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

PhD thesis: The Effect of Hospital-Based Case Management in Cancer Care Pathways
ISBN 978-87-90004-19-4

© Christian Nielsen Wulff, Email: christian.wulff@alm.au.dk
The Research Unit for General Practice in Aarhus, Research Centre for Cancer Diagnosis in Primary Care - CaP, Department of Public Health, Aarhus University, Bartholins Allé 2, 8000 Aarhus C, Denmark

This thesis was accepted for PhD defence by Health, Aarhus University, and it was defended the 14 August 2012.

Supervisors:
Jens Søndergaard, Professor, Specialist in General Practice and in Clinical Pharmacology, MD, PhD, The Research Unit for General Practice in Odense, Institute of Health Services Research, University of Southern Denmark

Peter Vedsted, Professor, MD, PhD, The Research Unit for General Practice in Aarhus, Research Centre for Cancer Diagnosis in Primary Care – CaP, Department of Public Health, Aarhus University

Søren Laurberg, Professor, Chief Surgeon, MD, DrMedSc, Surgical Department P, Aarhus University Hospital

Peter Chr. Rasmussen, Chief Surgeon, MD, Surgical Department P, Aarhus University Hospital

Assessment committee:
Kirsten Lomborg (Chair), Associate professor, PhD, Department of Public Health - Nursing Science, Aarhus University

Bengt Zöller, Associate professor, Family Physician, PhD, Center for Primary Health Care Research, Skåne University Hospital, Malmö, Sweden

Frans Boch Waldorff, Associate professor, General Practitioner, MD, PhD, The Research Unit for General Practice in Copenhagen, Department of Public Health, University of Copenhagen

Financial support: The Danish Cancer Society, the Novo Nordisk Foundation, the Danish Council for Independent Research – Medical Sciences, and the Quality and Continuing Training Council for General Practice in the Central Denmark Region

Print: SUN-TRYK Fællestrykkeriet for Sundhedsvidenskab og Humaniora, Aarhus University
PREFACE
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)
ACKNOWLEDGEMENTS

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!

My profound thanks go to everyone at the Research Unit and Section for General Practice in Aarhus. The setting formed an inspiring academic background, but was also an invaluable social milieu. Especially, I would like to thank Secretary Birthe Brauneiser for ongoing support and motherly care. Thank you, Secretary Eva Højmark, Secretary Kristine Bundgaard, and Birthe, again, for managing the concealed allocation of study participants. Thank you, Information Officer Hanne Beyer for developing the Access research databases and for swift and competent support as to hardware and software. Thank you, Data Manager Kaare Flarup for never failing help with hardware, software and registry retrievals. Thanks to Secretary Dorthe Toftdahl Nielsen for revision and translation of text and for fund accounting. I owe Statisticians Ineta Sokolowsky
and Morten Fenger-Grøn much gratitude for many discussions regarding statistical analyses and research methods. Thank you, Psychologist Mai-Britt Guldin for training the case managers in communication techniques. Not least, I would like to thank the Student Workers Lise Moth, Jannie Jensen and Ina Dalsgaard for dispatching and scanning the questionnaires.

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.

At the Aarhus University Hospital, I would like to thank Information Officer Lis Lund. At the University of Aarhus, I also want to thank: Librarian Janne Lytoft Simonsen, Statisticians Morten Frydenberg and Eva Ørbøl, Professor Morten Pilegaard, and MA Palle Lykke.

Thank you, Nurse and PhD, Marianne Thygesen for co-authorship on paper one.

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!
### ABBREVIATIONS/ ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<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 ............................................................................ 9
- 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 ................................................................. 11
- 1.4.2 The case management concept at a glance ............................... 11

### AIMS .................................................................................................... 12

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

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

- THE SYSTEMATIC REVIEW ...................................................................... 14
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
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
6.3 Methods and feasibility of the RCT testing CM (Aim 2) .................74
6.4 Effectiveness as to patient-reported outcomes (Aim 3) ...............75
6.5 GP-notable consequences of the CM intervention (Aim 4) ........75

Chapter 7: Perspectives and future research ...................................... 77
7.1 Perspectives and lessons learned ...............................................78
7.2 Proposals for future research ....................................................79

Chapter 8: References ........................................................................ 81
Chapter 9: English summary ............................................................... 99
Chapter 10: Dansk resumé .................................................................103
Chapter 11: Paper 1 ...........................................................................107
Chapter 12: Paper 2 ..........................................................................127
Chapter 13: Paper 3 ..........................................................................153
Chapter 14: Paper 4 ..........................................................................179

Appendix A: The CM manual ..............................................................207
Appendix B: Patient baseline questionnaire ......................................247
Appendix C: Patient follow-up questionnaire ...................................257
Appendix D: Data quality of patient responses .................................271
Appendix E: GP questionnaire ............................................................275
Appendix F: GP evaluation data quality ............................................283
Appendix G: Care coordination paper published in Ugeskrift For Læger ... 287
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).
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 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.
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
Chapter 2: Material and methods

17

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 (98) 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 (38), 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.
THE INTERVENTIONS

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.

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.

<table>
<thead>
<tr>
<th>Time</th>
<th>CM GROUP*</th>
<th>CONTROL GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 0</td>
<td>a</td>
<td>e</td>
</tr>
<tr>
<td>Week 0-8</td>
<td>1</td>
<td>c</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td>d</td>
</tr>
<tr>
<td>Week 9-30</td>
<td>1</td>
<td>c</td>
</tr>
<tr>
<td>Week 30</td>
<td></td>
<td>d</td>
</tr>
<tr>
<td>Week 31-52</td>
<td>1</td>
<td>c</td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td>d</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.

GP: general practitioner; CM: case management; HRQoL: health-related quality of life
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 outpatient 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.
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**

<table>
<thead>
<tr>
<th>654 potentially relevant RCTs identified in: PubMed, Cinahl, Web of Science, Embase, Cochrane Register of Controlled Trials, and by snowball search.</th>
</tr>
</thead>
<tbody>
<tr>
<td>629 promptly rejected by &quot;scanning&quot; headings or abstract.</td>
</tr>
<tr>
<td>25 RCTs retrieved for scrutiny by MT, PV and CW.</td>
</tr>
<tr>
<td>* Not CM: 15</td>
</tr>
<tr>
<td>Not cancer: 1</td>
</tr>
<tr>
<td>Not RCT: 2</td>
</tr>
<tr>
<td>Other reasons: 2</td>
</tr>
</tbody>
</table>

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

- 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)

Patient consent, baseline questionnaire and randomisation (Week 0: n=280)

Allocation

**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 of 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 of 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.)
## Chapter 3: The studies

### 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><strong>Gender</strong></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><strong>Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>72 (51.4%)</td>
<td>70 (50.0%)</td>
</tr>
<tr>
<td>Recurrent</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Rectal cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>64 (45.7%)</td>
<td>66 (47.1%)</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><strong>Surgery</strong></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><strong>One or more chronic diseases</strong>*</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><strong>Negative self-rated health status prior to cancer diagnosis</strong></td>
<td>8 (5.8%)</td>
<td>11 (8.0%)</td>
</tr>
<tr>
<td><strong>Negative evaluation of preceding diagnostics and care pathway</strong></td>
<td>12 (8.7%)</td>
<td>13 (9.6%)</td>
</tr>
<tr>
<td><strong>Cohabiting or married</strong></td>
<td>99 (72.3%)</td>
<td>103 (73.6%)</td>
</tr>
<tr>
<td><strong>Income &lt; 33,500 EUR/year</strong></td>
<td>56 (41.2%)</td>
<td>51 (37.0%)</td>
</tr>
<tr>
<td><strong>Education for 3 years or longer</strong></td>
<td>34 (24.2%)</td>
<td>41 (30.4%)</td>
</tr>
<tr>
<td><strong>Unemployed (senior citizen, unemployed etc.)</strong></td>
<td>90 (67.2%)</td>
<td>93 (67.2%)</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.

![Bar charts illustrating case manager contacts.](image)

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 rounding), 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>Global quality of life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>61.02 (25.90)</td>
<td>64.90 (23.68)</td>
<td>65.73 (22.19)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>64.38 (22.04)</td>
<td>68.09 (21.02)</td>
<td>67.21 (21.07)</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>Role functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>70.26 (32.95)</td>
<td>73.10 (31.36)</td>
<td>74.48 (30.10)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>71.14 (33.61)</td>
<td>74.37 (32.22)</td>
<td>75.81 (31.04)</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>73.00 (23.13)</td>
<td>74.87 (21.69)</td>
<td>75.62 (21.23)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>73.75 (23.43)</td>
<td>75.05 (20.66)</td>
<td>75.27 (20.68)</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 (15.93)</td>
<td>89.06 (15.09)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>87.98 (18.34)</td>
<td>88.84 (16.38)</td>
<td>89.36 (15.81)</td>
</tr>
<tr>
<td>Social functioning</td>
<td></td>
<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>86.19 (20.21)</td>
<td>87.10 (20.43)</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>Overall, the information was satisfactory</td>
<td>US: 50 (63.2) / 58 (63.2)</td>
<td>CM: 70 (69.7) / 70 (70.1)</td>
<td>PPR: 1.12 (0.85 to 1.58)</td>
</tr>
<tr>
<td>Doctors and nurses have overall been good at offering my family guidance, counselling, support and help</td>
<td>US: 39 (46.9) / 40 (46.4)</td>
<td>CM: 54 (53.3) / 54 (53.6)</td>
<td>PPR: 1.08 (0.80 to 1.59)</td>
</tr>
<tr>
<td>At no time have I been in doubt who to contact if I needed guidance, counselling, support and help</td>
<td>US: 59 (64.0) / 59 (64.0)</td>
<td>CM: 74 (71.0) / 74 (71.0)</td>
<td>PPR: 1.28 (0.95 to 1.73)</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>US: 53 (61.4) / 53 (61.4)</td>
<td>CM: 69 (64.4) / 69 (64.4)</td>
<td>PPR: 1.34 (0.98 to 1.86)</td>
</tr>
<tr>
<td>When I was discharged after surgery, I felt confident about going home</td>
<td>US: 60 (68.0) / 60 (68.0)</td>
<td>CM: 72 (67.0) / 72 (67.0)</td>
<td>PPR: 1.50 (1.07 to 2.11)</td>
</tr>
<tr>
<td>In my experience, my treatment course has been coherent</td>
<td>US: 57 (63.0) / 57 (63.0)</td>
<td>CM: 66 (60.8) / 66 (60.8)</td>
<td>PPR: 1.40 (1.08 to 1.82)</td>
</tr>
<tr>
<td>How do you assess the quality of your investigation and treatment at Department P so far?</td>
<td>US: 89 (96.8) / 89 (96.8)</td>
<td>CM: 94 (88.2) / 94 (88.2)</td>
<td>PPR: 1.15 (0.89 to 1.51)</td>
</tr>
<tr>
<td>How do you assess the quality of your overall diagnostics and treatment so far?</td>
<td>US: 77 (79.2) / 77 (79.2)</td>
<td>CM: 82 (80.0) / 82 (80.0)</td>
<td>PPR: 1.11 (0.89 to 1.35)</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.
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.
The Effect of Hospital-Based Case Management in Cancer Care Pathways

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-recruitment</td>
<td>4.99 (4.31 to 5.79)</td>
<td>5.12 (4.42 to 5.94)</td>
<td>1.03 (0.83 to 1.26)</td>
<td>0.91 (0.86 to 0.95)</td>
</tr>
<tr>
<td>1-90 days post inclusion</td>
<td>5.26 (4.52 to 6.13)</td>
<td>5.23 (4.49 to 6.09)</td>
<td>0.99 (0.80 to 1.23)</td>
<td>0.90 (0.84 to 0.94)</td>
</tr>
<tr>
<td>91-180 days post inclusion</td>
<td>5.08 (4.29 to 6.01)</td>
<td>4.76 (4.01 to 5.66)</td>
<td>0.94 (0.74 to 1.19)</td>
<td>0.86 (0.79 to 0.91)</td>
</tr>
<tr>
<td>181-270 days post inclusion</td>
<td>4.14 (3.43 to 4.99)</td>
<td>4.42 (3.67 to 5.33)</td>
<td>1.07 (0.82 to 1.39)</td>
<td>0.83 (0.76 to 0.89)</td>
</tr>
<tr>
<td>1-270 days post inclusion</td>
<td>14.61 (12.82 to 16.66)</td>
<td>14.76 (12.94 to 16.84)</td>
<td>1.01 (0.84 to 1.22)</td>
<td>0.99 (0.95 to 1.00)</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-recruitment</td>
<td>0.31 (0.20 to 0.48)</td>
<td>0.31 (0.20 to 0.49)</td>
<td>1.02 (0.95 to 1.91)</td>
<td>0.19 (0.13 to 0.27)</td>
</tr>
<tr>
<td>1-90 days post inclusion</td>
<td>0.24 (0.15 to 0.37)</td>
<td>0.40 (0.27 to 0.60)</td>
<td>1.68 (0.91 to 3.14)</td>
<td>0.14 (0.09 to 0.21)</td>
</tr>
<tr>
<td>91-180 days post inclusion</td>
<td>0.39 (0.23 to 0.64)</td>
<td>0.42 (0.25 to 0.72)</td>
<td>1.08 (0.52 to 2.25)</td>
<td>0.15 (0.09 to 0.22)</td>
</tr>
<tr>
<td>181-270 days post inclusion</td>
<td>0.18 (0.09 to 0.37)</td>
<td>0.40 (0.22 to 0.73)</td>
<td>2.24 (0.87 to 5.75)</td>
<td>0.08 (0.04 to 0.14)</td>
</tr>
<tr>
<td>1-270 days post inclusion</td>
<td>0.83 (0.57 to 1.20)</td>
<td>1.29 (0.90 to 1.85)</td>
<td>1.56 (0.93 to 2.61)</td>
<td>0.28 (0.21 to 0.36)</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
METHODS FOR THE SYSTEMATIC REVIEW

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.
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).

<table>
<thead>
<tr>
<th>Case management</th>
<th>Hypothesized consequences</th>
<th>RCT outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outreaching contacts from a dedicated health professional</td>
<td>Improved patient-experienced organisation of care</td>
<td>Health outcomes</td>
</tr>
<tr>
<td>Psychosocial support</td>
<td>Improved patient-experienced relational continuity</td>
<td>Improved health-related quality of life</td>
</tr>
<tr>
<td>Information</td>
<td>Improved patient-experienced information continuity</td>
<td>Quality of care indicators</td>
</tr>
<tr>
<td>Supervision and optimisation of the coordination of care</td>
<td>Improved coordination of care -&gt; Better care</td>
<td>Improved patient evaluations</td>
</tr>
<tr>
<td>Information to health professionals outside Department P</td>
<td>• Health professionals better informed</td>
<td>• Improved GP evaluations</td>
</tr>
<tr>
<td></td>
<td>• Better communication</td>
<td>• Less use of out-of-hours GP services</td>
</tr>
<tr>
<td></td>
<td>• Increased collaboration</td>
<td>• More contacts to the GP</td>
</tr>
</tbody>
</table>

**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.
Chapter 4: Discussion of methods

THE OUTCOME MEASURES

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). 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

---

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 binominal 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).
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.
AIM 4: EFFECTS NOTABLE TO THE GPS

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.
The Effect of Hospital-Based Case Management in Cancer Care Pathways
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 inconveniences 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:
REFERENCES


(15) Vinge S, Strandberg-Larsen M. Kontinuitet og koordination i sundhedsvæsenet [In Danish]. Ugeskr Laeger 2010;10:775.


(36) Mikkelsen TH, Soendergaard J, Jensen AB, Olesen F. Cancer surviving patients' rehabilitation - understanding failure through application of theoretical perspectives from Habermas. BMC Health Serv Res 2008 Jun;8:122.


(40) Madsen LP. Blandede karakterer til kontaktpersonsordningen. [In Danish]. Ugeskr Læger 2010 April;172(16):1184.

(41) Faber MT, Pedersen C, Grønvold M. Kontaktpersonordninger til kræftpatienter på danske hospitalsafdelinger [In Danish]. Ugeskr Læger 2009;171(46):3363.


(43) Danish Regions. Kræftbehandling uden ventetid (notat) [In Danish]. Copenhagen: Danish Regions; 2007.


(64) Sundhedsstyrelsen. Forløbsprogrammer for kronisk sygdom – Generisk model og Forløbsprogram for diabetes [In Danish]. Copenhagen: The National Board of Health; 2008.


(96) Danish Colorectal Cancer Group. Retningslinier for diagnostik og behandling af kolorektal cancer [In Danish]. Danish Colorectal Cancer Group; 2009.


(141) Metropolitan Jewish Health System. The Effects of Case Management in a Medicaid Managed Care Plan. In: ClinicalTrials.gov [Internet]. Available at: http://clinicaltrials.gov/ct2/show/NCT00385879?term=%22cancer%22+%22case+management%22&rank=2 (Accessed 01 April 2012)


(181) Mdege ND, Man MS, Taylor Nee Brown CA, Torgerson DJ. Systematic review of stepped wedge cluster randomized trials shows that design is
particularly used to evaluate interventions during routine implementation. J Clin Epidemiol 2011 Sep;64(9):936-948.
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.
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 helbredslaterede 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 evalueringer i CM-gruppen. **Artikel 4** præsenterede de APL’s evalueringer af informationen fra og samarbejdet med personalet på sygehuset (spørgeskema sendt 30 uger efter patienternes inklusion) og sammenlignede 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 evalueringer 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 diskuterer projektet i forhold til en model vedrørende ’komplekse interventioner’. Dernæst diskuteres 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 deltagere potentielt var bevidste om deres randomiseringsstatus, kan have medført, at patientevalueringerne i nogen grad var påvirket af informationsbias. Svarprocenten for spørgeskemaerne var høj, og vi mener, at resultaterne i Artikel 3 var fri for selekionsbias. På trods af, at lægespørgeskemaet tilsyneladende var utilstrækkelig pilot-testet, og af at ’kontaktanalyserne’ 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 kræftformen.

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 hospital og øgede antallet af kontakter til lægevagten.
CHAPTER 11:

PAPER 1
Case management used to optimize cancer care pathways: A systematic review

Christian N Wulff*1,2, Marianne Thygesen3, Jens Søndergaard4 and Peter Vedsted1

Address: 1The Research Unit for General Practice in Aarhus, University of Aarhus, Vennelyst Boulevard 6, 8000 Aarhus C, Denmark, 2Surgical Department P, Aarhus University Hospital, Tage-Hansens Gade 2, 8000 Aarhus C, Denmark, 3Institute of Clinical Research, Faculty of Health Science, University of Southern Denmark, JB Winsløws Vej 12, 2 floor, 5000 Odense C, Denmark and 4The Research Unit for General Practice, Institute for Public Health, University of Southern Denmark, JB Winsløws Vej 9, 5000 Odense C, Denmark

Email: Christian N Wulff* - christian.wulff@alm.au.dk; Marianne Thygesen - mthygesen@health.sdu.dk; Jens Søndergaard - jsoendergaard@health.sdu.dk; Peter Vedsted - p.vedsted@alm.au.dk

* Corresponding author

Abstract

Background: Reports of inadequate cancer patient care have given rise to various interventions to support cancer care pathways which, overall, seem poorly studied. Case management (CM) is one method that may support a cost-effective, high-quality patient-centred treatment and care.

The purpose of this article was to summarise intervention characteristics, outcomes of interest, results, and validity components of the published randomized controlled trials (RCTs) examining CM as a method for optimizing cancer care pathways.

Methods: PubMed, Embase, Web of Science, CINAHL and The Cochrane Central Register of Controlled Trials were systematically searched for RCTs published all years up to August 2008. Identified papers were included if they passed the following standards. Inclusion criteria: 1) The intervention should meet the criteria for CM which includes multidisciplinary collaboration, care co-ordination, and it should include in-person meetings between patient and the case manager aimed at supporting, informing and educating the patient. 2) The intervention should focus on cancer patient care. 3) The intervention should aim to improve subjective or objective quality outcomes, and effects should be reported in the paper.

Exclusion criteria: Studies centred on cancer screening or palliative cancer care.

Data extraction was conducted in order to obtain a descriptive overview of intervention characteristics, outcomes of interest and findings. Elements of CONSORT guidelines and checklists were used to assess aspects of study validity.

Results: The searches identified 654 unique papers, of which 25 were retrieved for scrutiny. Seven papers were finally included. Intervention characteristics, outcomes studied, findings and methodological aspects were all very diverse.

Conclusion: Due to the scarcity of papers included (seven), significant heterogeneity in target group, intervention setting, outcomes measured and methodologies applied, no conclusions can be drawn about the effect of CM on cancer patient care. It is a major challenge that CM shrouds in a "black box", which means that it is difficult to determine which aspect(s) of interventions contribute to overall effects. More trials on rigorously developed CM interventions (opening up the "black box") are needed as is the re-testing of interventions and outcomes studied in various settings.
Background

Case management (CM) is an expanding organizational approach used to optimize the quality of treatment and care for individuals within complex patient groups [1]. Denmark has seen the launch of several CM projects intended to improve the cancer trajectory. However, a systematic literature review of the studies evaluating the effect of CM applied on cancer patient treatment and care does not exist.

Donabedian proposed the integration of aspects of structure, process and outcomes when evaluating quality of care [2], and multidimensional assessment of quality now seems to have become generally accepted [3]. Examples of inadequate cancer treatment and care categorised based on these aspects are given below:

Structure

Concomitantly with the expansion of treatment options (owing, among others, to advances in medical knowledge and the introduction of technological equipment) lack of specially trained staff evidently hampers better treatment [3].

Process

Evaluations of treatment and care indicate that cancer patients and their relatives do not receive the support and information about diagnosis, treatment and postoperative course necessary for a satisfactory course and rehabilitation [4,5]. Moreover, considerable delay exists at all stages of diagnosis and treatment [6,7], which is also assumed to influence prognosis [8,9].

Outcomes

Mortality from cancer diagnoses vary substantially between countries [10]. Moreover, cancer patients and their relatives suffer from poor physical, psychological and social conditions, which could probably be improved.

Basically, the purpose of CM is to link and optimize quality and cost-effective care in both hospital and community settings [11]. CM is increasingly being regarded as a useful approach for remedying health care system inadequacies [1,11,12]. Definitions and specifications of CM-models are numerous [11,13]. The following is a mainstream definition: "[case management] is 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." [14]

Approaches to describe CM models also differ. One way draws on a conception-operation framework that involves three categories: 1. a brokerage model (whose primary focus is advocacy and linking of services and needs); 2. a social entrepreneurship model (where resource and budgetary control are central); or 3. a key-worker/care coordinator model (stressing the case manager functioning within an interdisciplinary team) [11]. Other ways of describing a CM model originate in the setting (hospital-based, hospital-to-community-based or community-based) [15,16] or in the disease (disease-specific context). Some CM models rely on interdisciplinary standards of care, critical pathways or disease management programmes, whereas the case manager in other models is merely the tool mapping client care [11,17]. Finally, CM models can be specified on the basis of activities performed (basic and advanced CM) [18], the mode of contact (contact per telephone, in-person meetings, accompaniment), etc. It should be noted that a model can fall simultaneously within several different frameworks.

CM is carried out by a pro-active, supportive, facilitating, multidisciplinary health care professional (or team). The case manager, most often a nurse [11], is exclusively committed to assist patients navigate the increasingly specialized and fragmented health care system. Seamless information, communication, coordination, patient involvement and shared decision-making ensure that the patient experiences a coherent and individually tailored care pathway within the existing framework of the health care system. Delivery of the right health care resources at the right time is essential [15-17].

In spite of the absence of a proper definition of where and how to introduce CM, attention to the concept generally expands [18]. Hence, decision makers, health professionals and patient societies often support the idea of using CM. However, we need to address the question of what constitutes the scientific basis for the effectiveness of CM among patient groups suffering from cancer [19]. The purpose of this paper is to systematically identify all published randomized controlled trials of CM-like interventions applied in cancer patient care and to present characteristics, effects studied and the methodological characteristics of these interventions.

Methods

Literature search

We performed database searches and concurrent snowball searches with the aim of detecting all published Randomized Controlled Trials (RCTs) in which CM had been applied to people with cancer. The following databases were searched for papers published in English, Norwegian, Swedish or Danish: PubMed, Embase, Web of Science, CINAHL, and The Cochrane Central Register of Controlled Trials. Articles published all years up to August 2008 were searched for.
Prior to the search, a batch of possible keywords was recorded. Thesauruses were examined and definitions looked up. The following words were searched: "case management", "case manager", "disease management", "oncologic nursing", "oncologic nurse", "home care services", "advance practice nurse", "advance practice nursing", "advanced practice nurse", "advanced practice nursing", "advance nursing", "advanced nurse", "advanced nursing", "nursing care intervention", "nursing care interventions", "care coordination", "care coordinator", "patient navigation", "patient navigator", "system navigation", and "system navigator". The above terms were combined with "neoplasms" and "cancer".

Due to database construction differences, various combinations of MeSH, key words and text words were used in the searches. Limiting publication type to "randomized controlled trial" by the use of a check box was possible in PubMed and Embase databases, whereas the Cinahl, Web of Science and Cochrane databases were searched for RCTs by adding "...randomly" OR "randomised" OR "randomized"* (free-text) to the search.

As an example the PubMed search is specified below:


Copies of all database searches can be obtained by contacting the author (CW).

Study selection
We included papers on CM-like interventions that fulfilled all of the following inclusion criteria:

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

2) The intervention should focus on cancer patient care (if other diseases than cancer were included, the majority of the included patients should suffer from cancer).

3) The intervention should aim to improve subjective or objective quality outcomes, and effects should be reported in the paper.

We used the following exclusion criteria: Studies centred on cancer screening or palliative cancer care.

Data extraction was conducted (without the use of any software) in order to obtain a descriptive overview of intervention characteristics, outcomes of interest and findings. Elements from the CONSORT guidelines and checklists [20,21] were used to assess elements influencing internal and external study validity.

Results
Our search identified 654 unique papers, which after initial assessment (CW) were reduced to 25. These remaining 25 were independently scrutinised for inclusion by PV, MT and CW. When the reviewers did not agree, the paper was discussed and consensus reached. Finally, seven papers were included. Figure 1 illustrates the "flow" of papers.

Study inclusion and exclusion

Figure 1
Study inclusion and exclusion. * Two articles were excluded for more than one reason. # Two articles reported on already included articles or components hereof.
The meticulous review of each included paper is reported in Tables 1, 2, and 3 (see additional file 1, 2, and 3). CW primarily filled in the Tables, and MT, PV and CW all read the included articles and checked the contents of the tables.

Characteristic elements of interventions are outlined in Table 1 (Consort items 1–5). Outcomes of interest, statistical methods, baseline data, number of participants analyzed, and effects found (Consort items 6, 8, 12, 15, 16, 17, and 18) are presented in Table 2. Table 3 presents elements of study validity found to be important: sample size, recruitment, random allocation, blinding of assessor, participant flow (Consort items 7, 14, 9, 11, and 13). Aspects of generalisability to non-participants are reported in second column points c) and d).

**Main findings**

Table 1 audits the characteristics of the seven included studies. Six trials were conducted in the USA, one in the UK. Only two of the six papers termed the intervention "CM" [19,22]. The five other studies were deemed to fulfil reviewers' inclusion criteria (viz. the quoted CM definition). Interventions were classified: "advanced practice nursing" [23,24], "home care interventions" (two were tested against usual care in a three armed trial) [25], "care coordination" [26], and "nurse-led follow-up" [27]. Despite the different naming, all interventions will be designated "CM" throughout the rest of this paper.

Two studies [19,23] included breast cancer patients only, two studies lung cancer patients only [25,27]. The last three included different cancer types of which one trial [26] also addressed other advanced illness (chronic obstructive pulmonary disease (COPD) and chronic heart failure (CHF)). Two studies tested hospital-to-community interventions [19,23], and three studies tested community interventions [22,24,25]. One study [27] tested a hospital (in-patient) intervention. The setting for one study was unclear, but the text implies an in-patient setting [26].

Health care professionals performed all interventions and nurses exclusively performed the intervention in five trials [19,22-24,27]. In one study, a nurse education was not a prerequisite to performing the intervention [26]. In another study [25] (the three-armed RCT), nurses were members of the intervention teams which included various professions.

Six studies described some sort of model, manual and/or use of supportive tools, e.g. assessment tool or checklist (Table 2). The sixth study [25] reported no such use of manual or tools, and offered no precise description of intended and performed intervention.

The patients' GPs were only expressly mentioned in the study from the UK [27]. This study also evaluated the intervention in terms of the GPs' satisfaction.

Table 2 presents outcomes studies. First of all, it is noteworthy that only three articles [19,24,27] mentioned which outcomes were primary and which were secondary. Since there is no overlap of outcomes studied (tool and methods of assessment) between the trials, no synthesis of effects can be made.

To further evaluate the effects, outcomes were divided (our own categories) into objective and subjective (= patient reported) elements. Objective elements studied included: survival [24,27], received therapy [19], physical function (arm function) [19], advance directives and "do-not-resuscitate and intubate"-wishes [26], service use and hospitalization [22,25,27], and costs [23,26,27]. Subjective elements studied included: patient-reported needs and symptoms [22,25], patient-reported "quality of life" [22,24,27], patient satisfaction and evaluation of the decision-making process [19,26,27], and relative-reported problems experienced in the interaction with the health care system [26].

When categorising outcomes according to the above criteria and taking nothing else into account, some dimensions of Quality of Life appeared to be improved. Similarly, all three papers reporting patient satisfaction reported improvements.

Looking at Table 3, it is obvious that validity elements of interventions were inadequately reported in most papers. Sample size measures were only reported in one paper [27], and one or more of the following elements were only poorly described: recruitment, allocation concealment method and blinding of assessor. Moreover, patient flows were incomprehensible in all papers except for one [27], which also included a flow diagram. All articles analysed whether randomization was successful regarding baseline covariates (Table 2).

**Discussion**

**Principal findings**

Only seven studies evaluating the effect of CM or a CM-like-intervention applied to cancer care were found.

Studies diverged much in terms of target group, intervention setting, outcomes measured and findings.

Some of the included studies reported improvements in patient satisfaction and dimensions of quality of life measures. However, the methods used to measure the effects were all different (tool and method of assessment) and validity of many of the tools was poor or unknown.
All in all, overall study validity was inadequate. Due to the heterogeneity of the studies found, it was hardly possible to score validity in a simple measure or to make a meta-analysis of the results.

Thus, no conclusions can be made about the effect of CM on cancer patient care on the present basis.

**Strengths and weaknesses of this review**

The weak definition of CM and detection of interventions not specifically labelled "CM" but imitating CM forced us to search for more terms than just "case management" and "case manager". Papers on patient and system navigation were considered to conceal CM interventions and were accordingly included. However, no navigation papers passed the study selection criteria. Our search made us realize that navigation studies primarily address screening and follow-up of abnormal screening findings among poor, vulnerable people [28].

Our widened search strategy is regarded as a strength, but it also blurred the convenient clear-cut boundary between which interventions to include and which to exclude. Despite the fact that the intervention by Mor et al [22] was one of the only two included articles categorised "CM" , the tested educational short-term CM intervention included very few multidisciplinary components which normally makes it possible to distinguish CM from other nursing care.

Palliative care where the focus is on "care-alleviating symptoms and not on curing the underlying disease" is regarded as an exclusive, medical and research discipline (with supportive elements resembling CM) for which reason such studies were not included [29]. Also, the rationale for not including palliative care CM intervention was rooted in our perception that a patient in a care situation involving diagnosing, treatment and follow-up and facing potential cure is experiencing problems other than those faced by a palliative care patient. Thus, our aim was to illuminate CM interventions targeting cancer patients early in their disease trajectories. It should be emphasized that our decision is not tantamount to claiming that it is irrelevant to test CM-like interventions in the palliative care setting.

Publication bias and inclusion of RCTs only may have reduced the number of papers found.

Publication bias is always a problem when conducting systematic reviews and performing meta-analyses. Theoretically, the temptation not to publish negative results of a study may be greater in the case of complex interventions than simple interventions because it is more difficult to describe the components of a complex intervention.

The present review is delimited to RCTs because this research design is considered to be superior to other trials when it comes to trusting reported effect estimates [30,31]. On the other hand, a decision to include RCTs only may be questioned when the aim is to evaluate complex intervention of which CM form part because of possible reproducibility problems regarding intervention content. It may be difficult to reproduce outcomes when the intervention tested is poorly described. MRC has set up a framework for developing complex interventions to be tested in the RCT [32-33]. When MRC’s framework is followed, the RCT design can be regarded as a "gold standard", also for complex interventions.

None of included papers mentioned MRC’s framework, but several made an effort to minimize the "black box" [18,34].

Manuals, tools and accounts of actually conducted activities (type and dosage) are essential to minimize the "black box". As mentioned, six studies described some sort of model, manual and/or use of supportive tools, e.g. assessment tool or checklist (Table 2). Moreover, three papers described attempts to check which CM activities had actually been conducted. Engelhardt et al [26] described that care coordinators completed checklists which afterwards were checked for intervention integrity. McCorkle et al [24] calculated and grouped nursing intervention (assessment, education, etc.) and the work by Goodwin et al [19] was succeeded by a paper based on intervention contacts [35].

**Comparisons with other studies**

Summaries of nursing and CM interventions have previously been made, but this is the first review of CM targeted at cancer patients. A literature review from 2004 on evidence-based nursing interventions applied to older adults who had cancer [36] concluded that the body of literature was small and heterogeneous. Among the studies summarized, two [19,24] were also included in our review.

Other reviews of CM seem to originate in the disease or the setting.

Two reviews of disease-specific CM have been conducted: A review of CM for people with diabetes concluded that CM was effective in improving both glycaemic control and provider monitration of glycaemic control for adults with type 2 diabetes both when delivered in conjunction with disease management and when delivered with one or more additional educational, reminder, or support interventions (setting: U.S. managed care) [1].

A review of nurse-led disease management for people with chronic obstructive pulmonary disease (COPD) con-
cluded that: “There is little evidence to date to support the widespread implementation of nurse led management interventions for COPD, but the data are too sparse to exclude any clinically relevant benefit or harm arising from such interventions” [37].

Two papers on in-patient/hospital (setting-specific) CM were found: A meta-analysis from 2005 on the effect of CM on hospital length-of-stay (LOS) and readmission concluded that hospital-based CM was not effective in reducing LOS and the percentage of patients readmitted at least once. The meta-analysis included 12 experimental studies, none of which focused on cancer patients [38]. Similarly, a research synthesis of in-patient CM (from 1998) did not support that effectiveness was improved in terms of patient and provider satisfaction, quality-of-care, cost savings and length of stay (the study included 13 quasi-experimental and five randomized trials) [39].

Conclusion
The purpose of CM is to optimize individual cost-effective quality care for patients suffering from chronic and/or complex diseases.

Generally, reviews on the effects of CM in somatic care have found inconclusive positive effects.

This is the first review studying CM applied in cancer patient care. Due to the scarcity of papers included (seven), significant heterogeneity of CM interventions and effects studied, and the methodological inadequacies, no conclusions on the effects of CM in cancer patient care can be made.

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. Instead of starting from scratch, CM developers are recommended to build research on existing models, outcome-tools and complementary research findings. Additionally, re-testing interventions in various settings could be interesting. Following MRC’s framework [32] when designing and evaluating complex interventions is recommended.

Competing interests
The authors declare that they have no competing interests.

Authors’ contributions
CW and PV initiated and conceptualised the study. CW, MT and PV developed the method. CW and MT received help from librarians and together searched the databases. Studies were selected by CW, MT and PV. CW primarily filled in the Tables, but MT, PV and CW all read the included articles and checked the contents of the tables. CW, PV, MT and JS prepared the manuscript.

Funding
CW and MT are financed by The Novo Nordisk Foundation grant "Coherent treatment for cancer patients".

Additional material

<table>
<thead>
<tr>
<th>Additional file 1</th>
<th>Table 1: Characteristics of the case management models in the seven included papers. Click here for file [<a href="http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S1.pdf">http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S1.pdf</a>]</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Additional file 2</th>
<th>Table 2: Randomization, data collection, analyses and results. Click here for file [<a href="http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S2.pdf">http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S2.pdf</a>]</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Additional file 3</th>
<th>Table 3: Important methodological aspects adapted from CONSORT [20,21]. Click here for file [<a href="http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S3.pdf">http://www.biomedcentral.com/content-supplementary/1472-6963-8-227-S3.pdf</a>]</th>
</tr>
</thead>
</table>

Acknowledgements
The authors acknowledge the assistance of research librarian Janne Lytoft Simonsen, The State and University Library, University of Aarhus, and Professor Morten Pilegaard, Knowledge Communication Lab, Aarhus School of Business, University of Aarhus, for careful review of the language.

CW appreciates Professor Frede Olesen, The Research Unit for General Practice in Aarhus, for motivating discussions and support.

References


Table 1: Characteristics of the case management models in the seven included papers

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Authors, publication year, country, setting and location</th>
<th>a) Aim</th>
<th>b) Patients and cancer type</th>
<th>c) Name of intervention</th>
<th>d) CM setting</th>
<th>e) Control group exposure</th>
<th>a) Contact mode</th>
<th>b) Quantity of intervention</th>
<th>c) Intervention duration</th>
<th>a) Numbers of case managers</th>
<th>b) Cm education</th>
<th>c) Cm training in the CM-model</th>
<th>d) CM manual, tools, or the like</th>
<th>Effects studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>[19]</td>
<td>Goodwin, 2003, USA, 13 community and two public hospitals in southeastern Texas (multicenter trial)</td>
<td>a) To assess the efficacy of nurse case management (NCM) in improving the medical care given to community-living older women diagnosed with breast cancer. b) Women aged 65 and older with newly diagnosed breast cancer. c) Nurse CM d) Hospital-to-community. e) ? (usual care?)</td>
<td>a) Home visits, telephone conversations, assist the patient at physician appointments, visiting the patient at hospital, and contacts made at other community locations. b) Patient needs determined the frequency of contact, minimum contact during the intervention period was at least one in-person assessment and monthly telephone calls. c) 12 months from first contact.</td>
<td>a) Three case managers b) Baccalaureate degree registered nurse with previous experience with CM in other settings. c) 40 hours of training and education in treatment, complications, community resources, assessment, communicating methods, etc. d) A checklist and several assessment tools (not used or analyzed by investigators)</td>
<td>Primary: cancer-specific therapies received Secondary: patient evaluations of the decision-making process; arm function on affected side.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[23]</td>
<td>Ritz, LJ et al, 2000, USA, One hospital in an integrated health care system in a midwestern suburban community.</td>
<td>a) To evaluate the quality of life (QoL) and cost outcomes of CM on women with newly diagnosed breast cancer. b) Women, 21 years of age and older, newly diagnosed from breast cancer. c) Advanced practice nursing d) Hospital-to-community e) “standard medical care”</td>
<td>a) During clinic visits, hospital, by telephone, and home visits. b) Patient, family and CM need-determined. CM on-call all days during the daytime. c) ?</td>
<td>a) Two advanced practice nurses b) Registered nurse with a master’s degree in nursing who has in-depth knowledge and skill in the care of the patient population. c) ? d) Manual not mentioned, but model developed on Brooten cost-quality model (ref), but modified and ONS Standards of Advanced Practice (ref).</td>
<td>Quality of Life measures Cost data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[25]</td>
<td>McCorkle, R. et al, 1989, USA, subject recruitment from 19 hospitals and one</td>
<td>a) To test the effects of two different home care treatment regimens against usual care on the psychosocial well-being of patients</td>
<td>a) Home visits (weak description) b) ? c) 24 weeks.</td>
<td>OHC: a) ? b) Nurses with master degrees c) ? (“trained to give personalized care to persons with</td>
<td>Patient Psychosocial Responses Number of hospitalizations Length of Stay (LOS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ref.</td>
<td>Authors, publication year, country, setting and location</td>
<td>a) Aim b) Patients and cancer type c) Name of intervention d) CM setting e) Control group exposure</td>
<td>a) Contact mode b) Quantity of intervention c) Intervention duration</td>
<td>a) Numbers of case managers b) Cm education c) Cm training in the CM-model d) CM manual, tools, or the like</td>
<td>Effects studied</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[24]</td>
<td>McCorkle, R et al, 2000, USA, out-patient setting at a Comprehensive Cancer Center in south-eastern Pennsylvania</td>
<td>a) To analyse whether follow-up by an advanced practice nurse can improve survival when compared to patients in an ambulatory setting. b) Patients aged 60 years or older newly diagnosed with and operated from a solid tumour (different types) having an anticipated survival of 6 months or more (primary surgical removal of cancer only). c) Advanced practice nurse specialized home care intervention. d) Community e) “usual follow-up care in an ambulatory setting”</td>
<td>a) Home visits and telephone. b) Pre-determined home visits (three) and telephone calls (five) + according to patients’ needs. APNs were available on a 24-hours basis. c) 4-weeks immediately after surgery and hospitalization</td>
<td>advanced cancer and their families *) d) ? SHIC: a) ? (a team) b) An interdisciplinary team of health professionals including registered nurses; c) ? d) ?</td>
<td>Primary: Length of survival Secondary: Identify psychosocial and clinical predictors of survival</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[26]</td>
<td>Engelhardt, JB et al, 2006, USA, three Dep. of Veterans Affairs Medical Centers (=VAMCs), a home care org., and two Managed Care Org.</td>
<td>a) To evaluate the Advanced Illness Coordinated Care Program (AICCP) on patient and surrogate satisfaction with health care and provider communication, Advance directive (=AD) wishes and health care costs. b) Patients suffering from advanced illness (Specified cancer diagnoses</td>
<td>a) In-patient meetings (?) b) 6-session format, but individualized. Patients could schedule extra meetings. c) ?</td>
<td>a) ? (6 sites) b) Nurses, nurse practitioners, or social workers familiar with institutional policies and who had ongoing relationships with providers (existing personnel who were replaced from normal duties).</td>
<td>Patients’ evaluations of patient/provider communication, satisfaction with care, and attitudes about participation in treatment planning. Surrogates’ experiences with the health care system. Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ref.</td>
<td>Authors, publication year, country, setting and location</td>
<td>a) Aim b) Patients and cancer type c) Name of intervention d) CM setting e) Control group exposure</td>
<td>a) Contact mode b) Quantity of intervention c) Intervention duration</td>
<td>a) Numbers of case managers b) Cm education c) Cm training in the CM-model d) CM manual, tools, or the like</td>
<td>Effects studied</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>----------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[22]</td>
<td>Mor, V et al, 1995, USA, two hospital based chemotherapy clinics and eight private medical oncology practices</td>
<td>a) To evaluate effect of a short-term, educationally-oriented CM model for chemotherapy patients. b) Residents 21 years of age or more initiating a new course of chemotherapy (different cancer types). c) Nurse CM d) Community e) Not mentioned (usual treatment?)</td>
<td>a) Home visits and telephone calls. b) Pre-determined initial and termination home visit (about 10 weeks later), and telephone calls at 2-week intervals. Patient could contact Cm for assistance for up to 3 months.. c) 3 month follow-up period.</td>
<td>c) Training and reviewed assigned readings, including the AICCP training manual. d) Manual, checklists, and worksheets.</td>
<td>Advance directives (AD) and “do-not-resuscitate and intubate (DNR[I])” wishes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[27]</td>
<td>Moore, S et al, 2002, UK, one specialist cancer hospital and three local cancer units</td>
<td>a) To assess the effectiveness of a nurse-led follow up in the management of patients with lung cancer. b) Lung cancer patients who had completed their initial anticancer treatment and were expected to survive for at least three months. c) Nurse-led follow up d) Hospital CM e) “conventional medical follow-up”</td>
<td>a) Over telephone or in a nurse-led clinic. b) Telephone assessment or clinic appointment two weeks after baseline, then every four weeks while patient is stable. Open access through clinic, telephone, and message pager service. c) ?</td>
<td>a) Two b) Clinical nurse specialist c) Observing outpatient lung cancer clinics and shadowing medical consultants. Regular clinical supervision sessions were given. d) Reference to published article describing the model.</td>
<td>Unmet needs Symptom severity Several dimensions of QoL Formal service utilization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

?: Not to be found in the article

Cm: Case manager, CM: Case management
OHC: Specialized oncology home care program, SHC: Standard home care program, OC: Usual office care
AICCP: Advanced Illness Coordinated Care Program, APN: Advanced practice nursing
COPD: Chronic obstructive pulmonary disease, CHF: Chronic heart failure
Table 2: Randomization, data collection, analyses and results

| Ref | a) Randomization type  
b) N, n-intervention,  
and n-control | Outcomes | a) Statistical methods  
b) Randomization evaluated?  
(yes, no)  
If yes: variables, potential differences  
and possible adjustment performed  
noted?  
c) Numbers included in analyses  
d) Intention-to-treat analyses  
(yes/no/not mentioned) | Main results |
|-----|-------------------------------------------------|-----------------|------------------------------------------------|-----------------|
| [19] | a) Stratified, cluster (stratification at surgeon level (experience of surgeon’s breast cancer practice); Within each stratum randomization was performed in blocks of four.  
b) N(Surgeons)=60; N(Patients)=335, n-CM=169, n-control=166 | Primary: cancer-specific therapies received  
(after 6 months)  
Secondary: patient  
evaluations of the decision-making process; arm  
function on affected side.  
(2 (and 12) months after diagnosis.) | Primary: medical records audit (A summary measure of receipt of appropriate therapy was created based on published consensus recommendations; ref)  
Secondary: home interview based on pilot tested questionnaires on logistics, decision-making, satisfaction and tamoxifen prescription (?) and objective assessment of arm functions (?). | Primary: More women in the intervention group saw a radiation oncologist at their initial evaluation (36.0 vs. 19.3%, P=0.006), received breast-conserving surgery (28.6 vs. 18.7%, p=0.031) and radiation therapy (36.0% vs. 19.0%; P=0.003).  
Secondary: Intervention group was significantly more satisfied (more components; p<0.05) and had significantly more normal or near-normal range of arm motion (93 vs. 84%, p=0.037).  
(Several subgroup analyses: “Women with poor social support were most likely to benefit from the nurse CM intervention.”) |
| [23] | a) Simple, two-arm randomization.  
b) N=210, n-int=106, n-control=104 | -Quality of Life (QoL)  
(At enrolment + 1, 3, 6, 12, 18, 24 months after enrolment.)  
-Cost data  
(24 months after date of diagnosis). | -QoL measured with three self-administered questionnaires:  
1. MUIS: uncertainty  
2. POMS: mood  
3. FACT-E: well-being/QoL on six dimensions.  
(yes, all validated + ref)  
-Charges and reimbursements were collected from billing systems.  
Length of hospitalization and number of visit to health care provider were recorded. | -Univariate analyses of QoL data: t-test + chi-square/Fisher’s exact test.  
Multiple regression for repeated QoL measures using baseline scores as a covariate.  
-Costs: Univariate analysis + multivariate regression.  
b) Yes (variables: demographics and disease characteristics). Difference found: Intervention group women had lower histology (p=0.04) and more received adjuvant hormone therapy (p=0.03); adj. performed.  
Uncertainty: Intervention group had less uncertainty at 1, 3 and 6 months (p=0.05). Effect size not specified. Mood and well-being: no sign. diff. between int. and control group.  
Overall costs: no difference found including subgroup analyses.  
(Some subgroups benefitted significantly from APN, e.g. unmarried women and women with no family history of breast cancer). |
<table>
<thead>
<tr>
<th>Ref</th>
<th>a) Randomization type b) N, n-intervention, and n-control</th>
<th>Outcomes</th>
<th>Outcome source (Validity account*)</th>
<th>a) Statistical methods b) Randomization evaluated? (yes, no) If yes: variables, potential differences and possible adjustment performed noted? c) Numbers included in analyses d) Intention-to-treat analyses (yes/no/not mentioned)</th>
<th>Main results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) Three-arm simple randomization b) N=166, Numbers assigned to each of the “arms” N/A.</td>
<td>-Measures of Patient Psychosocial Responses (Five interviews at 6-week interval; first before group assignment.) -Number of hospitalizations -Length of Stay (LOS) (continuously through 24 weeks).</td>
<td>-Cost of APN services were based on time logs.</td>
<td>c) QoL: ? Cost data: N=152 (n-int=78, n-contro=74; 58 excluded because of missing data)</td>
<td>Psychosocial Responses: Significant difference between the profiles of the two nursing groups and the office care group with regards to adjusted Symptom Distress (P=0.03) and adjusted Enforced Social Dependency (P=0.02) in favour of home care nursing. The OC group rather steadily reported improved health perceptions over time, whereas the two treatment groups reported worse health perceptions (p&lt;0.05). No of hospitalizations and LOS: No significant differences</td>
</tr>
<tr>
<td>[25]</td>
<td></td>
<td>-Psychosocial responses: Interview questionnaire (in-person or telephone ?); Scales: Symptom distress (The Symptom Distress Scale); Pain(McGill-Melzack Pain Questionnaire); Current Concerns (Weisman and Worden’s Inventory of Current Concerns); Mood state (Profile of Mood States) Functional status (General Health Rating Index) (ref to all above) -A Medical Record Review Instrument was developed.</td>
<td>a) Primary analyses: repeated measures and analysis of variance for each dependent variable (univariate mixed model and multivariate model). Plot of means for the core measures. b) Yes. No difference on demographics, Starting points for depending variables were discrepant for which reason adjustment was performed (Potential bias of adj. was discussed). c) Patient psychosocial responses: 78 patients completing four interviews (numbers in each group not stated). Number of hospitalizations: 77 of 78 completing four interviews (n-OHC=24, n-SHC=27, n-OC=26). LOS: 52 (had been hospitalized) of 78 completing four interviews (n-OHC=14, n-SHC=18, n-OC=20). d) Not mentioned</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ref</td>
<td>a) Randomization type  b) N, n-intervention, and n-control</td>
<td>Outcomes</td>
<td>Outcome source (Validity account)</td>
<td>a) Statistical methods  b) Randomization evaluated? (yes, no)  If yes: variables, potential differences and possible adjustment performed noted?  c) Numbers included in analyses  d) Intention-to-treat analyses (yes/no/not mentioned)</td>
<td>Main results</td>
</tr>
<tr>
<td>-----</td>
<td>----------------------------------------------------------</td>
<td>----------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>[24]</td>
<td>a) Simple randomization.  b) N=375, n-intervention=190, n-control=185</td>
<td>Primary: Length of survival (up to 44 months of follow up)  Secondary: To identify psychosocial and clinical predictors of patient survival (i.e. depressive symptoms, symptom distress, functional status, co-morbidities, length of hospital stay, age, and cancer stage). (baseline, 3, and 6 months)</td>
<td>Survival status was ascertained by letter, telephone, or death certificates (?)  Demographics: “obtained at accrual” (?)  Stage of disease: Surgical pathology reports and physician’s discharge summary (?)  Psychosocial questionnaires: Center for Epidemiological Studies-Depression Scale (CES-D), Symptom Distress Scale (SDS), and Enforced Social Dependency Scale (ESDS) (ref to all)</td>
<td>a) Stratified log-rank test was used to compare groups. Kaplan-Meier curves stratified by stage of disease at diagnosis. Cox’s proportional hazards regression model to compute adjusted hazard ratios (=HR; Proportional hazards assumption was Schoenfeld tested)  b) Yes (demographics and clinical variables; more late stage patients in intervention group (p=0.013). Adjusted and stratified analyses performed.  c) Survival status for all 375 included patients were obtained.  d) Not mentioned</td>
<td>Non-stratified analyses revealed no difference in survival status between groups (p=0.129). Stratified analyses: Late-stage patients’ 2-year survival were 66.7% in int. group vs. 39.6% in control group (p&lt;0.05). Adjusted for psychosocial and clinical covariates: Usual care had death-HR=2.04 (95% CI 1.33-3.12, p=0.001)  Late stage usual care patients had adjusted death-HR=4.55 (CI 2.92-7.08; p&lt;0.001)  Outcomes of psychosocial questionnaires were not mentioned at all in results paragraph.</td>
</tr>
<tr>
<td>Ref</td>
<td>Outcomes</td>
<td>Outcome source</td>
<td>a) Statistical methods</td>
<td>b) Randomization evaluated?</td>
<td>Main results</td>
</tr>
<tr>
<td>-----</td>
<td>----------</td>
<td>----------------</td>
<td>------------------------</td>
<td>-----------------------------</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| [26] | a) Block-randomization (blocks of 10; rationale not outlined)  
b) N=275; n-AICCP=133, n-UC=142 ; N-surrogates (relatives)=168, n-sAICCP =76, n-sUC=92.  
- Patients’ evaluations of patient/provider communication, satisfaction with care and attitudes about participation in treatment planning (enrolment, at 3 and 6 months)  
- Surrogates’ experiences with the health care system. (3 months post-enrolment.)  
- Costs (end of study)  
- Advance directives (AD) and do-not-resuscitate and intubate (DNR(I)) (enrolment, 3 and 6 months)  
- Patient/provider communication, satisfaction with care: Investigator-constructed, 10-item scale ( ?, but “reliability tested on enrolment”)  
- Participation in treatment planning was assessed by a single item ( ?, “asked” – questionnaire or interview?)  
- Surrogates´ experiences (problems in 7 domains were averaged to create a single overall rating): Modified EOL Family Interview (ref; “asked” - questionnaire or interview?)  
- Costs: Program contact, salary, and overhead costs collected from 3 sites (the VAMC patients). Other costs: medical records for VAMC patients.  
- AD and DNR(I): VAMC participants’ medical records  
| Outcome of interest* (Time of measure) | Outcome source (Validity account?) | -Patients’ evaluations: Scores were examined for effects of group, time, and group-by-time interaction using a random effects regression model.  
- Surrogates’ exp.: Post-intervention scores t-test compared.  
- AD: Chi-square comparison and t-test. Kaplan-Meier curves comparison of group membership and time to completion of ADs.  
- Costs: F test Effect sizes were calculated for most outcomes.  
| (yes, no) If yes: variables, potential differences and possible adjustment performed noted? | c) Numbers included in analyses  
| d) Intention-to-treat analyses (yes/no/not mentioned) | Patient satisfaction with care: Significant group-by-time interaction in favour of the AICCP group (Effect size 0.18, \( P = 0.03 \)). (Effect size is the ratio of the estimated treatment effect.)  
Surrogates post-test scores: Fewer problems (with the spiritual and emotional support delivered) reported by AICCP surrogates than UC surrogates (effect size 0.39, \( p=0.03 \))  
Costs: no stat. sign diff.  
AD: Median time to completion of first AD: AICCP=46 days vs. UC= 238 days (log-rank \( P=0.02 \))  
Proportion of patients having completed at least one AD, and the mean numbers of ADs per patient were sign. higher for the AICCP group at both 3 and 6 months (\( p=0.01 \)). |
| Ref   | a) Randomization type  
b) N, n-intervention,  
and n-control | Outcomes |
|-------|----------------------|----------|
|       | Outcomes of interest* 
(Time of measure) | Outcome source  
(Validity account) | a) Statistical methods  
b) Randomization evaluated?  
(yes, no)  
If yes: variables, potential differences and possible adjustment performed noted?  
c) Numbers included in analyses  
d) Intention-to-treat analyses  
(yes/no/not mentioned) | Main results |
|       |                      |          |                                  |                        |
| [22]  | a) Stratified randomisation (six strata; three strata based on unmet need status, and two strata based on gender).  
b) N=259, n-CM=130, n-control=129 | -Unmet needs (assessed by patients)  
-Reported symptom severity  
-Several dimensions of QoL  
-Formal service utilization (Data collection: At baseline, at 3 and 6 months) | -Aspects of daily living (three unmet needs-categories) (ref);  
-Standard questions on symptom severity (?)  
-Spitzer’s physical “QoL Index”(ref), five-item mood state score from SF-36 (ref), and a specially developed 4-item scale measuring patient experienced disruptions in treatment (?)  
All above: Telephone interviews  
-Service utilization: Patients’ reports and audit of patients’ medical records, | a) Chi-square and analysis of variance to test differences between intervention and control groups  
b) yes (no difference found on baseline demographic, medical and need status)  
c) 3 months: n-CM=109, n-control=108, 6 months: n-CM=93, n-control=92  
d) Not mentioned; unclear if 11 CM group patients who refused CM services were followed up and in which group they were analysed (?) | No statistically significant differences were observed on any outcome measure for the overall sample as well as for selected “at-risk” patient subgroups. |
| [27]  | a) Stratified randomisation according to hospital and treatment intent (rationale and numbers of strata not outlined)  
b) N=203 (n-nurse led follow-up=100, n-control=103) | Primary: QoL and patients’ satisfaction at three months (assessed at baseline, 3, 6, and 12 months)  
Secondary: Overall survival, Symptom-free survival, Progression-free survival.  
GPs’ satisfaction (at the end of study participation).  
Service use (3, 6 and 12 months) and cost effectiveness | -EORTC QLQ-C30 and module about lung cancer. (ref)  
-Patient satisfaction questionnaire incorporating three validated measures and tested in a pilot study (ref)  
No information on source of secondary outcomes. | a) QoL + satisfaction: Mann-Whitney U test  
Survival: Kaplan-Meier  
Costs: Mann-Whitney U test.  
b) Yes (no difference found on clinical, QoL and pat sat baseline variables)  
c) 3 months: n-int=76, n-control=74; 6 months: n-int=53, n-control= 58; 12 months: n-int=26, n-control=29  
d) Not mentioned, but it was mentioned that no intervention group patients reverted to medical follow-up. | Int. group had less dyspnoea (p=0,03; a QoL score) and significantly higher satisfaction in each subscale at three months.  
Int. group had longer time to symptomatic progression (p=0,01).  
Significant change in pattern of service use, but no difference in readmission rates. Significantly more patients in int. group died at home (p=0,04).  
No difference in costs, and GP satisfaction. |

? Not to be found in the article  
* Outcomes of interest: if primary and secondary was not indicated, “-” are used in front of each  
*Validity account categorised as follows: ?: validity not mentioned at all; ref: reference(s) quoted; yes: it is mentioned that measure is validated
Table 3: Important methodological aspects adapted from CONSORT [20,21]

<table>
<thead>
<tr>
<th>Ref</th>
<th>Methods paragraph</th>
<th>Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) Sample size calculation? (yes/ no)</td>
<td>a) Patient flow illustrated in diagram? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>b) Period of recruitment listed? (yes/ no)</td>
<td>b) Description of complete patient flow?</td>
</tr>
<tr>
<td></td>
<td>c) Described how patients were assessed for eligibility? (yes/ no)</td>
<td>c) Non-participants mentioned (i.e. patients meeting criteria but refusing participation)? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>d) Allocation concealment method (described/ not mentioned)</td>
<td>d) Non-participants characteristics compared with those included? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>e) Blinding of those assessing outcomes (yes/ not mentioned)</td>
<td>If yes: potential for selection bias was discussed?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e) Accounting for participants not followed? (yes/ no)</td>
</tr>
</tbody>
</table>
|     |                                         | If yes: Analyses performed to uncover potential skewed withdrawal? (yes/no)
|     |                                         | Potential bias discussed? |
|     |                                         | f) Clearly described categorisation and follow-up of possible intervention-group patients not wanting the intervention? (yes/ no) |

|      | b) Yes (1/11/93-> 31/11/96)            | b) No, numbers of patients followed up by interview not available. |
|      | c) Yes, both for patients and surgeons | c) Yes (10 surgeons) |
|      | d) Not mentioned                       | d) No |
|      | d) Yes                                 | e) No |
|      |                                         | f) Yes (14, they were intention-to-treat analysed) |

| [23] | a) No                                   | a) No |
|      | b) Yes (1995-97)                        | b) No, “Drop-out of intervention patients” and patients followed up with questionnaires not available. |
|      | c) Yes                                  | c) Yes (85 did not wish to participate) |
|      | c) Not mentioned                        | d) Participants were younger (p<0.0001) and were more likely to have invasive disease (p=0.003) than non-participants. Potential for selection bias not discussed. |
|      | d) Not mentioned                        | e) No |
|      |                                         | f) No (and “intention-to-treat” not mentioned) |

| [25] | a) No                                   | a) No |
|      | b) Yes (18-month period, dates not mentioned) | b) No. Numbers allocated to each group not stated and obscure flow of patients through each “arm”. |
|      | c) Yes                                  | c) No (more than 900 were asked to participate. Instead lung cancer registry cases in same County mentioned) |
|      | d) Not mentioned                        | d) Yes, compared with above reg. “Diff. explainable” and were not considered a validity threat. |
|      | e) Not mentioned                        | e) Yes, for the entire mass of included (111 withdrawn out of 166 randomized). Withdrawal reason for all 111 stated, but characteristics and group assignment of these not mentioned. No discussion. |
|      |                                         | f) No |

<p>| [24] | a) No                                   | a) No |
|      | b) Yes (February 1993- December 95)    | b) No, patients meeting criteria but not participating were not mentioned. Cause of attrition not accounted for. |
|      | c) No                                   | c) No |
|      | d) Yes                                  | d) No |
|      | e) Not mentioned                        | e) No accounted for in numbers but causes for not responding questionnaires not stated. No discussion. |
|      |                                         | f) No |</p>
<table>
<thead>
<tr>
<th>Ref</th>
<th>Methods paragraph</th>
<th>Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) Sample size calculation? (yes/ no)</td>
<td>a) Patient flow illustrated in diagram? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>b) Period of recruitment listed? (yes/ no)</td>
<td>b) Description of complete patient flow?</td>
</tr>
<tr>
<td></td>
<td>c) Described how patients were assessed for eligibility? (yes/ no)</td>
<td>c) Non-participants mentioned (i.e. patients meeting criteria but refusing participation)? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>d) Allocation concealment method (described/ not mentioned)</td>
<td>d) Non-participants characteristics compared with those included? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td>e) Blinding of those assessing outcomes (yes/ not mentioned)</td>
<td>If yes: potential for selection bias was discussed?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e) Accounting for participants not followed? (yes/ no)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If yes: Analyses performed to uncover potential skewed withdrawal? (yes/no)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potential bias discussed?</td>
</tr>
<tr>
<td></td>
<td>f) Clearly described categorisation and follow-up of possible intervention-group patients not wanting the intervention? (yes/ no)</td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>a) No</td>
<td>a) No</td>
</tr>
<tr>
<td></td>
<td>b) No</td>
<td>b) No, lack of explanation to numbers of participants not followed up.</td>
</tr>
<tr>
<td></td>
<td>c) No</td>
<td>c) No</td>
</tr>
<tr>
<td></td>
<td>d) Yes</td>
<td>d) No</td>
</tr>
<tr>
<td></td>
<td>e) Not mentioned</td>
<td>e) No</td>
</tr>
<tr>
<td></td>
<td>f) Yes (cross-over both ways described in detail, intention to treat analysed)</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>a) Yes, estimate not presented.</td>
<td>a) No</td>
</tr>
<tr>
<td></td>
<td>b) No</td>
<td>b) No, unclear if 11 CM group patients who did not want CM were followed up or not (?)</td>
</tr>
<tr>
<td></td>
<td>c) Yes</td>
<td>c) Yes (125 patients)</td>
</tr>
<tr>
<td></td>
<td>d) Not mentioned</td>
<td>d) No</td>
</tr>
<tr>
<td></td>
<td>e) Not mentioned</td>
<td>e) Yes. No difference in attrition characteristics between intervention and control group patients. (Participants who had at least one follow-up were younger (p&lt;0.01) and more likely to be female (p&lt;0.05). Patients diagnosed from lymphoma, lung, pancreatic, or stomach cancer were less likely to be followed-up than breast cancer patients. Patients lost to follow-up were also more likely to have received palliative treatment.)</td>
</tr>
<tr>
<td></td>
<td>f) Yes, by number, but unclear if 11 case managed patients who refused CM services were followed up (they could be categorised under “attrition”?) and if followed up, in which group they were analysed.</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>a) Yes</td>
<td>a) Yes</td>
</tr>
<tr>
<td></td>
<td>b) Yes</td>
<td>b) Yes</td>
</tr>
<tr>
<td></td>
<td>c) No</td>
<td>c) Yes</td>
</tr>
<tr>
<td></td>
<td>d) Yes</td>
<td>d) No</td>
</tr>
<tr>
<td></td>
<td>e) Yes, but no analyses performed</td>
<td>e) Yes</td>
</tr>
<tr>
<td></td>
<td>f) Yes, it was mentioned that no intervention group patients reverted to medical follow-up.</td>
<td>f) Yes</td>
</tr>
</tbody>
</table>
CHAPTER 12:

PAPER 2
Title:

A Randomised Controlled Trial of Hospital-based Case Management for Colorectal Cancer Patients: Methods and Feasibility

Authors:

Christian N. Wulff, PhD Fellow, MD\textsuperscript{1}; E-mail: christian.wulff@alm.au.dk
Peter Vedsted, Professor, MD, PhD\textsuperscript{1}; E-mail: p.vedsted@alm.au.dk
Frede Olesen, Professor, MD\textsuperscript{1}; E-mail: fo@alm.au.dk
Henriette V. Thaysen, PhD Fellow, Clinical nurse specialist\textsuperscript{3}; E-mail: henrthay@rm.dk
S\o{}ren Laurberg, Professor, Chief Surgeon, MD, DrMedSc\textsuperscript{3}; E-mail: soerlaur@rm.dk
Peter Chr. Rasmussen, Chief Surgeon, MD\textsuperscript{3}; E-mail: peterasm@rm.dk
Jens S\o{}ndergaard, Professor, Specialist in General Practice and Clinical Pharmacology, MD, PhD\textsuperscript{2}; E-mail: jsoendergaard@health.sdu.dk

\textsuperscript{1} The Research Unit for General Practice in Aarhus, Department of Public Health, Aarhus University, Aarhus, Denmark
\textsuperscript{2} The Research Unit for General Practice in Odense, Institute of Public Health, University of Southern Denmark, Odense, Denmark
\textsuperscript{3} Surgical Department P, Aarhus University Hospital, Aarhus, Denmark

Corresponding author:

Christian N. Wulff; E-mail: christian.wulff@alm.au.dk

Word count: 3,755 Figures: 2 Tables: 2

Abstract: 318 words (max. 350)

Short running title: Case Management in Cancer Care
Abstract

Background: Case management is a method used to optimise care pathways for patients with complex needs. Case management is most often conducted by a nurse (the case manager) assigned to the individual patient to improve continuity of care. However, evidence of the effects of case management in cancer care is sparse. A randomised controlled trial was conducted to analyse the consequences of case management in cancer care. The objective of this paper was to describe the methods and feasibility of the trial.

Methods: A 1:1 randomised controlled trial including colorectal cancer patients treated at one surgical department in Denmark. Patients allocated to the control group received usual treatment and care including usual supervision of the care pathway and usual patient support. Case management group patients received usual treatment and care supplemented by care pathway supervision and outreaching support from a nurse case manager.

Feasibility of the intervention was based on calculations from case notes made by the case managers.

The primary endpoints (not presented in this paper) were the global health status subscale of the EORTC QLQ-C30 and a priori selected items from a patient evaluation questionnaire.

Results: Of the 280 participants, 186 (66.4%) were male, 142 (51%) suffered from colon cancer, and 130 (46%) from rectal cancer. No differences between the randomisation groups were found at baseline. On average, the case managers made 9.7 (interquartile range: 5-13) contacts and spent 205 (interquartile range: 100-260) minutes in contact with the patient, relatives and health professionals. On average, 2.3 (interquartile range: 2-3) electronic letters were sent to the general practitioners.

Conclusion: This randomised controlled trial proved feasible with regard to recruitment and allocation of the participants. Regular conversations with the case managers and calculations of conducted activities indicate that the case management intervention was
adequately performed. If the upcoming results are positive, the intervention can possibly be used to improve other cancer patients’ care.

Trial registration: Clinicaltrials.gov identifier: NCT00845247.
Background

Over the last decades, innovations in cancer diagnostics and treatment have specialised and centralised cancer care (1) and survival for most cancer types have increased (2). As a consequence of the specialisation, many patients may experience inadequate continuity of care, i.e. experience their treatment as being fragmented, information as being inconsistent, and support from health professionals as being incoherent (3-6). In addition, most cancer patients suffer from reduced well-being due to the physical effects of the disease and treatment but also due to existential beliefs (7).

Case management (CM) is a method used increasingly to improve continuity of care for patients with complex health care needs. Many comparable CM definitions exist (8, 9), e.g.: “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 characterised by advocacy, communication, and resource management and promotes quality and cost-effective interventions and outcomes” (10).

CM is conducted by the case manager, most often an experienced nurse, who is committed to ensure that individual patients experience coherent and individually tailored care pathways. Common tasks comprise: optimisation of communication and information flow, coordination of services, increase of patient involvement, and shared decision-making (8, 9).

CM models can be described in numerous ways. One categorisation refers to the location of the case manager, i.e. hospital-based CM, hospital-to-community CM, or community-based / primary care-based CM (9). Another refers to the target population, e.g. CM for the elderly, CM for patients suffering from diabetes.

We conducted a systematic review focusing on the effects of hospital-based CM for patients undergoing cancer treatment. Based on seven studies which differed with regard to setting, intervention content and endpoints, no conclusion on the effectiveness could be made (11).
Colorectal cancer (CRC) is an example of a cancer type where patients could potentially benefit from hospital-based CM. CRC treatment most often takes place at more than one department. The typical CRC patient is 71 years old, and thus many patients suffer from comorbidity (12). Importantly, research has shown that both colon cancer patients and rectal cancer patients face similar problems and needs with regard to psychosocial well-being, information, and support (13, 14).

A randomised controlled trial (RCT) was designed to focus on the effects of hospital-based CM in CRC care. The primary hypotheses were that CM would improve patients’ quality of life, improve patients’ evaluations of care, and reduce the need for unplanned readmissions and contacts to the out-of-hours medical services. The objective of this paper is to describe the methods and the feasibility of the trial.

**Materials and methods**

**Setting**

The CM trial took place at Surgical Department P, Aarhus University Hospital in Aarhus, Denmark. Department P performs surgery for both benign and malignant diseases of the lower intestinal system (colon, rectum and anus). The department consists of three wards, an endoscopic clinic, an outpatient setting, 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 and patients are referred from other surgical centres to this department.

The Danish health care system is financed by tax revenues for which reason almost all health care services from the general practitioners (GPs), emergency services and public hospitals are free of charge. Ninety-eight per cent of Danes are listed with a GP, who acts as the gatekeeper as regards referral to specialised treatment and care. The GP is expected to function as the key health care coordinator for patients outside the hospital. The GPs in turn undertake the out-of-hours medical services situated at the hospitals. In general practice, medical records are fully computerised and communication between
hospitals and general practice is based on standardised electronic letters. Hospital medical records are still specific to each department, but shared and computerised medical records are being developed these years.

**Colorectal cancer treatment**

Appropriate CRC treatment hangs on meticulous disease staging. Most patients suffering from CRC are offered immediate intended curative intended surgery. 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 for the two cancer types are almost identical. The overall 1-year CRC survival rate is 73% and the overall 5-year survival rate is 45% (12).

**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 the multidisciplinary team (MDT) meeting. Patients with localised colon cancer had their treatment offer decided by the surgeon in the outpatient clinic. The patient-surgeon agreed treatment plan 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 the 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 (15) was standard treatment for primary colon cancer. Patients planned to go through fast-track surgery visited the ward prior to
hospitalisation where a dedicated nurse provided information on the perioperative procedures including planned discharge at day two after surgery.

*Patient sampling*

Eligible patients were consecutive patients admitted to Department P in the period from March 11th 2009 - December 29th 2010 with a surgeon-stated diagnosis of CRC or a ‘highly-probable diagnosis of CRC’. Some eligible patients were recruited to another research project and these patients were therefore not included in this trial. The residual eligible patients were assessed according to the following three exclusion criteria:
1. Cognitive impairment (dementia or mental retardation);
2. Lack of Danish language skills to read and fill in questionnaires;
3. No further visits planned at Department P (e.g. due to patient frailty, patient’s choice, or patient referred to oncological care only).

*CM intervention*

CM intervention was conducted supplementary to usual treatment and care. 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 patients experienced coherent and meaningful care from the randomisation until four weeks after the end of cancer treatment. CM intervention comprised four primary constituents:

1. Supervision of the patient’s planned health care with the purpose of anticipatory correction of inadequacies;
2. Regular, pro-active, scheduled patient contacts with the purpose of anticipating inconveniencies and preventing the patient’s feeling of ‘being left in limbo’;
3. Day-time reactive telephone support. The case manager functioned as a CRC knowledgeable, consistent and directly available health professional;
4. 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 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 note summarising planned treatment and potential barriers for optimal care 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 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, helped facilitate contact to a surgeon, a home nurse, the GP, etc. Such ‘disturbances’ made the case manager intensify pro-active contacts temporarily.

Needs assessments, similar to the one performed initially, were performed in relation to every change in the care setting. At discharge(s) from Department P, the case manager sent the GP a brief electronic note summarising the treatment status and potential barriers for optimal care. When relevant, the case manager informed health professionals at other institutions about the patients’ health status.

The case managers were introduced as members of the multidisciplinary team (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 manager tasks (including appointed time of contacts), the needs assessments, and areas of responsibility were described in a detailed manual. 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 in contact with the patients, relatives and other health professionals, and to characterise these contacts according to four documentation categories (information, support, coordination, and involvement) already used by other Danish nurses.

The control group patients received usual treatment and care at Department P. No particular health professional overlooked patients’ treatment and care. These patients were not pro-actively contacted by telephone. According to a section in the Danish Health Act, the assignment of a contact person is statutory (16) which is why all control group patients were given contact details of a contact person (most often a ward nurse) with the purpose of easy access to the department during the treatment period.

Table 1 is a so-called PaT plot of the trial (17) which provides an overview of CM intervention, usual care (control group) and outcomes assessment.

Outcomes and data collection

The trial had two primary outcomes. One was the global health status-subscale of the EORTC QLQ-C30 which is a validated measure of health-related quality of life (18). The other was a priori selected items of an ad hoc piloted patient evaluation questionnaire. Secondary outcomes were the functioning subscales of the EORTC QLQ-C30 measure, additional items from the patient evaluation questionnaire, the patients’ relatives’ and GPs’ evaluations of the care pathways using ad hoc piloted questionnaires, and patients’ use of health care services.

The outcome measures (and the development of the ad hoc questionnaires) will be described in following papers.

Data were collected in identical manners irrespective of allocation status (see Table 1 and Figure 1). Patient questionnaires were posted to patients alive at week 8, 30, and 52.
following inclusion. Non-responders were sent a reminder three weeks later and were contacted by phone three weeks later by the principal investigator (CNW), if necessary. The 30-week patient questionnaire enclosed a questionnaire to the patient’s nearest relative which the patient was asked to define. GP questionnaires were sent 30 weeks after the patients’ inclusion with a reminder three weeks later to non-responders. The GPs were identified from the medical records. Patients’ addresses and vital status were updated from the Danish Central Population Registry on the day of the questionnaire dispatch.

Data on readmissions, bed-days in hospitals, and use of daytime and out-of-hours GP services were retrieved from the Danish National Health Insurance Service Registry and the Danish National Registry of Patients.

Sample size
Sample size calculations on the global health status subscale of the EORTC QLQ-C30 revealed that responses from 116 patients were needed in each group (90% power, two-sided significance level of 5%, 1:1 allocation) to detect 10 units of difference between groups. Due to inevitable drop-out, the aim was to include 280 patients.

Recruitment and randomisation procedures
Most often, the first meeting between the recruiting nurse (RN) and an eligible patient took place in the outpatient clinic after the patient’s cancer had been staged and treatment had been booked. Non-excluded patients were asked to participate and were 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. If the patient returned the documents, the RN contacted an independent secretary who performed the computerised concealed allocation procedure. The patient was then immediately informed about the randomisation result.
Minimisation is a dynamic allocation method which might be considered instead of stratified block randomisation when several stratification factors are to be used. Minimisation seeks to even out imbalances between groups as to the predefined stratification factors. The stratification characteristics of the patient determine which group the patient will be allocated to. Most often, minimisation also incorporates a random factor [23]. One advantage of minimisation is that randomisation lists become unnecessary.

The SiMin (19) minimisation software was used to randomise participants using a 1:1 allocation ratio. To ensure comparable groups in terms of baseline characteristics possibly 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 was underrepresented).

**Blinding**

The individual patient’s allocation status was known by the patient and by the case managers, but blinded to researchers. A label on the front page of the paper version of the CM patients’ medical records informed health care professionals about which patients were supervised and supported by a case manager.

**Statistical analysis: The effects of the intervention**

All analyses focus on differences between the control group and the CM group and are intention-to-treat analyses. Questionnaire data are analysed for differences between the two groups at week 8, 30 and 52. Each patient’s use of health care services within 6 or 12 months from inclusion is summarised and differences between the two groups’ use of health care are analysed.

Subgroup analyses are conducted in order to analyse whether effects depend of cancer type, gender and age (20). Non-response analyses are performed to assess potential bias from non-response.
Ethics

The Danish Data Protection Agency approved the creation of a research database and the RCT was indexed at www.clinicaltrials.gov with registration ID number NCT00845247. According to the Danish Research Ethics Committee System (21), the trial was not a biomedical intervention and did not need the ethics committee’s approval. The project was deemed ethically acceptable to intervention patients as it did not expose intervention patients to any risks.

Development and piloting of the intervention

The case manager function corresponded to the description in the Danish Generic Model for Disease Management Programmes (22). The CM intervention and the CM manual were developed after a thorough review of reports and papers describing problems faced by cancer patients and interventions focused on improving psychosocial support, information and health care continuity. To build on best practice the descriptions of the seven CM interventions found during the systematic review were scrutinised (11).

Both nurses employed as case managers had several years of experience both in CRC care and from Department P. Before recruitment of trial participants began, the nurses spent more than two months studying and training CM. The formal introductory programme encompassed personalised education from key persons in terms of: health care system structure, colorectal diagnostics and treatment, use of computerised patient administration systems, and communication with cancer patients. The nurses made day visits to the surgery ward, two different GP surgeries, the local oncology department, and the local radiological department and 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, the manual was scrutinised and improved. All sections at Department P were informed about the thoughts behind CM and the study.

Results

Feasibility of recruitment and allocation methods

The recruitment period began on March 11th 2009 and ended December 29th 2010 when the a priori calculated sample size was reached. During this period, 532 patients were eligible for the trial and 280 patients (53%) were included. Reasons for non-participation appear from Figure 1. The 252 non-participants differed statistically significant from participants with regard to cancer type and age, but not gender. Thus, 83% (210 of 252) non-participants versus 46% (130 of 280) participants suffered from rectal cancer. The mean age of non-participants was 68.6 (12.40) years versus 66.3 (11.4) years for participants.

The randomisation seemed to establish two roughly comparable groups (Table 2).

Feasibility of intervention

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

The case managers’ actions for the first 61 included patients were calculated from the CM medical records. Case manager contacts within 12 months from inclusion were included in the calculations. The case managers averagely had 9.7 (median 8, IQR: 5-13) contacts with the patient and the relatives. Of these, 4 were face-to-face contacts; 2.1 were inbound and 3.6 were outgoing telephone calls. The case manager spent 205 minutes (median 150 minutes, IQR: 100-260 minutes) per patient in contact with the patient, the relatives and
health professionals. Figure 2 shows that the case managers spent most of their time in contact with the patients, and that ‘provision of support’ was the most time-consuming activity.

On average, the case managers sent 2.3 electronic letters to the GPs (median 2; IQR: 2-3) and 0.5 postal letters to other health care professionals (other departments).

**Discussion**

A RCT of hospital-based CM in CRC care was conducted to qualify the discussions regarding whether CM should be used as a method to improve continuity of care in cancer care pathways. This paper describes the methods and the feasibility (how the recruitment, the allocation and the intervention proceeded).

During 22 months, 532 patients were eligible for the trial and 280 patients (53%) were included. Non-participants were slightly, but statistically significant, older than participants. Statistically significantly more rectal cancer patients were found among non-participants than among participants because of the following: 1. another research project included patients suffering from primary, non-metastatic rectal cancer; and 2. rectal cancer patients were relatively often excluded because further visits at Department P were not planned (disseminated disease).

The allocation procedure established two comparable groups as measured for important potential confounders (Table 2). The aim was to include CRC patients only, but the decision to include patients at the time they had a ‘highly-probable diagnosis of CRC’ caused the inclusion of eight patients who later appeared not to suffer from CRC. Four persons (1%) proved to suffer from other cancers of the abdomen (carcinoid tumour of the small intestine, pseudomyxoma peritonei, and ovarian cancer). Another four persons appeared not to suffer from cancer (but an intra-abdominal lipoma, a colonic stricture due to ischemia, and benign adenomas of the rectum).
Conversations with the case managers together with calculations from the CM medical records indicate that the CM intervention was feasible and that the protocol was followed.

The case managers indicated that a caseload of 10-15 patients undergoing treatment per case manager was appropriate together with the time-consuming task of recruiting new participants.

The principal limitations of this trial were caused by the fact that control group patients and intervention group patients were treated concurrently at the same department. Staff from Department P might have found some elements of CM promising which they therefore adopted and used to optimise control group patients’ care. It is believed, however, that it is unlikely that the control group received major parts of the CM intervention as this would require some organisational restructuring (e.g. revised work plans) which did not take place during the trial.

CM is a complex intervention (23) and CM models differ with regard to intervention activities and the setting. It is noteworthy that the CM model tested in this trial did not include initial booking of diagnostics and treatment. If no financial constraints existed, it could have been interesting to test variations of the CM model and to include a randomisation arm where patients were given unstructured support.

In spite of the fact that non-participants and participants differed with regard to cancer types and age, it is believed that upcoming findings will be generalisable to a wider group of cancer patients. The reason is that reports indicate that even though patients suffer from different cancer types, they face comparable psychosocial problems and health care system-related barriers (24, 25).

**Conclusions**

This pragmatic RCT of hospital-based nurse CM in CRC care proved feasible with regard to recruitment and allocation procedures. Conversation with the case managers and
statements based on the case managers’ record-keeping indicate that the planned CM intervention was adequately conducted. Upcoming papers will present and discuss the study’s outcomes; patients’ health-related quality of life, patient evaluations of care, GPs’ and relatives’ evaluations of support and information, and the patients’ use of health care services. If the effects are positive, the intervention can possibly be used to improve care for patients suffering from cancer types different from CRC.

**List of abbreviations**

CM: case management  
CRC: colorectal cancer  
GP: general practitioner  
HRQoL: health-related quality of life  
IQR: interquartile range  
MDT: multidisciplinary meeting  
RCT: randomised controlled trial  
RN: recruiting nurse

**Competing interests**

The authors report no conflicts of interest.

**Authors’ contributions**

All authors contributed to the study design. CNW summed the data from the CM medical records. HVT and CNW both scrutinised participants’ medical records for disease and treatment data. CNW primarily wrote the manuscript. All authors revised preliminary versions of the manuscript. All authors approved the final manuscript.
**Acknowledgements**

The authors wish to thank all patients and health care professionals who took part in the trial. We also wish to thank colleagues at the Research Unit for General Practice in Aarhus for support, especially Hanne Beyer for creating research databases.

This trial is funded by the Danish Cancer Society, the Novo Nordisk Foundation, the Danish Council for Independent Research – Medical Sciences, and the Quality and Continuing Training Council for GPs in the Central Denmark Region.
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 informed consent form and the baseline questionnaire were randomised.

<table>
<thead>
<tr>
<th>Time 0</th>
<th>CM GROUP*</th>
<th>CONTROL GROUP*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 0</td>
<td>a b</td>
<td>e</td>
</tr>
<tr>
<td>Week 0-8</td>
<td>1 c d</td>
<td>1</td>
</tr>
<tr>
<td>Week 8</td>
<td>HRQoL and patient evaluation questionnaire</td>
<td></td>
</tr>
<tr>
<td>Week 9-30</td>
<td>1 c d</td>
<td>1</td>
</tr>
<tr>
<td>Week 30</td>
<td>HRQoL and patient evaluation questionnaire Questionnaire to patient’s relatives GP questionnaire</td>
<td></td>
</tr>
<tr>
<td>Week 31-52</td>
<td>1 c d</td>
<td>1</td>
</tr>
<tr>
<td>Week 52</td>
<td>HRQoL and patient evaluation questionnaire Data collection from registries</td>
<td></td>
</tr>
</tbody>
</table>

Legend:

- **a**: First contact between the case manager and the patient: Information about CM service and needs assessment.
- **b**: Electronic letter 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 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 letter from the case manager to the GP and other involved health care professionals, if relevant.
- **e**: Information about the statutory contact person (handover of calling card).

* Only planned activities are illustrated. In-going calls etc. are not depicted.

**Table 1** An overview of the trial illustrating the differences between the two interventions. GP: general practitioner; CM: case management; HRQoL: health-related quality of life Grey boxes: gathering of outcomes.
Patients with a diagnosis or a ‘highly-probable diagnosis’ of colorectal cancer at Department P (March 11 2009 – December 29 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 ethic considerations (n=8)
Did not want to participate (n=67)
Missed (n=5)

THE CONTROL GROUP (n=140)

Allocation

Follow-Up

Questionnaires were sent to patients at 8, 30 and 52 weeks after inclusion.
Questionnaires were sent to GPs at 30 weeks.
Register based follow-up at week 26 and 52 (readmissions, number of bed-days spent and use of GP services).

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.
Register based follow-up at week 26 and 52 (readmissions, number of bed-days spent and use of GP services).

Figure 1 Trial profile.

CM: case management; GP: general practitioner
### Table 2: Patient characteristics at baseline by group assignment.

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.

<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></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>64 (45.7%)</td>
<td>66 (47.1%)</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 disease †</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>

* 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.
Figure 2 Bar charts illustrating case manager contacts.

Time consumption (percentage-wise) classified according to contact with different persons.
(61 patients followed during 12 months; 12.525 minutes)

Time consumption (percentage-wise) categorised according to four different activities: Info.: Information, C: Coordination, Inv.: Involvement, S: Support
(61 patients followed during 12 months; 12.525 minutes)

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.
References


16. The Danish Health Act no. 913 of 13 July 2010. [https://www.retsinformation.dk/forms/r0710.aspx?id=130455]


CHAPTER 13:

PAPER 3
A randomized controlled trial of hospital-based case management to improve colorectal cancer patients’ health-related quality of life and evaluations of care

Authors:

Christian N. Wulff (CNW), PhD Fellow¹, ²
Peter Vedsted (PV), Professor¹
Jens Søndergaard (JS), Professor³

¹ The Research Unit for General Practice in Aarhus, Department of Public Health, Aarhus University, Bartholins Allé 2, DK-8000 Aarhus C, Denmark
² Section for General Medical Practice, Department of Public Health, Aarhus University, Bartholins Allé 2, DK-8000 Aarhus C, Denmark
³ The Research Unit for General Practice in Odense, Institute of Public Health, University of Southern Denmark, J.B. Winsløws Vej 9A, DK-5000 Odense C, Denmark

Corresponding author:

Christian Nielsen Wulff
The Research Unit for General Practice in Aarhus, Department of Public Health, Aarhus University Bartholins Allé 2, DK-8000 Aarhus C, Denmark
E-mail: christian.wulff@alm.au.dk
Cell phone number: +45 22997968

Abstract word count: 305; Manuscript word count: 3013 (up to and including Conclusions)

Figures: 3   Tables: 3
‘What this paper adds’ box

What is already known on this topic
Case management models are increasingly engaged in healthcare systems to improve coordination and continuity of care. Models diverge as to settings, target patients and core activities. One proposed model presently implemented in healthcare systems is based on case managers engaged at hospital departments where cancer patients are treated. However, scientific evidence of effect is non-existent.

What this randomized controlled study adds
Hospital-based case management did not affect colorectal cancer patients’ health-related quality of life as measured by the EORTC QLQ-C30, but improved patients’ evaluations of care received.
**ABSTRACT**

**Objective:** To analyse effectiveness of hospital-based case management in terms of patient-reported outcomes.

**Design:** Randomized controlled trial allocating participants 1:1 to either a case management intervention or a control group. Allocation status was evident to participants and case managers, but blinded to researchers.

**Setting:** Case management was conducted at one surgical department at a Danish university hospital treating colorectal cancer patients from all parts of Denmark.

**Participants:** Eligible for inclusion were all consecutive colorectal cancer patients treated at the department from 11 March 2009 to 29 December 2010. Exclusion criteria: participation in another study, poor Danish language skills or apparent cognitive dysfunctioning. 140 participants were randomized to each group.

**Interventions:** Control group patients had usual care. Intervention group patients had usual care supplemented by hospital-based case management commenced at diagnosis and ended four weeks after completed planned cancer treatment. Case management was conducted by nurse case managers who undertook care pathway supervision, information dissemination to health professionals and outreaching patient support.

**Main outcome measures:** Patient-reported global quality of life measured with the EORTC QLQ-C30 and eight ad hoc, piloted patient evaluation items assessed at eight, 30 and 52 weeks after randomization. Each data set was analysed separately.

**Results:** The two groups were comparable as to questionnaire response rates and completed scales/items. There were no statistically significant group differences on any of the health-related quality of life subscales at eight, 30 or 52 weeks. In patient evaluations, all but one difference point estimates favoured case management; five, three and zero of eight items were statistically significantly more positively answered by case management patients at week eight, 30, and 52, respectively.
Conclusions: We found no evidence that case management influenced colorectal cancer patients’ health-related quality of life. Patients allocated to case management evaluated their care more positively than patients receiving usual care.

Trial registration: Clinicaltrials.gov identifier: NCT00845247.
**Introduction**

Treatment modalities for cancer evolve rapidly and cancer survival rates are rising modestly (1), but cancer patients still suffer from reduced health-related quality of life (HRQoL) due to their disease, its treatment and the effects of existential concerns (2,3). Many cancer patients experience cancer care as episodic and incoherent as to treatment and care, information provided and relationship with health professionals (4-7). Importantly, some studies have found a positive correlation between patients’ evaluations of their care and their HRQoL (8,9).

Case management (CM) is often recommended as a method to improve coordination and continuity of care for individual patients having complex care needs. CM is usually conducted by a nurse, the case manager, who is engaged solely to function as a consistent and pro-active cross-disciplinary member of the health care team (10).

CM may be an effective method to improve coordination and continuity of cancer care and to improve cancer patients’ HRQoL. However, the effectiveness of CM in cancer care has been sparsely studied (11). In the present study, we tested the hypothesis that hospital-based CM during the treatment period would improve colorectal cancer (CRC) patients’ HRQoL and their evaluations of care.

**Materials and methods**

**Study design**

Randomized controlled trial (RCT) allocating CRC patients to a CM intervention group or a control group (ratio 1:1).

**Setting**

The Danish healthcare system is primarily tax-financed and grants Danish citizens free access to general practitioner (GP) and public hospital services. Almost all Danes (98%) are listed with a general practice. The GP is a gatekeeper with regard to the patient’s referral to specialist services and functions as a key health care coordinator outside the hospitals (12). The Surgical Department P, Aarhus University Hospital, Denmark, treats all categories of CRC patients, including those who suffer from locally advanced or recurrent disease.
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’ who were to undergo further investigation or treatment at Department P. Exclusion criteria were participation in another study (see Discussion), poor Danish language skills or apparent cognitive dysfunction.

Interventions

The CM intervention was pragmatically designed and operationalized the case manager’s function as described in the Danish Generic Model for Care Pathway Programmes (13). The main aims of the intervention were to streamline individual patients’ care pathways and improve their well-being and experiences of care. Two experienced nurses were employed from January 2009 to May 2011 to work principally as case managers. They had their office at Department P and worked daytime and weekdays only. Throughout the period of cancer diagnostics and treatment, their tasks were to oversee and optimise the coordination of health services, to provide patient support, and to secure that involved health professionals had sufficient information about the patient’s circumstances (information focused on treatment progress and barriers to optimal care).

A detailed manual, which was pilot-tested before the trial, chronologically described the case managers’ duties. As soon as possible after randomization, the case manager scheduled a meeting with the patient to provide detailed information about the CM services and availability. In addition, the case manager made a formal assessment of the patient’s medical and non-medical condition, his or her expectations regarding care, and his or her knowledge about the disease and care. An ad hoc developed needs assessment was used to guide the conversation. Throughout the period of treatment, the case manager regularly (~every fortnight) telephoned the patient to assess his or her bio-psycho-social status and screen for barriers to optimal care related to coordination and awareness of the care plan. Potential inadequacies were addressed by involving relevant health professionals and by increasing the frequency of outreach telephone calls. Patient-specific information was passed on to the GP and other relevant health professionals initially and at transitions between care settings.

The case managers attended all multidisciplinary meetings where most patients had their cancer staged and treatment options discussed.
Active CM ended four weeks after completed planned CRC treatment. The duration of active CM thus differed between different patients. There was no formal time at which patients could no longer exercise their option to contact the case manager by telephone.

**Control group** patients were treated and cared for as usual. No designated health professional overlooked the coordination of health services for this group and they did not receive telephone calls to systematically assess their well-being and the coordination and continuity of their care. In accordance with a paragraph in the Danish Health Act, all control group patients were given the name and a phone number on an employee at Department P to grant them easy access to the department during the treatment period (14).

Figure 1 provides an overview of the CM intervention and the usual care in a PaT plot (15).

**Outcome measures**

HRQoL was assessed with the use of the Danish version of the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire version 3.0 (EORTC QLQ-C30), which is a validated, cancer-specific, 30-item questionnaire measuring HRQoL on: one global health status scale, five functioning scales and nine symptom scales (16,17). The primary endpoint of this study was the global health status scale. The secondary endpoints were scores on the functioning scales: physical, role, cognitive, emotional, and social functioning.

EORTC QLQ-C30 scores were calculated according to the scoring manual (18). Thus, 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. For interpretation of EORTC QLQ-C30 results we set 10 units as the minimally relevant scale contrast regardless of the subscale (19,20).

Eight ad hoc items from a piloted questionnaire were pre hoc selected as the primary patient-evaluation endpoints (see Table 4). Six items meant to determine information and support from health professionals and continuity of care were answered using the following response categories: ‘Completely agree’, ‘Agree’, ‘Do not agree’, ‘Completely disagree’ and ‘Do not know/Not applicable’. Two items asked the patients to assess the quality of care at the surgical department and in general. These items used the following response categories: ‘Excellent’, ‘Very good’, ‘Good’, ‘Less good’, and ‘Bad’.
Follow-up

HRQoL and patient evaluations were assessed eight, 30 and 52 weeks after the patient’s inclusion with copies of the same questionnaire that featured the EORTC QLQ-C30 items plus 64 other items. The questionnaires and the reminders to non-responders (after three weeks) were sent by ordinary mail. Non-response six weeks after the time of the initial follow-up questionnaire prompted a reminder phone contact. HRQoL was also assessed at baseline using a questionnaire handed out at the hospital.

Sample size

Power calculations on the global health status scale revealed that we needed responses from 116 patients in each group (power of 90%, two-sided significance level of 5%, 1:1 allocation) to detect 10 units of difference between groups. Due to inevitable drop-out, we aimed at including a total of 280 patients.

Randomization and allocation concealment

The two case managers undertook recruitment in turns. After assessment of in- and exclusion criteria, potential patients were informed about the trial. Those who were willing to participate were asked to fill in a consent form and the baseline questionnaire. Patients returning these documents were randomized 1:1 by an independent secretary using the minimisation technique (21) and the SiMin software (22). To ensure comparable groups in terms of characteristics possibly 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. allocation included 20% randomness). Group assignment was evident to the patients and the case managers, but blinded to the researchers.

Analyses

Analysis of covariance (ANCOVA), which in effect adjusts each patient’s follow up score for his or her baseline score (23), was used to calculate the group difference on each of the HRQoL subscales at each time of follow up. Analyses were accompanied by graphical presentations of the groups’ mean scores stratified by the patients’ last consecutive questionnaire response. These longitudinal
Graphical presentations served two purposes: To provide an overview of all the data at the same time; and to suggest whether any data complexity might bias the statistical analyses (24).

The patient evaluation answers were dichotomised (‘Completely agree’ vs “the rest” and ‘Excellent’ plus ‘Very good’ vs “the rest”). The positive proportion of answers to each item was compared at each time of follow up using a generalised linear model (GLM) with log link for the Bernoulli family and robust variance; relative differences are presented as prevalence proportion ratios (PPRs) (25).

All analyses were conducted according to ‘intention-to-treat’ principle, i.e. patients were kept in the analyses regardless of their final diagnosis and exposure to CM (decided by duration treatment).

Non-response analyses using the minimisation variables and categories were performed to assess whether adjusted analyses should be conducted to eliminate potential attrition bias (26). Primary endpoints were tested for subgroup-treatment effect interaction as to cancer type, gender and age using same categories as used in the minimisation. Due to the multiple testing, effect measure modification should be present at minimally two time points to be accepted as indication of a subgroup-treatment effect (27).

Statistical significance was set to 0.05 or less (two-sided). All analyses were conducted with the use of Stata version 11.2.

**Ethics**

The project was ethically acceptable to both control group and intervention group patients because diagnostics and treatment were unaffected, and we did not know whether CM was superior to usual care. According to the Danish Act on Research Ethics, the Regional Ethical Committee should not be asked for approval. The Danish Data Protection Agency approved the research database (J.nr. 2008-41-2932). The RCT was indexed at www.clinicaltrials.gov (ID number: NCT00845247).
Results

Flow of participants

We assessed 532 patients for inclusion and included 280 patients. Figure 2 shows the reasons for non-participation and the group-wise flow of patients. Table 1 shows that the patients in the two groups were similar as to age, gender, disease characteristics and self-reported variables at baseline. The CM group had marginally higher mean baseline HRQoL scores than the control group, except for cognitive functioning.

Figure 2 shows similar response rates in the two groups at eight, 30 weeks and 52 weeks. Attrition occurred during the trial. 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 remaining patients’ characteristics (not shown). 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 (shown with asterisks in Table 3) but not HRQoL.

HRQoL

Table 2 presents the EORTC QLQ-C30 mean baseline and follow-up scores at each time of follow-up and the ANCOVA-calculated differences between the two groups. No statistically significant difference between groups appeared on any subscale at any time point.

Figure 3 offers a visual representation of the EORTC QLQ-C30 scale scores by group and over time. Seventy-one percent of all participants (103 control group patients and 95 CM patients) answered the baseline questionnaire and all answered the three follow-up questionnaires (complete follow-up; black markers and lines). Figure 3 shows that non-random drop-out applied to most scales, i.e. the non-responder group had statistically significantly lower scores at the assessment prior to non-response than the responder group. The mean scores of the two subgroups characterised by complete follow-up appear not to differ, and the profiles of the mean scores appear to change similarly over time. The partial follow-up profiles appear less uniform, but plots were based on a maximum of 20 responses per group.
Patient evaluation of care

Table 3 shows the dichotomised patient evaluations at week 8, 30 and 52. The two groups were almost identical as to numbers of ‘Don’t know/ Not applicable’ answers and skipped items so these ‘responses’ were omitted from analyses. The PPRs of 27 of 28 items favoured the CM group. Five, three and zero items differed statistically significant at week eight, 30, and 52, respectively.

We found no statistically significant subgroup-treatment effect interaction as to the global quality of life-scale or the patient evaluation items.

Discussion

Statement of principal findings

We found no effect of a manual-based CM intervention on patients’ global health status or their functioning as assessed from the EORTC QLQ-C30 questionnaire. Several patient evaluation items were answered statistically significantly more positively by CM patients than by the control group patients. The items regarding ‘the experience of being continuously followed by a doctor or a nurse’, and ‘confident about going home after surgery’ seemed, in particular, to be more positively evaluated by CM patients than by the control group. We found no statistical indication that any subgroup (gender, age, or cancer type) benefited differently from CM.

Strengths of the study

The principal strength of this study was the comprehensive, manual-based CM intervention performed in RCT design. A statement of the case managers’ activities from the CM records and a debriefing of the case managers indicated that the CM intervention was conducted according to the manual (28).

Another strength was the use of the EORTC QLQ-C30, which is the most used validated HRQoL instruments in CRC settings and available in Danish. EORTC QLQ-C30 focus domains relevant to most cancer patients and minimally clinically relevant cross-sectional contrasts have been proposed to guide interpretation of findings (19). In this study, all the confidence limits of the difference estimates were within +/-10 units. We are therefore convinced that we do not reject a clinically significant effect of CM.
**Weaknesses of the study**

Patient evaluations were assessed using ad hoc items which may be a potential weakness compared with instruments with established measurement properties and ‘benchmark scores’; still, the use of ad hoc items was deemed necessary because existing relevant measures were found to focus on either the inpatient or the outpatient setting and not on care across care interfaces.

This RCT was implemented with randomization at the patient level and with both patient groups being treated at the same department at the same time. We acknowledge that an intervention based on visibility and communication would have been more validly tested in a cluster-randomized trial with randomization performed at department or hospital level. Anyway, the success of a cluster randomized trial relies on its inclusion of several treatment units which was hindered by our budget (29). The two main limitations caused by the single unit set-up were: 1. Patient evaluations might have suffered from information bias because patients had information about the purpose of the trial and they were unblinded to group assignment. To reduce information bias caused by patients’ experience of ‘losing’ or ‘winning’ the randomization procedure, patients were neutrally informed about the purpose of the trial at recruitment. In addition, we believe patients over time ‘forgot’ about taking part in a randomized study for which reason the patient evaluations were unaffected by information bias. 2. The usual staff noticed ‘effective’ CM actions which they tried to ‘copy’ to improve control group patients’ care (spill-over effect). It is very unlikely that control group patients had ongoing support and supervision, because this would require organisational restructuring (e.g. revised work plans) or extra manpower, which did not take place.

A known problem when assessing patient-reported outcomes is missing data and, as for HRQoL-data, non-random dropout (24). Because death was the primary reason for missing data, dropout was found to be of the non-random type. Importantly, Figure 2 does not indicate that we have missed a positive effect of CM due to non-random drop-put.

Non-participants and participants differed in terms of cancer type and age. The group of CM participants counted statistically more rectal cancer patients than the usual care group and they were slightly, but statistically significantly older. The primary reason for this was that another
study included patients suffering from primary non-metastatic rectal cancer, whom we thus could not include.

The results can be generalised to a wider group of cancer patients, primarily for two reasons: 1) Interaction analyses indicated that no particular subgroup (gender, age or cancer type) benefited from CM, and 2) previous research has shown that patients suffering from different cancer types face identical psychosocial problems and health care system-related barriers (30,31).

Comparisons with other studies and meaning of the study
The present study found that although CM did not affect CRC patients’ HRQoL, it did improve their evaluation of care even if attrition over time reduced the power of the analyses. Improved patient evaluations have also been reported in other CM RCTs (32-34). That positive patient evaluations are consistent across trials despite the use of different measures is, indeed, important because patient ‘satisfaction’ may be seen as a quality criterion at par with ‘technical quality’ and objective outcomes (35). Evidence exists that CRC patients’ evaluations of care correlate positively with their HRQoL (8,9). Still, only few CM trials have assessed HRQoL (32,36,37), and evidence of clinically important impact of CM remains to be documented. Our study supports former research by indicating that CM alleviates neither the consequences of cancer symptoms and adverse treatment effects, nor the existential concerns relevant to patients’ HRQoL.

Unanswered questions and future research:
This CM study focused on patient-reported outcomes. CM may also be implemented to reduce the amount of ‘inappropriate’ health care services (duplicated services, unplanned readmissions and out-of-hours services) or if it enhances information transfer and professional collaboration around the patient. Yet, these issues remain to be explored.

Conclusions
In this RCT of CRC patients undergoing treatment, we found no impact of hospital-based CM on patients’ HRQoL at week eight, 30 or 52 after inclusion, but several patient evaluation items were statistically significantly improved by CM, and a tendency towards better patient evaluations in the CM group than in the usual care group was observed.
Acknowledgements

The authors wish to thank all patients and the staff at Surgical Department P, Aarhus University Hospital, Aarhus, Denmark and all the GPs who filled in the questionnaires. We also wish to thank IT-officer Hanne Beyer for creating research databases and statisticians Ineta Sokolowski and Morten Fenger-Grøn for discussions regarding the analyses. Thanks to Professor Frede Olesen for assistance developing and implementing the RCT.

This study was funded by the Danish Cancer Society, the Novo Nordic Foundation, the Danish Council for Independent Research - Medical Sciences, and the Quality and Continuing Training Council for GPs in the Central Denmark Region.

Contributors

CNW: guarantor of the paper, design of the study, handled the data and the statistical analysis, and drafted the manuscript. JS and PV: design of the study and drafted the manuscript. All authors read and approved the final manuscript.

Declaration of interest

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Data sharing statement

Participants’ filled in informed consent to participate, but not for data sharing outside the research team.

Copyright

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence on a worldwide basis to the BMJ Publishing Group Ltd to permit
this article (if accepted) to be published in BMJ editions and any other BMJPGL products and sublicences such use and exploit all subsidiary rights, as set out in the licence.
Consecutive colorectal cancer patients at Department P, Aarhus University Hospital were assessed according to 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 randomized.

<table>
<thead>
<tr>
<th>Time 0</th>
<th>CM GROUP*</th>
<th>CONTROL GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>a b</td>
<td>e</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 0-8</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 c d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRQoL and patient evaluation questionnaire</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 9-30</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 c d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRQoL and patient evaluation questionnaire</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 31-52</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 c d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 52</th>
</tr>
</thead>
<tbody>
<tr>
<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 letter 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 letter from the case manager to the GP and, if relevant, to other involved health care 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
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 ethic considerations (n=8)  
Did not want to participate (n=67)  
Missed (n=5)

THE CONTROL GROUP (n=140)

Allocation

THE CM GROUP (n=140)

Follow-Up

8 week questionnaire:
Dead: 6 (4% of included)
Sent to: 134 (96% of included)
Returned: 121 (90% of sent)

30 week questionnaire:
Dead: 17 (12% of included)
Sent to: 123 (88% of included)
Returned: 110 (89% of sent)

52 week questionnaire:
Dead: 20 (14% of included)
Withdraw*: 2 (1% of included)
Sent to: 118 (86% of included)
Returned: 109 (92% of sent)

HRQoL scales in analyses:
Baseline means: 135-139
Week 8 means and diff.: 116-119
Week 30 means and diff.: 101-104
Week 52 means and diff.: 96-99

HRQoL scales in plots:
Baseline, week 8, 30 and 52: 96-99
Baseline, week 8 and 30: 8-10
Baseline + week 8: 13-14
Baseline: 16-20

Patient evaluation items in analyses:
Week 8: 95-120
Week 30: 95-110
Week 52: 91-107

HRQoL scales in analyses:
Baseline means: 137-139
Week 8 means and diff.: 120-123
Week 30 means and diff.: 102-107
Week 52 means and diff.: 92-94

HRQoL scales in plots:
Baseline, week 8, 30 and 52: 92-94
Baseline, week 8 and 30: 12-16
Baseline + week 8: 17-20
Baseline: 10-13

Patient evaluation items in analyses:
Week 8: 99-123
Week 30: 93-109
Week 52: 81-98

Analysis boxes show the number of patients in calculations of scores/ proportions and in the analysis of differences (Tables 2 and 3) and the numbers of patients in the profiles (Figure 2). Diff.: differences

* Wish of withdrawal stated in previously returned questionnaire.
Table 1 Participants’ characteristics. Data are means (SD) or numbers (%).

<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></td>
<td></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 disease*</td>
<td>73 (52.1%)</td>
<td>74 (52.9%)</td>
</tr>
<tr>
<td>Negative self-rated health status prior to current disease*</td>
<td>8 (5.8%)</td>
<td>11 (8.0%)</td>
</tr>
<tr>
<td>Living in partnership 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>Without a job (senior citizen, unemployed etc.)*</td>
<td>90 (67.2%)</td>
<td>93 (67.9%)</td>
</tr>
<tr>
<td>EORTC QLQ-C30*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global quality of life</td>
<td>59.36 (25.54)</td>
<td>62.41 (22.96)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>80.96 (21.12)</td>
<td>83.39 (19.47)</td>
</tr>
<tr>
<td>Role functioning</td>
<td>67.78 (34.87)</td>
<td>69.71 (34.49)</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>71.88 (23.31)</td>
<td>72.56 (23.13)</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>86.47 (16.55)</td>
<td>85.27 (21.13)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>81.27 (24.95)</td>
<td>83.58 (22.51)</td>
</tr>
</tbody>
</table>

CM: case management
EORTC QLQ-C30: the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire version 3.0
* Eight patients were falsely thought to suffer from colorectal cancer at the time of inclusion.
* Reported by patients in the baseline questionnaire.
Table 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: 102-104</td>
<td>n-CM group: 92-94</td>
</tr>
<tr>
<td><strong>Global quality of life</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>61.02 (25.90)</td>
<td>64.90 (23.68)</td>
<td>65.73 (22.19)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>64.58 (22.04)</td>
<td>66.09 (21.02)</td>
<td>67.21 (21.07)</td>
</tr>
<tr>
<td><strong>Physical functioning</strong></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>Role functioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>70.26 (32.95)</td>
<td>73.10 (31.36)</td>
<td>74.48 (30.10)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>71.14 (33.61)</td>
<td>74.37 (31.22)</td>
<td>75.81 (31.04)</td>
</tr>
<tr>
<td><strong>Emotional functioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>73.00 (23.13)</td>
<td>74.87 (21.69)</td>
<td>75.62 (21.23)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>73.75 (22.43)</td>
<td>75.05 (20.65)</td>
<td>75.27 (20.68)</td>
</tr>
<tr>
<td><strong>Cognitive functioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td>87.11 (16.73)</td>
<td>88.46 (15.93)</td>
<td>89.06 (15.09)</td>
</tr>
<tr>
<td>CM GROUP</td>
<td>87.98 (18.34)</td>
<td>88.84 (16.38)</td>
<td>89.36 (15.81)</td>
</tr>
<tr>
<td><strong>Social functioning</strong></td>
<td></td>
<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>86.19 (20.21)</td>
<td>87.10 (20.43)</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
Figure 3 Average EORTC QLQ-C30 scale scores by group and by length of follow-up.

Hollow markers (○ □ △ ◊): Control group; Solid markers (● ■ ▲ ◊): CM group.

Black: Patients with baseline, 8, 30 and 52 week scale scores (n-Control: 96-99; n-CM: 92-94)
Red: Patients with baseline, 8 week and 30 week scale scores (n-Control: 8-10; n-CM: 12-16)
Blue: Patients with baseline and 8 week scale scores (n-Control: 13-14; n-CM: 17-20)
Green: Patients with baseline scale score only (n-Control: 16-20; n-CM: 10-13)

The figure shows scores for patients with monotone response patterns only (e.g. a patient with calculated scores at baseline, week 8 and 52 was included in the graph of patients followed until week 8).
**Table 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>
<th>PPR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual care N=121</td>
<td>CM N=124</td>
<td>Usual care N=110</td>
<td>CM N=111</td>
</tr>
<tr>
<td></td>
<td><strong>Very positive/less positive</strong></td>
<td><strong>PPR</strong></td>
<td><strong>Very positive/less positive</strong></td>
<td><strong>PPR</strong></td>
</tr>
<tr>
<td>Overall, the information was satisfactory</td>
<td>50 (0.43)/67 (0.57)</td>
<td>58 (0.48)/63 (0.52)</td>
<td>34 (0.33)/70 (0.67)</td>
<td>50 (0.47)/56 (0.53)</td>
</tr>
<tr>
<td>Doctors and nurses have overall been good at offering my family guidance, counselling, support and help.</td>
<td>35 (0.36)/63 (0.64)</td>
<td>40 (0.38)/64 (0.62)</td>
<td>28 (0.29)/67 (0.71)</td>
<td>33 (0.35)/60 (0.65)</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)/61 (0.53)</td>
<td>78 (0.63)/45 (0.37)</td>
<td>54 (0.50)/55 (0.50)</td>
<td>60 (0.57)/46 (0.43)</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>46 (0.43)/60 (0.57)</td>
<td>68 (0.65)/36 (0.35)</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>34 (0.35)/63 (0.65)</td>
<td>49 (0.49)/51 (0.51)</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>39 (0.38)/65 (0.62)</td>
<td>52 (0.50)/53 (0.50)</td>
</tr>
<tr>
<td>How do you assess the quality of your investigation and treatment at Department P so far?</td>
<td>89 (0.76)/28 (0.24)</td>
<td>105 (0.88)/15 (0.12)</td>
<td>89 (0.82)/19 (0.18)</td>
<td>96 (0.88)/13 (0.12)</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>77 (0.70)/33 (0.30)</td>
<td>85 (0.78)/24 (0.22)</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. * \(p \leq 0.05\) in adjusted analyses.
References


CHAPTER 14:

PAPER 4
The present paper was accepted for publication in the Oxford Family Practice on 11 July 2012. The manuscript differs slightly from the manuscript which the PhD thesis opponents reviewed. The principal differences between the reviewed manuscript and this manuscript are that the present manuscript: 1. more clearly describes the hypotheses behind this sub-study, 2. clearly states that this sub-study includes secondary endpoints from the trial which therefore were not used in the sample size calculation, and 3. better describes the elements of the intervention and the duration of the intervention. At last, the discussion section has been restructured and some paragraphs have been rephrased. Importantly, the sections regarding the analyses, the results and the interpretations of the findings have not been changed at all.
A randomized controlled trial of hospital-based case management in cancer care: A general practitioner perspective

Authors:
Christian N. Wulff, PhD Fellow, MD\textsuperscript{1,2}
Peter Vedsted, Professor, MD, PhD\textsuperscript{1}
Jens Søndergaard, Professor, Specialist in General Practice and Clinical Pharmacology, MD, PhD\textsuperscript{3}

\textsuperscript{1} The Research Unit for General Practice in Aarhus, Department of Public Health, Aarhus University, Aarhus, Denmark
\textsuperscript{2} Section for General Practice, Department of Public Health, Aarhus University, Aarhus, Denmark
\textsuperscript{3} The Research Unit for General Practice in Odense, Institute of Public Health, University of Southern Denmark, Odense, Denmark

Corresponding author:
Christian N. Wulff; e-mail: christian.wulff@alm.au.dk

Abstract word count: 247
Main text word count: 3092
Figures: 1
Tables: 4

Short running title: Is hospital-based case management helpful for GPs?
How this fits in

Case management (CM) programmes vary in terms of settings, targeted patients and core activities.

Most programmes are based on case managers who are experienced nurses engaged full-time to undertake coordination and support in relation to individual patients having complex health care needs.

Danish hospital departments treating cancer patients have been committed to deploy case managers to improve coordination and continuity of care. However, scientific evidence of the effect of CM in this context is scarce.

This paper reports the effects experienced by the general practitioners (GPs) of a randomized controlled trial of hospital-based CM for colorectal cancer patients. CM improved GPs’ evaluations of patient-specific information from the hospital staff, reduced GPs’ needs for contacting the hospital to obtain further information, but increased the number of patient contacts to the out-of-hours GP services.
Abstract

Background: Case management (CM) models based on experienced nurses are increasingly used to improve coordination and continuity of care for patients with complex health care needs. Anyway, little is known about the effects of hospital-based CM in cancer care.

Aim: To analyse the effects of hospital-based CM on: 1. GPs’ evaluation of information from the hospital and collaboration with the hospital staff; 2. patients’ contacts with GPs during daytime and out-of-hours.

Design: A randomized controlled trial allocated 280 colorectal cancer patients 1:1 to either a control group or CM intervention.

Setting: Patients were recruited at a Danish surgical department.

Methods: An ad hoc piloted questionnaire was sent to all patients’ GPs 30 weeks after patients’ recruitment and the responses from the two groups of GPs were compared. Registry data on patients’ contacts with general practice during daytime and out-of-hours were collected nine months after recruitment and the data from the two groups were compared quarterly.

Results: CM was associated with an overall tendency towards more positive GP evaluations, which for three of 20 items reached statistical significance. Statistically significantly fewer GPs of CM patients reported contacting the hospital. CM did not affect the number of patient contacts with the GPs during the daytime, but CM patients showed a tendency towards more contacts to the out-of-hours GP services than non-CM patients.
Conclusions: CM was appreciated by the GPs and reduced their need for subsequent hospital contact. CM increased the number of patient contacts to the out-of-hours GP services.

Keywords: Case Management; Cancer care/ Oncology; continuity of care; Multidisciplinary Care, Primary Care, Quality of Care
Introduction

In the year following a cancer diagnosis, the patient has on average ten contacts to the general practitioner (GP) of which roughly half are related to the cancer (1). Delayed and inadequate information transfer and inadequate communication between hospitals and GPs are common and result in suboptimal GP consultations (1-3) and, possibly, has an adverse effect on patient care (4,5). Research has found that cancer patients are less likely to receive the recommended care for chronic conditions and sufficient preventive care than age-matched non-cancer patients (6), which may be so because their confidence in their GPs’ competencies has declined in the course of their treatment in the secondary healthcare sector (7,8).

Case management (CM) is often advocated as a method that may improve coordination and continuity of care for patients having complex care needs. Although CM models diverge as to their setting, intervention content and outcomes studied, almost all models are based on similar principles and definitions (9). CM is generally conducted by nurses trained to work as case managers. Within cancer care, one proposed model is based on case managers situated in the hospitals, who are members of the multidisciplinary team (MDT), full-time dedicated to take on the following tasks: care pathway surveillance; to make outreach telephone calls to patients to pro-actively identify and tackle barriers for optimal care and well-being; to transfer medical and non-medical patient-specific information to relevant health professionals; and to take on the role as easily accessible hospital-based health professionals (10,11).

In Denmark, it was recently statutorily decided that hospitals are to engage case managers to improve the care pathways for patients suffering from cancer or heart disease (12). Anyway, little
is known about the effects of hospital-based CM in cancer care (9) and especially the implications for general practice are unknown.

In 2009-2011, we conducted a randomised controlled trial (RCT) of hospital-based CM for patients suffering from colorectal cancer (CRC). The questions relevant for primary care were: 1. Did the enhanced information to the GPs improve the GPs’ evaluations of intersectoral collaboration and information received from the hospital?, 2. Would CM pave the way for the patients to the GPs?, and 3. Would the outreach telephone contacts and the easy access to the hospital-based case manager reduce patients’ use of the out-of-hours GP services?

**Methods**

**Design**

An RCT allocating CRC patients to either the control group or the CM intervention group.

**Setting**

The Danish healthcare system is tax-financed with free access to GPs, out of-hours GP services and public hospitals. Ninety-eight per cent of all Danes are listed with a local general practice, and the GP acts as gatekeeper to the rest of the healthcare system (13). The GPs in turn (rota-system) undertake the out-of-hours GP services.

The setting of this RCT was Surgical Department P, Aarhus University Hospital, Denmark. The surgeons at the Department perform surgery for all stages of CRC, and patients suffering from recurrent and/or locally advanced CRC are referred to the Department from all parts of Denmark.
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’ who were to undergo further investigation or treatment at Department P. Exclusion criteria were participation in another study (see Discussion), poor Danish language skills or apparent cognitive dysfunction.

Control – Usual care

Control group patients received usual treatment and care. As statutorily prescribed for patients treated in hospitals, patients were informed that a named health professional at Department P would function as their ‘contact person’ during diagnostics and treatment (14). As usual, when a patient was diagnosed with cancer, the hospital informed the GP about the diagnosis by means of a brief electronic ambulatory note, whereas more detailed information about stage of the cancer, its treatment, etc. was communicated via electronic discharge summaries sent after surgery and after oncological treatment.

Intervention – Case management

The manual-based CM intervention was conducted as a supplement to usual treatment and care by two experienced and specially trained nurses, the case managers, working at Department P and being members of the MDT. The case managers undertook needs assessment at initiation of CM and at any transition in care setting where Department P was involved; a one page needs assessment checklist, which had been developed based on available instruments, was used. As long as Department was primarily responsible for the patient’s care, the case manager telephoned
the patient to systematically assess and facilitate the patient’s bio-psycho-social well-being and ensure that the patient was duly informed about the diagnosis, treatment plans, etc. These outreach contacts took place at least every fortnight and continued until four weeks after the patient had completed CRC treatment.

Important CM tasks were to keep the GP informed about the patient’s medical and non-medical status and, if needs within the GP’s remit were identified, to encourage the patient to take contact to the GP. An electronic summary message was sent to the GP after the case manager’s initial meeting with the patient and in relation to every transition in care setting where Department P was involved. The information in the summary messages was supplementary to the information sent by the hospital surgeons (see ‘Usual care’) and summarised three elements: problems and needs identified plus initiated and proposed initiatives, planned health care, and the patient’s knowledge about his or her situation. All summary messages included detailed information about the CM service and contact details.

For most patients, the initial meeting and the needs assessment took place before therapy was planned. The amount of active CM was decided by the length of the care pathway which was decided by the treatment offer. There was no formal time at which patients could no longer exercise their option to contact the case manager. As a consequence, the case manager had on average 9.7 face-to-face or telephone contacts with each patient and/or the carers (median: 8, IQR: 5-13), corresponding to an average of 170 minutes of contact (median: 130; IQR: 85-215). The case manager sent each GP 2.3 summary messages on average (median: 2; IQR: 2-3).
Sample size

The primary outcomes of the RCT which were used for the sample size calculations were patient-reported health-related quality of life and eight patient evaluation items (published elsewhere). The calculation based on the global health status subscale of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 indicated a need to minimally include 140 patients in each group (1:1 allocation, 90% power, two-sided significance level of 5%, a minimum relevant clinical difference = 10 units, and 15% drop-out).

Recruitment, randomisation and blinding

The two nurses engaged as case managers undertook recruitment in turn. Eligible patients were approached at their first visit to the Department after CRC was diagnosed or according to a surgeon was ‘highly probable’. Patients returning the consent form and the baseline questionnaire were randomized by an independent secretary using the minimisation technique (15) and the SiMin software (16). To ensure comparable groups in terms of characteristics possibly 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. allocation included 20% randomness).

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 health care professionals at Department P about which patients were allocated to CM. The GPs were not informed about that their patients took part in a trial. The cover letter of the GP questionnaire (see below) informed that the patient had approved that a questionnaire was sent to the GP.
Outcome measures

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 (Table 2), and deficiencies in patient-specific information (Table 3). 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 the contact(s).

The questionnaire including a pre-stamped envelope was posted 30 weeks after the patient’s recruitment, if necessary with a reminder including a new questionnaire three weeks later. The GP was paid a consultation fee for answering the questionnaire.

Data on the patients’ contacts with their GPs and out-of-hours GP services in the time span from three months before to nine months after the day of inclusion were collected through the Danish National Health Service Register (13). The following 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.

Analyses

The GPs’ answers to individual items were dichotomized and 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 (PPRs) (17).
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 (270 days) were analysed using two methods: 1) Number of contacts were compared using a negative binomial regression model which handles the dependent structure of contacts at the individual level (18); 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 (17), and differences are presented as PPRs.

All statistical analyses were conducted according to intention-to-treat using Stata version 11.2 (Stata Corporation, Texas, US). Statistical significance was set to 0.05 or less (two-sided).

**Ethics**

The Danish Data Protection Agency approved the creation of a research database and the RCT was indexed at www.clinicaltrials.gov with registration ID number NCT00845247. According to the Danish Research Ethics Committee System (19), the trial was not a biomedical intervention and did not need the ethics committee’s approval.

**Results**

The a priori sample size of 280 patients was included. Reasons for non-participation and the numbers of patients included in the analyses appear from Figure 1. Table 1 shows that the two groups were comparable at baseline.

**GPs’ evaluations:** In both groups, 114 (81%) GPs returned a completed questionnaire. Tables 2 and 3 show that use of CM was associated with an overall tendency towards more ‘positive’ GP
evaluations, which for three of 20 questionnaire items reached statistical significance. Table 3 also shows a post hoc summary measure of the seven items on information deficiencies. Fewer CM GPs than non-CM GPs had missed any type of patient-specific information from the hospital. Fewer CM GPs than non-CM GPs reported having contacted the hospital regarding their patients’ care (PPR = 0.41; 95% CI: 0.22 to 0.80; p=0.008), but no differences were observed for the two items addressing the ‘quality’ of the contacts (data not presented).

Patient contacts with the GPs and the out-of-hours GP services: Table 4 shows that no differences were observed between the groups as to daytime GP contacts. Both types of analyses of out-of-hours GP contacts indicated more contacts among CM patients than among non-CM patients. In the total follow-up period, the ratio of proportions of at least one contact with the out-of-hours services was 1.49 (95% CI: 1.07 to 2.07; p=0.019). The corresponding result in the period from day 181 and 270 was 2.34 (95% CI: 1.16 to 4.71; p=0.018).

Exploratory subgroup-treatment effect interaction analyses (20) were conducted to investigate whether certain patient characteristics (the variables and categories from the minimisation) were particularly associated with increased contacts to the out-of-hours GP services in the entire follow-up period. None of these analyses reached statistical significance.

Discussions

Summary: 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. Statistically significantly fewer GPs in the CM group than in the non-CM group reported contacting the hospital.

We found no difference between the two groups in terms of number of patient contacts with the GPs. Paradoxically, the CM group showed a tendency towards more contacts to the out-of-hours GP services than the non-CM group.

**Strengths and limitations:** Importantly, the CM activities took place as described in the manual. It was a strength that the choice of cancer type lends itself particularly well to study the effectiveness of CM for three reasons: First, multiple departments and specialists are often involved in CRC patients’ treatment. Second, the typical CRC patient is 71 years old and suffers from multimorbidity which may complicate treatment and heighten demands for coordination of care (21). Third, colon and rectal cancer patients are facing comparable problems and needs in terms of psychosocial support and general information (22,23).

It was a major strength that information regarding GP contacts was obtained from the Danish National Health Service Register whose data completeness is assumed to be very high because GPs’ reimbursement is connected with notification to this system (13). Thus, despite the relatively poor statistical strength of the contact analyses, we argue that the tendency of increased patient contacts to the out-of-hours services is an important finding.

The use of an ad hoc developed GP questionnaire was necessary because no existing, validated instrument suited our purposes.

All analyses presented in this paper were planned a priori but the sample size calculations of the RCT were based on the primary outcomes of the RCT, the patient-reported outcomes. As a
consequence, many of the presented analyses suffer from low statistical precision and wide CIs. Moreover, the general use of \( p \leq 0.05 \) as the level of statistical significance could be questioned as multiple comparisons are presented; importantly, even if we had adjusted the p-values to counteract the problem of type one error we would still have reported the tendencies summarised above.

**Generalizability:** Non-participants and participants differed statistically significantly in terms of cancer type and age. Among non-participants, 210 of 252 (83%) suffered from rectal cancer versus 130 of 280 (46%) among participants (chi2 \( p < 0.001 \)). The mean age of the non-participants was 68.6 (12.40) years versus 66.3 (11.4) years for the participants (Students t-test \( p = 0.026 \)). The primary reason for these differences was that another research project had recruited most patients suffering from primary non-metastatic rectal cancer, which we were therefore not allowed to include in the present RCT. Importantly, the described communication problems between specialists and GPs probably apply to cancer patients in general, for which reason the above differences do not limit the generalizability of the GP evaluations. Further, we have no reason to believe that the reasons for contacting daytime GPs and out-of-hours GP services should differ between colon cancer patients and rectal cancer patients.

**Comparison with existing literature:** In relation to cancer care, we have found one RCT testing a CM-like intervention which compared GPs’ ‘satisfaction with care’, but no difference between groups was reported (24). To our knowledge no previous CM trial has analysed cancer patients’ use of their GP or out-of-hours GP services, but three CM-like trials have analysed readmission rates and lengths of hospitalisation without reporting any differences between groups (24-26).
'Shared care' is a concept closely related to CM. Generally, shared care is about sharing the responsibility and coordination of care between two or more health care providers in different settings or locations with the use of existing resources (27). A Danish RCT of shared care between an oncology department and GPs which was based on enhanced discharge letters, clearly stated communication channels and patient empowerment found statistically significantly higher GP evaluations of the information in the discharge letter and of the intersectoral cooperation (28). 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 patients’ need for support (29).

*Implications for practice and research:* The tendency of improved GP-experienced information in the CM group was anticipated, but an important finding. The finding that fewer GPs reported contacting the hospital may be caused by a reduced need owing to the enhanced information transfer. Contrary to our hypothesis, the CM patients did not pay more visits to their GPs than control group patients. The reasons may be that the patients either did not have the need, that the CM-intervention did not pave the way for the patients to the GPs’ offices, or that it did, in fact, change the patients’ reasons for contacting the GPs. Thus, the number of GP contacts for psychosocial and information reasons may have been reduced, whereas contacts for chronic care conditions and initiation of rehabilitation may have increased; but the differences evened out as to the total number of contacts. Noteworthy, CM patients did not see their GPs less and the post-recruitment IR of daytime GP contacts were almost 15 in both groups; a finding that underpins the GP’s ‘key worker’ position with regard to care of comorbidities, prescriptions, work exemptions
etc. Paradoxically, we saw a higher number of out-of-hours GP contacts among CM patients than among controls. The mechanism might be that CM made patients more aware of symptoms and feelings which they immediately wanted to report to health professionals. Patients’ reasons for contacting the out-of-hours GP services are not yet compulsorily coded, but, if they had been registered, this could possibly have helped explain the findings. In addition, interviews with the patients could have explored whether CM influenced patients’ coping strategies and their preferences for contacting health professionals.

In conclusion, it is possible for hospital-based case managers to improve GP evaluations of the information from the hospital (28,29). Improved GP evaluations could possibly be achieved by other, cheaper methods than CM, e.g. by changing specialists’ attitudes to the importance of smooth knowledge transfer and collaboration. If hospital-based CM is to be routinely implemented, derived consequences such as its apparent tendency to increase patient contacts to the out-of-hours GP services should be further investigated.

**List of abbreviations**

CI: confidence interval

CM: case management

GLM: generalised linear model

GP: general practitioner

IQR: interquartile range

PPR: prevalence proportion ratio

RCT: randomized controlled trial
Declaration

Funding: This study was supported by the Danish Cancer Society, the Novo Nordisk Foundation, the Danish Council for Independent Research - Medical Sciences, and the Quality and Continuing Training Council for GPs in the Central Denmark Region.

Ethical approval: None required, see Ethics section for further information.

Conflict of interest: The authors declare that they have no competing interests.

Acknowledgements

The authors wish to thank all patients and staff at Surgical Department P, Aarhus University Hospital, Aarhus, Denmark and all the GPs who filled in the questionnaires. We also wish to thank Information Officer Hanne Beyer for creating research databases and Statistician Morten Fenger-Grøn for fruitful lectures and discussions regarding the analyses.
Patients with a diagnosis or a ‘highly-probable diagnosis’ of colorectal cancer at Department P (March 11 2009 – December 29 2010) N= 532

Exclusion criteria assessment and information about the project

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 ethic considerations (n=8)
- Did not want to participate (n=67)
- Missed (n=5)

Patient consent, baseline questionnaire and randomisation

THE CONTROL GROUP (n=140)

Use of GP services:
- Alive at Day 90: n=134 (96%)
- Alive at Day 180: n=126 (90%)
- Alive at Day 270: n=123 (88%)

30 week GP questionnaire:
- Sent to: 140 (100% of included)
- Returned: 116 (83% of sent)
- Not filled in: 2
- Completed: 114 (81% of sent)

THE CM GROUP (n=140)

Use of GP services:
- Alive at Day 90: n=130 (93%)
- Alive at Day 180: n=124 (89%)
- Alive at Day 270: n=116 (83%)

30 week GP questionnaire:
- Sent to: 140 (100% of included)
- Returned: 116 (83% of sent)
- Not filled in: 2
- Completed: 114 (81% of sent)

GP: general practitioner
CM: case management
### Table 1. Characteristics of patients in the control group and the case management intervention group (CM group). Data are numbers (%) if not otherwise stated.

<table>
<thead>
<tr>
<th></th>
<th>Control group (N=140)</th>
<th>CM group (N=140)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD)</strong></td>
<td>66.2 (11.7)</td>
<td>66.3 (11.1)</td>
</tr>
<tr>
<td><strong>Gender</strong></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><strong>Disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>72 (51.4%)</td>
<td>70 (50.0%)</td>
</tr>
<tr>
<td>Recurrent</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Rectal cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>64 (45.7%)</td>
<td>66 (47.1%)</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><strong>Surgery</strong></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><strong>One or more chronic disease</strong></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>
</tbody>
</table>

* Information found in medical records and hospital registers

* Eight patients were falsely thought to suffer from colorectal cancer at the time of inclusion

* Reported by patients in the baseline questionnaire
Table 2. GPs’ evaluation of aspects related to their patients’ care pathways.

Items were answered using the following response options: ‘Strongly agree’, ‘Agree’, ‘Disagree’, ‘Strongly disagree’ and ‘Don’t know/N.A.’. Figure refer to the number of GPs (%) who agreed the item (‘Strongly agree’ and ‘Agree’). ‘Don’t know /N.A.’ and missing answers omitted. A prevalence proportion ratio >1 indicates that more GPs of CM patients agreed the item.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Item</th>
<th>Control group (n=114)</th>
<th>CM group (n=114)</th>
<th>Prevalence proportion ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP’s evaluation of the patient-specific information from the hospital to general practice</td>
<td>I received information about the patient with convenient frequency. All in all, the information in discharge summaries, ambulant notes, etc. was sufficient. The information has helped me to manage better the patient’s...</td>
<td>106 (93.81)</td>
<td>106 (92.98)</td>
<td>0.99 (0.92-1.06)</td>
</tr>
<tr>
<td></td>
<td>... physical effects of the cancer illness.</td>
<td>79 (82.29)</td>
<td>89 (90.82)</td>
<td>1.10 (0.99-1.23)</td>
</tr>
<tr>
<td></td>
<td>... psychological effects of the cancer illness.</td>
<td>62 (65.26)</td>
<td>82 (85.42)</td>
<td>1.31 (1.11-1.55)*</td>
</tr>
<tr>
<td></td>
<td>... social effects of the cancer illness.</td>
<td>51 (63.75)</td>
<td>60 (78.95)</td>
<td>1.24 (1.01-1.52)**</td>
</tr>
<tr>
<td></td>
<td>... non-cancer-related conditions.</td>
<td>69 (75.82)</td>
<td>71 (83.53)</td>
<td>1.10 (0.95-1.28)</td>
</tr>
<tr>
<td>GP’s evaluation of the course of treatment</td>
<td>I consider that the hospital has taken proper care to the patient’s non-cancer-related conditions (e.g. social conditions, comorbidity, personality etc.).</td>
<td>68 (80.00)</td>
<td>74 (90.24)</td>
<td>1.13 (0.99-1.28)</td>
</tr>
<tr>
<td></td>
<td>I find the cooperation between general practice and hospital has been satisfactory.</td>
<td>102 (91.17)</td>
<td>101 (90.99)</td>
<td>1.00 (0.92-1.09)</td>
</tr>
<tr>
<td></td>
<td>I consider that the patient up till now has gone through a well-coordinated care pathway.</td>
<td>93 (85.32)</td>
<td>91 (91.67)</td>
<td>1.07 (0.98-1.18)</td>
</tr>
<tr>
<td></td>
<td>I consider that relevant rehabilitation has been started.</td>
<td>53 (84.13)</td>
<td>62 (88.57)</td>
<td>1.05 (0.92-1.21)</td>
</tr>
<tr>
<td></td>
<td>I consider that I has been properly involved in the decision making concerning the hospital’s planned treatment and rehabilitation steps.</td>
<td>95 (88.79)</td>
<td>93 (91.18)</td>
<td>1.03 (0.94-1.12)</td>
</tr>
</tbody>
</table>

Cl: confidence interval, CM: case management
*p=0.002, **p=0.039
* rephrased because the item was negatively worded in the questionnaire.
Table 3. GPs’ evaluation of deficiencies in the patient-specific information.

Items were answered using the following response options: ‘To a large extent’, ‘To some extent’, ‘To a small extent’, ‘Not at all’, and ‘Don’t know/N.A.’. Figure refer to the number of GPs (%) who agreed the item (‘To a great extent’ and ‘To some extent’). ‘Don’t know /N.A.’ and missing answers were omitted. A prevalence proportion ratio < 1 indicates that less GPs of CM patients agreed the item.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Item</th>
<th>Control group (n=114)</th>
<th>CM group (n=114)</th>
<th>Prevalence Proportion Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP’s evaluation of deficiencies in the patient-specific information</td>
<td>I have missed information from the hospital about ...</td>
<td>15 (13.16)</td>
<td>11 (10.19)</td>
<td>0.77 (0.37-1.61)</td>
</tr>
<tr>
<td></td>
<td>... the intended course of treatment.</td>
<td>22 (19.47)</td>
<td>17 (17.43)</td>
<td>0.90 (0.51-1.56)</td>
</tr>
<tr>
<td></td>
<td>... where the patient was in the course of treatment.</td>
<td>13 (12.87)</td>
<td>17 (17.89)</td>
<td>1.39 (0.71-2.71)</td>
</tr>
<tr>
<td></td>
<td>... changes in the prescribed medicine to the patient.</td>
<td>36 (32.14)</td>
<td>20 (19.61)</td>
<td>0.61 (0.38-0.98)*</td>
</tr>
<tr>
<td></td>
<td>... information given to the patient by the specialists.</td>
<td>31 (29.52)</td>
<td>19 (18.61)</td>
<td>0.68 (0.41-1.12)</td>
</tr>
<tr>
<td></td>
<td>... the patient’s identified problems and needs.</td>
<td>34 (34.34)</td>
<td>25 (26.88)</td>
<td>0.78 (0.51-1.21)</td>
</tr>
<tr>
<td></td>
<td>... suggested initiatives for general practice to implement.</td>
<td>30 (29.13)</td>
<td>17 (17.35)</td>
<td>0.60 (0.35-1.01)</td>
</tr>
<tr>
<td></td>
<td>... the hospital’s expectations to who should attend to and coordinate the different parts of treatment and rehabilitation.</td>
<td>67 (58.77)</td>
<td>49 (44.95)</td>
<td>0.76 (0.59-0.99)**</td>
</tr>
</tbody>
</table>

CI: confidence interval, CM: case management
* post hoc summary measure of the seven items.
*p=0.042, **p=0.043
Table 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-recruitment</td>
<td>4.99 (4.31 to 5.79)</td>
<td>5.12 (4.42 to 5.94)</td>
<td>1.03 (0.83 to 1.26) p=0.812</td>
<td>0.91 (0.86 to 0.95) 0.86 (0.80 to 0.92) 0.95 (0.87 to 1.03) p=0.185</td>
</tr>
<tr>
<td>1-90 days post inclusion</td>
<td>5.26 (4.52 to 6.13)</td>
<td>5.23 (4.49 to 6.09)</td>
<td>0.99 (0.80 to 1.23) p=0.949</td>
<td>0.90 (0.84 to 0.94) 0.85 (0.78 to 0.90) 0.94 (0.86 to 1.03) p=0.208</td>
</tr>
<tr>
<td>91-180 days post inclusion</td>
<td>5.08 (4.29 to 6.01)</td>
<td>4.76 (4.01 to 5.66)</td>
<td>0.94 (0.74 to 1.19) p=0.602</td>
<td>0.86 (0.79 to 0.91) 0.85 (0.77 to 0.90) 0.99 (0.89 to 1.09) p=0.783</td>
</tr>
<tr>
<td>181-270 days post inclusion</td>
<td>4.14 (3.43 to 4.99)</td>
<td>4.42 (3.67 to 5.33)</td>
<td>1.07 (0.82 to 1.39) p=0.624</td>
<td>0.83 (0.76 to 0.89) 0.87 (0.80 to 0.92) 1.05 (0.94 to 1.16) p=0.403</td>
</tr>
<tr>
<td>1-270 days post inclusion</td>
<td>14.61 (12.82 to 16.66)</td>
<td>14.76 (12.94 to 16.84)</td>
<td>1.01 (0.84 to 1.22) p=0.914</td>
<td>0.99 (0.95 to 1.00) 0.96 (0.92 to 0.99) 0.98 (0.94 to 1.02) 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-recruitment</td>
<td>0.31 (0.20 to 0.48)</td>
<td>0.31 (0.20 to 0.49)</td>
<td>1.02 (0.55 to 1.91) p=0.943</td>
<td>0.19 (0.13 to 0.27) 0.17 (0.11 to 0.24) 0.89 (0.54 to 1.46) p=0.643</td>
</tr>
<tr>
<td>1-90 days post inclusion</td>
<td>0.24 (0.15 to 0.37)</td>
<td>0.40 (0.27 to 0.60)</td>
<td>1.69 (0.91 to 3.14) p=0.094</td>
<td>0.14 (0.09 to 0.21) 0.24 (0.17 to 0.31) 1.65 (1.00 to 2.73) p=0.052</td>
</tr>
<tr>
<td>91-180 days post inclusion</td>
<td>0.39 (0.23 to 0.64)</td>
<td>0.42 (0.25 to 0.72)</td>
<td>1.08 (0.52 to 2.25) p=0.832</td>
<td>0.15 (0.09 to 0.22) 0.22 (0.15 to 0.30) 1.49 (0.89 to 2.51) p=0.128</td>
</tr>
<tr>
<td>181-270 days post inclusion</td>
<td>0.18 (0.09 to 0.37)</td>
<td>0.40 (0.22 to 0.73)</td>
<td>2.24 (0.87 to 5.75) p=0.094</td>
<td>0.08 (0.04 to 0.14) 0.19 (0.12 to 0.27) 2.34 (1.16 to 4.71) p=0.018</td>
</tr>
<tr>
<td>1-270 days post inclusion</td>
<td>0.83 (0.57 to 1.20)</td>
<td>1.29 (0.90 to 1.85)</td>
<td>1.56 (0.93 to 2.61) p=0.093</td>
<td>0.28 (0.21 to 0.36) 0.41 (0.33 to 0.50) 1.49 (1.07 to 2.07) p=0.019</td>
</tr>
</tbody>
</table>

CM: case management, IRR: incidence rate ratio
*Incidence rates (adjusted for different length of follow-up) and IRRs calculated using a negative binomial regression model.
* Proportions of patients alive at the beginning of the period.
The 95%- confidence intervals of all estimates are shown in brackets.
An IRR or a proportion ratio >1 indicates more contacts among CM patients.
References


(7) Mikkelsen TH, Soendergaard J, Jensen AB, Olesen F. Cancer surviving patients' rehabilitation - understanding failure through application of theoretical perspectives from Habermas. BMC Health Serv Res 2008 Jun;8:122.


APPENDIX A:

THE CM MANUAL

(including material used at recruitment)
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.: Behovsafdækkende 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 inclusion + inklusionsprocedure ...................................... 18
        Samtykkeerklæring ............................................................................................ 21
        PILOTPROJEKT SAMTYKKEERKLÆRING: .................................................. 22
    BILAG C: Brevkabeloner ......................................................................................... 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 ............................................................................................................................. 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 indholdsmæssigt 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-teknologiske rammer, at sikre høj kvalitet\(^1\) af individuelle komplekse patientforløb [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 sundhedsydelse:

> “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 aktiviteterne 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, patientønsker 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 formidle 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 kræftpakkernes succes. Om forløbskoordinator-funktionen fremgår: ”(denne).….kan defineres på forskellige måder…..”, ”blæksprutefunktion”. Endvidere fremgår at funktionen skal varetage bookerrolle og en monitorerende rolle. Sist 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 sammenligneffektmål for patienter, der er tilkøbte 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 ubørørt.

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 forløbskoordinerings en kompleks intervention [12], hvilket medfører betydelig mulighed for "black box".

"Black box" udgør et betydeligt problem med hensyn til interventionens reproducbarhed 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.

---

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 der, 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 inclusion 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:

---

* Ved inclusion: Mens patienten udøver samtyske og spørgeskema, ringes til sekretær på Forskningsenheden for Almen Praksis (89426010), som foretager 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.

![Diagram](image-url)
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 pårorende 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 prædikterer for gode patientforløb:

Sandoval et al [39] fandt i en større spørgeskemaundersøgelse af tilfredsheden med følgende fem områder prædikterede høj overall tilfredshede med "in-patient care": "skills of nursing staff", ‘courtesy of nursing staff’, ‘courtesy of people who drew blood’ and ‘cleanliness of hospital in general’…"

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 skel et til interventioner, der har vist sig effektive med hensyn til at optimere patientoplevelse behandlingsforløb.

Derimod har forskellige CM definitioner og den (vores) publicerede oversigtsartikel om CM benyttet ved cancersygdom kun givet sparsom grundlag for udvikling af ideel forløbskoordinator-intervention.

 interventionen udviklet med udgangspunkt i patientrapporterede uhensigtsmæssigheder og prædiktorer for gode forløb.

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 tilrettelæggelse af effektiv pleje og behandling.

Der er evidens for patienttilfredshed med behandlingsforløbet påvirkes positivt, når personalet er opmærksomt på patientens psykosociale problemer og behov samt giver patienten mulighed for at diskutere følelser omkring diagnose og behandling.

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 patientoplevde 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 problem løsning.

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 helbredstatus (og relaterede problemer), og b) Problemer/ behov relateret til ”selve patientforløbet”(denne opdeling er inspireret af [32,43,47]).

3 Der er sammenhæng mellem grad af patienttilfredshed og concordans og compliance, livskvalitet, psykologiske belastninger samt klinisk sygdomsforløb (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, kontaktmåde, problem, tiltag og opfølgningsplan (samt kode for forløbskoordinatorhandling) 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 - diagnosticer overlades til læger.

**Ad 2.: Forløbovervågning**

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 forløbovervågning (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. Forløbskoordinator’s deltagelse sikrer, at der tages højde for patientpåfører 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.

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

Forløbskoordinators forudsætninger, for at kunne deltagte 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 interventioner at forbedre livskvalitet i moderat grad (effekten er bedre relateret til varighed end type intervention) [54].

Kommunikationsstrænning
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].

Omvendt 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 interventioner 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 afstemp patientønske.

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

Ad 4. og 5.: Sammenhæng i behandlingsforløb
Som anført tidligere oplever patienterne kontiunitetsproblemer, 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, udover "appropriate medication". Dog vurderedes kvaliteten af hovedparten af de 20 inkluderede studier at være suboptimal. 19 af 20 inkluderede Studier analyserede komplekse/ multifaceterede interventioner, 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 sundhedstillstand, psykisk sundhedstillstand, 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]

Shared care og case management har nogenlunde ens formål og problemstillinger, henholdsvis optimeret behandling og ressourcebrug [68] og vedrørende evalueringen betydelige kvalitetsmangler forårsaget af uensartet brug af analysemetoder/-redskaber og "black box" problematik.

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). Afhængigt af behov kontaktes hjemmepleje, 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).

Ad 6.: Kontaktperson / nøgleperson

På trods af lovkrav om at patienter tilbydes en kontaktperson, efterlyses en kompetent ”kontaktperson” af patienter [29,32]. Samtidig efterspørger særligt de praktiserende 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 befojelser 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%) beskæftigt med koordinering og optimering af individuelle patientforløb.

---

6 Projektet går ikke ud på at forbedre kvaliteten af læge-udskrivningsbreve, men understøtter informationen i disse.
Sikring af forløbskoordinatorers kompetencer

Forløbskoordinatorers sikres forståelse af deres arbejdsområde 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, selvhjælpssteknikker 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 føl hos lægerne 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 lægesamtaler i afdelingen, men tilbyder ikke ud-af-huset kontakter (hjemmebesøg, ledagelse på onkologisk afd. o.l.).

Møder og telefoniske kontakter gennemføres i henhold til manuualens afsnit ”Beskrivelse relateret 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 lægesamtale, 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.

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 SUP). 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:

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 brevskabeloner 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 samtale 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**
Forløbskoordinator og patient mødes som minimum på indlæggelsens 1. dag og forud for udskrivelse.
Forløbskoordinator skal proaktivt forud for udskrivelse kontakte patienten, så de sammen kan identificere evt problemer og søge en løsning på disse.
Det vurderes løbende om forløbskoordinator skal deltage i samtaler med læge eller andre behandlere.
Det er forløbskoordinators opgave at facilitere kontakt mellem patient, pårørende og relevante professionelle ressourcepersoner.

**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.

Forløbskoordinator kontakter telefonisk patienten cirka en gang ugentligt mhp opfølgning på igangsatte handlinger samt opsporing af evt uhensigtsmæssigheder (=individuel, proaktiv tilgang).
Evt yderligere personlig og/eller telefonisk opfølgning sker på baggrund af individuel vurdering.

**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 forsatt mulighed for at kontakte forløbskoordinator.
Den reaktive, lovbemærkede "kontaktpersons-ordningen" er der ingen formel afslutning på.

**BILAG B**

**BILAG A: Funktionsbeskrivelse for forløbskoordinator (v. 050908)**

**Stillingsbetegnelse:** Projektstigeplejerske - 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 hensigtmæssige 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 (korriger 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.

Arbejdsgiverne løses gennem planlagte og ad hoc møder i afdeling P mellem patient og forløbskoordinator samt telefoniske kontakter foranledigt 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 samarbejdslag.
Sygeplejersken skal besidde gode kommunikative evner.

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

INKLUSIONSPROCEDURE

Tidligst muligt efter sandsynlighed for diagnosen colorectal-cancer er sandsynlig, afklarer Afdeling P’s forskningspersonale om patienten kan 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-metastasereende c. recti.

Således ønsker vi, at afdelingerne hjælper med at screene patienter:
Afdelingernes 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 inclusion kontaktes forløbskoordinator mhp den videre inklusionsprocedure. NB: Vi ønsker at tilkoble forløbskoordinator 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

Dato for vurdering: Udfyldt af:

Eksklusion?

<table>
<thead>
<tr>
<th></th>
<th>Ja</th>
<th>Nej</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Demens</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Manglende evner til at læse og besvare spørgeskemaer (fx udlænding, svær psykisk lidelse, retardation mv). Anfør:________________________</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Patienten er inkluderet i/ er sandsynlig kandidat til Katrine Emmertsens projekt (primære, ikke-metastaserende c. recti)</td>
<td></td>
</tr>
</tbody>
</table>

• 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>I</td>
<td>Mundtlig information om projektet + udfyldt samtykkeerklæring</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Baselinespørgeskema udleveres, anfør løbenr:________________________</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Spørgeskema er udfyldt og returneret</td>
<td></td>
</tr>
</tbody>
</table>

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 undervejs 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 udelveres og udfyldes Samtykkeerklæring og Baselinespørgeskema.

B. Efter aflevering af baselinespørgeskema og randomisering:

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 sundhedsvæsenet.


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 for at arrangere 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 tilrettelægge optimale behandlingsforløb."
Samtykkeerklæring

Jeg LABEL PÅKLISTRES

indvilger i at deltage i projektet:
**Effekt af forløbskoordinering 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 behovsafdekende 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, forst 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 behovsafdækkende 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:……
Særlige 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-epikrisen")**

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-epikrisen 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, forsøg er velkommen til at kontakte forløbskoordinatoren ved uklarheder omkring behandling m.v.
BILAG D: Vurderings ark (Basis- og journalark)

Formål:
1. at udgøre forløbskoordinatorers arbejdsmidler
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.


**Sundhedstilstand:**

<table>
<thead>
<tr>
<th>Tidligere sygdom, co-morbiditet og handicaps</th>
<th>Syn og hørelse</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 Kost</td>
</tr>
<tr>
<td></td>
<td>Aktivitetsniveau Motion</td>
</tr>
</tbody>
</table>

**Socialt og økonomisk-materielt**

<table>
<thead>
<tr>
<th>Beskrivelse af bo-situation (alene/ samboende (med hvem og varighed)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Børn (antal, alder, grad af kontakt)</td>
<td></td>
</tr>
<tr>
<td>Netværkskarakteristika</td>
<td></td>
</tr>
<tr>
<td>Ressourcepersoner (anfør evt kontaktoplysninger)</td>
<td></td>
</tr>
<tr>
<td>Jobsituation (aktuelt, tidligere m.v.)</td>
<td></td>
</tr>
<tr>
<td>Praktisk hjælp i hjemmet (udover evt hjemmepleje)</td>
<td></td>
</tr>
</tbody>
</table>

**Udfyldt dato:**

Initialer:
### Brug af egen læge, hjemmepleje mv:

<table>
<thead>
<tr>
<th>Egen læges navn, adresse og telefonnr:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kender e.l. godt? Hyppig bruger?</td>
</tr>
<tr>
<td>Brug af samt tilfredshed med e.l. i.f.m. aktuelle?</td>
</tr>
<tr>
<td>Kontakt til hjemmepleje/-sygeplejerske</td>
</tr>
<tr>
<td>Navn på nøgle/-kontaktperson, evt telefonnr.</td>
</tr>
</tbody>
</table>

### 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>Reaktion på CRC diagnose, udredning og behandling, patientrolle m.v.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ønske (=præferencer) om information og involvering, evt pårørendes ønske om information og involvering</td>
</tr>
</tbody>
</table>

### Udfylt 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>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 vejrtrækning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vægttab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Appetit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kvalme/ opkastning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diáre</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Obstipation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sexuelle fys. problem.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evt stomifunktion</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>Fysisk funktion</td>
<td>Fysisk formåen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fysisk aktivitetsniveau</td>
<td></td>
<td></td>
<td></td>
<td></td>
</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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Angst/ frygt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Selvværd</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kropspofattelse/ seksualitet</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>
</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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Andet:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kognitiv</td>
<td>Forvirret</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hukommelsesbesvær</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Koncentrationsbesvær</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>Socialt</td>
<td>Påvirkning af relationer/ social kontakt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mulighed for at udøve interesser/ fritidsaktiviteter</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>Arb.mæssigt og materielt</td>
<td>Arbejdsmæssige</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Finansielle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Materielt/ hjælpe midler</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>
</tbody>
</table>

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

Evt fundne problemer/ behov "overføres" til journalark

**Udfyldt dato:**

**Initialet:**
Problemer relateret til behandlingsforløbet/ det at være patient
Nedenstående spørgsmål er forslag til samtale. Emnerne, der skal gennemgåes/ screenes for ses markeret til højre.

1. Bruger læger og sygeplejersker et sprog du forstår?
2. Har vi lyttet til din sygdomshistorie?
3. Har vi spurt nok til hvordan du ellers har det?
4. Synes du vi har forståelse for dig som person? Synes du vi forstår din situation?
5. Synes du, der bliver taget hensyn til dig som person i behandlingen?
7. Vurderer du, at du ved nok om: a) diagnose, b) prognose, c) behandling og d) efterfølgb
8. Har du fået mulighed for at stille spørgsmål? Har der været tid til dette?
9. Ved du hvor du skal gå hen, når du har spørgsmål?
10. Er du tilfreds med hvor meget du bliver involveret i beslutninger omkring din behandling?
    i. Hvis problem: Hvordan vil du inddrages? Hvad er gået galt?
11. Har du behov for mere støtte?
12. Har vi spurt til din familie? Vurderer du, at de har behov for støtte?
13. Har dine pårørende behov for mere information? Skal vi involvere dem mere?
14. Oplever du behandlingsforløbet som sammenhængende?
15. Føler du at tingene giver mening?
16. Er du generelt tilfreds med dit forløb?
17. Synes du, at der er noget vi mangler at snakke om?

Kommunikation

Forståelse og empati

Information
Tilgængelighed

Inddragelse/
shared-decision making

Støtte og pårørende

Kontinuitet (informations-, beh-
mæssigt samt relationelt)

Overordnet tilfredshed

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:
| Journalark | Datum | Reeltiv Kontak | Oplevende Kontak | Vurderingsakt | Anden Person | Teknisk Person | Personlig | Tidsforbrug | Kontakt | Kontakt | Kontakt | Kontakt | Kontakt | Kontakt |
|-----------|-------|---------------|------------------|--------------|--------------|--------------|------------|------------|---------|---------|---------|---------|---------|---------|---------|
| Årsag til kontakten | (Beskrev venligst problem, årsag til opfølgning mv.) | Færskes handling/Plan Status | Handling iht VIPS | | | | | | | | | | | | |

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 Oleens 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>CRC behandling:</td>
<td>avanceret rectum cancer: Peter Rasmussen ikke-avanceret colon+rectum: Henrik Christensen</td>
<td>2 t</td>
<td>6. januar 11-13</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td>2 t</td>
<td>21. januar 10-12</td>
<td>Ja</td>
<td></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</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>21. jan kl 13</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ja, 5258/ <a href="mailto:lisbroed@rm.dk">lisbroed@rm.dk</a> Ja, Lissy C 8949 7843</td>
<td></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 kl 13</td>
<td>Ja</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ja</td>
<td></td>
</tr>
<tr>
<td>Det sammenhængende sundhedsvæsen:</td>
<td>Frede Oleesen</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></td>
<td></td>
<td></td>
<td>Ja</td>
<td></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 opsætning, telefoner, mapper, kalender, udl.materiale</td>
<td>På egen hånd</td>
<td>5/1 over middag + løbende</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deltage ved operation</td>
<td></td>
<td></td>
<td>23/1: Mette og Trine</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
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.

<table>
<thead>
<tr>
<th>Sæt kun ét kryds ud for hvert 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>

<table>
<thead>
<tr>
<th>I den forløbne uge:</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>
<td>☐</td>
</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 smerter?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.10 Havde du brug for at hvile dig?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.11 Har du haft besvær med at sove?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.12 Har du følt dig svag?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.13 Har du savnet appetit?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.14 Har du haft kvalme?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.15 Har du kastet op?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Spørgsmål</td>
<td>Slet ikke ▼</td>
<td>Lidt ▼</td>
<td>En del ▼</td>
<td>Meget ▼</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
<td>---------</td>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>1.16 Har du haft forstoppelse?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.17 Har du haft diarré (tynd mave)?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.18 Var du træt?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.19 Vanskelliggjorde smerter dine daglige gøremål?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.20 Har du haft svært ved at koncentrere dig om ting som f.eks. at læse avis eller se fjernsyn?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.21 Følte du dig anspændt?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.22 Var du bekymret?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.23 Følte du dig irritabel?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.24 Følte du dig deprimeret?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.25 Har du haft svært ved at huske?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.26 Har din fysiske tilstand eller medicinske behandling vanskeliggjort dit familieliv?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.27 Har din fysiske tilstand eller medicinske behandling vanskeliggjort din omgang med andre mennesker?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.28 Har din fysiske tilstand eller medicinske behandling medført økonomiske vanskeligheder for dig?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

De næste 2 spørgsmål besvares ved at sætte ring omkring det tal mellem 1 og 7, som passer bedst på dig.

<table>
<thead>
<tr>
<th>Spørgsmål</th>
<th>1 2 3 4 5 6 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.29 Hvordan vil du vurdere dit samlede helbred i den forløbne uge?</td>
<td>Meget dårligt</td>
</tr>
<tr>
<td>1.30 Hvordan vil du vurdere din samlede livskvalitet i den forløbne uge?</td>
<td>Meget dårlig</td>
</tr>
</tbody>
</table>
På de sidste sider besvares spørgsmålene ved at afkrydse de svar, som passer bedst på dig. Der er ingen "rigtige" eller "forkerte" svar. De oplysninger, som du giver os, vil blive behandlet strengt fortroligt.

### 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*

- [x] 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, rygsygdom, 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*

- [x] Fremragende
- [ ] Vældigt godt
- [ ] Godt
- [ ] Mindre godt
- [ ] Dårligt
## Sammenhæng i behandlingsforløb

### Patientspørgeskema

<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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.4</strong> Min praktiserende læge er fagligt dygtig</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.5</strong> Min praktiserende læge er god til at lytte til mig</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<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>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.7</strong> Min praktiserende læge er god til at hjælpe mig med at håndtere mine følelser omkring helbredsproblemer</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.8</strong> Min praktiserende læge har været god til at forberede mig på det, der skulle ske på sygehuset</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.9</strong> Jeg er meget tilfreds med min praktiserende læge</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

## Holdninger til eget helbred

<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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.10</strong> Mit helbred afhænger i høj grad af, hvor godt jeg passer på mig selv</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.11</strong> Mit helbred er i høj grad påvirket af tilfældigheder</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>2.12</strong> Når man er syg, har man selv et stort ansvar for igen at blive rask</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<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>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
### 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)
- □ Lærning, 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!*
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

[Signatur]

Christian Wulff, Projektansvarlig læge og ph.d.-studierende
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.

<table>
<thead>
<tr>
<th>Sæt kun ét kryds ud for hvert 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>

<table>
<thead>
<tr>
<th>I den forløbne uge:</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>
<td>☐</td>
</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 sm water?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.10 Havde du brug for at hvile dig?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.11 Har du haft besvær med at sove?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.12 Har du følt dig svag?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.13 Har du savnet appetit?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.14 Har du haft kvalme?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>1.15 Har du kastet op?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Vær venlig at forsætte på næste side
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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.17 Har du haft diarré (tynd mave)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.18 Var du træt?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.19 Vanskeliggjorde smerter dine daglige gøremål?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.20 Har du haft svært ved at koncentrere dig om ting som f.eks. at læse avis eller se fjernsyn?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.21 Følte du dig anspændt?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.22 Var du bekymret?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.23 Følte du dig irritabel?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.24 Følte du dig deprimeret?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.25 Har du haft svært ved at huske?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.26 Har din fysiske tilstand eller medicinske behandling vanskeliggjort dit familieliv?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.27 Har din fysiske tilstand eller medicinske behandling vanskeliggjort din omgang med andre mennesker?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.28 Har din fysiske tilstand eller medicinske behandling medført økonomiske vanskeligheder for dig?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

De næste 2 spørgsmål besvares ved at sætte ring omkring det tal mellem 1 og 7, som passer bedst på dig

1.29 Hvordan vil du vurdere dit samlede helbred i den forløbne uge?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meget dårligt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Særdeles godt</td>
</tr>
</tbody>
</table>

1.30 Hvordan vil du vurdere din samlede livskvalitet i den forløbne uge?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meget dårlig</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Særdeles godt</td>
</tr>
</tbody>
</table>

Vær venlig at fortsætte på næste side
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>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 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>2.2 Læger og sygeplejersker har været gode til at forstå min situation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Læger og sygeplejersker har i passende grad interesseret sig for....   |            |      |       |             |                        |
| 2.3 ...mit fysiske helbred                                            |            |      |       |             |                        |
| 2.4 ...mit psykiske helbred                                            |            |      |       |             |                        |
| 2.5 ...mine bekymringer grundet sygdommen                             |            |      |       |             |                        |
| 2.6 ...hvordan mine pårørende har haft det                            |            |      |       |             |                        |
| 2.7 ...at mine pårørende har været velinformerede om min situation    |            |      |       |             |                        |
| 2.8 ...mine ikke-helbredsmæssige forhold (bolig- og arbejdssituation, økonomi m.v.) |            |      |       |             |                        |
## 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>Sæt kun ét kryds ud for hvert udsagn</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 Informationen om undersøgelserne (=udredningen) af min sygdom har været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Informationen om behandlingen af min sygdom har været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 Informationen om mulige bivirkninger til behandlingen har været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4 Informationen om mulige senfølger af min sygdom og behandling har været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5 Informationen om hjælpe- og støttetilbud (sociale ydelser, psykolog, fysioterapi mv.) har været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.6 Jeg har på intet tidspunkt savnet mundtlig information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.7 Jeg har på intet tidspunkt savnet skriftlig information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.8 Informationen er blevet givet på de rigtige tidspunkter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.9 Jeg er i passende omfang blevet spurgt om mit behov for at modtage information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.10 Samlet set har informationen været tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.11 Jeg er i passende grad blevet inddraget i beslutningerne om min behandling og pleje</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>Sæt kun ét kryds ud for hvert udsagn</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1 Jeg vurderer, at mine pårørende er blevet passende informeret om min sygdom og behandling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2 Mine pårørende er i passende grad blevet inddraget i beslutninger om min behandling og pleje</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.3 Læger og sygeplejersker har samlet set været gode til at tilbyde mine pårørende vejledning, rådgivning, støtte og hjælp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Vær venlig at fortsætte på næste side
# Sammenhæng i behandlingsforløb

**Patientspørgeskema**

---

## 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/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

---

[Vær venlig at fortsætte på næste side]
## Angående eventuel operation

_Du skal kun besvare spørgsmål 7.1-7.6, hvis du er blevet opereret._

<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><em>Sæt kun ét kryds ud for hvert udsagn</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.1 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 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 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 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 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 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>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><em>Sæt kun ét kryds ud for hvert udsagn</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.1 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 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 Ventetiden på at blive opereret var tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.4 Ventetiden på at starte strålebehandling var tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.5 Ventetiden på at starte med kemoterapi var tilfredsstillende</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Din oplevelse af fejl i dit behandlingsforløb**

Anfør din grad af enighed i følgende udsagn:
*Sæt kun ét kryds ud for hvert udsagn*

<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>9.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet problemer med henvisninger mellem forskellige afdelinger på sygehuset</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<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>
<td>☐</td>
</tr>
<tr>
<td>9.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet, at svar på prøver eller undersøgelser kom senere end lovet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet at svar på prøver eller undersøgelser forsvandt</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet at få forkert svar på en prøve eller en undersøgelse</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet, at der skete fejl med min medicin</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet at få forkert behandling eller pleje (ikke medicin)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet at få modstridende information af personalet på sygehuset</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet, at sygehuspersonale og egen læge har givet mig modstridende information</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg mener, at der er sket fejl, der har forløbet unødigt</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9.11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jeg har oplevet, at der er sket andre fejl end nævnt ovenfor (9.1-9.9) Anfør venligst:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Vær venlig at fortsætte på næste side
### Om din oplevelse af at være tryg

<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>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>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>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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sundhedsvæsenets samarbejde om din behandling og pleje

<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>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

**12.1** Hvordan vurderer du kvaliteten af dit undersøgelses- og behandlingsforløb ved Afdeling P indtil nu?
- [ ] Fremragende
- [ ] Vældig god
- [ ] God
- [ ] Mindre god
- [ ] Dårlig

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

Besvar venligst følgende:

<table>
<thead>
<tr>
<th>12.2</th>
<th>Har du i dette behandlingsforløb efter du fik diagnosen haft kontakt med din praktiserende læge?</th>
<th>Ja ▼</th>
<th>Nej ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.3</th>
<th>Har du i dette behandlingsforløb efter du fik diagnosen haft kontakt med din praktiserende læge, hvor I talte om dit behandlingsforløb?</th>
<th>Ja ▼</th>
<th>Nej ▼</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td></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>
</tr>
<tr>
<td>☐</td>
<td>God</td>
</tr>
<tr>
<td>☐</td>
<td>Mindre god</td>
</tr>
<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

**12.5** Hvordan vurderer du kvaliteten af dit samlede undersøgelses- og behandlingsforløb indtil nu?
- [ ] Fremragende
- [ ] Vældig god
- [ ] God
- [ ] Mindre god
- [ ] Dårlig
Det udfyldte 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>
<td>1 (1)</td>
<td>2 (2)</td>
</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>
<td></td>
<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>
<td>8 (7)</td>
</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>
</tr>
<tr>
<td>Laparotomy</td>
<td>90 (67)</td>
<td>87 (66)</td>
<td>85 (69)</td>
<td>85 (70)</td>
<td>83 (69)</td>
<td>74 (68)</td>
</tr>
</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>
<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>Non-responders</td>
<td>19 (14)</td>
<td>16 (11)</td>
<td>30 (21)</td>
<td>29 (21)</td>
<td>31 (22)</td>
<td>41 (29)</td>
</tr>
<tr>
<td>Responders</td>
<td>121 (86)</td>
<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>
<td></td>
<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>
</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>57 (47)</td>
<td>55 (44)</td>
<td>55 (50)</td>
<td>48 (43)</td>
<td>54 (50)</td>
<td>45 (45)</td>
</tr>
<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>
</tr>
<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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>60 (50)</td>
<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>
<td>2 (2)</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td>1 (1)</td>
<td>2 (2)</td>
</tr>
<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>
</tr>
<tr>
<td>Follow-up surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<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>
</tr>
<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>
</tr>
</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; % 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>
<thead>
<tr>
<th></th>
<th>Sent/ returned/ not returned</th>
<th>Returned but ‘Don’t know/ N.A.’/ Returned but ‘missing’</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.10</td>
<td>4.3</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>134/121/13</td>
<td>1/3</td>
</tr>
<tr>
<td>CM</td>
<td>132/124/8</td>
<td>0/3</td>
</tr>
<tr>
<td>Week 30</td>
<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 lege 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.


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

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

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

Jens Søndergaard  
Professor, praktiserende læge, ph.d.  
Forskningsenheden for Almen Praksis, SDU
Sammenhæng i behandlingsforløb
Lægespørgeskema

Dette spørgeskema vedrører sygdomsforløbet for patienten anført i følgebrevet. Spørgeskemabet 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>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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informationen har hjulpet mig til bedre at kunne håndtere patientens psykiske følger af kræftsygdommen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informationen har hjulpet mig til bedre at kunne håndtere patientens sociale følger af kræftsygdommen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>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>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>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>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>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><strong>Jeg har manglet information fra sygehuset om……..</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 ...det af sygehuset påtænkte behandlingsforløb</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.2 ...hvor i behandlingsforløbet patienten befandt sig</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.3 ...ændringer i patientens ordinerede medicin</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.4 ...hvad patienten var blevet informeret om på sygehuset</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.5 ...identificerede problemer og behov hos patienten</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.6 ...forslag til tiltag, som praksis kunne igangsætte</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3.7 ...hvem, sygehuset forventede, skulle varetage og koordinere de forskellige dele af behandling og rehabilitering</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### Eventuel opsøgende kontakt fra almen praksis til sygehuset

4.1 Har du / praksis på eget initiativ kontakttet 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:

Anfør din grad af enighed i følgende udsagn:

<table>
<thead>
<tr>
<th>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>4.2 Jeg / praksis fik hurtigt fat i en sundhedsprofessionel, som kunne hjælpe</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4.3 Jeg / praksis fik løst de(-t) problem(-er), som foranledigede kontakten til sygehuset</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

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?
☐ ☐
Ar

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

Dato for udfyldelse af spørgeskemaet:

---

Hvis du har kommentarer, kan du anføre dem her:

---

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

Mange tak for hjælpen!
APPENDIX F:

GP EVALUATION DATA QUALITY
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/</td>
<td>‘Don’t know/</td>
</tr>
<tr>
<td></td>
<td>N.A.’</td>
<td>N.A.’</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.
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 tiltagende 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 tiltagende 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 DANSE FUNKTIONSÆVNELSER

Nedenfor beskrives de danske funktionsbænksevnelser »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«.

I rapporten anførtes det videre, at »tovholderfunck-
koordinatoren har typisk ikke behandlings- og plejepædagogiske opgaver. Effekten af forløbskoordinatorens arbejde skal kunne måles med hensyn til klinisk kvalitet (funktionsevne, sygelighed mv.), prosesmål (antal indlæggelser, brug af vægtlæge, utilstede 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 flaskehæler og slip« [9]. Derudover er forløbskoordinatoren til tider blevet sammenlignet med den lovbestemte kontaktperson, men deres formål og handlemuligheder er vidt forskellige. Det skal her nævnes, at effekten af kontaktpersonsordeningen er ukendt.

**FORLØBSPROGRAMMER**

Et forløbsprogram (engelsk: *disease management program*) beskrives som »den samlede tverrags, TVærsæktorielle og koordinerede sundhedsfaglige indsats for en given kronisk tilstand, der sikrer anvendelse af evidensbaserede anbefalinger for den sundhedsfaglige indsats, en præcist beskrivelse af opgavefordeling samt koordinering og kommunikation mellem alle involverede parter« [10].

Formålet med et forløbsprogram er at sikre en optimal individuel behandling samtidig med ensartet kvalitet af patientgruppens forløb.

Forløbsprogrammer indeholder typisk *risikostratificering* af sygdomspopulationen med henblik på at sikre en graduert indsats. *Risikostratificeringen* består i, at patienter opdeles efter risiko for komplikationer (sygdommens sværhedsgrad, komorbiditet og evne til egenomskæring) og er en forudsætning for en effektiv indsats [10]. Den generiske risikostratificeringspyramide viser omsorgsniveau og baggrund for rubricering i de aktuelle lag (Figur 1).


**EFFEKTER AF FORLØBSKOORDINATORER VED SOMATISK SYGDOM**

I udlandet er der udført forskningsprojekter, i hvilke man har fokuseret på effekterne af forløbskoordinatorer. Forskningsprojekterne har analyseret kliniske, processuelle og patientrapporterede effektmål, hvorimod man kun i få projekter har vurderet de sundhedsøkonomiske konsekvenser. I det følgende resumeres oversigtsartikler vedrørende forløbskoordinatorer.

**Diabetes**

Der synes udelukkende at være konsensus om, at tilknytning af forløbskoordinatorer reducerer langtidsblodsukker (HbA1c) [12].
**Kronisk obstruktiv lunghæmme**


**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 genindlæg, og i syv af ni forsøg, som havde sammenlignet indlæggelsesdage, medførte forløbskoordinatorer færre genindlæg. Ingen af studierne resulterede i bedre udfald af effektmålet i kontrolgruppen [14].

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


**Kraft**

I en oversigtsartikel, der belyste effekten af forløbskoordinatorer i kædeforløb, afbrørrerede de inkluderede otte studier flere enkelstæende statistisk signifikant positivt påvirkede effektmåler som følge af forløbskoordinator.

Imidlertid konkluderede oversigtsartiklen, at vidensmængden var for sparsom til, at man kunne udtale sig om effekten af at tilskynde forløbskoordinatorer til kædepatienter [17].

**HVAD KAN MAN KONKLUDERE OM EFFEKTER AF FORLØBSKOORDINATOREN?**

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 metod til forbedring af klinisk komplekse patientforløb. I alle oversigtsartikler efterlystes veltilrettelagte og transparente forskningsprojekter.

Da en implementering af forløbskoordinatorer, som er baseret på en falsk antagelse om positiv effekt, vil medføre spild af sparsomme sundhedsressurser, er der et pressende 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 primær- og sekundærsektor.

Det er nødvendigt at udbrede kendskabet til forløbsprogrammer samt til at implementere forløbskoordinatorer.

---

**FIGUR 1**

Fordelingen af en gruppe kronisk syge patienter med hensyn til behov for behandlingsunderstøttende indsats [18].

- **Intensiv omsorg**
  - Fremkredens sygdom, komplicerende komorbiditet, komplicerende psykosociale forhold, svage ældre
  - 1-3%

- **Understøttende omsorg**
  - Behov for tæt observation af symptomer, medicinering og intensiv uddannelse i egenomsorg: ikkeoptimal kontrol, kompliansproblemer, kompleks medicinering, komorbiditet
  - 20-30%

- **Støtte til egenomsorg**
  - Behov for medicin og livsstilsændringer, er under kontrol
  - 65-80%
Sundhedsstyrelsens tovholderbegreb fastslår, at den praktiserende læge er en central aktør i koordineringen af indsatser i patienters sygdomsforløb.

Forløbskoordinatorens og den lovbestemte kontaktpersons formål og muligheder er ganske forskellige. Betegnelsen forløbskoordinator bør forholde sig en sundhedsprofessionel, der tilknyttes udvalgte patienter med komplekse tæversektorielle behov, og forløbskoordinatorer forsøg så anses for at være et lovligt værktyg til forbedring af patientforløb i tilfælde af udvalgte kliniske komplikationer. I det danske sundhedsvæsen er det effektive forløbskoordinatorer imidlertid ukendt. Uanset effekt anbefaler vi, at forløbskoordinatorbegrebet bruges ensartet og i overensstemmelse med Sundhedsstyrelsens definition [10].

**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 Okkels Jensen:**

**Coronary artery remodelling in diabetic and non-diabetic patients assessed by intravascular ultrasound**

Disputats

**KORRESPONDANCE:** Christian Wulff, Forskningsenheden for Almen Praksis, Institut for Folkesundhed, Aarhus Universitet, DK-8000 Århus C.

E-mail: christian.wulff@alm.aau.dk

**ANTAGT:** 15. februar 2010

**INTERESSEKONFLIKTER:** Ingen