PATIENT AND DOCTOR'S PARTNERSHIP CANCER STUDY

Reinforcing partnership between cancer patient, general practitioner and oncologist during chemotherapy - a randomised controlled trial

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Background

In line with international guidelines and research, the Danish Health and Medicines Authority and the Danish Cancer Society have underlined the importance of strengthening the coordination and continuity of cancer care during and following cancer treatment. Each cancer patients should Ideally have their needs thoroughly assessed and be involved in decision-making, and furthermore be informed about which healthcare providers are taking care of their individual needs.[1-5]

Problem insight

When receiving a cancer diagnosis, patients are often faced with psychological distress and loss of control [6] [7]. They undergo exhausting treatment, are often challenged with complex information and may be involved in difficult decisions concerning their treatment and care [8]. This pose a huge challenge for the involved care providers and patients might have difficulties realising which care provider can help with a specific problem. Improved self-efficacy in decision-making may decrease their distress and improve control and it is thought to have a central role in how cancer patients cope with their diagnosis and treatment [9-11]. Previous studies have found that patients with high self-efficacy are less distressed, and show improved adjustment to disease and treatment [10 12-14].

Several studies have shown that unmet needs regarding physical and psychosocial problems are frequent and diverse among cancer patients. Furthermore, care gaps regarding treatment of comorbidities are substantial.[15-18] The general practitioners (GPs) have been given a central role as coordinators of the cancer patients' course. However, supporting cancer patients with regard to rehabilitation needs still poses a huge challenge for GPs during and following long-term hospital-based cancer treatment.[19-21]

A Danish study from about unmet needs of rehabilitation of 3,439 cancer patients demonstrated that a total of 60% expressed unmet needs in at least one of six different areas: physical, emotional, family-oriented, sexual, work-related and financial. [16 22] Unmet needs in several areas were common.[22] Unmet needs with regard to physical and emotional support were most common.[22] Furthermore, the authors found that unmet needs were associated with lower quality of life according to EORTC QLQ C-30, thereby showing that unmet needs and reduced quality of life are correlated.[22] From the time of diagnosis to long after the treatment and the regular contact to the hospital are completed, needs for rehabilitation occurs and often changes during the cancer trajectory. [21 23] This supports the fact that GPs should play a central role in rehabilitation early in the treatment.[24-27] However, a Danish survey of 4,401 cancer patients two years after diagnosis showed that 21.7% of the participants had apparently not retrieved sufficient information about how their GP could provide support, and 30.7 to 59.8% had not retrieved adequate help from their GP regarding cancer-related physical, emotional and social problems.[18] Furthermore, 42 % of patients have one or more comorbidity but only 42 % found that the hospital had handled it well. [18]

Continuity of care is expected to have a vital impact on the quality of care that patients receive. Interventions focusing on care gaps of continuity may improve patients' outcomes.[28] Furthermore, increased experienced continuity of care may be associated with lower health care needs in the future.[29] A Canadian survey on continuity of care found that over 55.2% of the patients did not feel they had been informed about patient resources and supports to help consolidate continuity of care.[30] Within the Danish healthcare setting, three large-scaled ambitious clinical cancer trials tried to improve share decision-making, continuity of cancer care and rehabilitation across healthcare sectors. The concepts consisted of a shared-care programme, an intensive hospital-based case management programme, and a rehabilitation

programme and were headed by Nielsen, Wulff and Bergholdt, respectively. [27 31 32] Despite rigorous designs these studies did not succeed to point out effective solutions. In Canada and Holland focus has been on the so-called survivorship care plans, but a rigorous randomised controlled trial including Canadian patients with breast cancer did not show the hypothesised effects.[33]

Patient information is an essential factor in the support for cancer survivors across the whole cancer trajectory.[34 35] Providing patients with appropriate information about their services through informed decision-making may result in lower levels of distress, improved satisfaction with care and enhanced health-related quality of life.[35-37] There is still a substantial gap between patients' and families' wishes about the level of information they want to obtain, and how they want to receive it, and their satisfaction with what they really get. [18 38]

Bringing the oncologist and GP together face-to-face with the patient in focus may improve communication between the primary and secondary sector, enhance patient involvement, improve continuity of care and thereby provide relief to cancer patients and their overall treatment results. Due to geographical reasons and shortage of time this is impossible as part of routine cancer care. Video-based communication may therefore be an alternative solution.[39-44] Video consultations connect physicians and patients located at different places and enable them to actively share knowledge, decision-making and treatment planning. Seeing each other is important for both the doctor-patient and the doctor-doctor relationship.[41 45 46] It gives access to rich non-verbal emotional signals and enhances the building of empathy between participants sitting apart.

In this study a new and innovative model of communication and shared decision-making will be developed and evaluated in a rigorous, randomised controlled trial. A video consultation at the start of chemotherapy including the cancer patient, the GP and the oncologist constitutes the core of the intervention. This study intervention thereby aims to support the delivery of continuity and coordinated, shared care of general as well as cancer-related health problems among cancer patients treated with chemotherapy.

Study aims

Further research based on innovative ideas is required to improve the cancer healthcare trajectory, with a conceptual idea of improving cancer care based on doctors´ partnership in a patient-centred context. The aim of the study is, to design and evaluate a new way of communication and shared decision-making that brings the patient, the oncologist and GP together in a shared video consultation. A multi-modal intervention will be evaluated in a randomised controlled trial through a retrospective design.

Specific aims of the intervention will include

1) To reach agreement upon sharing or transfer of care between oncologist and GP during and following cancer treatment with chemotherapy.
2) To improve patient-perceived continuity of care by reinforcing information, management and relations among participants involved in the patients' treatment.
3) To reduce cancer patients' unmet needs of rehabilitation during and following chemotherapy.
4) To increase quality of life and reduce illness intrusiveness for cancer patients during and following chemotherapy.

Material and methods

A randomised controlled trial including 340 cancer patients referred to chemotherapy at Department of Oncology, Vejle Hospital. The included cancer patients will test the effect of this multimodal intervention aiming to enhance patient involvement, shared decision-making and sharing or transfer of care between oncologists and GPs. The effect of the intervention in addition to traditionally organised care will be compared with regard to result and process outcomes. Data will be obtained from registers and questionnaires to patients, GPs and oncologists.

Setting

Patients will be recruited at the Department of Oncology, Vejle Hospital, at their first appointment for chemotherapy. In 2013 The Department had 1.200 referrals and started chemotherapy. The five most frequent diagnoses were breast, gastrointestinal, pulmonary, gynaecological, and urinary cancer. During the inclusion period all adult patients referred for chemotherapy will be invited for the study regardless of cancer type.

Inclusion criteria

- Newly referred cancer patient scheduled for chemotherapy at the Department for Oncology, Vejle Hospital
- Aged 18 years and over
- Expected survival of median 7 month
- Able to speak and read Danish
- Mentally able to cooperate
- Listed with a GP
- Written and verbal informed consent given

Intervention

The final design of the study intervention will be based upon experience from the feasibility period. Apart from the video consultation this multi-modal intervention will include, advice on effective communication, preparation and management of the meeting, expected topics for the meeting, advice on active patient involvement, practical issues, E-learning programs, etc. [31 39-42 44 47 48]

The core element of the intervention consists of a video consultation, which unifies the cancer patient, the GP and the oncologist in the early phase of cancer chemotherapy treatment, thereby facilitating a powerful partnership. The video consultation is expected to last 10-25 minutes. One or more video consultations may be planned during or at the end of treatment. A project nurse will schedule the consultation. The patient may sit with the oncologist or the GP depending on the patient' request. The footage of the consultation will be available for patients to watch at home. The consultation is expected to facilitate that individual needs are timely addressed during and after treatment.

Randomisation

During a 12 to 18 months period of inclusion, all adults referred for chemotherapy will be invited for the study. Oral and written information are given at first appointment. Randomisation takes place after a baseline questionnaire and the written informed consent has been completed.
Patients are allocated to the intervention and control group, respectively, in a 1:1 ratio. Subsequently, the general practitioner is invited for the consultation. Both GPs and oncologist may thus have patients in the

control as well as the intervention group. No significant spillover effects between groups at the physicians level are expected.
The software program RedCap® will manage all handling of the questionnaire data, which is capable of automatically sending out by mail secured links to participants and retrieving answers online. The randomisation will be computer-generated by RedCap®.

The sample size of at least 214 (107 in the intervention and control group, respectively) subjects should ensure a well-balanced design. No strong evidence regarding relevant stratification factors for this type of outcome is available. Thus, the randomisation will not be stratified. However, in exploratory analysis the influence of additional factors such as: age, gender, education and cancer type will be investigated.

IT equipment and security

The requirements of video conferencing equipment should be as easily available, flexible and acceptable as possible.[39 44] Since GPs are faced with a variety of IT communication options, an individual solution that is simple and easy to activate, should be provided. The oncologists at Vejle Hospital share consultation rooms and change location during a workday, and equipment for their disposal should be portable and easy to set-up. The project group therefore intends to use an already existing video conferencing system the Tandberg E20, which is used for video translation at hospitals and in some general practice in the Region of Southern Denmark. Those general practice how do not have the conference system will be offered a free set up and support by Syddansk Sundhedsinnovation. For does general practice how don't want the conference system a second solution call Jabber Guest is offered.
The video consultation will be stored on the Region of Southern Denmark's servers and will be available to the patient on a website with a secure login.

Outcomes

Data will be retrieved from registers and Internet-based questionnaires to patients at baseline and after 4 and 7 months and to GPs and oncologists at 4 months. All handling of the questionnaires will be managed using the software program RedCap®. The initial part of the questionnaire at baseline will include demographic and clinical information like age, cancer type, cancer recurrence status, and completion of previous chemotherapy treatment.

The primary study outcome is the total score of the decision self-efficacy scale for patients at 7 month[49]. This 11-item questionnaire has previously been translated from English to Danish and used in a Danish, mixed oncology setting [8].
The global score of the quality of life questionnaire EORTC QLQ C-30 is very often the choice of primary outcome in psychosocial cancer clinical trials. However, to target the core of the intervention as precise as possible we have selected self-efficacy of decision-making, i.e. the total scores of the cancer specific patient questionnaire Decision self-efficacy (decision-SE)[49]. It assesses confidence in one's ability to participate in decision making to the extent desired. It is suggested that this measure clearly trump the global score of the EORTC QLQ-C30 with regard to our study intervention. This 11-item questionnaire has previously been translated from English to Danish and used in a Danish, mixed oncology setting [8].

Secondary outcomes covering patients perspectives will include the following questionnaires: Global Health Status of the EORTC QLQ C-30 subscales and single items of the EORTC QOL C-30 which has high validity, knowledge from reference populations and strong correlation to unmet needs of rehabilitation. [15 22 31 50-53], Cancer Care Coordination questionnaire (CCCQ) assessing the patient perception of the coordination of

their cancer care in 22 items[54], The Illness Intrusiveness Rating Scale (IIRS) assessing the extent to which an illness or its treatment is viewed as interfering with different aspects of an individual's life [55 56] , and EORTC QLQ INFO 25 [37] covering several aspects of patient information during cancer treatment, and The hospital depression and anxiety score (HADS) assessing patient depression and anxiety symptoms. Additionally, health-seeking behaviour to the general practitioner and the oncologic department (contact form, date and aim) will be asked about.

Patients in the intervention group will additionally evaluate the content, form, expectation and experience of the video consultation. This is achieved by presenting them to ad hoc items inspired among others by the work of the Australian College of Rural & Remote Medicine. [57]

In addition to patients' evaluation of health, health-seeking behaviour and the care given, evaluations from the GPs and the oncologists primarily responsible for their treatment are included as secondary outcomes. Until now, we are not aware of appropriate validated scales and therefore ad hoc item will be formulated to cover perceived benefit of the video-consultation, subsequent influence on care and coordination, satisfaction with own care, relevance of patient contacts, comorbidity care and adherence to cancer care.

Data from registers will include the National Patient Register and the National Health Insurance Register (Statistics Denmark). Furthermore, the footage of the consultations, which contributes with an important data source, will be analysed qualitatively regarding content, communication, roles etc., but this is beyond the scope of my PhD study.

Sample size calculation

Knowledge obtained from a previous study on decision self-efficacy in a mixed Danish oncology setting includes normal distribution of data with a mean of 36 and a standard deviation of 9 [8], meaning that data from 107 patients in each group allows detection of a 4 point difference with 90 % statistical power at an significance level of 0.05. Under the assumption of a high initial acceptance by general practitioners to support the individual patient´s study participation (expected to be 90 % but will be proved by piloting), and patient dropout up to 30 % during follow-up (based on a prior RCT in the same setting [31]), it is planned to recruit 340 patients i.e. 170 patients in the control and the intervention group, respectively.

Design phase and pilot testing

The intervention will be pilot tested by inclusion of 10 to 15 patients and their health professionals, and adjusted accordingly. Observations will include expectations by patients, relatives, and professionals, study acceptance, study material, feasibility of the video consultations, and perceived usefulness.

Analyses

The effectiveness of this intervention will primarily be analysed based on the intention-to-treat principle, where data from all participants', having at least one post-baseline measurement of the primary outcome will be included in the data analysis.

Standard descriptive statistics will be used to report demographics, clinical characteristics and baseline status for the different outcomes.

Analysis of differences between outcome means at follow-up between the intervention and control group will be by linear regression, adjusted for baseline value of the outcome.

Statistical program Stata® version 13 will be used for data analyses.

Publications

A PhD Thesis entitled The PARTNERSHIP CANCER STUDY will be based on four papers with the following working titles:

Papers

1) Reinforcing partnership between cancer patient, general practitioner and oncologist during chemotherapy – study protocol for a randomised controlled trial
2) Patient perceived quality of life, continuity of care and unmet needs after a multimodal intervention bringing cancer patient, general practitioner and oncologist together during chemotherapy – a randomised controlled study
3) Sharing of medical responsibility and obtained knowledge from a General Practitioners point of view during a video consultation bringing cancer patient, general practitioner and oncologist together – results from a randomised controlled study
4) Benefits for Oncologist bringing cancer patient, general practitioner and oncologist together in a video consultation – results from a randomised controlled study

Perspectives

The study will add a new dimension to the organisation of cancer treatment and may be useful in other phases of cancer treatment. The intervention furthermore includes room for professional learning and sharing of knowledge. Although the study intervention is not logistically simple, it's suggested, that it can be implemented in routine cancer care. Data for qualitative analysis and economic evaluation is sampled during the trial period and will provide further knowledge important for implementation.

Budget

The overall budget of the project period 2014-2017 is estimated to be DKK 4.924.628, which covers PhD salary, salary for senior researchers including statistical assistance, running expenses, tuition fee and conference and travel expenses.

Ethics

The Regional Ethics Committee on Biomedical Research and the Danish Data Protection Agency are asked to approve the study, which will also be indexed at www.clincialtrials.gov. All participants will receive oral and written information about the study, and participation requires written informed consent. All aspects of the study will be conducted in accordance with national and international standards and laws. It should be underlined that there will be specific focus on safety regarding the video conferencing and patient access to footage.

One may expect that some patients might bring up subjects in confidentially with a given health care provider, which they have not discussed with other health care providers, for instance alcohol consumption. Both GPs and oncologist should be aware of this. The study material and consultation guidelines will include a note about it.

The study will be described and reported in accordance with the CONSORT statement.[48]

Time schedule

01.09.2014 – 01.09.2015: Preparation of information material for patients and health staff. Apply authorisation from Danish Data Protection Agency, Danish Health and Medicines Authority, and the regional ethic committee. The feasibility of the study intervention will be analysed by inclusion of 10 to 15 patients and their health professionals in a pilot study. The different element of the intervention, inclusion procedures, study material, logistics and questionnaires are analysed.

01.09.2015 – 01.09.2016: Inclusion of patients for the randomised controlled trial.
01.09.2016 – 01.12.2017: Follow-up 7 month, analysis, result procurement and preparation of manuscripts.

Organisation

This study will be developed and conducted in a research group including supervisors and collaborators: Professor Helle Ploug Hansen, PhD health economist Troels Kristensen and senior statistician René dePont Christensen, Research Unit of General Practice, University of Southern Denmark, Professor Kirsten Kaya Roessler, Department of Psychology, University of Southern Denmark; "Doctors Partnership" an innovative quality development group established and headed by Hospital Manager PhD, MD, Dorte Gylling Crüger, Vejle Hospital, who launched the overall idea of the project, and furthermore the patient and relative Council, Vejle Hospital.

The applicant, MD Theis Bitz Trabjerg, will by head of the PhD research project.

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