



Targeted Psychosocial Care throughout Full Disease Trajectories for Better Self Efficacy in Cancer Patients: Study Protocol for a Randomized Controlled Trial

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Abstract

Main Objective: Continuously support and coordination of psychosocial care to patients, added to usual care in whole cancer trajectories will better support patient self-efficacy, than will usual care.

Participants: Patients in the diagnostic period of colorectal cancer.

Methods: In a randomized controlled trial, 280 Danish patients will be assigned to one of two groups. 1) Usual care: Patient-centered and performed by nurses and secretaries, who can answer department specific questions. They work in separate relevant hospital units. 2) Usual care plus intervention: An additional offer of one or two nurse navigators to follow patients throughout the whole cancer trajectory. Nurse navigators offers a family-centered approach targeting patient self-efficacy by assessment of distress and unmet needs, and intelligent integration of psychosocial care activities from hospitals, primary care, spiritual and social care, not-for-profit organizations, and families. Data is collected with questionnaires. The primary outcome measure is change in patients' self-efficacy for cancer. Secondary outcomes are unmet needs, continuity of care, health related quality of life and nurse navigation time spent. The adjustment of the intervention after pilot test is reported.

Conclusion: The study will be performed in primarily low and middle-income areas in Denmark, and as the intervention is complex, the underlying evidence based theories will serve for good guesses of causal processes. If positive results, we will be able to further advise the clinic in their efforts to reach a goal of optimal support in cancer trajectories.

Keywords: Self-efficacy; Needs assessment; Psychosocial support; Nurse navigation; Cancer

Introduction

Cancer patients lack psychosocial care, and we do not know how to advice the clinic.

Patients with cancer often experience high distress levels, and may not get proper psychosocial support throughout the cancer trajectory [1]. An integrated approach to psychosocial care might be, what is needed [2]. Distress comprises non-wellbeing due to physical, psychosocial, emotional, and spiritual circumstances, and there is evidence that lowering distress leads to better Quality of Life (QOL) and self-efficacy [3-5]. Needs due to distress may be apparent in the diagnostic phase before a cancer diagnosis, and most often peaks within a week after diagnosis [1]. A gradual decline will follow, but with a risk of a sustained elevated level of distress up to ten years after diagnosis [1]. Social networks include all with whom we engage; the nuclear family as well as more distant people. A good enough social network (i.e. rich, varied and engaged) seems to support the immune system and emotional resilience, but a long period with illness erode the social network and put all patients with cancer in risk of emotional instability and longer recovery [6]. The erodation might be due to taboo, or the fact, that throughout cancer trajectories, patients and caregivers have to face a

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Received Date: 29 Apr 2021

Accepted Date: 26 May 2021

Published Date: 24 Jun 2021

Citation:

Thygesen MK, Wehberg S, Sondergaard J, Dieperink KB, Perdawood SK, Qvist N. Targeted Psychosocial Care throughout Full Disease Trajectories for Better Self Efficacy in Cancer Patients: Study Protocol for a Randomized Controlled Trial. *Clin Oncol.* 2021; 6: 1815.

ISSN: 2474-1663

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possible life-threatening disease, acute appointments, investigations, treatments, and possible adverse effects, which all might trigger patients' distress [7]. Anxiety, worries, pain, nausea, fatigue and difficulties of concentration are some of the major sufferings [1,8-10]. After treatment with curative intent the burden of emotional distress might be somewhat reduced but still comprises anxiety, depression, panic, avoidance of social activities, and numbing of emotions [1,11]. This might change relations, and if the social network is not good enough (i.e. meagre, scarce and distant), it seems to lower the immune response and emotional resilience [6].

Moreover, the widely specialized healthcare system is often fragmented [12], and in such a system, cancer patients and their families may experience a lack of continuity of care [13-15], and express feelings of isolation and powerlessness [16,17]. Personalized information's and emotional support are called for in all parts of the care trajectory [16,17], and a continuous healthcare contact can become one of the most important in the social network [6]. An early and continuing support throughout diagnostics and treatment phases might benefit the patients both in the period with illness, and after end of full treatment. Psychosocial interventions in cancer trajectories have been tested with conflicting results, and to the best of our knowledge, none reaches out in full cancer trajectories [4,5,18-23]. Moreover, notably, when targeting the psychosocial area in a part of a cancer trajectory, it leaves the rest period in the trajectory with the risk of interactions deteriorating what eventually was gained in an intervention [2]. Further, psychosocial care is regarded delivered mainly by healthcare workers [4,5,18-23], but also primary caregivers and other family [24], lay persons in municipalities [25], social workers [26], and non-for-profit organizations like cancer society's can add to psychosocial care. We lack evidence to more precisely advice the clinic on psychosocial care to the benefit of patients.

The situation calls for an intervention trial with a theoretical and evidence based base behind the intervention, in order to have a good chance of guessing causal processes, and a qualitative evaluation [27]. The intervention must start in the diagnostic phase before the psychological pressure peaks [1], and an approach based on cognitive behavioral therapy and/or self-management strategies must be used, as such approaches seems to support self-regulation of distress [4,11,18]. Other requirements include the possibility of face-to-face interventions, only few healthcare persons involved, regular follow-up throughout the disease trajectory, and a personalized support to the patient and/or family, as it seems to benefit such users [14,18,28]. The Canadian nurse navigation model seems suitable to build an intervention on. It is widely described in the scientific literature as an intervention that throughout the cancer trajectory targets patients' psychosocial health and has proven feasible and efficient in longitudinal qualitative and quantitative research [14,29-31], though newer tested in a rigorous design. A pilot study with evaluation from patients, nurse navigators, and leaders found such an intervention feasible, acceptable, and useful. Only the quantitative study will be presented here.

Objectives, hypothesis and aims

We will test a nurse navigation intervention including an integration hub for psychosocial care from different professions, sectors, and organizations in- and outside healthcare. In a randomized design we will test the hypothesis, that adding the special designed nurse navigation model to usual care in full cancer trajectories is superior to only usual care. The primary outcome will be the patients'

change in self-efficacy from diagnostic examination to end of treatment. Secondary outcome measures will be patients' change in self-efficacy throughout the disease trajectory, and change in fulfilled needs, experiences of continuity of care, health-related quality of life, and nurse navigation time spent.

Methods

Inclusion and exclusion

Eligible participants are persons >18 of age with a suspicion of colorectal cancer after colonoscopy at one of four participating endoscopy units in two of five regions in Denmark. Non-eligible are those who do not speak or understand Danish, or have a diagnosis (or are in a diagnostic phase) of dementia, severe psychiatric disease, mental retardation, or an American Society of Anesthesiologists (ASA)-score of IV [32]. Written informed consent must be obtained before inclusion.

Participant characteristics and setting

Patients with colorectal cancer are chosen due to pragmatic reasons, as the cancer type is in the top five of incident cancers in western countries, with a relatively good prognosis, and both genders are affected [8]. The endoscopy units both serve country sites, cities and remote low-income islands, and together they serves approximately 660,000 inhabitants. Screening for colorectal cancer is standardized with invitations each second year to citizens between 50 and 74 years of age, and those referred due to symptoms are mainly in same age or older. All physicians in Denmark are obligated to handle symptoms of colorectal cancer as acute events, colposcopist takes biopsies of cancer suspect areas, and at hospitals, multi-disciplinary team conferences are normal procedure [33]. All healthcare services are governmental with free access.

Together with the invitation for a colonoscopy, patients receive a study-pamphlet including written patient information and a phone number to the main researcher with the possibility to get more information. After the colonoscopy, eligible patients are handed the same study pamphlet again plus a specific invitation to participate.

Sampling procedure

A two-arm non-blinded trial will be conducted with experimental manipulation with participants in one group found by equal parallel-group randomization (rct) [1:1] and stratification on sex and age (years 18 to 69 and 70+). In all units, ward nurses can include patients after informed consent, and a computer-generated randomization list will be used to randomly assign participants. In all, four questionnaires will be handled electronically or in paper format of the preference of patients, and questionnaire one to tree is possible to answer at the hospital, but all are possible to answer at home and forward to the project either *via* a secure link or in pre-prayed envelopes. No payment for participation will be performed. The trial does not require ethical approval but is registered at the Danish Data Protection Agency with number 19/26956, at Clinicaltrial.gov with ID NCT03281447, and at the national committee on health research ethics with number S-20150120. As an additional patient safety, we monitor the disease trajectory of all participants in both groups, and if we identify unexplained gaps in the disease trajectories, we inform the in-house administrator, who immediately will take action. The Helsinki declaration is followed [34]. All receive written and verbal information about the study and their rights, including the possibility to withdraw without any consequence to further care, before they sign consent to participate.

Usual care

When the endoscopist at the colonoscopy takes biopsy due to cancer suspicion, patients receive phone numbers to department specific in-house administrators, which they can contact in office hours with questions regarding the department specific course of disease. These administrators are educated secretaries or nurses; they attend the multidisciplinary team conferences and make a summary of the decisions available in the patient’s records within two hours of the conference. Whenever the patient shift treatment, the in-house administrators from the new departments will take over (The upper line in Figure 1).

Patients receive scheduled appointments to examinations and treatment(s) on fast tracks according to Danish regulations, and they have contact to healthcare professionals in wards and outpatient clinics according to their course of cancer treatment. Six weeks after surgery, all patients get a proactive care call from a ward nurse, and six weeks after full treatment (i.e. if patients need further oncology treatment), the care call includes a systematic needs assessment in relation to their cancer situation and follow-up within the healthcare system. Usual care is patient-centered. It does not include an initial systematic screening for distress and unmet needs and targeted follow-up throughout the cancer trajectory and it does not include the patient’s GP and/or community level resources in the ongoing psychosocial care. In-house administrators are encouraged to continue to do as usual, including to keep their friendly and helpful attitude.

Intervention

The intervention will be carried out by one nurse navigator (and one in back-up) throughout a patient’s entire cancer trajectory (The lower part of Figure 1). In this trial, nurse navigators are restricted not to put pressure on physicians to priorities intervention patients’ treatment. Thus, the nurse navigators will not attend the multi-disciplinary team conferences but will receive all information from the conferences and report verbally or written to the multi-disciplinary team.

After inclusion patients receive the telephone number to their

personal nurse navigator (all women), who can be contacted by telephone *via* an answering machine 24 h a day and seven days a week. The nurse navigator calls back within four hours during office hours. In case the patient does not contact the navigator, she will be proactive and will assure contact to the patient at four time points (massive arrows bottom-up in Figure 1), the first in the diagnostic phase: within 72 h after inclusion, the second before cancer treatment start, the third 7 to 10 days after first cancer treatment and the last a week later, or when a new treatment eventually is offered. There might be more proactive care calls, if the single patients wish for this. The nurse navigator attention is phased out in a pace suitable for the patient (Figure 1). Within the first days, they will together perform a screening for distress, a global unmet psychosocial needs assessment, eventually map the patient’s resources, and always discuss related relevant care. In their common communication trajectory, they will follow-up on earlier discussions, and eventually perform new screenings. As a standardized tool to the nurse navigators, we adapted a tested and widely used screening for distress and global unmet needs assessment tool from the Canadian nurse navigation, and adjusted it to the Danish setting following a back-and-forth translated approach [35]. It includes a distress VAS score, a symptom list, and the Edmonton Symptom Assessment Scale (ESAS). A cut-off value for VAS distress on >5/10 or for ESAS on >7/10 is suggested by the Pan-Canadian practice guidelines [35], and was chosen on agreement between research-practitioners, lay persons and clinician representatives from the GPs and the surgical department; if patients score above cut-off value, the patients’ GP will be informed. However, all the nurse navigators’ work are guided by the results of the screening, and in this work, they must act in accordance to the theories outlined in the following, supported by links and ideas for psychosocial support outside the hospital.

Nurse navigator competencies. Nurses have been recruited from surgery or oncology departments and were assigned to the job by their head nurses. They have a minimum of two years of experience in cancer care, show good collaborative skills, and they are able to take the lead in a situation and perform telephone consultations. They are not allowed to work as in-house administrators, but as nurses in

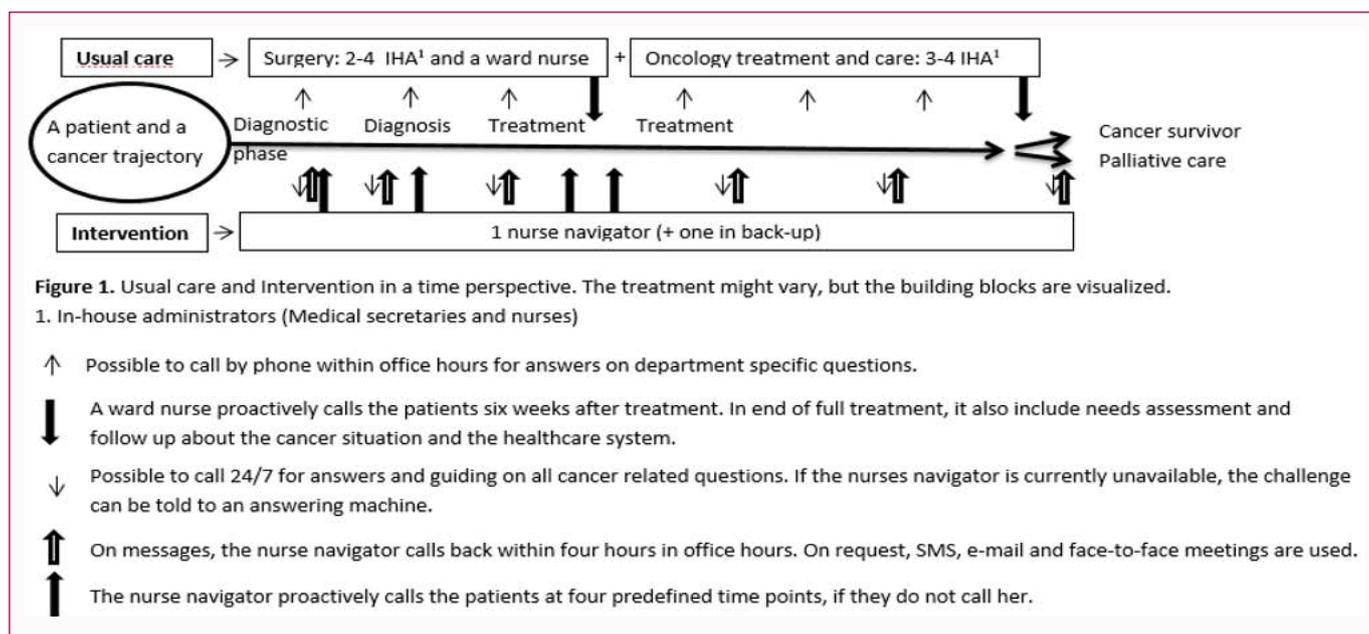


Table 1: The nurse navigator course a full time two-week course.

Theme	Details
Nurse Navigation	The broader frame of Canadian nurse navigation was presented and used as a frame for all further education on the course.
Self-efficacy	Banduras theory as outlined in Figure 2 was presented, and many examples were discussed.
Family Nursing	A family focus contra a patient focus and different ways to address the role in the family were presented and discussed. Presented different ways to map resources and encouraged the nurses to use them where family systems are very complex, and encouraged them to train it at home.
Communication	The Calgary Cambridge Guide was presented and discussed, as well as Motivational Interviewing parts, primarily how to keep a good energy in the conversation, but also how to support patients to take a next step.
Continuity of care	Person continuity, System continuity, and Information continuity were presented and how to practice it were discussed.
The care trajectory	Nurses from surgery department and oncology department told about the course in each their part of the cancer trajectory, followed by discussion on how to best learn the new parts.
The patient view	Scientific literature on patient experiences in the cancer trajectory was presented and discussed against all information given and received on the course.
Psychosocial resources	An example list of psychosocial resources including all basic resources was shown and discussed.
Use of screening instrument	Presentation of the screening instrument and practical training on minimum two volunteer patients at outpatient clinics or wards. All practical training included screening as well as mapping family system and use of all communication techniques learned on the course. All practical training was voice recorded, some parts were transcribed verbatim by the nurses themselves, and all sound was audited by and discussed with the teacher.

out-patient clinics and able to priorities time as nurse navigators (corresponding to one or two days a week). The navigator training is outlined in Table 1. It included use of the screening for distress and unmet needs tool, and they were presented to ways of mapping the patient's resources if they feel the need, either mapping an extended family tree, or mapping resources' closeness to the patient [6,36]. Further, they got theoretical learning and practical training within the theories from nurse navigation: Empowerment [37], and continuity of care [38]. More underlying theories regarding family nursing, and focused communication were included, plus local relevant psycho-social resources in and outside the hospital, the whole cancer trajectory view regarding treatments and care, and patient preferences [36,39-45].

From the pilot study we learned the importance of coaching the nurse navigators, and they will be coached individually by the first author on a weekly basis from start, and later fading slowly to once or twice each second month. The nurse navigators will have the opportunity to spar with each other between coaching sessions.

The intended mechanisms in the complex intervention are visualized in Figure 2.

Nurse navigators will support patients to increase their perceived self-efficacy for situations related to their cancer. Overall, they will follow Banduras theory, that states that social persuasion, and positive enactive and vicarious mastery experiences will support/increase the self-efficacy, but will as well be affected by the physiological and emotional state of the day (arrow and squares in Figure 2) [46]. With an acknowledging and respectful attitude, the nurse navigators will systematically scan for unmet psychosocial needs using a holistic view on a patient's situation as part of their families, facilitate relevant psychosocial offers and follow-up on challenges, which we also expect will better satisfy the patient's needs [36,39,40]. Such relevant handpicked psychosocial offers can be guiding, counseling, information, pall group participation, and listening/support, and can be offered from hospitals, primary health care, the social sector, churches, non-for-profit organizations, the municipality, or the family, and most will be free of charge (bubbles in Figure 2). The continuous contact with the same healthcare person and a logical structure of information are as well expected to increase experienced continuity of care and all parts will possible also increase health related quality of life [38,41-45] (band in Figure 2).

Nurse navigation will be the frame (the encircle in Figure 2). It offers a coherent attention guided by its overall theory, that "a) providing information and education, b) providing emotional and supportive care, and c) facilitating coordination of services and continuity of care within the context of an interdisciplinary team approach" are "essential for the achievement of continuity of care and patient empowerment": [30 pp 46+51].

Data collection

Validated questionnaires for use include self-efficacy (Cancer Behavior Inventory-Brief (CBI-B)), unmet needs, Health-related Quality of Life (HQLQ-30), and experienced continuity of care [38,47-49]. They will be distributed throughout the study period at well-defined time points: a) before randomization (T1), at treatment start (T2), after full treatment or at the latest one year after inclusion (T3), and a follow-up one and a half months after the questionnaire at T3 is completed (T4) (Table 1). At baseline (T1), socio-demographics will be included. Non-responders will receive a reminder by e-mail or conventional mail after one week and a phone call after two weeks in case of no reply. All data are stored on electronic platforms meeting the European legislation and hosted by one region in Denmark.

Sample size, power, and precision

Previous research suggests a clinical relevant change in self-efficacy measured with the CBI-B questionnaire to be eight points [50]. We assume that the baseline CBI-B total-score is 88 with a standard deviation of 20. With results from 100 patients in each group, we have 80% power at the two-sided 5% level to detect a difference of at least eight points in mean change of CBI-B. Taking drop-out into account [51], we aim to include 280.

Audit

Nurse navigators will be audited on their continuously written notes and periodically audio-recorded conversations with participants. All support to, and control of, nurse navigators serves to standardize the intervention to the described theoretical frame.

Quality of measurements and data handling

Those patients in usual care and all healthcare workers except nurse navigators are masked to details in the intervention. Healthcare professionals will not help the patients answer the questionnaires, but if needed, a project assistant masked for group assignment and

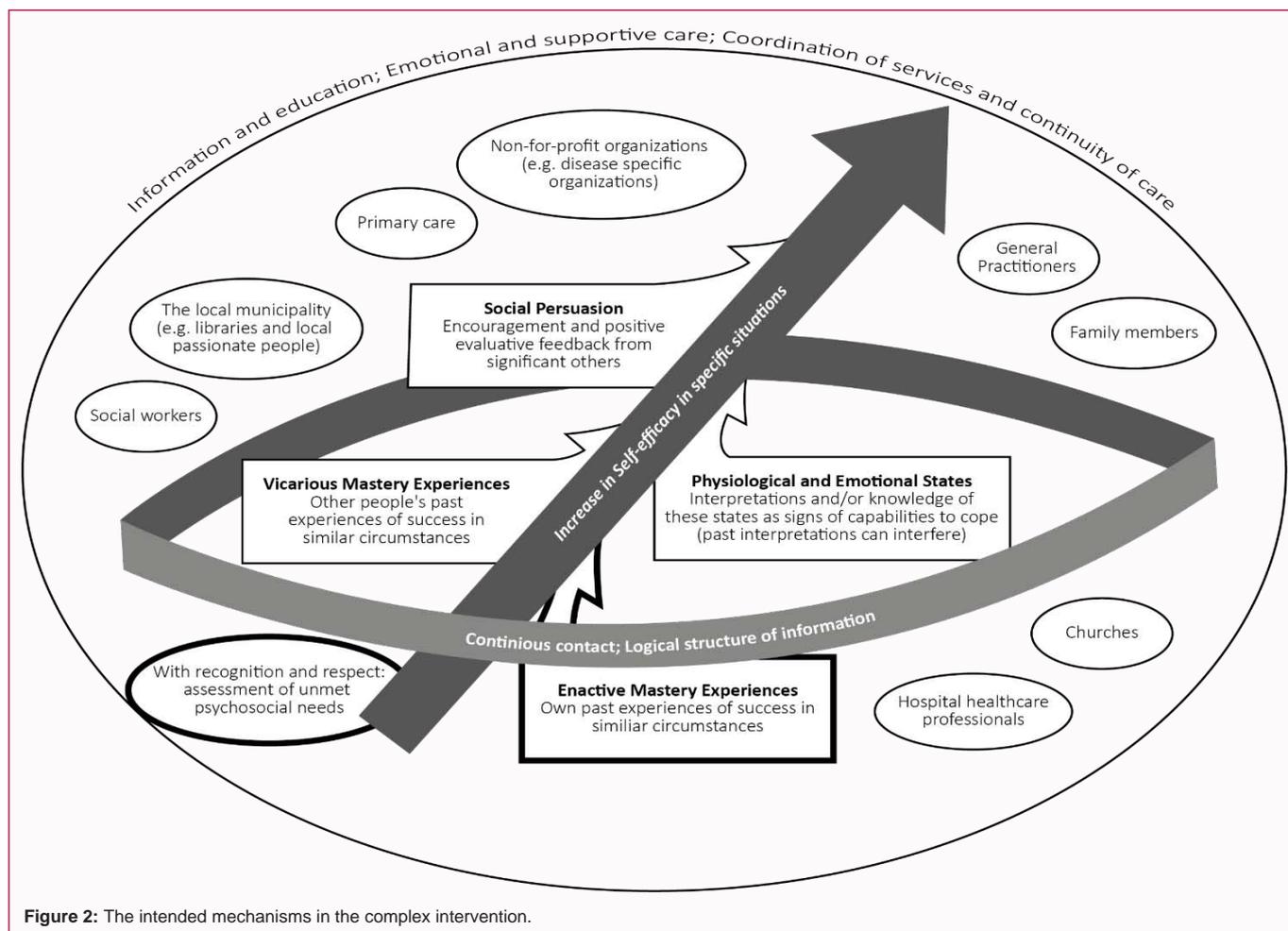


Figure 2: The intended mechanisms in the complex intervention.

trained in non-biased support will assist *via* phone. The statistician will be masked to the randomization group until primary endpoint is analyzed.

Statistical analyses

Descriptive statistics will be used to summaries baseline characteristics. The primary analysis will be an analysis of covariance on the outcome at T3, adjusted for randomization group and outcome at baseline (T1). In secondary analyses, we investigate the change over time, i.e. T1, T2, T3 and T4, by mixed effects repeated measures analysis with randomization group as factor and random effects for subjects. Adjustment for relevant subject-level confounders such as treatment, age, etc. will be performed in subsequent analyses. These analyses will be repeated within the subgroup of cancer patients treated with curative aims, and cancer patients treated with an aim of controlling the cancer. Wherever possible, the intention-to-treat principle will be applied.

Discussion

The planned study will examine the efficacy of a coherent and controlled intervention aimed to integrate psychosocial care to cancer patients from in the diagnostic phase to post-treatment.

The trial is not possible to blind, but we mask where possible. The randomization and the centrally distributed appointments for colonoscopy are expected to distribute conditions equally, but we stratify on age and sex, as these factors might present different kinds of support needs [52,53]. With four measurement points, we

risk stressing the patients and get too many dropouts. However, we have balanced the questionnaire burden in relation to the expected burden of distress, and in order to avoid an underpowered study, we calculate with an attrition rate of 30% (both deaths and withdrawals) based on a previous study using psychological questionnaires in colorectal cancer trajectories [51]. Our measurement times differ from others, but we find it important to let measurements reflect patient experiences at comparable events in the disease trajectory, e.g. at the start and end of treatment. This is expected to improve internal validity of results from psychological measures, compared to where standardized intervals e.g. at one and three weeks after diagnosis were applied, regardless of specific disease trajectories [4,5,19-21,54-57].

Our complex intervention is well underpinned with existing evidence, and present a new way of integrating care in the psychosocial sphere. As in all complex intervention studies, we will not identify causal processes in details. However, with positive results and by focusing on the theories behind the intervention, we will have suitable ideas of predictors for patient experienced success, which are called [27,58,59]. Further, we might need an even deeper understanding of what worked and why [60], and therefore a qualitative interview study in both arms are planned as well.

We will include participants for the RCT from four units and (from distance) follow patients through multiple cancer trajectories. Moreover, nurse navigators use their general and specific knowledge in the intervention with a focus on achieving as much well-developed self-efficacy as possible in the individual patient. All of this adds to

generalizability of our results.

Conclusion

We will test a special nurse navigation model with an added psychosocial care integration hub. Analysis of data from this randomized trial will determine whether this complex intervention gives benefit to patients.

Funding

This study is funded from the non-commercial funds: Free Research Fund at Odense University Hospital, Funds from Southern Region of Denmark, The joint fund between Region Zealand and Odense University Hospital, The Danish Cancer Society, The Fionia Fund, and Sister Marie Dalgaard's fund.

None of the funds have had any influence on the study design and will not have influence on analysis and publications.

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