation groups.

All sorts of publically paid GP services can be analysed using the above Register. We chose to analyse contacts only and not any additional services provided with the contacts. Different methods for analysing the contact data were considered, and it was decided to compare proportions of patients having at least one contact, because it was hypothesized that CM would motivate patients who never or very rarely consulted their GP to begin to take contact (the case manager ‘paved the way’ to the GPs’ office). We also wanted to compare cumulative numbers of contacts because it was hypothesized that the introduction of CM would cause the number of GP contacts to rise also among those who were already frequent attenders.

The proportions of patients in each of the two groups with at least one contact were compared using the same method as that which was deployed to analyse the patient evaluations.

The cumulative number of contacts was analysed using a negative binomial regression model because interpersonal differences in proneness for taking GP contact caused ‘over-dispersion’ on the standard Poisson distribution. A negative binomial regression model includes a frailty parameter that a ‘standard’ Poisson regression model does not which handles the extra interpersonal variability (137). The duration of follow-up was included in the model as some patients died.

The number/frequency of contacts with GPs was analysed for the entire CM study period and for 90-day intervals to determine if the pattern and volume of GP contacts changed during the course of the CM period. Follow-up was limited to nine months due to delayed updating of the Danish National Health Service Register and the limited time frame of this PhD project.

The analyses of contacts to the out-of-hours GP services within 90 days appeared to suffer from low power. For example, although the IRR for the first period after inclusion suggested a marked impact of CM (IRR=1.65), the 95% CI was very wide (0.92 to 3.14; p=0.094). Moreover, the trial was not scaled for
subgroup analyses (by simply splitting the data); if conducted, the risk of ‘false negative’ results would be much higher than the accepted 10%, which was the threshold defined for the sample size calculation (on the primary outcome). More importantly, the risk of ‘false positive’ results would far exceed 5% (136). CM patients showed a tendency towards more out-of-hours GP contacts than non-CM patients, and subgroup treatment effect interaction analyses were therefore conducted to explore whether certain patient characteristics were particularly associated with an increased number of contacts. Simulation studies have found this type of analysis to be “reliable with a false positive rate of 5% at $p<0.05$ which is robust to differences in the size of subgroups” (136). On the other hand, the ‘false negative’ rate remained large because it “depends on the size of the interaction effect relative to the overall treatment effect” (136).
SUMMARISING VALIDITY

4.5.1 Summarising internal validity

This chapter has so far discussed the study design, the CM intervention and the outcomes. The below section summarises the internal validity of the study.

First of all, the manual-based CM intervention was developed based on the principles of CM and intervention fidelity was acceptable. Furthermore, the RCT design secured an even distribution of known and unknown confounders at baseline.

The RCT was implemented at a single department only and with randomisation at the individual patient level. The theoretical consequence of this set-up was a ‘spill-over’ effect. The patients were un-blinded to their allocation status and had some knowledge about the purpose of the trial, so their evaluations might have suffered from information bias even if we argued that such bias had minimal influence on the results.

The two groups had similar patient questionnaire response rates. Attrition caused by death together with questionnaire non-response reduced the strength of the PRO analyses. Because of some skewness across groups with regard to the number of patients who were dead at 52 weeks, the PROs were analysed both with and without adjustment for patient characteristics. Importantly, this gave rise to no change in the interpretation of the results.

The single-unit setup was not believed to burden GPs’ evaluations with an element of information bias; nor were their evaluations expected to be biased by selection of responding GPs; however, a ‘ceiling effect’ and the relatively high number of ‘Don’t know/N.A.’ answers to several items may have compromised the significance of any differences. Sensitivity analyses indicated that ‘contamination’ caused by the fact that some GPs were caring for and answered questionnaires on patients from different allocation groups was not a problem.

We argue that the GP contact analyses possess high internal validity because data came from an administrative register widely recognised for the validity of its data. Further, we do not believe that the fact that patients were aware of their allocation group per se influenced their urge to take or not to take GP contact. Any selection bias of contact analyses was eliminated by including adjustment for the duration of the follow-up and by delimiting analyses to those patients who were alive at the beginning of each period.
4.5.2 External validity

External validity, i.e. the generalisability of the results beyond the present research context, depends on both setting characteristics and sample characteristics (146,147).

Regarding the setting, the case managers’ personalities and competencies were not particularly unusual or special. The nurses engaged were experienced colorectal cancer nurses, but had received no special education or training prior to their engagement in this trial. Moreover, even if Department P is an academic setting, its usual coordination and its usual ‘supportive care’ resembled that of other Danish hospital departments where cancer patients are being treated.

Regarding the sample characteristics, the inclusion of a relatively homogeneous trial population (CRC patients only) was a strength because it possibly reduced ‘noise’ and thus enhanced chances of establishing evidence of effect if present. On the other hand, a too homogeneous cancer population might have reduced the general applicability of the results of the trial. The findings of the present study are believed to be generalisable to a broader cancer population because previous research has shown that patients suffering from different cancer types are facing identical psychosocial problems and health care system-related barriers (5,164). Moreover, interaction analyses demonstrated the absence of subgroup effect differences, wherefore we argue that even the statistically significant differences between participants and non-participants in terms of cancer types and mean age do not compromise the generalisability of the results.

4.5.3 Summarising internal and external validity

The internal validity of the present study is found to be acceptable and the CM intervention and the results to be reproducible in other settings where cancer patients are being treated.
CHAPTER 5:

DISCUSSION OF RESULTS
AIM 1: ESTABLISHING THE EVIDENCE AND BEST PRACTICE

Only seven papers with an RCT design have reported on the effectiveness of CM. The studies diverged much in terms of their settings, target groups, intervention contents, outcomes measured, findings and methodological quality, and no conclusions could therefore be made about best conduct or effectiveness of CM within cancer care. Noteworthy, all three RCTs analysing patient evaluations reported statistically significantly better care evaluations (some aspects) among CM patients than among non-CM patients (125,128,130).

5.1.1 Comparison with existing literature focusing on cancer
Numerous systematic reviews have sought to establish evidence regarding the effects of CM within chronic care (53,58-61). In general, study methodology, interventions tested and findings are mixed (see Section 1.2.4). Reviews of related concepts to improve cancer patients’ care have also covered a dearth of high-quality research. Conclusions from a few of these reviews are summarised below:

A literature review (from 2004) on ‘evidence-based nursing interventions applied to older adults who had cancer’ (165) concluded that the body of literature was small and heterogeneous. Two of 15 cited studies focused on delivering ongoing care and support to cancer patients (125,131); both were included in our review.

Ouwens et al published a systematic review (from 2009) of papers on interventions evaluating the effects of ‘integrated care for cancer patients’. Integrated care was defined as care “based on principles of patient-centredness, organization of care and multidisciplinary care” (80). All in all, 33 interventions were included; none focused on all three integrated care principles, and only two interventions focused on two principles. CM was categorised as ‘organization of care-intervention’. Two CM studies were identified (125,166). As far as integrated care interventions for cancer patients are concerned, Ouwens et al concluded: “that the heterogeneous nature of the studies [...] and methodological deficiencies [...] did not permit the use of formal statistical techniques, such as meta-analysis (80).”

A review by Gagliardi et al (from 2011) regarding ‘collaborative cancer management’ concluded: “Few studies have been applied to overcome these challenges [delivering cancer care that involves multiple health professionals], and empirical research in this area appears to be limited in volume and
conceptual underpinning.” The authors identified CM as one of four conceptual models within collaborative cancer management (167).

CM can be seen as a ‘psychosocial intervention’. A review by Newell et al (from 2002) concluded that the effectiveness of psychosocial interventions for cancer patients on HRQoL was uncertain due to a variety of settings, interventions and outcome measures (168).

Conclusively, besides CM being a distinct and defined concept, it can also be seen as an intervention embedded within other concepts. Common for these concepts are that they can be characterized as ‘complex interventions’ and that they suffer from both unknown effectiveness and unknown ‘active ingredients’.
AIM 2: FEASIBILITY OF THE CM INTERVENTION

The complex nature of the CM intervention called for a thorough description of the intervention and the publishing of a Paper detailing its feasibility.

Paper 2 concluded that both the trial and the CM intervention were conducted as intended. Below we briefly discuss the ‘feasibility results’.

5.2.1 Conducted CM activities and patient caseload

The statement of activities was based on the first 61 consecutively included patients only because summarising the hand-written data from the ‘CM medical records’ was very time-consuming.

As reported in Chapter 2, the case managers had a median of eight contacts per patient (and or relatives) and spent a median of 150 minutes in contact with each patient and his or her relatives and health care professionals. Roughly 70% of the contact time was spent on providing information and supporting the patients; less than 25% of the time was used on coordination with other professionals. The case managers sent a median of two electronic summary messages to the GPs. Halfway through the trial, each case manager was looking after 10-15 patients.

This study cannot be used to comment on the appropriateness of the patient caseload because the case managers also undertook recruitment of new patients. Conversations with the case managers indicate that together with the recruitment task, a caseload of 10-15 patients per case manager was appropriate.

We have no comparison data from similar settings on number of GP notes sent per patient, time spent per patient and case manager time spent on various activities. The information gives an indication of the amount of case manager-exposure which is useful for interpreting the results from Papers 3 and 4, and for further research.
AIM 3: PATIENT-REPORTED OUTCOMES

The effect of CM on HRQoL and patients’ evaluations was analysed from data obtained eight, 30 and 52 weeks after the patients’ inclusion. We found no evidence that CM improved any aspect of HRQoL measured with the EORTC QLQ-C30. Several ad hoc patient evaluation items were statistically significantly more positively answered by CM patients than by control group patients, and all analysed differences favoured CM patients. We found no indication that any subgroup of cancer type, age or gender had differential effect of CM. However, this statement was based on subgroup-treatment interaction analyses which entail high rates of ‘false negative’ results for which reason even important subgroup effects may have been missed (136).

The discussion of the PROs is divided into a discussion of HRQoL and a discussion of the patient evaluations.

5.3.1 HRQoL
5.3.1.1 Conceptual model of HRQoL and comparison with the literature

Before discussing our findings in relation to other studies, a conceptual model of HRQoL developed by Wilson and Cleary will be presented (73). The model, see Figure 5.1, proposes causal relationships (the arrows) between four ‘levels’ of HRQoL and states that individual and environmental characteristics influence these ‘levels’. The model assumes that biological and physiological factors are the fundamental determinants of HRQoL. The first ‘level’ of HRQoL is ‘symptom status’, which includes emotional, cognitive and physical symptoms. The second level, ‘functional status’, includes physical, social, role and psychological functioning; the third level, ‘general health perceptions’, is a subjective evaluation that integrates all the preceding components; and the last level, ‘overall quality of life’, is a general measure of the respondent’s happiness and/or satisfaction with life as a whole (70,73).

![Figure 5.1 Wilson and Cleary’s conceptual model of HRQoL (73).](image-url)
5.3.1.2 HRQoL-results in comparison with other research

Wilson and Cleary’s model suggests that CM (‘a characteristic of the environment’) may improve cancer patients’ HRQoL. We found that all 95% CIs of the EORTC QLQ-C30 difference estimates were between +/- 10 units (after round off), which has been proposed as the minimal clinically relevant difference on any scale (122). Based on these differences and the graphical presentations of the average scale scores plotted by group and by length of follow-up, we conclude that CM did not positively influence HRQoL as measured with the EORTC-QLQ 30.

From the systematic review (Paper 1) we know of three CM trials that have assessed HRQoL aspects (126,128,129). Two studies reported positive effect on one subscale each (126,128), which we believe might have been caused by multiple testing.

Numerous observational and qualitative studies have sought to establish factors associated with better/ poorer HRQoL in CRC cancer. Despite some conflicting findings regarding specific variables (169), the findings generally fit the above model and state that sociodemographic, cancer/health, and healthcare variables predict HRQoL in interaction (29,30,169). An observational study found that a higher perceived quality of treatment information predicted higher scores on subscales of the FACT-C instrument (30); a finding that may be relevant in the context of CM.

‘Supportive care’ is an umbrella term for activities meant to reduce the adverse effects of cancer and cancer treatment and to maximize patients’ and their carers’ well-being (170,171). Observational research has found an association between HRQoL and supportive care needs as to psychological, social, physical (e.g. pain management), informational and practical domains (172,173) although evidence of the use of supportive care interventions (below here psychosocial interventions) to improve HRQoL has been less consistent (174,175).

5.3.1.3 Concluding remarks on effectiveness of CM on HRQoL

Based on ‘neutral findings’ in the present and previous CM trials, we may speculate whether it is possible for case managers to improve cancer patients’ HRQoL during the treatment phase. The reason may be that HRQoL is dominated by other factors than those targeted by CM. In addition, we cannot rule out that the ‘neutral’ effect of CM could be ascribed to a poor responsiveness of the EORTC QLQ-C30 in present context (discussed in Section 4.4.2.1). On the other hand, the directions of the point difference estimates
indicate that CM may have influenced HRQoL; yet at a level below statistical and clinical significance. Thus, at eight weeks, all six difference estimates favoured the CM group, whereas all estimates at both 30 and 52 weeks favoured the control group. A possible explanation for this is the phenomenon of ‘response shift’, which refers to the fact that individuals over time integrate their situation into their life, meaning that “a given score by the same patient may not have the same meaning at two different time points.” (133) We believe that response shift took place in participants of both groups, but maybe the case managers in some way influenced patients to cope differently, so that they developed a tendency towards a worse perceived global health status and functioning than control group patients.

5.3.2 Patient evaluations

Our finding of generally improved patient evaluations fits the results of other RCTs of CM within cancer care (125,128,130). That several trials have found CM to improve patient evaluations is important because patient evaluations can be seen as a succinct quality-of-care indicator that equals ‘technical quality’ and clinical outcomes (24). Further, patient evaluations may also be an indirect measure of patient behaviour, for example health-seeking and compliance (28), although these important interconnections are vaguely established. According to Walker et al, “Having a chance to discuss one’s feelings about diagnosis, and staff attention to other psychosocial issues, also predicted patient satisfaction.” (176) Actually, we wonder whether a cultural change within the usual staff might be enough to similarly improve patient evaluations.

Conclusively, the ‘positive’ impact of CM on patient evaluations is encouraging but CM would be expensive to implement in routine practice for which reason we believe it is important to investigate whether less-structured (and less expensive) interventions could similarly influence patient evaluations.
Paper 4 discusses effectiveness in terms of GPs’ evaluations of information from and collaboration with the hospital staff (ad hoc items) and patients’ contacts to the GPs at daytime and out-of-hours (the National Health Service Register). The below section discusses the GP evaluations and the patients’ contacts to GP-led services.

5.4.1 GP evaluations

We found a tendency towards more positive GP evaluations in the CM group than in the non-CM group. Three items regarding information from the hospital (psychological effects of the cancer, social effects of the cancer and information given to the patient by the specialists) and one summary measure of information deficiencies differed statistically significantly and favoured the CM group. Fewer CM GPs reported contacting the hospital, which was very likely a consequence of the enhanced information from the hospital achieved through the intermediary of the case manager. It would have been valuable to explore which types of requests were reduced. We thus regret not having included items about the direction of the request (which department), to whom it was directed and for which reason it was made.

Other interventions (conducted in similar settings) have aimed to improve GPs’ knowledge about their patients’ treatment status and the GPs’ cooperation with the specialists and have likewise reported positive effects. A Danish RCT of shared care between an oncology department and GPs based on enhanced discharge letters found that clearly outlined communication channels and patient empowerment statistically significantly improved GPs’ evaluations in the intervention group (177). A Swedish qualitative study of the effect of an ‘extended information routine’ from the specialists to the GPs concluded that extended information (copies of the hospital medical records) increased the GPs' knowledge about diseases and treatments and appeared to improve their possibilities to determine the patients' need for support (178).

Conclusively, better GP-perceived information from and cooperation with the specialist is feasible by different methods. None of above studies analysed the consequences of GP involvement on patients’ care, well-being and safety, but as a consequence of the plausible associations between GP involvement and outcomes (presented in Chapter 1, Section 1.2.2), we believe that interventions that increase the GPs’ involvement should be given high priority.
5.4.2 Patients’ contacts to GPs at daytime and out-of-hours

CM did not affect the patients’ number of contacts to GPs at daytime, but resulted in a tendency of increased number of contacts to the out-of-hours GP services.

Ancillary subgroup-treatment effect interaction analyses (entire follow-up period only) did not indicate differential use of the out-of-hours GP services in any patient subgroup (cancer type, age or gender), but this type of analysis entails a high rate of ‘false negative’ results for which reason even important subgroup effects may have been missed (136).

The reason for the absence of any difference in daytime contacts could theoretically be that patients experienced no unfulfilled needs or that they did not express their needs to the case managers. We believe both explanations are unlikely because previous research has found that most cancer patients experience both medical and non-medical unfulfilled needs (21,179), which they prefer be facilitated by a hospital-based professional (preferably a nurse) (36). Another explanation is that the case managers did not succeed in restoring the GP’s role as a key healthcare professional. This could be caused by the highly specialised cancer treatment so to speak ‘colonised the patient’s lifeworld’ (36) with the consequence that patients preferred hospital personnel to handle any health care problem or need. This theory fits with research reporting that cancer patients’ confidence in their GPs decrease across cancer treatment (180), and low confidence has been found to be a strong predictor for not having contact with the GP after discharge (179). At last, an explanation might be that the case managers changed the patients’ reasons for contacting the GPs but not the number of contacts.

The above-mentioned ‘hospital colonization’ and reduced confidence in GPs established during cancer treatment may also explain the tendency of an increased number of contacts to the out-of-hours GP services among CM patients compared to non-CM patients.

Interviews with patients focusing on reasons for contacting health professionals and an audit of trial participants’ GP-medical records (contacts to the out-of-hours GP services are not coded) might have been useful to explore whether or how CM influenced patients’ reasons for healthcare contacts.
CHAPTER 6:

MAIN CONCLUSIONS
6.1 Overall aim of the PhD project
This project succeeded in achieving its overall aim: to explore the contents and effectiveness of CM in cancer care. In relation to the specific aims (stated in Section 1.5.2), the following brief conclusions may be drawn:

6.2 What was already known on CM in cancer care? (Aim 1)
A systematic literature review was performed to determine what was already known on the contents and effects of CM in cancer care. Only seven RCTs had analysed the effectiveness of CM within cancer care. The heterogeneity of these studies as to their settings, target groups, intervention contents, outcomes measured, findings and methodological quality hindered a summary of the best conduct of CM and a statement on its effectiveness. Anyway, three papers reported that CM improved aspects of 'patient evaluations'. Paper 1 concluded: “Further evaluations of CM in cancer patient care are needed. Future research needs to focus on the elimination of the "black box" through thorough descriptions and reporting of interventions.” (138)

6.3 Methods and feasibility of the RCT testing CM (Aim 2)
Deploying the principles of CM and a Danish definition of the case manager function published in chronic care publications from the Danish National Board of Health (63), a CM intervention was developed and customized to Department P, Aarhus University Hospital. The four primary constituents of the CM intervention in relation to individual patients were:

- Supervision of care pathways and correction of any inadequacies.
- Regular, pro-active, scheduled patient contacts with the purpose of anticipating inconveniencies and preventing the patients from feeling ‘being left in limbo’.
- Day-time reactive telephone support. The case manager functioned as a CRC knowledgeable, consistent and directly available health professional.
- Provision of scheduled written information to the patient’s GP and other relevant health professionals concerning the patient’s planned treatment, level of information and potential psychosocial concerns.

The intervention was tested in an RCT implemented at Department P. Two experienced nurses functioned as case managers. Included patients suffered from CRC.

Based on ongoing surveillance of the CM intervention and a statement of conducted CM activities, Paper 2 concluded that both the RCT and the CM
intervention were conducted as intended. We believe that the CM intervention may be reproduced in other settings where cancer patients are being treated.

6.4 Effectiveness as to patient-reported outcomes (Aim 3)

The effectiveness of the CM intervention was analysed in terms of HRQoL (EORTC QLQ-C30) and patient evaluations (eight ad hoc items) assessed at eight, 30 and 52 weeks after inclusion; each data set was analysed separately. We found no evidence that CM improved any aspect of HRQoL. Several patient evaluation items were filled in statistically significantly more positively by CM patients than by control group patients, and we found a tendency towards better patient evaluations in the CM group. Although information bias caused by patients’ awareness of their allocation status might to some degree have influenced their evaluations, we believe that the results are trustworthy.

6.5 GP-notable consequences of the CM intervention (Aim 4)

The effectiveness of the CM intervention was analysed in terms of GP-notable effects, i.e. the GPs’ evaluation of information from and collaboration with the hospital (ad hoc developed questionnaire), and patients’ contacts to the GPs at daytime and out-of-hours (the National Health Services Registry).

We found a tendency towards improved GP evaluations in the CM group and several GP evaluation items statistically significantly favoured CM over non-CM. Moreover, fewer CM GPs than non-CM GPs reported contacting the hospital about their patients.

CM did not affect the patients’ number of GP contacts at daytime, but increased their number of contacts to the out-of-hours GP services. We believe that the GP-notable results were minimally influenced by information and selection bias.
CHAPTER 7: PERSPECTIVES AND FUTURE RESEARCH
7.1 Perspectives and lessons learned

Suboptimal coordination of health care together with suboptimal patient-perceived continuity of care challenge present healthcare systems in developed countries. A persistent effort to deliver integrated, across-the-continuum, cost-effective care is needed because the burden on healthcare will continue to rise because the population is ageing, the pace of centralisation and specialisation of healthcare is growing, and advances in treatment methods are rapid and ongoing.

In Denmark, recent years have therefore seen various proposals and initiatives designed to meet these challenges, for instance ‘contact person-scheme’, shared electronic medical records, telemedicine, disease management programmes and cancer packages. In 2005, the Danish National Board of Health introduced CM (and the case manager function) as an element in disease management programmes for patients suffering from chronic diseases. The Danish term ‘forløbskoordinator’ was coined as a synonym of ‘case manager’, which is a relatively well-described concept in the English literature, although evidence of CM effectiveness is dubious in general.

This PhD study set out to analyse the effectiveness of the case manager within cancer care. Based on the presented systematic review and results from our RCT, we conclude that CM can be used to improve patients’ evaluations of care. The tested CM-model also improved GPs’ perceptions of information from and collaboration with the hospital staff. Anyway, other simpler and cheaper methods may cause similar ‘positive’ effects. For instance, a little more attention by the usual staff to patients’ feelings about their diagnosis and other psychosocial issues would very likely improve their evaluations without extra costs (176). Shared electronic medical records will hopefully be implemented within a few years and will probably automatically entail better knowledge transfer between all healthcare professionals involved (including the GP).

The tested CM intervention did not improve patients’ HRQoL, which would have been a strong argument in favour of the implementation of CM. On the other hand, the intervention triggered a rise in contacts to the out-of-hours GP services; yet, the present PhD thesis cannot explain why this happened. We recommend that the possible impact of CM on patients’ health seeking behaviour should be further investigated before CM is routinely implemented in cancer care.

Although one of the arguments for implementing case managers is a wish to improve coordination of care, this RCT offers only an indirect analysis of aspects of coordination evaluated through patients’ evaluations of care, GPs’
perceptions of knowledge transfer and coordination of care, and the use of GP-led services. Post hoc, we plan to analyse patients’ utilisation of hospital-based services, e.g. the number of readmissions, the length of stay and the use of specific health care services based on data retrieved from the Danish National Patient Registry. Furthermore, we plan to analyse questionnaires from patients’ relatives, which were sent together with the 30-week patient questionnaire.

Along with the implementation of the revised cancer packages (2012?), Danish policymakers recently decided to implement a ‘forløbskoordinator’ function for all cancer patients. This function may differ from the ‘forløbskoordinator’ function described in chronic care publications from the National Board of Health. We hope for a common definition of the term ‘forløbskoordinator’ and for the formulation of a generic duty list that still allows some tailoring of tasks to the specific populations and contexts. Further, we hope for a proper evaluation before or along with the implementation of the ‘forløbskoordinator’ function.

7.2 Proposals for future research

Regardless of the method used to streamline cancer care, we believe that valid and reliable measures to assess improvements should be developed. At least two measures are needed:

- A measure to assess patient-experienced across-the-continuum cancer care.
- A standardised, objective measure of health care coordination. Today, the primarily used measures of care coordination appear to be ‘days from referral to diagnosis’, ‘days from referral to treatment initiation’, etc. In our point of view, a coordination measure could also include the processes of care, for instance the number of investigations, the number of out-patient clinic visits, the number of readmissions and the number of inadvertent events and complaints.

Facing the fact that Danish policymakers have decided to implement a ‘forløbskoordinator’ function in cancer care, we propose the following research foci along with its implementation:

- For the purpose of establishing evidence of ‘positive’ activities, different duty lists could be used in different regions, or a stepped wedge RCT could be included. A stepped wedge RCT would allow changing components of the intervention over time (181).
- Assessment of intervention fidelity should be included together with assessment of outcomes.
The possibilities for targeting of the ‘forløbskoordinator’ to particular subgroups of patients should be investigated. Patients with certain characteristics (or needs) may not benefit from being supported by a ‘forløbskoordinator’, whereas other patients with other characteristic (or needs) possibly would benefit significantly from the services provided.

Cost-effectiveness analyses should be conducted parallel to analysing costs in the setting where the ‘forløbskoordinator’ is implemented. Inadvertently, ‘forløbskoordinatorer’ could be used to increase productivity in the setting where this function is implemented, while decreasing productivity in other settings.

Qualitative research should be conducted to gain insight into the patients’, the carers’ and the health professionals’ perspectives on the ‘new’ function. For instance, qualitative research may be the best way to explore whether the ‘forløbskoordinator’ make the usual staff disclaim responsibility for coordination of care and for properly informing the patient. Qualitative research may also be the best way to study reasons for unanticipated effects such as the increased use of out-of-hours GP services found in present RCT of CM.
CHAPTER 8:

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CHAPTER 9:

ENGLISH SUMMARY
This PhD thesis is based on the project “The Effect of Hospital-Based Case Management in Cancer Care Pathways”, which has also been reported in four scientific papers. The chapters of the thesis are summarised below:

Chapter 1 initially introduces general healthcare challenges, cancer care in Denmark and the concept of case management (CM). The chapter proceeds to define relevant concepts and terms and lists the aims of the thesis.

Many cancer patients experience inadequate coordination and continuity of care. In addition, cancer patients’ GPs often report inadequate communication with and information from hospital staff regarding their patients. Deficits in communication and information transfer among health professionals may compromise the quality of care and patient safety. It has been proposed that CM is an effective method to improve coordination and continuity of care for patients with complex health care needs. Usually, CM is conducted by experienced nurses, case managers, performing care pathway supervision, information dissemination, patient outreach and support, and serving as easily accessible health professionals for all involved persons. However, the effectiveness of CM has been sparsely studied in cancer care settings. The specific aims of this thesis are:

1. To compile the contents and effects of CM in cancer care based on a systematic literature review (Paper 1).
2. To develop, implement and present the feasibility of an RCT that involved a hospital-based CM intervention customized to the Danish healthcare system, colorectal cancer (CRC) patients and Department P, Aarhus University Hospital (Paper 2).
3. To analyse the effectiveness of the CM intervention in terms of health-related quality of life (HRQoL) and patient evaluations (Paper 3).
4. To analyse the effects of the CM intervention in terms of GPs’ evaluations and patients’ contacts to the GPs and the out-of-hours GP services (Paper 4).

Chapters 2-3 present the methods and the main results. The systematic review (Paper 1) identified seven RCTs that had analysed the effectiveness of CM within cancer care. The studies diverged much in terms of settings, targeted patients, intervention contents, outcomes measured, findings and methodological quality. No conclusions could be made about best conduct or the effectiveness of CM in cancer care. Paper 2 presented the RCT and the CM intervention, and concluded that the trial was conducted as intended and that the CM intervention was feasible. Data for Paper 3 were gathered from questionnaires sent to patients at eight, 30 and 52 weeks after their inclusion.
Chapter 9:

CM did not improve any aspect of HRQoL measured with EORTC QLQ-C30. Several patient evaluation items were statistically significantly more positively answered by CM patients than by control group patients and a tendency towards improved evaluations among CM patients was found. Data for Paper 4 comprised GPs’ evaluations of information from and collaboration with the hospital (questionnaire sent at 30 weeks) and data on patients’ contacts with the GPs at daytime and out-of-hours (retrieved from the National Health Services Registry). Several GP evaluation items favoured CM statistically significantly and a tendency towards improved GP evaluations was found. CM did not affect the patients’ number of GP contacts at daytime, but increased their number of contacts to the out-of-hours GP services.

Chapter 4 discusses aspects of internal and external validity. First, the RCT and the CM intervention are discussed against the backdrop of a guideline on complex interventions. Then the outcome measures are discussed in detail. The RCT design minimised selection and confounding at baseline, but the single setting set-up with patients having knowledge about their allocation status might to some degree have caused information-biased patient evaluations. Questionnaire response rates were high and we argue that the patient-reported outcomes were more or less free from selection bias. Although inadequate piloting of the GP questionnaire limited its ability to identify differences between groups and the analyses of patient contacts to GP services suffered from low statistical strength, we argue that the GP-notable effects were internally valid. Conclusively, we argue that the results could possibly be reproduced in similar settings for patients suffering from other cancer types.

In Chapter 5 the results are discussed and parallels are drawn to findings from other studies. Chapter 6 offers the main conclusions: CM can be used to improve patients’ evaluations of care. The tested CM model did not improve the patients’ HRQoL, but improved the GPs’ perceptions of information from and collaboration with the hospital staff and triggered a rise in the number of contacts to the out-of-hours GP services.

Chapter 7 describes the perspectives of the study and offers proposals for future research. The presented ‘positive’ findings could possibly be reached by simpler and cheaper methods than CM. One purpose of CM is to improve coordination of care, which this study did not assess directly. Standardised and validated measures to assess ‘coordination of health care’ and ‘patient-experienced continuity of care’ are needed for future evaluation of methods meant to improve cancer care pathways. If CM is still seen as a method to improve cancer patients’ care, the consequences of different CM models ought to be analysed using both quantitative and qualitative research methods.
CHAPTER 10:

DANSK RESUMÉ
Denne Ph.d.-afhandling beskriver projektet “The Effect of Hospital-Based Case Management in Cancer Care Pathways”, som også er afrapporteret i fire videnskabelige artikler. Nedenfor gennemgås afhandlingens kapitler:

**Kapitel 1** introducerer udfordringerne for sundhedsvæsenet, kræftindsatsen i Danmark og begrebet case management (CM: ‘forløbskoordinering ved hjælp af case manager’). Dernæst præsenteres relevante begreber og termer samt afhandlingens formål.


Imidlertid er virkningen af ‘case managers’ på kræftområdet kun sparsomt undersøgt. Denne afhandlings formål er:

1. At præsentere indholdet og effekterne af CM på kræftområdet baseret på en systematisk litteraturgennemgang (Artikel 1).
3. At præsentere effekten af den udviklede CM-model på den patientvurderede helbredsmæssige livskvalitet (HRQoL) og patientevalueringer (Artikel 3).
4. At belyse effekten af CM interventionen på baggrund af de praktiserende lægers evalueringer samt patienternes kontakter til APL og vagtlægeordningen (Artikel 4).

**Kapitel 2-3** præsenterer de anvendte metoder og hovedresultaterne. Litteraturgennemgangen (Artikel 1) fandt syv RCT’er, der havde analyseret virkningen af CM på kræftområdet. Undersøgelserne var meget forskellige
m.h.t. ’setting’, målgruppe, indholdet i interventionerne, effektmålene, resultaterne og den metodologiske kvalitet. Vi kunne ikke fremsætte nogen konklusion vedrørende den bedste udførsel eller virkningen af CM brugt på kræftområdet. **Artikel 2** præsenterede den randomiserede, kontrollerede undersøgelse og CM interventionen og konkluderede, at forsøget og CM-modellen blev gennemført som planlagt. **Artikel 3** var baseret på data fra et spørgeskema, som blev sendt til patienterne otte, 30 og 52 uger efter deres inklusion i projektet. CM forbedrede ingen aspekter af HRQoL målt med EORTC QLQ-C30. Der var flere statistisk signifikante forskelle mellem gruppernes patientevalueringersbesvarelser, og forskellene var til fordel for CM. Vi fandt en tendens til bedre evaluatoringer i CM-gruppen. **Artikel 4** præsenterede de APL’s evaluatoringer af informationen fra og samarbejdet med personalet på sygehuset (spørgeskema sendt 30 uger efter patienternes inklusion) og sammenligne de to patientgruppens kontakter til de APL og lægevagten (udtræk fra Sygesikringsregisteret). Der var statistisk signifikant forskel mellem flere af udsagnene i ’lægeevalueringerne’ til fordel for CM, og der var en tendens til bedre evaluatoringer blandt APL, hvor patienten blev fulgt af en case manager. CM påvirkede ikke patienternes antal af kontakter til APL, men øgede antallet af kontakter til lægevagten.

Kapitel 4 diskuterer forhold af betydning for undersøgelsens interne og eksterne validitet. Indledningsvist diskuteres projektet i forhold til en model vedrørende ’komplekse interventioner’. Dernæst diskuterer de anvendte måleredskaber og –metoder. RCT-designet minimerede risikoen for selektion og konfounding ved projektstart, men det, at projektet blev afprøvet på (kun) én afdeling, hvor deltagerne potentielt var bevidste om deres randomiseringstatus, kan have medført, at patientevalueringerne i nogen grad var påvirket af informationsbias. Svareprocenten for spørgeskemaerne var høj, og vi mener, at resultaterne i Artikel 3 var fri for selektionsbias. På trods af, at lægespørgeskemaet tilsyneladende var utilstrækkelig pilot-testet, og af at ’kontaktenalyserne’ havde lav statistisk styrke, argumenterer vi for, at resultaterne i Artikel 4 er troværdige.

Vi mener, at resultaterne ville kunne reproduceres i lignende ’settings’ for patienter med andre kræftformer.

I **Kapitel 5** diskuteres resultaterne i lyset af resultaterne fra andre undersøgelser. **Kapitel 6** præsenterer hovedresultaterne: CM kan bruges til at forbedre patienternes evaluering af deres behandlingsforløb. Den testede CM-model forbedrede ikke patienternes HRQoL, men forbedrede APL’s oplevelse af informationen fra og samarbejdet med personalet på hospitalet og øgede antallet af kontakter til lægevagten.
APPENDIX A:

THE CM MANUAL

(including material used at recruitment)
The Effect of Hospital-Based Case Management in Cancer Care Pathways
Manual for forløbskoordinator-funktion
ved afdeling P, Århus Sygehus

Introduktion ........................................................................................................................................... 2
  Begrebsafklaring: case management og forløbskoordinering ............................................................. 2
  Case management (CM) - definition og formål .................................................................................. 2
  Indhold/ aktiviteter i nurse-case management ................................................................................... 2
  Fra case management til forløbskoordinering ............................................................................... 3
    Kronisk Sygdom ............................................................................................................................... 3
    Kræft ................................................................................................................................................. 3
  Formål, baggrund og rammer ................................................................................................................ 4
  Forventet kritik af valgt forskningsmetode ......................................................................................... 4
  Forskningspersonalets information ifm inklusion .............................................................................. 6
  Varighed af forløbskoordinering for den enkelte patient .................................................................. 6
  Baggrunden for forløbskoordinatorprojektet ved afdeling P og forløbskoordinatorers hovedopgaver. .. 7
  Forløbskoordinatorernes hovedopgaver og den videnskabelige baggrund ..................................... 8
    Ad 1.: Behovsafdekende samtaler med patienten ............................................................................ 8
    Ad 2.: Forløbsovervågning ............................................................................................................. 9
    Ad 3.: Information og støtte til patienten ....................................................................................... 10
    Ad 4. og 5.: Sammenhæng i behandlingsforløb .............................................................................. 11
    Ad 6.: Kontaktperson / nøgleperson ........................................................................................... 12
  Sikring af forløbskoordinatorers kompetencer ............................................................................. 13
  Uddybning af udvalgte elementer i interventionen ........................................................................ 14
    Kontakten til patienten .................................................................................................................... 14
    Redskaber (papir-journal og pc brug) ............................................................................................. 14
    Brevveksling .................................................................................................................................. 14
    Komplementær og alternativ behandling samt eksperimentel behandling .................................... 15
    Første personlige møde .................................................................................................................. 16
    Under indlæggelse(-r) på afdeling P ............................................................................................. 16
    Mellemliggende perioder og behandling ved anden afdeling ....................................................... 16
    Afslutning af forløbet ved afdeling P ............................................................................................ 16

BILAG .................................................................................................................................................. 17
  BILAG A: Funktionsbeskrivelse for forløbskoordinator (v. 050908) .................................................. 17
  BILAG B: Screening for inklusion + inklusionsprocedure .............................................................. 18
    Samtykkeerklæring ........................................................................................................................... 21
    PILOTPROJEKT SAMTYKKEERKLÆRING: ............................................................................. 22
  BILAG C: Brevskabeloner .................................................................................................................. 23
    Informationsbrev .............................................................................................................................. 23
    Statusbrev fra forløbskoordinator: ................................................................................................. 24
    Overleveringsbrev (=”forløbskoordinator-epikrise”) ..................................................................... 25
  BILAG D: Vurderings ark (Basis- og journalark) ............................................................................... 26
  BILAG E: Introduktionsprogram for forløbskoordinatorer ............................................................... 33

Litteratur: Introduktionsprogram for forløbskoordinatorer ............................................................... 34
Introduktion

Begrebsafklaring: case management og forløbskoordinering

Der er i Danmark endnu ikke enighed om indholdet i eller definitionen af begrebet forløbskoordination [1]. Sundhedsstyrelsen har nyligt benyttet begrebet forløbskoordinator synonymt med case manager, hvorfor case management indledningsvist begrebsliggøres [2].

Case management (CM) - definition og formål

Der findes talrige forskellige men indholsmæssigt nært beslægtede engelsksprogede definitioner af CM. The American Case Management Association definitionslignende beskrivelse af case management ses nedenfor:

“Case Management in Hospital/Health Care Systems is a collaborative practice model including patients, nurses, social workers, physicians, other practitioners, caregivers and the community. The Case Management process encompasses communication and facilitates care along a continuum through effective resource coordination. The goals of Case Management include the achievement of optimal health, access to care and appropriate utilization of resources, balanced with the patient's right to self determination.”

http://www.acmaweb.org/

Formålet med CM er, indenfor sundhedsvæsenets eksisterende økonomiske og medicinsk-teknilgiske rammer, at sikre høj kvalitet¹ af individuelle komplekse patientfølg [4,5].

Indhold/ aktiviteter i nurse-case management

Sygeplejersker er velegnede som udøvere af CM pga professionens grundlæggende humanistiske og holistiske patienttilgang [5,6].

Elementer fra følgende roller indgår i case managers funktionsbeskrivelse: koordinator, underviser, rådgiver, facilitator, leder, forhandler, kliniker og forsker [7,8].

Nurse-case management beskrives som en cirkelgående proces bygget op omkring følgende fire aktiviteter: 1) assessment, 2) planning, 3) implementation, and 4) evaluation [7,9].

¹ Amerikanske Institute of Medicine (=IOM) definerer kvaliteten af en sundhedsvæske:
“The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” [3]
En illustration af en nurse-case management-model ses ovenfor [7], og aktiviteternes indhold er kort beskrevet nedenfor:

**Assessment (=patientvurdering):** Journalgennemgang, indhentning og ”samling” af klinisk, finansiel og psykosocial patientinformation mhp målrettet indsats.

**Planning (=planlægning):** Gennemgå og informere omkring det samlede behandlingsforløb. Sikre at patienten er passende informeret omkring og involveret i det planlagte forløb.

**Implementation (=implementering og facilitering):** Eventuelle ”barrierer” (=misforhold mellem behandlingsplan, patientonsker og –kundskaber) korrigeres ved hjælp af patientundervisning, rådgivning og/ eller emotionel støtte samt eller facilitering af løsning ved kontakt med andre professionelle/ forløbsimplicerede. Det er helt centralt at fremme og sikre positiv interaktion med forløbsimplicerede.

**Evaluation (=evaluering):** Evaluering af tidligere identificerede problemer og handlinger. Eventuelle afvigelser undersøges ved hjælp af ”ny” assessment, planlægning og implementering. ”Forløb behandling og/ eller igangsatte handlinger som planlagt?” (bemærk figurens ringslutning)

Følgende sætninger beskriver på fortræffelig vis case managers’ funktion og succes:

”Case managers are engaged to meet “with the patients and their families at the initial consultation and throughout the course of treatment to fully assess needs, coordinate appointments, provide patient education, and bridge any gaps in patient-provider or provider-provider communication across disciplines.[10]”

” The factors underlying the success of various case management models include clear communication, identification of the needs of the patient, identification of the roles of professionals, regular review of the progress of shared care, and the involvement of patients in the planning of their care.” [11]

**Fra case management til forløbskoordinering**

**Kronisk Sygdom**
I lighed med formålet med case management, anfører SST i ”Forløbsprogrammer for kronisk sygdom – Generisk model” at formålet med ”forløbskoordinering er at ” sikre en bedre behandlings- og livskvalitet for den enkelte patient og samtidig et hensigtsmæssigt ressourceforbrug.” Sundhedsstyrelsen anfører, at de funktioner en forløbskoordinator skal varetage ”i samarbejde med patienten og eventuelt pårørende samt ud fra patientens behov er, at:

- understøtte patientens gennemførelse og fastholdelse af behandling og rehabilitering.
- understøtte patientens muligheder for egenomsorg.
- sikre opfølgning og justering af initiativer.
- aktivt formidele kontakt til relevante dele af sundhedsvæsenet, når patienten skal eller har skiftet mellem sektorer eller forskellige behandlere." [2]

**Kræft**
Af forskellige notater fra Danske Regioner (”7 punkts plan” mm) fremgår, at forløbskoordinatorer og forløbsledere skal sikre kræftpakkerne succes. Om forløbskoordinator-funktionen fremgår: ”(denne)….kan definieres på forskellige måder…..”, ”blæksprutefunktion”. Endvidere fremgår at funktionen skal varetage bookerrolle og en monitererende rolle. Sidst men ikke mindst: ”En forløbskoordinator må ikke forveksles med en forløbsleder eller patientens kontaktperson”
Således konkluderes, at forløbskoordinator-begreb ikke er tilsvarende veldefineret indenfor kræftområdet, som indenfor kronisk sygdom! Det ville være hensigtsmæssigt med tilsvarende definition indenfor det danske sundhedsvæsen.
**Forløbskoordinatorprojektet ved afdeling P**

**Formål, baggrund og rammer**

Formålet med dette projekt er i et randomiseret kontrolleret forsøg at afprøve case management i cancerbehandlingsforløb. Således sammenlignes effektmål for patienter, der er tilkoblet forløbskoordinator (interventionsgruppe) med effektmål for patienter, der modtager sygehusvæsenets normale understøttende behandling (kontrolgruppe).

Den medicinsk-teknologiske behandling påvirkes ikke, ligesom overordnede organisatoriske forhold så vidt muligt ønskes uberørt.

Forløbskoordinatorerne pålægges ikke andre opgaver end at arbejde med individuelle patientforløb i interventionsgruppen. Inklusion af patienter, outcomes-registrering, andre forskningsopgaver mv er således forbeholdt forskningspersonale ved afdeling P samt forskergruppe.

At vi har valgt at inkludere biomedicinsk forskellige cancertyper (colon og rectum cancer) skyldes antagelsen om, at cancerpatienter, uanset diagnose, har tilsvarende problemer. Derfor er vores hypotese, at case management, uanset cancertype, kan optimere patienters evalueringer af cancerbehandlingsforløb.

Som det fremgår af indledningens begrebsliggørelse af CM, er forløbskoordinering en kompleks intervention [12], hvilket medfører betydelig mulighed for "black box".

"Black box" udgør et betydeligt problem med hensyn til interventionens reproducerbarhed og søges i dette projekt minimeret ved grundig beskrivelse af modellen i en forløbskoordinator-manual samt at forløbskoordinatorer pålægges at føre regnskab kontakter og udførte aktiviteter.

Forløbskoordinatormodellen er udviklet med udgangspunkt i følgende:

- grundigt kendskab til afdeling P organisation og rutiner
- kendskab til patientoplevede mangler, prioriteringer, præferencer og patientevalueringer i forbindelse med behandling for cancersygdom (kvantitativ og kvalitativ litteratur)
- læsning af CM-litteratur (+ udarbejdelse af oversigtsartikel om CM brugt ved cancersygdom[14]) og effektstudier af forskellige simple og komplekse interventioner udført mhp optimering af cancerforløb
- MRCs "rammer" for udvikling og afprøvning af komplekse interventioner [12,15].

Det evidensbaserede grundlag for indholdet i modellen er uddybet i afsnittet: Hovedopgaver for forløbskoordinatorer ved afdeling P.

Et element af ”black box”, som er svært at fjerne og/ eller korrigere, skyldes forløbskoordinators personlighed, der påvirker behandler-patient-relationen og dermed outcomes i ukendt retning.

(Dette kan evt efterfølgende afdækkes ved interviews med patienter og/ eller forløbskoordinatorer).

**Forventet kritik af valgt forskningsmetode**

Der kan samtidig med projektet forekomme ændringer i organiseringen ved afdeling P og/ eller den medicinsk-teknologiske behandling. Da projektet er et randomiseret kontrolleret forsøg (RCT) forventes en eventuel effekt heraf at påvirke effektmål ensartet i kontrol og interventionsgruppe.

Et multicenter-RCT ville have medført ”højere” evidens, men har ikke været muligt indenfor vores økonomiske og tidsmæssige rammer.

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2 ”Black box” hentyder til risikoen for, at det kan forblive uklart, hvilke aktiviteter, der forårsagede effekt, og hvilken mængde og på hvilke tidspunkter, aktiviteterne mest hensigtsmæssigt doseres [13].
**Inklusionsmetode**

Tidligst muligt, når behandling for colorectal-cancer planlægges, afclarer Afdeling Ps forskningspersonale inklusion / eksklusion i henhold til nedenstående kriterier:

**Inklusionskriterier:**
Patienter hvor, efter vurdering ved afd P, planlægges behandlingsforløb for colon cancer eller rectum cancer tilknyttet afdelingen.

**Eksklusionskriterier:**
Demente samt personer, som ikke forstår og taler dansk.
Patienter, der er eller planlægges inkluderet i Katrine Emmertsens projekt om primære, ikke-metastaserende c. recti.

Optimalt ”tilkobles” forløbskoordinator ved patientens første møde på afdeling P.
Forskningspersonalet skal sikre sig at alle colorectal cancer-patienter ved afdeling P er vurderet mhp inklusion og eksklusion, og derefter enten er: 1) i interventionsgruppe, 2) i kontrol-gruppe, eller 3) ekskluderet.
De forskellige ”veje” ind i et patientforløb og forskningspersonalets arbejde er illustreret nedenfor:

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* Ved **inclusion:** Mens patienten udfylder samtykke og spørgeskema, ringes til sekretær på Forskningsenheden for Almen Praksis (89426010), som forestår randomiseringen.

* Forløbskoordinator: Informer patienten og ring til forløbskoordinator.
Mhp at undgå efterfølgende ”convenience-sample”-mistanke udfylder forskningspersonale vurderingspapir på alle ”nye” patienter mistænkt for colorektalcancer.
Vi skal kunne tegne flow charts for alle screenede patienter; gruppering i følgende grupper: n- ”screenede”, n-opfyldte inklusions- og eksklusionskriterier, n-samtykkede, og blev N-randomiseret til n-control og n-intervention.

Inklusion af patienter er i særdeleshed afhængig af forskningspersonalets tilstedeværelse og opmærksomhed på dette projekt.

Sandsynligvis ”opdages” nogle patienter ikke primært, andre vil givetvis komme ind på afdelingen af andre ”veje” end illustreret på flowchart. Hvis/ når en ”svipser” opdages, vurderes patienten mhp in- og eksklusion, hvorefter evt inklusion foregår.
Omvendt er det uundgåeligt at nogle patienter, pga at endoskopisk mistanke om CRC, vil blive inkluderet i projektet, hvorefter det erfares, at patienten ikke har cancer. De af ovennævnte patienter, der er randomiseret til CM-gruppe, afsluttes efter lægebesked om det ”gode” patologifund (fx ekskluderes ”dysplasi-patienter” behandlet med Transanal Endoskopisk Mikrokirurgi).

**Forskningspersonalets information ifm inklusion**
Er beskrevet i BILAG B. Følgende information er beskrevet:
- Information til patienter forud for samtykke og baselinespørgeskema
- Information til CM-patienter efter aflevering af baselinespørgeskema
- Information til kontrolpatienter efter aflevering af baselinespørgeskema

**Varighed af forløbskoordinering for den enkelte patient**
Som ovenfor nævnt ”tilkobles” forløbskoordinator tidligst muligt, når behandling for colorectal-cancer ved afd P planlægges.
”Tilkoblingen” af forløbskoordinator afsluttes, når ”tovholderrollen” for patienten overdrages til egen læge (i forbindelse med afsluttet behandlingsforløb i sygehusvæsenet) eller til anden afdeling (i forbindelse med overflytning til hjemsygehus efter operation på afdeling P). Afslutning sker således senest ved afslutningen af den behandlingsrelaterede kontrolperiode, illustreret i nedenstående figur.

**Kronologiske faser i et cancerforløb**
Baggrunden for forløbskoordinatorprojektet ved afdeling P og forløbskoordinatorers hovedopgaver
For at forstå indholdet i forløbskoordinatormodellen og dermed forløbskoordinatorernes arbejdsopgaver resumeres nogle udvalgte ikke-patient-rapporterede problemer samt patientrapporterede problemer i forbindelse med behandling af cancersygdom:

**Ikke-patient-rapporterede problemer i forbindelse med behandling af cancersygdom**
- Kortere overlevelse blandt socialt dårligt stillede [16,17], som bl.a. skyldes avanceret stadie på diagnosetidspunkt, betydelig komorbiditet, og forskellig behandlingsindsats [18].
- Patientsikkerhedsproblemer i forbindelse med overgange i behandlingsforløb ("care transitions") [19-21], herunder fejlmedicinering [22], manglende eller forkert follow-up, forårsaget af kommunikations- og informations-mangler imellem sundhedsprofessionelle [23].
- Overdiagnosticering af psykiatriske lidelser/ sygdomme, hyppigst depression og reaktive psykiatriske forstyrrelser [24-27]. Depression ved cancersygdom er prædiktor for tidligere død [28].

Spørgeskema-undersøgelser og patientinterview har afklaret følgende **patientrapporterede problemer ved behandling af cancersygdom (ikke cancerdiagnose-specifikke)**
- Mangelfuld information, vejledning m.v. om diagnose, behandling, følgevirkninger og efterforløb [29-33]
- Uforståeligt sprogbrug/ dårlige kommunikative evner hos sundhedsprofessionelle [29]
- Manglende kendskab til kontakt- og/ eller noglepersoner i sekundærsektor [29,32]
- Mangelfuld personlig menneskelig omsorg / psykosocial støtte [29-32]
- Manglende interesse for familie og pårørende samt støtte til disse fra sundhedsprofessionelle [29]
- Manglende sammenhæng i behandlingsforløb mellem afdelinger og sektorer [29,30,32,33]. Bl.a. opleves egen læge at mangle information om behandlingsplan mv. [34]
- Mangelfuld involvering i beslutninger [32,33]
- Nedsat livskvalitet [35] samt andre psykologiske påvirkninger [36]

Flere af ovenstående problemer skyldes problemer med **kontinuitet i behandlingsforløbet**; kontinuitetsbegrebet hovedelementer har at gøre med information, organisering og relation [37,38].

Med henblik på forbedring af patientevalueringer, kan det være hensigtsmæssigt at belyse karakteristika/ prædiktorer for gode patientforløb:


En lignende spørgeskemaundersøgelse af Gesell et Gregory [40] inkluderende 5906 "cancer outpatients" fandt, at ”performance improvements in [the following ten] areas should be accompanied by the greatest increases in patient satisfaction: 1. Staff sensitivity to the personal difficulties and inconvenience that the patient's condition and treatment can cause, 2. Degree to which staff addressed the patient's emotional needs, 3. Staff concern to keep family informed about what to expect from the patient's condition and treatment, 4. Waiting time between calling and first scheduled appointment, 5. Ease of reaching the office staff on the telephone, 6. Waiting time in the registration area, 7. Instructions about how to care for self at home, 8. Degree to which care was well coordinated among physicians/other caregivers, 9. Ease of the registration process, 10. Waiting time in the chemotherapy area.”

En spørgeskemaundersøgelse blandt 232 "ambulatory cancer patients" [41] konkluderede, at specielt ”technical quality of medical care, the interpersonal and communication skills of doctors, and the accessibility of care” var prædiktorer for høj patienttilfredshed med behandlingsforløbet.
Forløbskoordinatorernes hovedopgaver og den videnskabelige baggrund

Da dette projekts primære effektmål er patienternes evaluering af behandlingsforløb (samt livskvalitet) er interventionen udviklet med udgangspunkt i patientrapporterede uhensigtsmæssigheder og prædiktorer for gode forløb. Herudover har vi skelet til interventioner, der har vist sig effektive med hensyn til at optimere patientoplevede behandlingsforløb.


**Forløbskoordinatorernes hovedopgaver er følgende:**

1. Afdække ”patient-barrierer” for optimale forløb gennem (patientcentreret) dialog med patienten.
2. Forløbsovervågning ved brug af journalsystemer og deltagelse i multidisciplinære møder mhp at afdække uhensigtsmæssigheder/ ”andre barrierer” for optimale behandlings- og rehabiliterings-forløb.
4. Optimere patientforløb gennem dialog med og involvering af sundhedsprofessionelle/ andre ressourcepersoner i primær- og sekundærsektor. Facilitere løsninger (korrigering og koordinering af aktiviteter i forløbet) i dialog med alle forløbsimplicerede.
5. Sikre shared care ved skift i ”care setting”, herunder:
   a. Sikre at der sker relevant informationsudveksling mellem sundhedsprofessionelle
   b. Sikre at sundhedsprofessionelles forståelse af og forventninger til hinanden er realistiske.
   c. Sikre at alle forløbsimplicerede er informerede om, hvem der står for hvad (=tydeliggøre opgavefordeling).
6. Sikre at alle forløbsimplicerede er informeret om at konkrete patientforløb er tilkoblet en pro- og re-aktiv kontaktperson ved afdeling P.

Punkter er ikke rangordnet, men nummeret af hensyn til forklaring nedenfor.

**Ad 1.: Behovsafdækkende samtaler med patienten**

At kende patient-oplevede problemer, behov, præferencer og værdier er fundamentalt for tilretteleggelse af effektiv pleje og behandling [32,43,44]. Der er evidens for patienttilfredshed med behandlingsforløbet påvirkes positivt, når personalen er opmærksomt på patientens psykosociale problemer og behov samt giver patienten mulighed for at diskutere følelser omkring diagnose og behandling [36,42,45].

Overordnet er der to metoder til problem-/ behovsafdækning:
1) ved standardiserede spørgeskemaer og 2) ved semi-strukturerede interviews [36].

Der findes flere gode, udenlandske spørgeskemaer mhp afdække patientoplevede behov (=”needs assessment”), men der mangler viden omkring, hvordan man skal reagere på fundne behov [43].

Et kvalitativt studie af Hellbom et al [46] fandt, at sygeplejersker følte sig mere fortrolige med håndteringen af psykosociale problemer, når de havde modtaget træning i ”assessment” (patientvurderings-teknik), kommunikation og problemløsning.

**Vores projekt:** Patientens behov/ problemer afdækkes ved at forløbskoordinator systematisk gennemgår vurderingsark og efterfølgende udfylder journalark.

Patientvurderingen søger at afdække: a) Problemer/ behov relateret til helbredsstatus (og relaterede problemer), og b) Problemer/ behov relateret til ”selve patientforløbet” (denne opdeling er inspireret af [32,43,47]).

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3 Der er sammenhæng mellem grad af patienttilfredshed og concordans og compliance, livskvalitet, psykologiske belastninger samt klinisk sygdomsforløb [42] (se referencer i denne ref.).
Vurderingsark er udviklet på baggrund af artikler om kommunikation og behovsafdekning [47], screening for psykosociale problemer [36,44,48]}, ”needs assessment tools” [43] samt ”quality of care” [49,50].

Afhængigt af forløbskoordinators vurdering gennemgås og afkrydses vurderingsarkets emner: ”intet problem” / ”problem” / ”ikke vurderet” eller ”ikke relevant”, Vurderingsark gennemgås indledningsvist samt ved hvert skift i ”care setting”. Samtlige kontakter påføres journalark, hvor dato, kontaktnår, problem, tiltag og opfølgningsplan (samt kode for forløbskoordinatorshandling) anføres mv).

Udover disse konsultationslignende møder, kontakter forløbskoordinator regelmæssigt patienten telefonisk mhp proaktiv problemopsporing [51].

Forløbskoordinators forudsætninger for at kunne afdække behandlingsrelaterede problemer og behov er sygeplejerske-uddannelse samt erfaring med pleje af colorectal-cancerpatienter. Med hensyn til afdækning af evt psykosociale problemstillinger og løsning af disse, er det planlagt at forløbskoordinatorer skal deltage på patient-rehabiliteringskurset, ”Patienten med Stomi”, på Dallund og kursus i kommunikation samt supervision ved psykolog.

Der planlægges ikke brug af ”vurderingsværktøjer” som f.eks. HADS og MMSE, da forløbskoordinator ikke er kliniker - diagnosticering overlades til læger.

Ad 2.: Forløbsovervågning

Overvågning af patientforløb kan, udover gennem dialog med patienten, ske ved deltagelse i multidisciplinære møder (MDM) samt brug af elektroniske journalsystemer og databaser. Formålet med multidisciplinære møder er forløbsovervågning (og videreuddannelse) hvormed eventuelle uhensigtsmæssigheder kan ospores og rettes. Tilfredsheden med MDM er stor, når man spørger sundhedsprofessionelle [52].

Vores projekt:
Metoderne hvorpå forløbskoordinator udfører forløbsovervågning er: regelmæssige samtaler med patienten, deltagelse i rectumkonference (=MDM), adgang til PAS, Grønne System og EPJ.

Forløbskoordinatoren deltager hver fredag ved rectumkonference. Forløbskoordinators deltagelse sikrer, at der tages højde for patientpræferencer og evt ”barrierer” (afdækket af forløbskoordinator, som følge af dennes nære relation med patienten). Herudover bliver forløbskoordinator informeret om det planlagte forløb samt kender til de overvejelser, som behandlergruppe har gjort sig angående behandlingen af den enkelte patient. Deltagelsen sikrer desuden, at forløbskoordinator kan informere patienten i overensstemmelse med det øvrige behandlerteam og at behandlerteamet ”kender” til forløbskoordinator.

Forløbskoordinatører udstyres med pc’ere til overvågning af forløbet via ”Det grønne system” (for de sygehuses, der har det), ”Standardiseret Udtrek af Patientdata”4 og EPJ. Forløbskoordinator foretager ikke egenhændigt booking, men kontrollerer at patientforløb tilrettelægges hensigtsmæssigt for patient og behandler.

Forløbskoordinators forudsætninger, for at kunne deltage aktivt i rectumkonferencen og bruge journalsystemer, er sygeplejerskeuddannelse og indgående kendskab til udredning, behandling og efterforløb ved CRC. Ved ansættelsesstart gennemgår forløbskoordinatorer: 1. undervisning i CRC ved afdelingens overlærer, 2. gennemgang af det logistiske i patientforløb ved booking-nøglepersoner, samt 3. oplæring i brug af EPJ mv ved sekretærer samt edb-ansvarlig fra Planlægningsafdelingen ved Århus Sygehus.

4 ”MedComs SUP-projekt har til formål at etablere mulighed for opslag (”pull”) via Internettet i andre PAS- og EPJ-systemer, såvel inden for eget amt som på tværs af amter.” (http://www.epj-observatoriet.dk/publikationer/SUP-vurdering1.2.pdf)
Overordnet om 1. og 2.: Forløbskoordinators kendskab til hvorledes patientforløb opleves og organisatorisk forløber er en forudsætning for at kunne interagere med patient, pårørende og sundhedsprofessionelle.

Ad 3.: Information og støtte til patienten
Overordnet set ønsker patienter mere information og støtte samt mulighed for inddragelse i beslutninger vedrørende deres behandlingsforløb [29,47,53]. Individuelt tilpasset information og patientinddragelse i beslutninger (ved patient involvement og shared decision-making) bedrer det patientoplevede forløb [54].

"Supportive care" er ”sidegren” af sygepleje, som beskæftiger sig med ”patient-centreret” behandling og pleje. Iflg Fincham [32] er kerneområderne:
- Valuing: respecting others and the patients as individuals
- Connecting: establishing and continuing a good relationship with the family
- Empowering: facilitating strengths within the family by encouraging and defusing
- Doing for: enabling the patient as necessary by controlling pain and resolving problems
- Finding meaning : helping to focus on living and acknowledging death
- Preserving own integrity: valuing oneself as a nurse and being aware of one's own needs and attachments.

Patienter værdesætter ”supportive care”[32]. Et studie rapporterer at sygeplejersker, trænede i at give psykosocial støtte, er ligeværdige med psykologer, hvad angår patienttilfredshed, men at patienter foretrækker sygeplejersker, da de også kan håndtere somatiske problemstillinger [48].

De, af patienter påpegede, vigtigste kompetencer hos sundhedsprofessionelle er teknisk kompetence, at være empatisk og udvise respekt (relationen), evne til at formidle vigtig information [31,32,55,56].

Der er betydelig evidens for at patientuddannelse af ”kronikere” positivt påvirker klinisk sygdomsforløb [57]. Således kan sundhedspersonale i kraft af den specielle relation til patienten træne/ uddanne patienten i ”self-care” og ”self-management”[54]. Ved cancersygdom synes sådanne (forskellige) psykosociale intervensjoner at forbedre livskvalitet i moderat grad (effekten er bedre relatert til varighed end type intervention) [54].

Kommunikationstræning
Der synes at være effekt af, at sundhedsprofessionelle, der har med cancerpatienter at gøre, deltager i kommunikationskursus [58-61].

Telefonisk patientkontakt
Udover direkte patientkontakt kan dialog mellem patient og sundhedsprofessionel foregå telefonisk. Formålet med telefonisk proaktiv patientkontakt er forløbsovervågning (opsporing af ”barrierer”) samt individuel undervisning, rådgivning og støtte.

Artikler omhandlende ”telephonic counseling” and/ or ”telephonic monitoring” rapporterer positiv effekt af telefonisk rådgivning med hensyn til at reducere psykosociale problemer (depression, angst, stress, træthed mm) [62-64].

Et studie af Dudas et al, involverende telefoniske opkald af en farmaceut til patienter (ikke kun cancer) efter udskrivelse reducerede fejlmedicinering, genindlæggelser og øge patienttilfredshed [65].

Omventd kunne Coleman ikke finde positiv effekt af ”telephone social support and education on adaptation to breast cancer during the year following diagnosis” på humør, bekymringer, følelse af ensomhed, symptomer, relationer [66].

De fleste CM intervensjoner indeholder fast telefonisk kontakt mellem case manager og patienten, men få studier (iflg Riegel kun fire) har evalueret ”telephonic CM” alene. Iflg Riegel reducerer telefonisk CM ressourcebrug og optimerer tilfredshed med forløb. Det er dog uafklaret, hvordan telefonisk case management bedst implementeres, men en standardiseret intervention, påpeges at være en prædiktor for effekt [67].
Vores projekt:
Ved at planlægge faste personlige og telefoniske kontakter afsættes tid til at patienten kan blive informeret, stille spørgsmål og informeret tage stilling til ”involveringsgrad” i beslutninger. Der planlægges ikke formaliseret patientundervisning, men gerne ”opportunistisk” - emne og dosis bestemt af de identificerede ”barrierer”/ behov og afstemt patientønske.

Gode kommunikationsevner hos forløbskoordinator er et ”must”. Ud over forløbskoordinators personlige kompetencer trænes forløbskoordinatorers kommunikative evner vejledt af psykolog, som også står for løbende supervision.

Ad 4. og 5.: Sammenhæng i behandlingsforløb
Som anført tidligere oplever patienterne kontinuitetsproblemer, af såvel behandlingsmæssig, informationsmæssig og relationsmæssig art, i forbindelse med deres skift mellem afdelinger og sektorer [29,30,32,33]. I forlængelse af dette oplever sundhedsprofessionelle dårlig informationsudveksling mellem primær og sekundærsektor, f.eks. forsinket og/ eller mangelfuld og/ eller forkert epikrise [23].

Overgangene (”care transitions”) skaber risiko for problemer med patientsikkerheden [19-21], herunder fejlmedicinering [22], manglende eller forkert follow-up, forårsaget af kommunikations- og informationsmangler imellem sundhedsprofessionelle [23].

Som ovenfor nævnt er en hensigten med multidisciplinære møder (MDM) problemløsning i dialog med det øvrige hospitals-behandlerteam. Sammenhængen på tværs af sektorer sikres dog ikke ved MDM. Shared care⁵, som hyppigt bruges indenfor kronikeromsorgen, fokuserer på at skabe sammenhæng af patientforløb på tværs af afdelinger og sektorer.

Shared care er defineret: ”the joint participation of general practitioners and hospital consultants in the planned delivery of care for patients with a chronic condition, informed by an enhanced information exchange over and above routine discharge and referral letters” [69].

Et Cochrane review [70] om evidensen for shared care i forbindelse med behandling af kronisk sygdom fandt ingen forbedrede effektmål, uᴅᴏᴅ ”appropriate medication”. Dog vurderedes kvaliteten af hovedparten af de 20 inkluderede studier at være suboptimal. 19 af 20 inkluderede studier analyserede komplekse/ multifacerede interventionaler, herunder: ”combinations of prior agreement to care roles within each sector, clinical and referral guidelines, defined patient reviews in each sector, education and training for patients and professionals (principally for primary care professionals and workers at the primary–specialty care interface), and synchronized patient records and recall systems.” De studerede effektmål var: fysisk sundhedstilstand, psykisk sundhedstilstand, psykosociale funktioner/ behov, hospitalsindlæggelser, medicinforbrug og ”adherence”, samt ”andet” (patienttilfredshed mv) [70]. Smith konkluderede: ”The increasing awareness of the importance of preventing medical errors needs to be designed into future shared care […] Future research may be best directed at assessing shared care for those with more serious conditions or combinations of conditions, and considering service issues such as time and resources spent by clinicians in managing patients in both sectors.” [68]


Ved brug af dialogbaseret metode i mødet med patienten sikres at patientens præferencer inddrages i fagligt begrundede beslutninger [71]

⁵ synonym: integrated care [68]
Dette projekt:
Forløbskoordinator primære funktion er at facilitere løsninger på problemer. Alle barrierer mod optimale patientforløb søges løst i dialog med patient og behandlere. Således er det f.eks. vigtigt, at forløbskoordinator arrangerer kontakt til anden, relevant sundhedsprofessionel, så snart der fattes mistanke om depression, uerkendt demens mv.
De shared care metoder, der tages i brug er: optimeret patientspecifik informationsudveksling til alle forløbsimplicerede, generel information om sygdommen til e.l., udlevering af kontaktkort til patient og e.l. på forløbskoordinator. Midlerne for shared care er brevveksling (evt via journalsystem) og evt telefonisk kontakt.

I forbindelse med patientens overgange mellem afdelinger og sektorer (skift af ”care setting”) faciliterer forløbskoordinator denne ved uddybende skriftlig overlevering ( supplement til lægeepikrise) til modtagende instans, evt ledsaget af telefonisk kontakt.
Egen læge informeres skriftligt ved hvert skift i ”care setting” ved at forløbskoordinator afsender ”statusbrev” via Det Grønne System (forløbskoordinator skriver selv brevene)⁶. Afhængigt af behov kontaktes hjempleje, rehabiliteringstiltag o.l.

Ved afslutning af behandlingsforløbet og dermed forløbskoordinering, sker overlevering af ”tovholderrolle” til egen læge skriftligt ved brev afsendt via Det Grønne System (forløbskoordinator skriver selv brevet).

At forløbskoordinator forstår arbejdsgange i onkologisk regi sikres ved praktikophold på onkologisk afd D, Århus Universitetshospital. Tilsvarende planlægges praktik i almen praksis med henblik på at sikre forståelse af denne sundhedspersons arbejdsområder og –muligheder.

Ad 6.: Kontaktperson / nøgleperson
På trods af lovkrav om at patienter tilbydes en kontaktperson⁷, efterlyses en kompetent ”kontaktperson” af patienter [29,32]. Samtidig etterspørger særligt de praksiserende læger en funktion, som kan tage imod (telefonisk) henvisning og varetage et koordinerende arbejde.
På trods af, at der findes en klar definition af sundhedsvæsenets kontaktperson til den enkelte patient [72], forvaltes funktionen, herunder indhold, ansvar og bebojelser meget forskelligt fra afdeling til afdeling.
Formålet med kontaktpersonsordningen er at ”sikre, at patienten får en personlig indgang til sygehusvæsenet, en bedre koordination af behandlingsforløbet, og at patienten bliver bedre informeret om sin sygdom og behandling.” Regionerne er fra 1. januar 2009 forpligtet til at tilbyde alle sygehuspatienter en kontaktperson [73].

Dette projekt:
Forløbskoordinator varetager rollen som personlig pro- og reaktiv kontaktperson. Det er derfor vigtigt at alle forløbsimplicerede er bekendtgjort, at patienten er tilkoblet en forløbskoordinator, som i tilfælde af patientrelaterede spørgsmål, kan kontaktes alle hverdage i dagtid. Forløbskoordinator er fuldtids (100%) beskæftiget med koordinering og optimering af individuelle patientforløb.

⁶ Projektet går ikke ud på at forbedre kvaliteten af læge-udskrivnings breve, men understøtter informationen i disse.
Sikring af forløbskoordinatorers kompetencer
Forløbskoordinatorers sikres forståelse af deres arbejdsmåde ved grundigt kendskab med denne manual samt "uddannelse" i henhold til introduktionsprogram, se bilag E

Kendskab til kolorektalcancer-sygdom, udredning samt behandling
- Gennemgang af behandlingsmuligheder ved afdeling Ps overlæger.
- Klinisk erfaring med pleje af CRC.
- 2-3 dages praktik på onkologisk afdeling D, Århus Universitetshospital, NBG.
- Undervisning i CT og MR ved relevant personale

Rehabilitering af cancerpatienter og god kommunikation
- Ugekursus på Rehabiliteringscenter Dallund i selskab med cancerpatienter.
- Kommunikationskursus, der fokuserer på psykosociale aspekter, selvhjælpesteknikker og basal psykologisk behandling, samt efterfølgende supervision: ved psykolog fra det Palliative team, Århus Sygehus.
- Træning i brug af assessment tjekliste i forbindelse med pilottestning af interventionen.

Kendskab til primærsektor
- Minipraktik i almen praksis. Snuse til ”livets gang i praksis” – dels være foh hos lærerne og dels se, hvordan klinikpersonalet håndterer telefoner, epikrise-ankomst m.v.

Fortrolighed med forløbskoordinering:
- Pilottestning af forløbskoordinator-funktionen inden afprøvning i det kontrollerede randomiserede forsøg.
Uddybning af udvalgte elementer i interventionen

Kontakten til patienten

Interventionen består af planlagte og ad hoc/ behovsbestemte konsultationslignende møder mellem patient og forløbskoordinator i forbindelse med udredning, indlæggelse og efterforløb. Herudover telefoniske kontakter foranlediget af forløbskoordinator (proaktivt) og af patienten (reaktivt). Forløbskoordinator har kontor til rådighed, hvor samtaler med patient og evt pårørende kan foregå. Forløbskoordinatorer skal så vidt muligt ledsage patienten til lægesamtales i afdelingen, men tilbyder ikke udf-huset kontakter (hjemmebesøg, ledsagelse på onkologisk afd. o.l.).

Møder og telefoniske kontakter gennemføres i henhold til manuærens afsnit ”Beskrivelse relatertet til tidspunkter i behandlingsforløb”.

Alle kontakter noteres i forløbskoordinatorjournal (Bilag D). Forløbskoordinatorer kan i den udstrækning det vurderes formålstjenligt udlevere patientspecific information (feks resumé af lægesamtales, skriftlig eliminering af uklarhed) samt generel sygdomsspecific skriftlig materiale. Denne information udvælger forløbskoordinator selv, hvorimod afgrænset ”Vidensbank” ikke udvikles.

Ved hvert skift i ”care setting”, se figur nedenfor, laves systematisk gennemgang og udfyldelse af ”vurderingsark” i forløbskoordinatorjournal. Identificerede problemer og handlinger skrives i forløbskoordinatorjournalen.

![Diagram](image-url)

Når forløbskoordinator er den første ikke-læge, der har samtal med patienten i afdeling P regi, videreformidles relevant information (kopi af Basisark mv.) til stamafdeling. Sygeplejejournal udfyldes således forsø af afdelingens faste personale.

Redskaber (papir-journal og pc brug)

På forløbskoordinatorernes kontor opbevares et ringbind for hver patient indeholdende papirformat af patientens forløbskoordinatorjournal. Journalen består af vurderingsark og journalark (se BILAG D). Forløbskoordinatorer har pc til brug for forløbsovervågning samt brevveksling (Grønne System og SUP8).

Brevveksling

Forløbskoordinator fremsender breve til patienternes praktiserende læger via det ”Grønne System”. Da det kun er muligt at sende én epikrise/ forløb/ patient, er formatet ”ambulant notat” eller ”stuegangsnotat”

Egen læge informeres minimum to gange i forløbet:

8 SUP: Herfra kan foretages udtræk af patientdata fra PAS-system og EPJ-systemer i MedComs SUP-format. Brugere i sundhedsvæsenet kan søge patientdata i SUP-databaserne. Formålet er at åbne de forskellig IT-systemer i sundhedsvæsenet og give data-adgang for alle relevante parter.
1. Umiddelbart efter 1. møde mellem forløbskoordinator og patienten sendes informationsbrev (beskrivende forløbskoordinators funktion og kontaktoplysninger) samt statusbrev med resumé af evt. identificerede problemer og iværksatte handlinger.


Følgende brevkabeloner foreligger (BILAG C)
- Informationsbrev: indeholdende kontaktoplysninger, samt kort information om projektet
- Statusbrev
- Overleveringsbrev

Komplementær og alternativ behandling samt eksperimentel behandling

Forholdsregler ved spørgsmål angående alternativ behandling
Dette emne diskuteres og trænes i introduktionsprogrammet.

Forholdsregler ved spørgsmål angående eksperimentel behandling
Ved evt spørgsmål angående eksperimentel behandling formidles kontakt til en af afdelingens speciallæger.
Dette emne diskuteres og trænes i introduktionsprogrammet.
Beskrivelse relateret til tidspunkter i behandlingsforløb

**Første personlige møde**

Om muligt møder forløbskoordinator patienten ved dennes første møde på afdelingen. Alternativt kontakter den tilkoblede forløbskoordinator patienten telefonisk mhp aftale om første personlige kontakt.

Problemområder afdækkes ved systematisk gennemgang af punkter i forløbskoordinatorjournal. Skriftligt materiale med kontaktoplysninger på forløbskoordinator udelveres. Yderligere relevant materiale udelveres. Patient og evt pårørende informeres om at e.l. tilsendes information om forløbskoordinatorfunktionen, dagens samtal samt løbende status for behandlingsforløbet og at andre forløbsimplicerede informeres på tilsvarende vis, når det skønnes relevant.

Fremadrettede handlinger iværksættes, noteres og relevante øvrige behandlerteams / instanser inddrages telefonisk eller pr brev. Evt kopieres Basisark (Bilag D) og videregives til sengeafsnit. De vigtigste problemområder videregives til stamafdeling mhp brug i sygeplejejournal. Statusbrev til patientens egen læge tilsendes umiddelbart efter vurderings-samtale.

**Under indlæggelse(-r) på afdeling P**


**Mellemliggende perioder og behandling ved anden afdeling**

**I forbindelse med udskrivelse fra afdeling P (ikke afsluttet behandlingsforløb)**

To dage efter udskrivelse samt efter evt ambulant pato-svar kontakter Cm patienten telefonisk.

**I forbindelse med henvisning til behandling ved anden afdeling**

Skriftligt ”overleveringsbrev” samt evt telefonisk kontakt foranlediget af forløbskoordinator.


**Afslutning af forløbet ved afdeling P**

Når patienten out-sources til operation/ at komme sig på anden afdeling

"Overleveringsbrev” til ”modtageafdeling” og egen læge. Evt telefonisk kontakt til ”modtager”.

Samtale med patienten og evt pårørende om forestående forløb og forventningsafstemning.

Opfølgende kontakt til patienten efter en uge mhp at sikre at god overlevering er sket.

Når patienten afsluttes fra afd P efter operativ behandling eller anden behandling

Patienten kontaktes telefonisk to-tre dage efter udskrivelse. Herefter yderligere en-to gange indenfor den første måned.

Cm kan efter individuel vurdering foretage yderligere proaktive opringninger.

Forløbskoordinering afsluttes altid med ”overlevering” til e.l. ved hjælp af ”overleveringsbrev”. Hvis det skønnes nødvendigt kontakter forløbskoordinatoren telefonisk egen læge, hjemmepleje, rehabiliteringspartnere mv. Efter den formelle afslutning har patienten f.eks. mulighed for at kontakte forløbskoordinator. Den reaktive, lovbestemte9 ”kontaktpersons-ordningen” er der ingen formel afslutning på.

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BILAG

BILAG A: Funktionsbeskrivelse for forløbskoordinator (v. 050908)

Stillingsbetegnelse: Projektsygeplejerske - forløbskoordinator ved afd P (Ansættelse er midlertidig svarende til 20 måneder).

Organisatorisk placering:
Faglig og organisatorisk reference til projektteam ved afdeling P. I forhold til daglige organisatoriske forhold refereres til projektteam.
Løn- og ansættelsesmæssigt er funktionen indplaceret under Forskningsenheden ved afd P.

Ansvars- og kompetenceområder:
Forløbskoordinator er medansvarlig for hensigtsmæssige patientforløb.

Forløbskoordinatorens hovedopgaver er følgende:
1. Afdække ”patient-barrierer” for optimale (patientcentrerede) forløb gennem dialog med patienten.
2. Forløbsovervågning ved brug af journalsystemer og deltagelse i multidisciplinære møder mhp at afdække uhensigtsmæssigheder/ ”andre barrierer” for optimale behandlings- og rehabiliterings-forløb.
4. Optimere patientforløb gennem dialog med og involvering af sundhedsprofessionelle/ andre ressourcepersoner i primær- og sekundærsektor. Facilitere løsninger (korrigering og koordinering af aktiviteter i forløbet) i dialog med alle forløbsimplicerede.
5. Sikre shared care ved skift i ”care setting”, herunder:
6. Sikre at der sker relevant informationsudveksling mellem sundhedsprofessionelle
7. Sikre at sundhedsprofessionelles forståelse af og forventninger til hinanden er realistiske.
8. Sikre at alle forløbsimplicerede er informerede om, hvem der står for hvad (=tydeliggøre opgavefordeling).
9. Sikre at alle forløbsimplicerede har personlig, kontinuerlig og (pro- og re-)aktiv kontakt i afdelingen.

Arbejdsopgaverne løses gennem planlagte og ad hoc møder i afdeling P mellem patient og forløbskoordinator samt telefoniske kontakter anført af forløbskoordinator (proaktivt) og af patienten (reaktivt) i forbindelse med udredning, indlæggelse og efterforløb.
Møder og telefoniske kontakter gennemføres i henhold til udarbejdet manual til dette projekt og noteres i selvstændig forløbskoordinatorjournal.

Kvalifikationskrav:

Uddannelsesmæssige:
Autorisation som sygeplejerske med minimum to års praktisk erfaring med pleje af patienter med colorectalancer.

Personlige:
Sygeplejersken skal være i stand til at arbejde selvstændigt og samtidig kunne indgå i tvær-faglige og -sektorielle samarbejdsrelationer.
Sygeplejersken skal besidde gode kommunikative evner.

Faglig udvikling:
Kurser i rehabilitering og kommunikation tilbydes.
Opnåelse af teoretisk viden samt praktisk erfaring med case management (forløbskoordinering).
BILAG B: Screening for inklusion + inklusionsprocedure

INKLUSIONSPROCEDURE

Tidligst muligt efter sandsynlighed gøres et diagnosere colorectal-cancer er sandsynlig, det er sandsynligt, at Afdeling P's forskningspersonale om patienten can deltage.

Følgende kriterier gælder for deltagelse i projektet:

**Inklusionskriterier:**
- Planlæggelse af patientforløb for colorectal cancer tilknyttet Afdeling P, Århus Sygehus.

**Eksklusionskriterier:**
- Demente og andre personer, med dårlige danskkundskaber (nogle udlændinge, retardation mv)
- Patienter, der er eller planlægges inkluderet i Katrine Emmertsens projekt om primære, ikke-metastaserende c. recti.

Således ønsker vi, at afdelingerne hjælper med at screene patienter:

Afdelingeren faste personale "screener" patienter iht "Registreringsskema" Del A:
- Hvis patienten ikke kan inkluderes gemmes sedlen og afleveres til Christian Wulff.
- Hvis det vurderes, at patienten er kandidat til inklusion kontaktes forløbsekordinator mhp den videre inklusionsprocedure. NB: Vi ønsker at tilkoble forløbsekordinator tidligst muligt i udrednings- og behandlingsforløbet.

Afdeling 240, 260 og 280 samt ambulatoriet bedes "screene" alle colorectal cancer-patienter.

Endoskopien bedes "screene" nydiagnosticerede coloncancerpatienter.

Nydiagnosticerede rectumcancer "screenes" ikke, da der er en stor sandsynlighed for at patienten skal deltage i Katrine Emmertsens projekt.

(Med "nydiagnosticeret" menes begrundet mistanke om cancer efter skopi).
### REGISTRERINGSSKEMA MHP STILLINGTAGEN TIL INKLUSION I PROJEKTET

Effekt af forløbskoordinering til optimering af kræftforløb fra diagnose til afsluttet behandling

Patientlabel:

#### Del A Udfyldes af det faste personale Afdeling P

<table>
<thead>
<tr>
<th>Dato for vurdering:</th>
<th>Udfyldt af:</th>
</tr>
</thead>
</table>

**Eksklusion?**

<table>
<thead>
<tr>
<th>Ja</th>
<th>Nej</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

1. Demens ☐ ☐


3. Patienten er inkluderet i/ er sandsynlig kandidat til Katrine Emmertsens projekt (primære, ikke-metastaserende c. recti) ☐ ☐


**•** Hvis alle 3 punkter er afkrydset "Nej", kontaktes forløbskoordinator på følgende telefonnr:

**Lige uger:** 8949 9604 / **Ulige uger:** 8949 9603

#### Del B Udfyldes af inkluderende forløbskoordinator

<table>
<thead>
<tr>
<th>Krav for deltagelse:</th>
<th>Ja</th>
<th>Nej</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**I** Mundtlig information om projektet + udfyldt samtykkeerklæring ☐ ☐

**II** Baselinespørgeskema udleveres, anfør løbenr: __________________________ ☐ ☐

**III** Spørgeskema er udfyldt og returneret ☐ ☐

**Når punkterne I-III er afkrydset "Ja" kan patienten randomiseres:**

- Ring til Forskningsenheden for Almen Praksis på: 8942 6010, hvor du kommer i kontakt med Birthe Brauneiser eller anden sekretær.
- Oplys patientens cpr.nr og (mistænkt) cancerdiagnose (colon cancer eller rectum cancer)
- Du får besked om patienten skal have tilknyttet en forløbskoordinator eller ikke.
- Du oplyser patienten om resultatet af lodtrækningen og formidler kontakt til den anden forløbskoordinator.

**Hvis patienten ikke kan eller vil udfylde skemaet ved første møde:**

- Udleveres konvolut, så patienten selv kan returnere det udfyldte spørgeskema.
- Patienten oplyser om at du ønsker at ringe op næste hverdag mhp videre oplysninger om tilhørsgruppe mv. Der skal tilskyndes til at patienten udfylder spørgeskemaet inden denne opringning.

#### Del A+B Ved problemer af enhver art kontakter du:

Christian Wulff, Projektansvarlig læge, Forskningsenheden for Almen Praksis i Århus
På telefon 2299 7968 eller e-mail: christian.wulff@alm.au.dk
Mange tak for hjælpen.
MUNDTLIG INFORMATION TIL PATIENT

Forløbskoordinatorers information til kandidater til projektet

A. Information om projektet forud for samtykke og baselinespørgeskema:
"Afdeling P og Århus Universitet samarbejder om et projekt, der har til hensigt at forbedre din og kommende patienters oplevelse af det samlede behandlingsforløb.

Du kan deltage i undersøgelsen, hvis du indvilger i at besvare spørgeskemaer underejs i dit behandlingsforløb, giver projektgruppen tilladelse til at vi må indhente oplysninger fra din egen læge om dit forløb, samt at du indvilger i at du ved lodtrækning tildeles en af to forskellige behandlings-organiseringsmåder.

Den væsentligste forskel på de to behandlingsforløb, som du vil mærke, er forskellig organisation af kontaktpersonsordningen.
Uanset om du deltager eller ej, ændrer projektet ikke din lægefaglige behandling.
Det skal understreges at det er frivilligt at deltage i projektet."

Hvis patienten siger "ja" til deltagelse udeliveres og udfyldes Samtykkeerklæring og Baselinespørgeskema.

B. Efter aflevering af baselinespørgeskema og randomiserings:

Information til CM-patienter
"Vi vil gerne tilbyde dig at få tilknyttet en forløbskoordinator.
En forløbskoordinator er en person, som skal sikre, at du får den information du har behov for samt sikre sammenhæng i dit behandlingsforløb mellem afdelinger og sektorer. Forløbskoordinatoren vil være tilkoblet dit forløb, indtil din egen læge igen er din primære kontaktperson i sundhedsvesenet.


Du får uddybende information omkring forløbskoordinatoren, når du møder denne.
Vi ønsker at du tidligst muligt i dit forløb møder forløbskoordinatoren.
Må jeg have lov at ringe til forløbskoordinatoren først til arrangement jeres første møde? - Evt kan hun møde dig nu / have lov at kontakte dig telefonisk?"

Information til kontrolpatienter:
"Du vil modtage den behandling, der aktuelt er den normale ved afdelingen.
Vi vil gerne senere i dit forløb bede dig om at besvare yderligere to spørgeskemaer omhandlende din vurdering af dit forløb.
Din besvarelse er meget vigtig for at vi efterfølgende kan tilrettelegge optimale behandlingsforløb."
Samtykkeerklæring

Jeg indvilger i at deltage i projektet:

*Effekt af forløbsoordinering til optimering af patientforløb fra diagnose til afsluttet behandling*

Jeg er informeret om at projektet indebærer lodtrækning mellem to forskellige måder at organisere behandlingsforløbet på. *Den medicinsk-kirurgiske behandling er fuldstændigt ens i de to grupper.*

Jeg giver med min underskrift tilladelse til at min kontaktperson må:
- kontakte mig telefonisk
- tilsende min praktiserende læge og andre sundhedsprofessionelle information om min tilstand og behandlingsstatus.

Samtidigt giver jeg med min underskrift tilladelse til, at forskerne bag projektet må:
- bruge oplysninger fra min journal og offentlige registre
- tilsende mig spørgeskemaer undervejs i mit forløb
- indhente oplysninger via min egen læge

Alle de indsamlede oplysninger behandles i anonymiseret form og vil ikke blive udleveret til andre.

Hvis jeg undervejs beslutter mig for, at de af forskergruppen indhentede oplysninger ikke må blive analyseret, giver jeg besked til forskergruppen, hvorefter oplysningerne vil blive slettet.

Hvis jeg undervejs beslutter mig for, at kontaktpersonen ikke må kontakte mig telefonisk eller tilsende min praktiserende læge og andre information, kan jeg uafhængigt af min deltagelse i forskningsprojektet trække disse tilladelser tilbage.

Jeg kan når som helst udtræde af projektet, hvorefter jeg vil modtage sygehusvæsenets vanlige understøttende behandling af min sygdom.

MIN PRAKTISERENDE LÆGES NAVN ER: ______________________________________________________

____________________________________________________

DATO: ____ _____________________                    STED: ______________________________________________________

UNDERSKRIFT:____________________________________________________________________________
PILOTPROJEKT SAMTYKKEERKLÆRING:

Samtykkeerklæring til deltagere tildelt forløbskoordinator i projektet:

Effekt af forløbskoordinering til optimering af patientforløb fra diagnose til afsluttet behandling

Jeg giver med min underskrift tilladelse til at min kontaktperson, en forløbskoordinator (eller dennes stedfortræder i tilfælde af sygdom), må:

- kontakte mig telefonisk
- sende information til min praktiserende læge og andre relevante sundhedsprofessionelle involveret i mit forløb om min tilstand og min behandlingsstatus.

Min praktiserende læge navn og adresse er:

____________________________________________________________________________________

____________________________________________________________________________________

Jeg kan når som helst trække dette samtykke tilbage.

DATO:____________________________

STED:____________________________

UNDERSKRIFT:______________________________
**BILAG C: Brevskabeloner**

**Informationsbrev**

Kære

Hermed gøres opmærksom på at

patientnavn og data

i forbindelse med et behandlingsforløb ved Afdeling P, Århus Sygehus er tilknyttet **forløbskoordinator, sygeplejerske XX, YY**

**Ved behandlingsrelaterede spørgsmål kan forløbskoordinatoren kontaktes alle hverdage mellem 8.00 og 16.00 på telefon 8949 ZZZZ.**

Forløbskoordinatoren er ansat til at koordinere og sikre patientinddragelse i behandlingsforløb.

Forløbskoordinator varetager ikke traditionelle sygepleje-aktiviteter.

Forløbskoordinator og patienten planlægges at have behovsfældende samtaler. Forløbskoordinator udfylder rollen som sygehusvæsenets gennemgående kontaktperson ved at kende til den planlagte behandling og det forventelige forløb i forbindelse hermed.

Hvis der opstår uklarheder om behandling eller lignende er forløbskoordinatoren behjælpelig og kontaktes som ovenfor anført. Til orientering bemærkes, at der er ansat to forløbskoordinatorer. Således vil der ved ovenståendes evt fravær, forsat være en forløbskoordinator tilgængelig på telefon.

MVH

Forløbskoordinator, **sygeplejerske XX, YY**

Afdeling P, Århus Sygehus

**Der er vedlagt/ ikke vedlagt:** Statusbrev

**NB** dette brev supplerer, men er **ikke** erstatning for læge-epikrise(-r)
Statusbrev fra forløbskoordinator:

Forløbskoordinator og…… patientnavn og data

har i dag haft et personligt behovsafsløkkende møde, hvor planlagt udredning, behandling, samt eventuelle komplikationer blev drøftet.

_Følgende punkter er suppleringer til informationen i læge-epikrise afsendt den ……:_
Mulige problemer samt iværksatte handlinger:……
Særlege behov:
Patienten har kendskab til: ……..? diagnose, prognose og planlagt behandling?
Næste / kommende behandling(er) er:……

MVH
Forløbskoordinator XX,
Træffes hverdage mellem 8.00 og 16.00 på telefon 8949 ZZZZ.
**Overleveringsbrev (=”forløbskoordinator-epikrise”)**

Patienten og forløbskoordinator, XX, har i dag haft afsluttende samtale, hvor kommende behandling/opfølgning og ”hjælp” blev drøftet.

*Følgende punkter er suppleringer til informationen i læge-epikrise afsendt den ......:*

Patienten ”afsluttes” til:

- Mulige problemer samt iværksatte handlinger:……
- Særlige behov:
- Følgende tiltag iværksat ved ”afslutning”:
- Patienten er vidende om hvor ”hjælp” søges?:

......

Det bemærkes at patienten og øvrige forløbs-implicerede, i perioden indtil egen læge igen er primære tovholder, forsat er velkommen til at kontakte forløbskoordinatoren ved uklarheder omkring behandling m.v.
BILAG D: Vurderings ark (Basis- og journalark)

Formål: 1. at udgøre forløbskoordinatorers arbejdssredskaber
         2. at danne grundlag for efterfølgende analyse af udførte aktiviteter

Forsiden vedrører almene oplysninger om patienten
Side 2 og 3 er vurderingsark, der ”screeningsagtigt” gennemgås
Journalark påføres alle kontakter (problemer/ behov og handlinger samt plan)

Forløbskoordinator handlinger iht VIPS

Information og undervisning: Information, undervisning, rådgivning, vejledning. Til Pt. og pårørende for at øge kundskab, forståelse, motivation, forankring i virkeligheden og mindske risikoen for tilbagefald. Individuelt eller i grupper om f.eks. undersøgelser, behandling, diagnoser, resultater, metoder til selvhjælp mm.


Koordineret plejeplanlægning: sammenfatning og ordinationer fra behandlings- og netværksmøder.

Udskrivningsplanlægning: forberedelser samt kontakter, navn og telefonnummer etc. Pårørendes ønsker og deltagelse.

### Sundhedstillstand:

<table>
<thead>
<tr>
<th>Tidligere sygdom, co-morbiditet og handicaps</th>
<th>Syn og høreelse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rygning</td>
</tr>
<tr>
<td></td>
<td>Alkohol</td>
</tr>
<tr>
<td></td>
<td>Vægt, højde, BMI</td>
</tr>
<tr>
<td></td>
<td>Kost</td>
</tr>
<tr>
<td></td>
<td>Activitetsniveau</td>
</tr>
<tr>
<td></td>
<td>Motion</td>
</tr>
</tbody>
</table>

### Socialt og økonomisk-materielt

<table>
<thead>
<tr>
<th>Beskrivelse af bo-situation</th>
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<tbody>
<tr>
<td>(alene/ samboende (med hvem og varighed)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Børn (antal, alder, grad af kontakt)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Netværkskarakteristika</th>
</tr>
</thead>
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<table>
<thead>
<tr>
<th>Ressourcepersoner</th>
</tr>
</thead>
<tbody>
<tr>
<td>(anfør evt kontaktoplysninger)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Jobsituation (aktuelt, tidligere m.v.)</th>
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</table>

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<thead>
<tr>
<th>Praktisk hjælp i hjemmet</th>
</tr>
</thead>
<tbody>
<tr>
<td>(udover evt hjemmepleje)</td>
</tr>
</tbody>
</table>

---

**CRC-Diagnose:**

**Tidligere behandling af CRC:**

---

**Udfyldt dato:**

**Initialer:**
**Brug af egen læge, hjemmepæleje mv:**

<table>
<thead>
<tr>
<th><strong>Egen læges navn, adresse og telefonnr:</strong></th>
</tr>
</thead>
</table>

| **Kender e.l. godt? Hyppig bruger?** |
| **Brug af samt tilfredshed med e.l. i f.m. aktuelle?** |
| **Kontakt til hjemmepæleje/-sygeplejerske** |
| **Navn på nøgle-/kontaktperson, evt telefonnr.** |

**Livsstil, Fritidsinteresser, personlighed o.l:**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
</table>

**Tanker og ønsker vedrørende dette (kommende) forløb**

<table>
<thead>
<tr>
<th><strong>Reaktion på CRC diagnose, udredning og behandling, patientrolle m.v.</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Ønske (=præferencer) om information og involvering, evt pårørendes ønske om information og involvering</strong></th>
</tr>
</thead>
</table>

**Udfyldt dato:**

**Initialer:**
### Problemer relateret til helbredstilstand

<table>
<thead>
<tr>
<th>Domæne</th>
<th>Emne</th>
<th>Intet problem</th>
<th>Problem</th>
<th>Ikke vurderet</th>
<th>Ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fysiske symptomer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Smerte</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Træthed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Påvirket vejtrækning</td>
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<tr>
<td></td>
<td>Vægttab</td>
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<tr>
<td></td>
<td>Appetit</td>
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<tr>
<td></td>
<td>Kvalme/ opkastning</td>
<td></td>
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<tr>
<td></td>
<td>Diáre</td>
<td></td>
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<tr>
<td></td>
<td>Obstipation</td>
<td></td>
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<tr>
<td></td>
<td>Sexuelle fys. problem.</td>
<td></td>
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<tr>
<td></td>
<td>Evt stomifunktion</td>
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<tr>
<td></td>
<td>Andet:</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fysisk funktion</td>
<td>Fysisk formåen</td>
<td></td>
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<tr>
<td></td>
<td>Fysisk aktivitetsniveau</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Dagligdagens gøremål</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Andet:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psykiske symptomer</td>
<td>Depressive symptomer</td>
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<tr>
<td></td>
<td>Angst/ frygt</td>
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<tr>
<td></td>
<td>Selvværd</td>
<td></td>
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<tr>
<td></td>
<td>Kropsofattelse/ seksualitet</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Andet:</td>
<td></td>
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</tr>
</tbody>
</table>

Evt fundne problemer/ behov ”overføres” til journalark

### Andre problemer

<table>
<thead>
<tr>
<th>Domæne</th>
<th>Emne</th>
<th>Intet problem</th>
<th>Problem</th>
<th>Ikke vurderet</th>
<th>Ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spirituelt</td>
<td>Tanker omkr. mening med livet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tanker omkring døden</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Kognitivt</td>
<td>Forvirret</td>
<td></td>
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<tr>
<td></td>
<td>Hukommelsesbesvær</td>
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<tr>
<td></td>
<td>Koncentrationsbesvær</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Socialt</td>
<td>Påvirkning af relationer/ social kontakt</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Mulighed for at udøve interesser/ fritidsaktiviteter</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Arb. mæsigt og materielt</td>
<td>Arbejdsmæssige</td>
<td></td>
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<tr>
<td></td>
<td>Finansielle</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Materielt/ hjælpemidler</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Andet:</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Ad co-morbiditet (se side 1)
Anfør, hvis problem:

Evt fundne problemer/ behov ”overføres” til journalark

**Udfyldt dato:**

**Initialer:**
<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>Kommunikation</th>
<th>Forståelse og empati</th>
<th>Information</th>
<th>Tilgængelighed</th>
<th>Inddragelse/ shared-decision making</th>
<th>Støtte og pårørende</th>
<th>Kontinuitet (informations-, behørsmæssigt samt relationelt)</th>
<th>Overordnet tilfredshed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Bruger læger og sygeplejersker et sprog du forstår?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. Har vi lyttet til din sygdomshistorie?</td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>3. Har vi spurgt nok til hvordan du ellers har det?</td>
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<td></td>
<td></td>
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<tr>
<td>4. Synes du vi har forståelse for dig som person? Synes du vi forstår din situation?</td>
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<tr>
<td>5. Synes du, der bliver taget hensyn til dig som person i behandlingen?</td>
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<tr>
<td>7. Vurderer du, at du ved nok om: a) diagnose, b) prognose, c) behandling og d) efterføløb</td>
<td></td>
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<tr>
<td>8. Har du fået mulighed for at stille spørgsmål? Har der været tid til dette?</td>
<td></td>
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<tr>
<td>9. Ved du hvor du skal går hen, når du har spørgsmål?</td>
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<tr>
<td>10. Er du tilfreds med hvor meget du bliver involveret i beslutninger omkring din behandling?</td>
<td></td>
<td></td>
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<tr>
<td>i. Hvis problem: Hvordan vil du inddrages? Hvad er gået galt?</td>
<td></td>
<td></td>
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<tr>
<td>11. Har du behov for mere støtte?</td>
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<tr>
<td>12. Har vi spurgt til din familie? Vurderer du, at de har behov for støtte?</td>
<td></td>
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<tr>
<td>13. Har dine pårørende behov for mere information? Skal vi involvere dem mere?</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>14. Oplever du behandlingsforløbet som sammenhængende?</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>15. Føler du at tingene giver mening?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>16. Er du generelt tilfreds med dit forløb?</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Synes du, at der er noget vi mangler at snakke om?</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Forløbskoordinators vurdering afgør ”problem” / ”ikke problem”. Problemer ”overføres” til journalark.
Spørgsmål skal sikre et patientcentreret forløb (der anerkender brug af EBM, men fokus på patientinvolvering, god kommunikation og information)
Hvis der identificeres uerkendt (for patienten) problem, informeres og inddrages patienten i dette.

Dato for gennemgang:
Initialer:
<table>
<thead>
<tr>
<th>Dato</th>
<th>Årsag til kontakten (Beskrivelse af problem, årsag til opfølgning mv.)</th>
<th>Iværksat handling/ Plan/ Status</th>
<th>Handlinger iht VIPS</th>
<th>Kontakt</th>
<th>Formål</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Personlig</td>
<td>Telefonisk</td>
</tr>
</tbody>
</table>

239
Anden inspiration i forbindelse med assessment/vurderingspørgsmål:
1: Hellbom: Assessment and treatment of psychosocial problems in cancer patients: an exploratory study of a course for nurses [46]
2: PASQOC studiet, Nedenfor ses items med rapporterede problem områder [33]:

![Diagram showing items with high mean problem frequencies (>30%)](image)

Fig. 2 Specific items of the PASQOC questionnaire with mean PFs of >30%
**BILAG E: Introduktionsprogram for forløbskoordinatorer**

<table>
<thead>
<tr>
<th>EMNE:</th>
<th>Ansvarlig person og sted:</th>
<th>Var.</th>
<th>Dato</th>
<th>Er aftalt?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velkomst og morgenbrød</td>
<td>Mandag den 5. januar kl 9.00 på Frede Olesens kontor, Forskningsenheden for Almen Praksis</td>
<td>1-1,5 t</td>
<td>5/1</td>
<td>Ja</td>
</tr>
<tr>
<td>Information om case management, manual, forskningsprojekt (RCT). Forventningsafstemning.</td>
<td>CW Forskningsenheden for Almen Praksis</td>
<td>2 t</td>
<td>5/1, ca 10-12</td>
<td>Ja</td>
</tr>
<tr>
<td>Logistik af beh.forløb:</td>
<td>Av. rectum cancer: Vibeke + Tina P, afd 280 Simple rectum: ? Colon: Inga Have, ”endoskopien”</td>
<td>1 dag i alt</td>
<td>16/1 kl 13</td>
<td>Ja</td>
</tr>
<tr>
<td>Praktik onkol afd:</td>
<td>Århus Sygehus, NBG</td>
<td>1 dag</td>
<td>13. jan</td>
<td>Ja</td>
</tr>
<tr>
<td>Billeddiagnostik:</td>
<td>MR på Skejby, Lisbeth Roed mfl CT på Tage-Hansens Gade, Basal intro ved Lissy</td>
<td>1 dag</td>
<td>14. jan 8.30 21. jan kl13</td>
<td>Ja, <a href="mailto:Lisbroed@rm.dk">Lisbroed@rm.dk</a> Ja, Lissy C 8949 7843</td>
</tr>
<tr>
<td>Brug af EPJ PAS + Skrive i Grønne System</td>
<td>Lis Lund</td>
<td>? t</td>
<td>9/1 12.30 It lok 20/1 12.30 It-lok 3/2 kl13</td>
<td>Ja</td>
</tr>
<tr>
<td>Det sammenhængende sundhedsvæsen:</td>
<td>Frede Olesen</td>
<td>2 dage a 3 t</td>
<td>9/1 kl 9-12 FE 7/1 kl 9-12 FE</td>
<td>Ja</td>
</tr>
<tr>
<td>Almen praksis</td>
<td>Peter Vedsted</td>
<td>2 t</td>
<td>7/1 13-15 FE</td>
<td>Ja</td>
</tr>
<tr>
<td>”Føl” i almen praksis</td>
<td>APU’en kontakt Birger Aaen Skødstrup lægepraksis ved Roar Maagaard</td>
<td>4 t*2</td>
<td>22./1(M)+20(T) 15./1(M)+ 22./1(T)</td>
<td>Ja</td>
</tr>
<tr>
<td>Komm.træning (+supervision+video)</td>
<td>Mai-Britt Guldin, Forskningsenheden for AP</td>
<td>2 dage a 3 t +?</td>
<td>26.+27. jan 9-12 + supervision</td>
<td>Ja</td>
</tr>
<tr>
<td>Klargøring af kontor, PC opætning, telefoner, mapper, kalender, udl.materiale</td>
<td>På egen hånd</td>
<td></td>
<td>5/1 over middag + løbende</td>
<td></td>
</tr>
<tr>
<td>Deltage ved operation</td>
<td>23/1: Mette og Trine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehab. Kursus</td>
<td>Dallund</td>
<td>5 dage</td>
<td>Uge 7</td>
<td>Ja, program tilsendes</td>
</tr>
</tbody>
</table>

Pilottest af interventionen starter tidligst muligt, gerne uge 3 eller 4. Trine og Mette vælger selv nogle patienter
Litteratur


59. Fellowes D, Wilkinson S, Moore P. Communication skills training for health care professionals working with cancer patients, their families and/or carers. Cochrane Database Syst Rev 2003;CD003751.


Appendix B:

Patient baseline questionnaire

APPENDIX B:

PATIENT BASELINE QUESTIONNAIRE
The Effect of Hospital-Based Case Management in Cancer Care Pathways
Vi er interesserede i at vide noget om dig og dit helbred. Vær venlig at besvare alle spørgsmålene ved at sætte et kryds ud for det svar, som passer bedst på dig. Der er ingen "rigtige" eller "forkerte" svar. De oplysninger, som du giver os, vil blive behandlet strengt fortroligt.

### Sæt kun ét kryds ud for hvert spørgsmål

<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>Slet ikke</th>
<th>Lidt</th>
<th>En del</th>
<th>Meget</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Har du nogen vanskeligheder ved at udføre anstrengende aktiviteter, som f.eks. at bære en tung indkøbstaske eller en kuffert?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Har du nogen vanskeligheder ved at gå en lang tur?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Har du nogen vanskeligheder ved at gå en kort tur udendørs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4 Er du nødt til at ligge i sengen eller at sidde i en stol om dagen?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 Har du brug for hjælp til at spise, tage tøj på, vaske dig eller gå på toilettet?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### I den forløbne uge:

<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>Slet ikke</th>
<th>Lidt</th>
<th>En del</th>
<th>Meget</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6 Var du begrænset i udførelsen af enten dit arbejde eller andre daglige aktiviteter?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1.7 Var du begrænset i at dyrke dine hobbyer eller andre fritidsaktiviteter?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8 Havde du åndenød?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.9 Har du haft smerten?</td>
<td></td>
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</tr>
<tr>
<td>1.10 Havde du brug for at hvile dig?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.11 Har du haft besvær med at sove?</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1.12 Har du følt dig svag?</td>
<td></td>
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<tr>
<td>1.13 Har du savnet appetit?</td>
<td></td>
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</tr>
<tr>
<td>1.14 Har du haft kvalme?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.15 Har du kastet op?</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
I den forløbne uge:

<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>Slet ikke ▼</th>
<th>Lidt ▼</th>
<th>En del ▼</th>
<th>Meget ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.16 Har du haft forstoppelse?</td>
<td></td>
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<td></td>
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<tr>
<td>1.17 Har du haft diarré (tynd mave)?</td>
<td></td>
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<tr>
<td>1.18 Var du træt?</td>
<td></td>
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</tr>
<tr>
<td>1.19 Vanskeliggjorde smerten dine daglige gøremål?</td>
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<td>1.23 Følte du dig irritabel?</td>
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<td>1.24 Følte du dig deprimeret?</td>
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De næste 2 spørgsmål besvares ved at sætte ring omkring det tal mellem 1 og 7, som passer bedst på dig

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<tr>
<th>Spørgsmål</th>
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### Dit helbred før aktuelle sygdom

2.1 Hvordan syntes du alt i alt dit helbred var, før du oplevede de første symptomer på det, du aktuelt bliver undersøgt eller behandlet for? *Sæt kun ét kryds*

- [ ] Fremragende
- [ ] Vældigt godt
- [ ] Godt
- [ ] Mindre godt
- [ ] Dårligt

### Anden sygdom

2.2 Har du inden for de seneste 12 måneder haft en eller flere af nedenstående sygdomme? *Sæt eventuelt flere kryds*

- [ ] Forhøjet blodtryk, åreforkalkning, hjertekrampe, blodprop, hjerneblødning
- [ ] Aldersdiabetes, type 2 sukkersyge
- [ ] Bronkitis, store lunger, rygerlunger, KOL, astma
- [ ] Slidgigt, ledegigt, diskusprolaps, rygssygdom, dårlig ryg
- [ ] Psykisk sygdom, mentale forstyrrelser
- [ ] Migræne, hyppig hovedpine
- [ ] Anden langvarig sygdom, angiv:_____________________________________

### Dit udrednings- og behandlingsforløb indtil nu

2.3 HVordan vurderer du, at din udredning og behandling er forløbet indtil nu? *Sæt kun ét kryds*

- [ ] Fremragende
- [ ] Vældigt godt
- [ ] Godt
- [ ] Mindre godt
- [ ] Dårligt

Vær venlig at forsætte på næste side
## Sammenhæng i behandlingsforløb

### Patientspørgeskema

#### Din vurdering af din praktiserende læge
**(evt den læge i et lægehus, som du har mest kontakt med)**

<table>
<thead>
<tr>
<th>Er du enig eller uenig i følgende udsagn?</th>
<th>Meget enig ▼</th>
<th>Enig ▼</th>
<th>Uenig ▼</th>
<th>Meget uenig ▼</th>
<th>Ved ikke/ ikke relevant ▼</th>
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<tr>
<td><strong>2.4</strong> Min praktiserende læge er fagligt dygtig</td>
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<tr>
<td><strong>2.5</strong> Min praktiserende læge er god til at lytte til mig</td>
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<tr>
<td><strong>2.6</strong> Min praktiserende læge er god til at tale med mig om symptomer og sygdom, så jeg føler mig velinformeret</td>
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<td><strong>2.7</strong> Min praktiserende læge er god til at hjælpe mig med at håndtere mine følelser omkring helbredsproblemer</td>
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<tr>
<td><strong>2.8</strong> Min praktiserende læge har været god til at forberede mig på det, der skulle ske på sygehuset</td>
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<td><strong>2.9</strong> Jeg er meget tilfreds med min praktiserende læge</td>
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#### Holdninger til eget helbred

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<td><strong>2.10</strong> Mit helbred afhænger i høj grad af, hvor godt jeg passer på mig selv</td>
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<td><strong>2.11</strong> Mit helbred er i høj grad påvirket af tilfældigheder</td>
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<td><strong>2.12</strong> Når man er syg, har man selv et stort ansvar for igen at blive rask</td>
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<td><strong>2.13</strong> Når man er syg, er den bedste måde til igen at blive rask at følge lægernes råd til punkt og prikke</td>
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Vær venlig at forsætte på næste side
### Dit forhold til familie og venner

**Besvar hvert spørgsmål med ét kryds**

#### 2.14 Hvor ofte træffer du familie, som du ikke bor sammen med?

- [ ] Dagligt eller næsten dagligt
- [ ] Et par gange om ugen
- [ ] Et par gange om måneden
- [ ] Sjældnere end et par gange om måneden
- [ ] Aldrig
- [ ] Ved ikke

#### 2.15 Hvor ofte træffer du venner og bekendte?

- [ ] Dagligt eller næsten dagligt
- [ ] Et par gange om ugen
- [ ] Et par gange om måneden
- [ ] Sjældnere end et par gange om måneden
- [ ] Aldrig
- [ ] Ved ikke

#### 2.16 Hvis du har brug for hjælp til praktiske problemer, kan du da regne med at få hjælp fra andre?

- [ ] Ja, helt sikkert
- [ ] Ja, måske
- [ ] Nej
- [ ] Ved ikke

#### 2.17 Sker det nogensinde, at du er alene, selvom du egentlig havde mest lyst til at være sammen med andre?

- [ ] Ja, ofte
- [ ] Ja, en gang imellem
- [ ] Ja, sjældent
- [ ] Nej
- [ ] Ved ikke
# Personlige oplysninger

*Besvar hvert spørgsmål med ét kryds*

## 2.18 Hvad er din ægteskabelige status?

- ☐ Gift
- ☐ Samlevende
- ☐ Enlig (ikke tidligere gift eller samlevende)
- ☐ Enlig (skilt, separeret, afbrudt fast samlivsforhold)
- ☐ Enlig (enke, enkemand)

## 2.19 Har du børn?

- ☐ Ja, jeg har hjemmeboende børn
- ☐ Ja, jeg har børn, som er flyttet hjemmefra
- ☐ Ja, jeg har både hjemmeboende og udeboende børn
- ☐ Nej

## 2.20 Hvor stor var din husstands årsindkomst før skat sidste år?  
(Med husstand menes: dig og din eventuelle ægtefælle eller samlever)

- ☐ Under 99.999 kr.
- ☐ 100.000 - 249.999 kr.
- ☐ 250.000 - 449.999 kr.
- ☐ 450.000 - 699.999 kr.
- ☐ Over 700.000 kr.
- ☐ Ved ikke

## 2.21 Har du selv eller en fra din husstand bil?

- ☐ Ja
- ☐ Nej

## 2.22 Ejer du selv eller en fra din husstand den bolig, du bor i?

- ☐ Ja
- ☐ Nej
**Personlige oplysninger**

_Besvar hvert spørgsmål med ét kryds_

### 2.23 Hvilken erhvervsuddannelse har du?

- [ ] Ingen
- [ ] Et eller flere kortere kurser (fx specialarbejderkurser, arbejdsmarkedskurser)
- [ ] Handelsskolernes grundforløb (HG) eller erhvervsfaglig grunduddannelse (EFG)
- [ ] Faglært inden for håndværk, handel, kontor
- [ ] Kort videregående uddannelse under 3 år (fx social- og sundhedsass., tekniker, merkonom)
- [ ] Mellemlang videregående uddannelse 3-4 år (fx folkeskolelærer, journalist, socialrådgiver, fysioterapeut)
- [ ] Lang videregående uddannelse på 5 år eller mere (fx civilingeniør, læge, psykolog)
- [ ] Andet: ___________________________________________________________

### 2.24 Hvad er din nuværende stilling?

- [ ] Specialarbejder eller ufaglært arbejder
- [ ] Faglært arbejder
- [ ] Funktionær eller tjenestemand
- [ ] Selvstændig erhvervsdrivende (inkl. medhjælpende ægtefælle)
- [ ] Lærling, elev, studerende
- [ ] Folkepensionist / førtidspensionist
- [ ] På efterløn
- [ ] Arbejdsløs med understøttelse
- [ ] På kontanthjælp
- [ ] Hjemmegående (uden andet arbejde)
- [ ] På orlov (barselsorlov, uddannelsesorlov mv.)
- [ ] Andet: ___________________________________________________________

**Dato for udfyldelse af spørgeskemaet:**

[ ] dag - [ ] måned - [ ] år

_Kontrollér venligst, at du ikke er kommet til at springe spørgsmål over i skemaet! Du er velkommen til at skrive på bagsiden, hvis du har kommentarer._

_Mange tak for hjælpen!_

7 / 7
The Effect of Hospital-Based Case Management in Cancer Care Pathways
APPENDIX C:

PATIENT FOLLOW-UP QUESTIONNAIRE
Kære NN

I forbindelse med dit behandlingsforløb ved Afdeling P, Århus Universitetshospital, har du tidligere givet tilsagn om at deltage i forskningsprojektet ”Sammenhæng i behandlingsforløb”.

Som et led i forskningsprojektet, sender vi dette spørgeskema til dig. Det omhandler din aktuelle livskvalitet og din tilfredshed med behandlingsforløbet.

Det er meget vigtigt for undersøgelsens brugbarhed, at flest mulig patienter deltager. Vi håber derfor, at du har mulighed for at besvare det vedlagte spørgeskema.

Ønsker du i stedet at blive ringet op, og besvare spørgeskemaet telefonisk, kan du skrive dette samt telefonnummer på spørgeskemaets forside, hvorefter du bedes returnere det i den frankerede kuvert. Du bliver herefter ringet op af en person fra projektgruppen.

Ønsker du ikke at besvare spørgeskemaet, beder vi dig skrive dette på forsiden af spørgeskemaet ("Ønsker ikke at besvare") og returnere det i den frankerede kuvert.

Hvis vi ikke har modtaget spørgeskemaet efter 3 uger, tillader vi os at sende dig en påmindelse.

Har du spørgsmål til spørgeskemaet eller til forskningsprojektet, er du velkommen til at kontakte den projektansvarlige læge, Christian Wulff.

På forhånd tak for hjælpen.

Med venlig hilsen

Christian Wulff, Projektansvarlig læge og ph.d.-studerende
Forskningsenheden for Almen Praksis i Århus
Aarhus Universitet
Direkte tlf. 89 42 6067/ 22997968

samt:
Peter Rasmussen, overkirurg, Afdeling P, Århus Universitetshospital
Frede Olesen, professor, dr.med., Peter Vedsted, professor, ph.d. og Jens Søndergaard, professor, ph.d., Forskningsenheden for Almen Praksis i Århus
Vi er interesserede i at vide noget om dig og dit helbred. Vær venlig at besvare alle spørgsmålene ved at sætte et kryds ud for det svar, som passer bedst på dig. Der er ingen "rigtige" eller "forkerte" svar.

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<tbody>
<tr>
<td>1.1 Har du nogen vanskeligheder ved at udføre anstrengende aktiviteter, som f.eks. at bære en tung indkøbstaske eller en kuffert?</td>
<td>☐ ☐ ☐ ☐ ☐</td>
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<td>1.2 Har du nogen vanskeligheder ved at gå en lang tur?</td>
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<td>1.3 Har du nogen vanskeligheder ved at gå en kort tur udendørs?</td>
<td>☐ ☐ ☐ ☐ ☐</td>
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<td>1.4 Er du nødt til at ligge i sengen eller at sidde i en stol om dagen?</td>
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<tr>
<td>1.5 Har du brug for hjælp til at spise, tage tøj på, vaske dig eller gå på toilettet?</td>
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<th>I den forløbne uge:</th>
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<tr>
<td>1.6 Var du begrænset i udførelsen af enten dit arbejde eller andre daglige aktiviteter?</td>
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<td>1.7 Var du begrænset i at dyrke dine hobbyer eller andre fritidsaktiviteter?</td>
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<td>1.8 Havde du åndenød?</td>
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<td>1.9 Har du haft smerter?</td>
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<tr>
<td>1.10 Havde du brug for at hvile dig?</td>
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<tr>
<td>1.11 Har du haft besvær med at sove?</td>
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<td>1.12 Har du følt dig svag?</td>
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<td>1.13 Har du savnet appetit?</td>
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<td>1.14 Har du haft kvalme?</td>
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<td>1.15 Har du kastet op?</td>
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<td>1.16 Har du haft forstoppelse?</td>
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<td>1.17 Har du haft diarré (tynd mave)?</td>
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<td>1.18 Var du træt?</td>
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</table>
På de sidste sider besvares spørgsmål og udsagn ved at afkrydse de svar, som passer bedst på dig. Der er undervejs anført, om du må besvare med mere end et kryds. Der er ingen "rigtige" eller "forkerte" svar.

Uanset om du har afsluttet behandling eller ej, beder vi dig besvare spørgsmålene ved at tænke på de oplevelser, som du har haft i dit behandlingsforløb indtil nu.

### Din kontakt med læger og sygeplejersker på sygehuset

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn: Sæt kun ét kryds ud for hvert udsagn</th>
<th>Meget enig ▼</th>
<th>Enig ▼</th>
<th>Uenig ▼</th>
<th>Meget uenig ▼</th>
<th>Ved ikke/ ikke relevant ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1</strong> Læger og sygeplejersker har været gode til at lytte til mig</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.2</strong> Læger og sygeplejersker har været gode til at forstå min situation</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>Læger og sygeplejersker har i passende grad interesseret sig for....</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2.3</strong> ...mit fysiske helbred</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.4</strong> ...mit psykiske helbred</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.5</strong> ...mine bekymringer grundet sygdommen</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.6</strong> ...hvordan mine pårørende har haft det</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.7</strong> ...at mine pårørende har været velinformede om min situation</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td><strong>2.8</strong> ...mine ikke-helbredsmæssige forhold (bolig- og arbejdssituation, økonomi m.v.)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

Vær venlig at fortsætte på næste side
# Information fra læger og sygeplejersker om din sygdom og behandling

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn:</th>
<th>Meget enig ▼</th>
<th>Enig ▼</th>
<th>Uenig ▼</th>
<th>Meget uenig ▼</th>
<th>Ved ikke/ ikke relevant ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.1 Informationen om undersøgelserne (=udredningen) af min sygdom har været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.2 Informationen om behandlingen af min sygdom har været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.3 Informationen om mulige bivirkninger til behandlingen har været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.4 Informationen om mulige senfølger af min sygdom og behandling har været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.5 Informationen om hjælpe- og støttemuligheder (sociale ydelser, psykolog, fysioterapi mv.) har været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.6 Jeg har på intet tidspunkt savnet mundtlig information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.7 Jeg har på intet tidspunkt savnet skriftlig information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.8 Informationen er blevet givet på de rigtige tidspunkter</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.9 Jeg er i passende omfang blevet spurt om mit behov for at modtage information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.10 Samlet set har informationen været tilfredsstillende</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.11 Jeg er i passende grad blevet inddraget i beslutningerne om min behandling og pleje</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Information og støtte til dine pårørende

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn:</th>
<th>Meget enig ▼</th>
<th>Enig ▼</th>
<th>Uenig ▼</th>
<th>Meget uenig ▼</th>
<th>Ved ikke/ ikke relevant ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.1 Jeg vurderer, at mine pårørende er blevet passende informeret om min sygdom og behandling</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4.2 Mine pårørende er i passende grad blevet inddraget i beslutningerne om min behandling og pleje</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4.3 Læger og sygeplejersker har samlet set været gode til at tilbyde mine pårørende vejledning, rådgivning, støtte og hjælp</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Vær venlig at fortsætte på næste side
### Tillid til læger og sygeplejersker på sygehuset

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn:</th>
<th>Meget enig ▼</th>
<th>Enig ▼</th>
<th>Uenig ▼</th>
<th>Meget uenig ▼</th>
<th>Ved ikke/ikke relevant ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.1 Jeg har stor tillid til lægernes faglige dygtighed</strong></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>5.2 Jeg har stor tillid til sygeplejerskernes faglige dygtighed</strong></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### Oplysninger om din behandling på sygehuset

**6.1 Jeg har gennemgået eller er i gang med følgende behandling:**
*(sæt eventuelt flere kryds)*

- ☐ operation
- ☐ behandling med kemoterapi
- ☐ strålebehandling
- ☐ andet, anfør:______________________________________
- ☐ ingen
- ☐ ved ikke

**6.2 Jeg venter på følgende behandling:**
*(sæt eventuelt flere kryds)*

- ☐ operation
- ☐ behandling med kemoterapi
- ☐ strålebehandling
- ☐ andet:_____________________________________________
- ☐ ingen
- ☐ ved ikke
### Angående eventuel operation

*Du skal kun besvare spørgsmål 7.1-7.6, hvis du er blevet opereret.*

<table>
<thead>
<tr>
<th>Udsagn</th>
<th>Meget enig</th>
<th>Enig</th>
<th>Uenig</th>
<th>Meget uenig</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>En læge eller sygeplejerske havde forud for operationen informeret mig godt om mulige følger af indgrebet (f.eks. stomi og smerter)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>En læge eller sygeplejerske havde forud for operationen informeret mig godt om, hvordan jeg bedst kunne håndtere de mulige følger af indgrebet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dagene efter operationen var værre, end jeg havde forventet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg vurderer, at min udskrivelse efter operationen var godt tilrettelagt</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ved udskrivelsen efter operationen var jeg godt informeret om eventuel yderligere kontrol og behandling.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Da jeg blev udskrevet efter operationen, følte jeg mig tryg ved at skulle hjem</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### Din oplevelse af ventetid i dit behandlingsforløb

*Er et udsagn (f.eks. om strålebehandling) ikke relevant for dig, afkrydser "Ved ikke/ikke relevant"*

<table>
<thead>
<tr>
<th>Udsagn</th>
<th>Meget enig</th>
<th>Enig</th>
<th>Uenig</th>
<th>Meget uenig</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventetiden på at få svar på undersøgelser og prøver har været tilfredsstillende</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventetiden, fra jeg blev henvist, til min kræftdiagnose blev stillet, var tilfredsstillende</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventetiden på at blive opereret var tilfredsstillende</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventetiden på at starte strålebehandling var tilfredsstillende</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventetiden på at starte med kemoterapi var tilfredsstillende</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Nøgle</td>
<td>Forløb</td>
<td>Udsagn</td>
<td>Meget</td>
<td>Enig</td>
<td>Uenig</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>---------</td>
<td>-------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>9.1</td>
<td>Jeg har oplevet problemer med henvisninger mellem forskellige afdelinger på sygehuset</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.2</td>
<td>Jeg har oplevet problemer, som skyldes, at min praktiserende læge manglede information om mit behandlingsforløb på sygehuset.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.3</td>
<td>Jeg har oplevet, at svar på prøver eller undersøgelser kom senere end lovet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.4</td>
<td>Jeg har oplevet at svar på prøver eller undersøgelser forsvandt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.5</td>
<td>Jeg har oplevet at få forkert svar på en prøve eller en undersøgelse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.6</td>
<td>Jeg har oplevet, at der skete fejl med min medicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.7</td>
<td>Jeg har oplevet at få forkert behandling eller pleje (ikke medicin)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.8</td>
<td>Jeg har oplevet at få modstridende information af personalet på sygehuset</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.9</td>
<td>Jeg har oplevet, at sygehuspersonale og egen læge har givet mig modstridende information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.10</td>
<td>Jeg mener, at der er sket fejl, der har forlænget mit forløb unødigt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.11</td>
<td>Jeg har oplevet, at der er sket andre fejl end nævnt ovenfor (9.1-9.9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Anfør venligst:

---

Vær venlig at fortsætte på næste side

7 / 10
### Om din oplevelse af at være tryg

Anfør din grad af enighed i følgende udsagn:

_Sæt kun ét kryds ud for hvert udsagn_

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn</th>
<th>Meget enig</th>
<th>Enig</th>
<th>Uenig</th>
<th>Meget uenig</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10.1</strong> Jeg er tryg ved den plan, der er lagt for mit forløb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10.2</strong> Når jeg har været hjemme, har jeg vidst, hvor jeg skulle henvende mig med spørgsmål vedrørende min sygdom og behandling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10.3</strong> Jeg har ikke på noget tidspunkt i mit forløb været i tvivl om, hvor jeg skulle henvende mig, hvis jeg havde behov for vejledning, rådgivning, støtte og hjælp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10.4</strong> Jeg er blevet informeret om at have en kontaktperson på sygehuset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10.5</strong> Jeg har oplevet, at en læge eller sygeplejerske på sygehuset har været der for mig hele vejen igennem mit behandlingsforløb</td>
<td></td>
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</tr>
</tbody>
</table>

---

### Sundhedsvæsenets samarbejde om din behandling og pleje

Anfør din grad af enighed i følgende udsagn:

_Sæt kun ét kryds ud for hvert udsagn_

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn</th>
<th>Meget enig</th>
<th>Enig</th>
<th>Uenig</th>
<th>Meget uenig</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11.1</strong> Forskellige sygehusafdelinger har samarbejdet godt omkring mit behandlingsforløb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11.2</strong> Jeg vurderer, at min praktiserende læge er blevet godt informeret om mit behandlingsforløb på sygehuset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11.3</strong> Jeg vurderer, at min praktiserende læge er blevet godt informeret om sygehusets plan med hensyn til videre behandling og kontrol af min sygdom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11.4</strong> Jeg vurderer, at samarbejdet mellem sygehuset og min praktiserende læge har fungeret tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11.5</strong> Samarbejdet omkring mit behandlingsforløb har samlet set fungeret tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11.6</strong> Jeg har oplevet mit behandlingsforløb som sammenhængende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Din vurdering af afdeling P

<table>
<thead>
<tr>
<th>12.1</th>
<th>Hvordan vurderer du kvaliteten af dit undersøgelses- og behandlingsforløb ved Afdeling P indtil nu?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Fremragende</td>
</tr>
<tr>
<td></td>
<td>□ Vældig god</td>
</tr>
<tr>
<td></td>
<td>□ God</td>
</tr>
<tr>
<td></td>
<td>□ Mindre god</td>
</tr>
<tr>
<td></td>
<td>□ Dårlig</td>
</tr>
</tbody>
</table>

### Din kontakt med praktiserende læge/ den læge i lægehuset, som du har mest kontakt med

<table>
<thead>
<tr>
<th>Besvar venligst følgende:</th>
<th>Ja ▼</th>
<th>Nej ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.2</td>
<td>Har du i dette behandlingsforløb efter du fik diagnosen haft kontakt med din praktiserende læge?</td>
<td>□</td>
</tr>
<tr>
<td>12.3</td>
<td>Har du i dette behandlingsforløb efter du fik diagnosen haft kontakt med din praktiserende læge, hvor I talte om dit behandlingsforløb?</td>
<td>□</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.4</th>
<th>Hvordan vurderer du kvaliteten af din praktiserende læges indsats i dette behandlingsforløb?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Fremragende</td>
</tr>
<tr>
<td></td>
<td>□ Vældig god</td>
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<tr>
<td></td>
<td>□ God</td>
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<tr>
<td></td>
<td>□ Mindre god</td>
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<tr>
<td></td>
<td>□ Dårlig</td>
</tr>
<tr>
<td></td>
<td>□ Det kan jeg ikke vurdere</td>
</tr>
</tbody>
</table>

### Din samlede tilfredshed med dit udrednings- og behandlingsforløb

<table>
<thead>
<tr>
<th>12.5</th>
<th>Hvordan vurderer du kvaliteten af dit samlede undersøgelses- og behandlingsforløb indtil nu?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Fremragende</td>
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<tr>
<td></td>
<td>□ Vældig god</td>
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<td>□ God</td>
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<tr>
<td></td>
<td>□ Mindre god</td>
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<tr>
<td></td>
<td>□ Dårlig</td>
</tr>
</tbody>
</table>
**Sammenhæng i behandlingsforløb**  
**Patientspørgeskema**

---

**Dato for udfyldelse af spørgeskemaet:**

- [ ] dag  
- [ ] måned  
- [ ] år  

Hvis du har kommentarer, kan du anføre dem her:

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
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</tr>
</tbody>
</table>

Kontrollér venligst at du ikke er kommet til at overse spørgsmål eller udsagn.

Det udfylde skema bedes returneret til Forskningsenheden for Almen Praksis i Århus i vedlagte frankerede svarkuvert.

**Mange tak for hjælpen!**
APPENDIX D:

DATA QUALITY OF PATIENT RESPONSES
**Table D1. Characteristics of patients alive at the three assessments**

<table>
<thead>
<tr>
<th></th>
<th>8 weeks</th>
<th></th>
<th>30 weeks</th>
<th></th>
<th>52 weeks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>CM</td>
<td>Control</td>
<td>CM</td>
<td>Control</td>
<td>CM</td>
</tr>
<tr>
<td>Dead</td>
<td>6 (4)</td>
<td>8 (6)</td>
<td>17 (12)</td>
<td>18 (13)</td>
<td>20 (14)</td>
<td>31 (22)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>134 (96)</td>
<td>132 (94)</td>
<td>123 (88)</td>
<td>122 (87)</td>
<td>120 (86)</td>
<td>109 (78)</td>
</tr>
<tr>
<td>Gender:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>45 (34)</td>
<td>43 (33)</td>
<td>43 (35)</td>
<td>39 (32)</td>
<td>41 (34)</td>
<td>36 (33)</td>
</tr>
<tr>
<td>Female</td>
<td>89 (66)</td>
<td>89 (67)</td>
<td>80 (65)</td>
<td>83 (68)</td>
<td>79 (66)</td>
<td>73 (67)</td>
</tr>
<tr>
<td>Age group:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-64</td>
<td>62 (46)</td>
<td>58 (44)</td>
<td>60 (49)</td>
<td>54 (44)</td>
<td>59 (49)</td>
<td>50 (46)</td>
</tr>
<tr>
<td>65-79</td>
<td>58 (43)</td>
<td>60 (45)</td>
<td>53 (43)</td>
<td>55 (45)</td>
<td>51 (43)</td>
<td>48 (44)</td>
</tr>
<tr>
<td>≥80</td>
<td>14 (10)</td>
<td>14 (11)</td>
<td>10 (8)</td>
<td>13 (11)</td>
<td>10 (8)</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Disease:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>68 (51)</td>
<td>65 (49)</td>
<td>63 (51)</td>
<td>60 (49)</td>
<td>63 (53)</td>
<td>56 (51)</td>
</tr>
<tr>
<td>Rectum</td>
<td>62 (46)</td>
<td>63 (48)</td>
<td>56 (46)</td>
<td>58 (48)</td>
<td>54 (45)</td>
<td>49 (45)</td>
</tr>
<tr>
<td>Other cancer</td>
<td>2 (1)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
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</tr>
<tr>
<td>Not cancer</td>
<td>2 (1)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Follow-up surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No surgery</td>
<td>15 (11)</td>
<td>16 (12)</td>
<td>11 (9)</td>
<td>12 (10)</td>
<td>10 (8)</td>
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</tr>
<tr>
<td>Endoscopic</td>
<td>9 (7)</td>
<td>5 (4)</td>
<td>8 (7)</td>
<td>5 (4)</td>
<td>8 (7)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>20 (14)</td>
<td>24 (18)</td>
<td>19 (15)</td>
<td>24 (20)</td>
<td>19 (16)</td>
<td>22 (20)</td>
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<tr>
<td>Laparotomy</td>
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<td>87 (66)</td>
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<td>85 (70)</td>
<td>83 (69)</td>
<td>74 (68)</td>
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</tbody>
</table>

Tables show absolute number (%).

**Table D2. Characteristics of patients responding to questionnaires**

<table>
<thead>
<tr>
<th></th>
<th>8 weeks</th>
<th></th>
<th>30 weeks</th>
<th></th>
<th>52 weeks</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>CM</td>
<td>Control</td>
<td>CM</td>
<td>Control</td>
<td>CM</td>
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<tr>
<td>Non-responders</td>
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<td>30 (21)</td>
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<td>31 (22)</td>
<td>41 (29)</td>
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<tr>
<td>Responders</td>
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<td>124 (89)</td>
<td>110 (79)</td>
<td>111 (79)</td>
<td>109 (78)</td>
<td>99 (71)</td>
</tr>
<tr>
<td>Gender:</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>39 (32)</td>
<td>40 (32)</td>
<td>36 (33)</td>
<td>36 (32)</td>
<td>38 (35)</td>
<td>33 (33)</td>
</tr>
<tr>
<td>Female</td>
<td>82 (68)</td>
<td>84 (68)</td>
<td>74 (67)</td>
<td>75 (68)</td>
<td>71 (65)</td>
<td>66 (67)</td>
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<tr>
<td>Age group:</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>0-64</td>
<td>57 (47)</td>
<td>55 (44)</td>
<td>55 (50)</td>
<td>48 (43)</td>
<td>54 (50)</td>
<td>45 (45)</td>
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<tr>
<td>65-79</td>
<td>53 (44)</td>
<td>55 (44)</td>
<td>47 (43)</td>
<td>50 (45)</td>
<td>47 (43)</td>
<td>44 (44)</td>
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<tr>
<td>≥80</td>
<td>11 (9)</td>
<td>14 (11)</td>
<td>8 (7)</td>
<td>13 (12)</td>
<td>8 (7)</td>
<td>10 (10)</td>
</tr>
<tr>
<td>Disease:</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon</td>
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<td>62 (50)</td>
<td>55 (50)</td>
<td>56 (51)</td>
<td>56 (51)</td>
<td>52 (53)</td>
</tr>
<tr>
<td>Rectum</td>
<td>57 (47)</td>
<td>58 (47)</td>
<td>52 (47)</td>
<td>51 (46)</td>
<td>50 (46)</td>
<td>43 (43)</td>
</tr>
<tr>
<td>Other cancer</td>
<td>2 (2)</td>
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<td>1 (1)</td>
<td>2 (2)</td>
<td>1 (1)</td>
<td>2 (2)</td>
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<tr>
<td>Not cancer</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
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<tr>
<td>Follow-up surgery</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No surgery</td>
<td>14 (12)</td>
<td>14 (11)</td>
<td>9 (8)</td>
<td>9 (8)</td>
<td>8 (7)</td>
<td>8 (8)</td>
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<tr>
<td>Endoscopic</td>
<td>9 (7)</td>
<td>5 (4)</td>
<td>8 (7)</td>
<td>5 (5)</td>
<td>8 (7)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>18 (15)</td>
<td>23 (19)</td>
<td>18 (16)</td>
<td>23 (21)</td>
<td>18 (17)</td>
<td>20 (20)</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>80 (66)</td>
<td>82 (66)</td>
<td>75 (68)</td>
<td>74 (67)</td>
<td>75 (69)</td>
<td>67 (68)</td>
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</tbody>
</table>

Tables show absolute number (%).
### Table D3. EORTC QLQ-C30 data quality

<table>
<thead>
<tr>
<th></th>
<th>Sent/ returned/ not returned</th>
<th>Returned questionnaire but &lt; ½ of items in scale filled in</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>q12</td>
<td>pf2</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>140/140/0</td>
<td>2</td>
</tr>
<tr>
<td>CM</td>
<td>140/140/0</td>
<td>3</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>134/121/13</td>
<td>2</td>
</tr>
<tr>
<td>CM</td>
<td>132/124/8</td>
<td>1</td>
</tr>
<tr>
<td>Week 30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>123/110/13</td>
<td>2</td>
</tr>
<tr>
<td>CM</td>
<td>122/111/11</td>
<td>3</td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>118/109/9</td>
<td>1</td>
</tr>
<tr>
<td>CM</td>
<td>109/99/10</td>
<td>2</td>
</tr>
</tbody>
</table>

Note: q12, pf2, rf2, ef, cf, sf refer to scale names and not item numbers.

### Table D4. Patient evaluations data quality

<table>
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<tr>
<th></th>
<th>Sent/ returned/ not returned</th>
<th>Returned but ‘Don’t know/ N.A.’/ Returned but ‘missing’</th>
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</thead>
<tbody>
<tr>
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<td>3.10</td>
<td>4.3</td>
</tr>
<tr>
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<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>123/110/13</td>
<td>3/3</td>
</tr>
<tr>
<td>CM</td>
<td>122/111/11</td>
<td>2/3</td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>118/109/9</td>
<td>2/3</td>
</tr>
<tr>
<td>CM</td>
<td>109/99/10</td>
<td>1/2</td>
</tr>
</tbody>
</table>

Note: 3.10, 4.3, 7.6, 10.3, 10.5, 11.6, 12.1, 12.5 refer to item number in questionnaire.
Appendix E: GP questionnaire
Doktor NN  
XX Gade YY  
YYYY By  

Århus, den /

Forskningsenheden for Almen Praksis i Århus og Kirurgisk Afdeling P, Århus Universitetshospital gennemfører en undersøgelse af sammenhæng i behandlingsforløb for patienter med colorektalcancer.

Vi beder den læge i praksis, som har mest kontakt med, læse dette brev.

Vi sender dette spørgeskema, da (tilknyttet din praksis) har fået diagnosticeret colon eller rectumcancer og er blevet behandlet ved Afdeling P, Århus Sygehus. Patienten har med sin underskrift indvilget i at deltage i projektet *Sammenhæng i behandlingsforløb*, herunder accepteret, at vi må tilsende praktiserede læge et spørgeskema om sygdomsforløbet.

Forskningsprojektet analyserer patienters og praktiserende lægers vurderinger af behandlingsforløb og sammenholder dette med behandlingsforløbets organisering. Vi beder dig besvare lægespørgeskemaets ca 25 spørgsmål / udsagn, som omhandler din vurdering af information fra sygehuset til almen praksis, sygehusets og praksis’ handlinger og samarbejde, koordination af behandlingsforløbet, komorbiditet samt lidt om dig selv.

Det tager ca 5-10 minutter at besvare skemaet. Du vil blive honoreret for udfyldelse af skemaet svarende til et 10 minutters modul pr. skema.

Det er vigtigt, at du selvfølgelig kan anvende dit samarbejde og spørgeskemaet indenfor sin praksis, husholdning, tidspunkt osv. Vi tillader almindelig adfærd.


Alle besvarelser behandles i anonymiseret form. Undersøgelsen er godkendt af Datatilsynet og DSAMs og PLOs Udvalg vedrørende multipraksisundersøgelser (MPU).

Har du spørgsmål eller kommentarer er du meget velkommen til at kontakte os.

På forhånd mange tak for hjælpen.

Med venlig hilsen

Christian Wulff  
Projektansvarlig læge og ph.d.-studerende  
Forskningsenheden for Almen Praksis i Århus  
Direkte tlf. 89 42 6067/22997968

Peter Vedsted  
Adj. professor, læge, ph.d.  
Forskningsenheden for Almen Praksis i Århus

Søren Laurberg, professor, overkirurg, dr.med.  
Peter Rasmussen, overkirurg  
Afdeling P, Århus Universitetshospital

Jens Søndergaard  
Professor, praktiserende læge, ph.d.  
Forskningsenheden for Almen Praksis, SDU

277
Sammenhæng i behandlingsforløb
Lægespørgeskema

Dette spørgeskema vedrører sygdomsforløbet for patienten anført i følgebrevet. Spørgeskemaet bedes udfyldt af den læge, som primært har varetaget kontakten, mens patienten er blevet behandlet for colorectalcancer.

### Din vurdering af patient-specifik information fra sygehus til almen praksis

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn: Sæt kun ét kryds ud for hvert udsagn</th>
<th>Meget enig □</th>
<th>Enig □</th>
<th>Uenig □</th>
<th>Meget uenig □</th>
<th>Ved ikke/ikke relevant □</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Jeg modtog med passende hyppighed information om patienten</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Informationen i de tilsendte epikriser, ambulante notater m.v. opfyldte alt i alt mit behov for information om patienten</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Informationen har hjulpet mig til bedre at kunne håndtere patientens fysiske følger af kræftsygdommen</td>
<td></td>
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<td></td>
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<tr>
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<tr>
<td>1.5 Informationen har hjulpet mig til bedre at kunne håndtere patientens sociale følger af kræftsygdommen</td>
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</tr>
<tr>
<td>1.6 Informationen har hjulpet mig til bedre at kunne håndtere patientens øvrige helbredsforhold</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Din vurdering af behandlingsforløbet

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn: Sæt kun ét kryds ud for hvert udsagn</th>
<th>Meget enig □</th>
<th>Enig □</th>
<th>Uenig □</th>
<th>Meget uenig □</th>
<th>Ved ikke/ikke relevant □</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Jeg vurderer, at sygehuset har taget passende hensyn til andet end patientens cancerrelaterede forhold (dvs. sociale forhold, komorbiditet, personlighed mv.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 Jeg ville ønske, at jeg i højere grad var blevet inddraget i beslutninger vedrørende de af sygehuset påtænkte behandlings- og rehabiliteringstiltag</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 Jeg vurderer, at samarbejdet mellem almen praksis og sygehuset har fungeret tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Jeg vurderer, at patienten indtil nu har gennemgået et velkoordineret behandlingsforløb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Jeg vurderer, at relevant rehabilitering er påbegyndt eller gennemgået</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Din oplevelse af manglende patient-specifik information fra sygehus til almen praksis

<table>
<thead>
<tr>
<th>I hvor høj grad passer følgende udsagn:</th>
<th>I høj grad</th>
<th>I nogen grad</th>
<th>I ringe grad</th>
<th>Slet ikke</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sæt kun ét kryds ud for hvert udsagn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Jeg har **manglet** information fra sygehuset om......

| 3.1  | ...det af sygehuset påtænkte behandlingsforløb | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.2  | ...hvor i behandlingsforløbet patienten befandt sig | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.3  | ...ændringer i patientens ordinerede medicin | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.4  | ...hvad patienten var blevet informeret om på sygehuset | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.5  | ...identificerede problemer og behov hos patienten | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.6  | ...forslag til tiltag, som praksis kunne igangsætte | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3.7  | ...hvem, sygehuset forventede, skulle varetage og koordinere de forskellige dele af behandling og rehabilitering | ☐ | ☐ | ☐ | ☐ | ☐ |

### Eventuel opsøgende kontakt fra almen praksis til sygehuset

**4.1** Har du / praksis på eget initiativ kontaktet sygehuset for at indhente information om patienten?  
☐ Nej (gå til 5.1)  
☐ Ja (gå til 4.2)

**4.2 og 4.3 besvares kun hvis du svarede "Ja" til 4.1:**

<table>
<thead>
<tr>
<th>Anfør din grad af enighed i følgende udsagn:</th>
<th>Meget enig</th>
<th>Enig</th>
<th>Uenig</th>
<th>Meget uenig</th>
<th>Ved ikke/ikke relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sæt kun ét kryds ud for hvert udsagn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**4.2** Jeg / praksis fik **hurtigt** fat i en sundhedsprofessionel, som kunne hjælpe

☐ ☐ ☐ ☐ ☐

**4.3** Jeg / praksis fik løst de(-t) problem(-er), som foranledigede kontakten til sygehuset

☐ ☐ ☐ ☐ ☐

Vejledning: Hvis du / praksis flere gange har kontaktet sygehuset for at indhente information om patienten, besvares udsagnene som en samlet vurdering.
Patientens øvrige helbredstilstand

5.1 Hvilke andre sygdomme har patienten? (sæt evt. flere kryds)
- □ Anden cancersygdom end nuværende. Hvilken? ____________________________
- □ Hypertensio arterialis
- □ Iskæmisk hjertesygdom
- □ Følger efter apopleksia cerebri
- □ Diabetes
- □ Stofskiftesygdom
- □ KOL (kronisk bronkitis og emfysem) eller astma
- □ Artrose eller anden gigtsygdom
- □ Osteoporose
- □ Psykisk sygdom (alvorlig depression, alvorlig panikangst, skizofreni mv.)
- □ Lettere psykisk lidelse (let depression, angst mv.)
- □ Allergi
- □ Anden. Hvilken? ____________________________
- □ Ingen
- □ Ved ikke

Oplysninger om udfyldende læge

6.1 Hvilken stilling har du i praksis?
- □ Fast læge i praksis med ydernummer (inkl. deleydernummer)
- □ Uddannelseslæge
- □ Aflastningsamanuensis eller vikar for praktiserende læge

6.2 Hvor mange års anciennitet har du som alment praktiserende læge?

6.3 Hvilket køn er du?
- □ Mand
- □ Kvinde
**Oplysninger om udfyldende læge med henblik på honorering**
(du kan eventuelt indsætte oplysningerne ved hjælp af et stempel)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.4</strong> Anfør dit navn med BLOKBØGSTAVER:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6.5</strong> Anfør ydernr:</td>
<td></td>
<td>Stempel:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6.6</strong> Anfør SE-nr:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6.7</strong> Anfør reg.nr. og kontonr. på din bankkonto:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Dato for udfyldelse af spørgeskemaet:**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hvis du har kommentarer, kan du anføre dem her:**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Det udfyldte skema bedes returneret til **Forskningsenheden for Almen Praksis i Århus** i vedlagte frankerede svarkuvert.

**Mange tak for hjælpen!**
APPENDIX F:

GP EVALUATION DATA QUALITY
The Effect of Hospital-Based Case Management in Cancer Care Pathways
Table F1. GP evaluation data quality

<table>
<thead>
<tr>
<th>Item</th>
<th>Control (N=114)</th>
<th>CM (N=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>'Don’t know/ N.A.'</td>
<td>Missing answers</td>
</tr>
<tr>
<td>1.1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1.2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1.3</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>1.4</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>1.5</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>1.6</td>
<td>22</td>
<td>1</td>
</tr>
<tr>
<td>2.1</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>2.2</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>2.3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2.4</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>2.5</td>
<td>50</td>
<td>1</td>
</tr>
<tr>
<td>3.1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3.2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3.3</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>3.4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>3.5</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>3.6</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>3.7</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>4.1</td>
<td>Not possible</td>
<td>0</td>
</tr>
<tr>
<td>4.2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4.3</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

GP questionnaire could be sent to all patients’ GPs (140 in each group).
Table shows number of responses.
Note: 1.1, 1.2, 1.3, etc. refer to item number in questionnaire.
The Effect of Hospital-Based Case Management in Cancer Care Pathways
APPENDIX G:

CARE COORDINATION PAPER PUBLISHED IN UGESKRIFT FOR LÆGER
Forløbskoordinering for kronisk syge og kræftpatienter

Læge Christian Wulff, professor Jens Søndergaard, professor Frede Olesen & professor Peter Vedsted

Forløbskoordinering, forløbsprogram, forløbskoordinator og tovholder er begreber, der i taltagende grad benyttes i kroniker- og kræftindsatsen. Desværre bruges begreberne ofte inkonsistent. Denne artikels formål er derfor at definere og beskrive begreberne samt at belyse effekter af forløbsprogrammer og af forløbskoordinatorfunktionen.

Sundhedsvesenets taltagende specialisering og fragmentering synes at have medført et øget behov for at levere koordinerede indsatser samt grundig og overensstemmende information til kronisk syge og kræftpatienter [1, 2]. I adskillige forskningsprojekter har man imidlertid tydeliggjort betydelige relationelle, informationsmæssige og organisatoriske kontinuitetsproblemer i patientforløb på tværs af afdelinger, sektorer og faggrænser [3-7].


NYERE DANSKE FUNKTIONSÆNVELSER

Nedenfor beskrives de danske funktionsbenævnelser »tovholder« og »forløbskoordinator« (se også Tabel 1).

Tovholder

I Sundhedsstyrelsens generiske model for forløbsprogrammer beskrives tovholderfunktionen således:

»Det anbefales, at alle patienter med kronisk sygdom har en tovholder, der har ansvar for:

1. at sikre koordinering af den samlede sundhedsfaglige indsats
2. at vurdere patientens helbred løbende
3. at følge systematisk op, herunder sikre en proaktiv indsats
4. at bidrage til fastholdelse af behandlingsmål«.


Forløbskoordinator

Den danske funktionsbenævnelse forløbskoordinator skal opfattes synonymt med det engelske begreb case manager [10]. En forløbskoordinator kan i afgrænsede perioder tilknytte patienter, som har særlige behov for koordineret indsats og støtte. Opgaverne omfatter:

- At overvåge og koordinere den patientspecifikke sundhedsfaglige indsats på et givet område (f.eks. relateret til kæftbehandling) samt at udbyde information om indsatsen til relevante sundhedsprofessionelle.
- At sikre, at man i patientforløbet tager hensyn til psykosociale behov, konkurrende lidelser m.v. (dvs. patientcentreret tilretteleggelse).
- At informere, guide og støtte patienten og dennes pårørende.

Forudsættelserne for at kunne løse disse opgaver er en god forståelse af sundhedsvesenets opbygning og muligheder for samarbejde samt at udvidet kendskab til de sygdomsspecifikke sundhedsydelser. Forløbs-
koordinatoren har typisk ikke behandlings- og plejemæssige opgaver. Effekten af forløbskoordinatorens arbejde skal kunne måles med hensyn til klinisk kvalitet (funktionsevne, sygelighed mv.), procesmål (antal indlæggelser, brug af vagtårme, utilisitgade hændelser, klagesager mv.) samt patientrapporterede effekter (livskvalitet, oplevelse af tryghed, fejl i forløbet mv.).

Man kender ikke berettigelsen af forløbskoordinatorer i det danske sundhedsvæsen [10], og endvidere er der blevet oprettet et betydeligt antal stillinger, hvis funktionsbeskrivelser er vidt forskellige fra Sundhedsstyrelsens definition af forløbskoordinator. Eksempelvis beskriver man i kræftpakkerne forløbskoordinatoren som den administrative person, der skal »overvåge og dokumentere patientforløbene og informere om eventuelle flaskehale og slip« [9]. Derudover er forløbskoordinatoren til tider blevet informeret om eventuelle flaskehale og slip« [9].

Korte funktionsbeskrivelser for tovholder, forløbskoordinator og kontaktperson.

<table>
<thead>
<tr>
<th>Begreb</th>
<th>Forståelse af begreb</th>
<th>Hvem?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tovholder</td>
<td>Skal tilbydes alle patienter med en kronisk sygdom</td>
<td>Egen læge</td>
</tr>
<tr>
<td></td>
<td>Tovholderen har ansvaret for:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. at sikre koordinering af den samlede sundhedsfaglige indsats for en given kronisk tilstand, der sikrer anvendelse af evidensbaserede anbefalinger for den sundhedsfaglige indsats, en præcis beskrivelse af opgavefordeling samt koordinering og kommunikation mellem alle involverede parter« [10].</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. at vurdere patientens helbred løbende</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. at følge systematisk op, herunder at sikre en proaktiv indsats</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. at bidrage til fastholdelse af behandlingsmål</td>
<td></td>
</tr>
<tr>
<td>Forløbskoordinator</td>
<td>Kan i afgrænsede perioder efter konkret vurdering tilknyttet »højrisikopatienter« med kronisk sygdom eller kræft</td>
<td>Specialuddannet sygeplejerske (kan være placeret på sygehus eller uden for)</td>
</tr>
<tr>
<td></td>
<td>Assisterer tovholder med det forløbskoordinerende og patientstøttende arbejde</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ofte er personen udelukkende ansat med det formål at optimere udvalgte patientforløb</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hvis forløbskoordinatoren er placeret på et sygehus, synes det hensigtsmæssigt, at denne varetager kontaktpersonrollen</td>
<td></td>
</tr>
<tr>
<td>Kontaktperson</td>
<td>Lovbestemt ordning, som medfører, at sygehusafdelinger skal informere alle patienter om, at navngivne sundhedsprofessionelle har et særligt ansvar for kontinuiteten i deres behandlingsforløb</td>
<td>Primærlæge eller sygeplejerske på sygehus</td>
</tr>
</tbody>
</table>
Kronisk obstruktiv lungesygdom

Efter metaanalyse af overlevelsesdata fra syv af ni studier konkluderedes, at der ikke var effekt på overlevelsen. De inkluderede studier havde bl.a. vurderet indlæggelsessvarighed, antal indlægelser, livskvalitet og rygestop. I flere artikler konkluderede man, at forløbskoordinatorer påvirkede effektmålene statistisk signifikant positivt, men studierne var for få og for metodisk svage til, at man i oversigtsartiklen kunne konkludere, at forløbskoordinatorer kunne optimere KOL-omsorgen [13].

Ældre og "blandede« kronisk syge

I en oversigtsartikel, der var baseret på 15 kliniske forsøg, fokuserede man på forskellige effekter af forløbskoordinatorer i forbindelse med udskrivelse fra sygehus. Otte forsøg resulterede i færre genindlægelser, og i syv af ni forsøg, som havde sammenlignet indlæggelsesdage, medførte forløbskoordinatorer færre indlæggelsesdage. Ingen af studierne resulterede i bedre udfald af effektmål i kontrolgruppen [14].

I en metaanalyse fra 2005 analyserede man effekten af hospitalsbaserede forløbskoordinatorer på indlæggelsessvarighed og antal genindlægelser. Begge effektmål blev analyseret i ti af 12 studier. Der var ingen statistisk signifikant forskel på kontrol- og forløbskoordinatorgruppen med hensyn til de to effektmål [15].

I en litteraturgennemgang fra 2009, der var baseret på ni kliniske forsøg, så man på, om forløbskoordinatorer, der var tilknyttet ikkeindlagte, sårbare ældre samt kronisk syge, påvirkede sundhedsudgifterne og antallet af sundhedsdydelser (antal indlæggelser på hospitaler og nursing homes samt indlæggelsessvarighed). Tilknyttningen af forløbskoordinatorer øgede ikke sundhedsdydelser og -udgifter, men om det modsatte var tilfældet, blev ikke kommenteret [16].

Kraft

I en oversigtsartikel, der belyste effekten af forløbskoordinatorer i kæftforløb, afrapporterede de inkluderede otte studier flere enkelstående statistisk signifikant positivt påvirkede effektmål som følge af forløbskoordinator. Imidlertid konkluderede oversigtsartiklen, at vidensmængden var for sparsom til, at man kunne udtale sig om effekten af at tilknytte forløbskoordinatorer til kæftpatienter [17].

HVAD KAN MAN KONKLUDERE OM EFFEKTEN AF FORLØBSKOORDINATORER?

I de refererede oversigtsartikler konkluderede man, at forløbskoordinatorer påvirkede effektmålene i enten positiv eller neutral retning, mens ingen konkluderede, at der var en negativ effekt. Et stort antal af de studier, der indgik i oversigtsartiklerne, resulterede i en statistisk signifikant positiv påvirkning af effektmålene.

Da de hidtidige interventioner har været vidt forskelligt tilrettelagt, og da indholdet ofte har været upræcist beskrevet, kan man imidlertid ikke generelt konkludere, at ansetning af forløbskoordinatorer er en sikker metode til forbedring af klinisk komplekse patientforløb. I alle oversigtsartikler efterlystes veltilrettelagde og transparente forskningsprojekter. Da en implementering af forløbskoordinatorer, som er baseret på en falsk antagelse om positiv effekt, vil medføre spild af sparsomme sundhedsresurser, er der et presserende behov for veltilrettelagte danske forløbskoordinatorer. Man kender (endnu) ikke til bivirkninger ved at implementere forløbskoordinatorer.

KONKLUSION OG PERSPEKTIVER

Tiltagende kendskab til kontinuitetsproblemer i patientforløb på tværs af afdelinger, sektorer og faggrænser gør, at levering af koordinerede ydelser og information bør være en kerneopgave for sundhedsvæsenet. Forløbskoordinerende arbejde bør understøttes af andre forløbsoptimerende initiativer, der sikrer mulighed for hurtig personlig kontakt mellem sundhedsprofessionelle i primer- og sekundærsektor.

Det er nødvendigt at udbrede kendskabet til forløbsprogrammer samt til tovholder- og forløbskoordinatorfunktionen.
Bivirkninger: Der findes ingen dansk definition af ordet. Denne artikels forfattere foreslår: 
«Alt tilsiget arbejde med at skabe optimalt sammenhængende behandlingsforløb for kronisk syge og kæftpatienter». De engelske nært beslægtede begreber care coordination, disease management og integrated care behandler emnet, hvorfra man ofte organiserer udrednings-, behandlings- og rehabiliteringsforløb for patienter med kompleks tæversektorielle behov.

Forløbsprogram (engelsk: disease management programme): »Den samlede værftafaglige, tær- sektorielle og koordinerede sundhedsfaglige indsats for en given kronisk tilstand, der sikrer anvendelse af evidensbaserede anbefalinger for den sundhedsfaglige indsats, en præcis beskrivelse af opgavefordeling samt koordinering og kommunikation mellem alle involverede parter.«


LITTERATUR:

AKADEMISKE AFHANDLINGER

Overlæge Søren Tang Knudsen:
Ambulatory blood pressure, endothelial perturbation, and microvascular complications in type 2 diabetes
Disputats

Cand.med., ph.d. Lisette Oikkels Jensen:
Coronary artery remodelling in diabetic and non-diabetic patients assessed by intravascular ultrasound
Disputats

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OPPONENTER: Hans Ibsen, Peter Rossing og Hans Erik Bøttger.

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OPPONENTER: William Wijns, Belgien, og Thomas Engstrøm.