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Efficacy of open dialogue about complementary and alternative medicine compared with standard care in improving quality of life in patients undergoing conventional oncology treatment (CAMONCO 2): protocol for a randomised controlled trial

Mette Stie ,[1,2] Charlotte Delmar,[3] Birgitte Nørgaard,[4] Lars Henrik Jensen[2]

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For numbered affiliations see end of article.

Correspondence to
Dr Mette Stie;
mette.stie@rsyd.dk

ABSTRACT

Introduction Complementary and alternative medicine (CAM) has been shown to reduce symptoms and adverse effects and improve quality of life of patients undergoing conventional oncology treatment, but CAM might also cause symptoms and adverse effects such as headache and fatigue. Thus, patients need guidance towards safe and healthy use of CAM. According to published results, open dialogue about CAM (OD-CAM) between health professionals and patients as an integral part of anticancer treatment may improve patients' quality of life and well-being. Since the literature on the issue is sparse, the aim of this study is to assess the efficacy of OD-CAM integrated early in conventional oncology treatment versus standard care (SC) in patients undergoing standard anticancer treatment.

Methods and analysis The study is a randomised controlled trial, being conducted at an oncology outpatient clinic in Denmark. 207 patients undergoing curative or palliative oncology treatment for breast, gynaecological, prostate, pulmonary, colorectal, anal or pancreatic cancer will be randomly assigned to SC with or without OD-CAM. A nurse specialist will facilitate the OD-CAM in one or two sessions. The primary endpoint is patient reported quality of life in relation to psychological well-being 8 weeks after enrollment. Secondary endpoints are patient reported level of depression and anxiety, top concerns, and decision regret 8, 12 and 24 weeks after enrolment, and overall survival.

Ethics and dissemination According to the Committee on Health Research Ethics for Southern Denmark, ethics approval of this study is not required (S-20202000-5, 20/1019). The Region of Southern Denmark (Journal no. 20/11100) approved the storing and handling of data. Participants' informed consent will be obtained before inclusion and randomisation. The results of the study, whether positive, negative or inconclusive, will be disseminated through open-access, peer-reviewed publications, stake-holder-reporting and presentations at relevant conferences.

Strengths and limitations of this study

- The CAMONCO 2 study is the first randomised controlled trial to specifically assess the efficacy of open dialogue about complementary and alternative medicine on psychological quality of life and well-being and decisional as to conventional treatment.
- The use of validated patient-reported questionnaires is a strength of the study.
- The use of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire computerised adaptive test CORE questionnaire increases measurement precision, flexibility, questions relevance to the individual patients and reduces respondent burden.
- The complexity of the intervention makes it difficult to determine the potential effects.
- The pragmatic choice of including patients with different cancer diagnoses and prognoses may be too broad.

Trial registration number NCT04299451.

INTRODUCTION

An upward trend in patients' use of complementary and alternative medicine (CAM) as an adjunct to conventional oncology treatment and care is shown in Denmark[1 2] and internationally.[3–8] The term CAM refers to therapies such as acupuncture, meditation, herbs and dietary supplements used as a supplement to conventional cancer treatment.[9] A cross-sectional descriptive survey with 956 patients from 14 different European countries including Denmark has shown that herbs together with homeopathy, vitamins/minerals, medicinal teas, spiritual therapies

and relaxation techniques are the most commonly used CAM modalities among patients with cancer.[10] In the management of cancer-related symptoms and adverse events of conventional oncology treatment CAM is relevant as supportive therapy. Acupressure and acupuncture have been shown to reduce nausea and pain,[11] aromatherapy alleviates sleep and anxiety disorders,[12] and massage, yoga, mindfulness and meditation have been shown to increase quality of life (QoL) and reduce stress and fatigue.[13] CAM may also relieve fear, fatigue and depression[14] and enhance hope,[4] self-care, self-control and empowerment.[15 16] The level of evidence, however, ranges from high to low, and some CAM modalities include risk of interaction when combined with conventional oncology treatment.[17–19] To ensure patient safety and high-quality care some cancer centres thus practice integrative oncology.[20–24] Integrative oncology is a patient-centred, evidence-informed field of cancer care that uses mind and body practices, natural products and/or lifestyle modifications from different traditions alongside conventional cancer treatments. The fundamental starting point of integrative oncology is that patients and health professionals openly discuss safe and healthy use of CAM.[9] Studies have shown that counselling about CAM as an integral part of conventional oncology treatment engages patients in their own healthcare, increases patient-centred communication and leads to higher clinician[25] and patient satisfaction.[26] Counselling about CAM also addresses patient stress and uncertainty because it reduces exposure to misleading information. Furthermore, it enhances the patient–physician relationship, which is essential in delivering high-quality care.[27] Measurable clinically significant improvements on patients' main concerns and well-being has also been associated with CAM counselling when integrated in conventional oncology treatment.[20] Improvements in relation to depression, anxiety, well-being, psychological distress and global distress (sum of pain, fatigue, nausea, depression) have also been identified.[28–31] These studies, however, are limited by the fact that the elements of the CAM counselling were heterogeneous with no clear description, and the changes in symptoms, QoL and well-being lack comparison with a control group. In a previous phase II randomised, controlled study including 112 patients and a qualitative interview of 15 patients (The CAMONCO 1 study),[32] we developed and described the intervention 'open dialogue about CAM' (OD-CAM). Based on a person-centred and evidence-based approach a specialist nurse guides the patient in safe and health promoting use of CAM. The OD-CAM is conducted early in the conventional oncology treatment trajectory. A detailed description is provided in table 1. We tested the effects of OD-CAM on adverse events of conventional cancer treatment, QoL, psychological well-being and perceived information. We found that OD-CAM does not increase the frequency and degree of adverse events of conventional cancer treatment and might contribute to reduced psychological stress and improve QoL. Based on data from the interview study, the participants found that OD-CAM was beneficial for reducing uncertainty and decisional regret as to conventional oncology treatment. Although a tendency towards improved survival was observed, a study with greater statistical power is warranted in order to assess significant effects of OD-CAM. To our knowledge, the efficacy of OD-CAM integrated early in the conventional oncology treatment trajectory has not yet been investigated with specific focus on psychological well-being, QoL, decisional regret and survival.

Although there is an urgent need for interventions fulfilling patients' needs for guidance in safe and health promoting use of CAM, the evidence on conducting OD-CAM integrated in conventional oncology care is sparse. Sufficiently powered, randomised controlled trials are needed to explore the effects of OD-CAM integrated in conventional oncology care.

Aim

The overall hypothesis of this study is that patients newly diagnosed with a primary cancer or a recurrence of cancer will benefit from OD-CAM that is integrated early in the conventional oncology treatment trajectory. The primary aim of this randomised controlled study (CAMONCO 2) is to compare OD-CAM integrated early in the conventional oncology treatment trajectory with standard care (SC) in relation to psychological QoL in patients undergoing conventional anticancer treatment. Secondary endpoints are the impact of OD-CAM on patient-reported level of depression, anxiety and decision regret regarding conventional anti-cancer treatment, patient-reported concern and well-being and overall survival. Whether the attitude of the patients towards and/or use of CAM mediates the potential effect of OD-CAM will also be explored.

METHODS AND ANALYSIS

Design

The CAMONCO 2 study is a randomised (1:1), controlled superior trial with two parallel groups investigating the efficacy of OD-CAM vs SC in improving the QoL of patients undergoing anticancer treatment. There is no consensus in the literature of which time point a potential effect of OD-CAM will be identified. However, data from the interview study in CAMONCO 1 indicated that participants did not experience the benefits of OD-CAM right after the OD-CAM session; they need time to consider and adopt the provided advice about CAM. The time of the primary outcome measure in this study is therefore set at 8 weeks after enrolment. CAMONCO 2 investigates patient-reported QoL as opposed to adverse events of conventional cancer treatment and, cancer-related symptoms[33] and patient satisfaction.[29–31] Although the latter are important factors for patients with cancer, overall QoL and survival is fundamental.

Table 1 Guideline for open dialogue about complementary and alternative medicine (OD-CAM)

Setting		
Preparation	The patient is asked to prepare for the session, including considerations as to current and future use of CAM.	
Environment	The OD-CAM takes place in a consultation room designed specifically to provide a healing environment with soft and natural lighting, flowers, and relaxing furniture. The room is separate from the clinic.	
Schedule	The OD-CAM must be conducted no later than 2 weeks after randomisation and scheduled to last 60 min.	
Nurse specialist	The nurse specialist has completed the programme Fellowship in Integrative Medicine at the University of Arizona. This is a training programme for health professionals in empowering individuals and communities to optimise health and well-being through evidence-based, sustainable and integrative approaches.	
Integrative	Integrative includes a healing oriented approach viewing and respecting patients as whole and unique physical, emotional, social and spiritual beings with values, knowledge, preferences and beliefs. It aims to optimise health, quality of life, clinical outcomes, and support patients to become active participants in their own healing and health. It emphasises the therapeutic relationship between health professional and patient. Based on evidence, CAM-information is provided alongside conventional cancer treatment.	
Content	**In collaboration with the patient**	**Examples of questions to ask**
1. Understand	Elicit the patients' understanding of their situation. Clarify information preferences before asking about CAM use. Ask open questions focusing on psychological/ existential issues.	What is your understanding of the situation at this point? What concerns you most about your illness and treatment? What are your hopes for the future?
2. Respect	Respect cultural, linguistic and belief diversity. Awareness of attitudes and information needs in relation to models of illness and treatment	What do you believe might have caused your illness?
3. Ask	Ask questions about CAM use. Adopt an inquisitive, open minded and non-judgmental approach. Clarify reasons for asking about CAM.	Are you currently doing or considering doing anything else for your condition/adverse effects, your overall health or well-being? Are you taking any other medications or treatments? It is very important for me to know about any initiatives you have taken to address your illness so I can help you the best way possible. I am not an expert in this (CAM) but it is important to make sure that any actions or medications you take do not interact negatively with the treatment we give you.
4. Explore (if the patient is already /considering using CAM)	Explore the details of CAM use and actively listening. Enquire about current and considered CAM use Ask about reasons for and expected outcomes of CAM use. Ask about expected outcomes of conventional treatment. Ask if there is a provider of the CAM (if relevant), who it is and what their role will be in relation to the CAM use. Explore the evidence for the CAM's efficacy and safety. Provide balanced evidence advice in relation to the CAM. Help respond to advice from family and friends (if relevant).	Can you tell me more about this CAM, please? What does it involve? How often do you use it? Have you used it before? What are your reasons for using this CAM? What are you hoping for from this CAM? Has it been helpful so far? How will you know it is helpful for you? Whom are you seeing for this CAM? (if relevant) Do you know if there has been any research on the effect of this CAM? Others want the best for you. Let's talk about these suggestions. What do you think of these suggestions?
5. Respond	Respond to the patient's emotional state, encourage expression of feelings Express empathy. Support the desire for hope and control; address issues the patient seeks to influence by using CAM (e.g. symptom control, alleviation of adverse effects, control, desire to live longer)	How are you feeling emotionally? How are you coping with your situation? It sounds like you want to do everything possible. It is natural to feel a need to explore the possible options and I fully support you in that (if relevant)
6. Discuss	Discuss relevant concerns about CAM while respecting the patient's beliefs. Possible concerns: ► caution about substances with unknown effect and quality ► high financial or time cost for CAM of unknown benefits ► potential for psychological harm Discuss a reasonable trial period over which an assessment can be made regarding benefits/efficacy of CAM. A symptom diary may help determine whether the CAM is beneficial for the individual patient. Explore alternative ways of addressing the patients underlying needs, hopes or fears (especially if there are concerns about potential harms of the CAM)	I believe there is little evidence about the benefit or harm associated with this CAM. Therefore, we should be cautious. Might the time involved prevent you from doing other things you like to do? How do you think you might feel if you followed this advice (CAM use) but did not achieve the outcome you hoped for? How long would you expect it to take to see a benefit from this CAM? I can see that you hope this CAM will help you/your cancer/ symptoms/adverse effects/well-being. There are other options we can look at, too. Would you like to hear about them?

Continued

Table 1 Continued

Content	In collaboration with the patient	Examples of questions to ask
7. Advise	Encourage use of CAM that may be beneficial. Accept use of CAM for which there is no evidence of physical harm or benefit. Support the decision, even though it conflicts with your private view. Discourage use of CAM where there is no good evidence. It will be unsafe or harmful. Particularly, discourage use of unproven CAM if it is to be used in place of potentially beneficial treatment, especially potentially curative treatment. Balance advice with an acknowledgement of the patient's rights for self-determination and autonomy.	I recommend this CAM; The evidence suggests that it could help you. We do not know much about this CAM, but it does not seem to be harmful and it may even help you. I respect that this is what you wish to do. I have to be honest with you. I am concerned that this CAM may do you greater harm than good. I respect and support your right to make this decision. However, I firmly believe that you have a better chance of a good outcome if you follow this treatment plan. While there is little evidence for us to know if this CAM will be helpful, of course the decision is yours.
8. Summarise	Summarise main points of discussion and check patient's understanding. Provide websites and other information or resources, for example, information about supplements, dietary, breathing exercises, yoga, meditation, etc.	We have covered a lot today. Just so that I can check that I have explained things properly, can you summarise what we have discussed? Do you have any further questions or issues you would like to discuss?
9. Document	Document the discussion in the patient's medical record and send a copy to the patient.	I will document what we have discussed today in your medical record and we will send a copy to your secure inbox.
10. Follow-up	Follow-up discussion about CAM if relevant	

Setting

The study is conducted at the Oncology Outpatient Clinic, Vejle Hospital, University Hospital of Southern Denmark. The Oncology Outpatient Clinic offers conventional treatment and care to adult patients with breast, gynaecological, prostate, pulmonary, colorectal, anal and pancreatic cancer. Annually, the number of outpatient visits amounts to 57 000 with 23 000 radiotherapy fractions and 9300 chemotherapy and immunotherapy treatments administered. In Denmark, CAM is not a part of the official healthcare system. CAM is practised outside the official healthcare system and paid out of pocket.

Participants

Adult patients aged ≥18 years, diagnosed with primary cancer or recurrence within the last 3 months, are offered enrolment. The inclusion criteria include planned antineoplastic treatment for at least 2 months. Life expectancy of 6 months or more and signed informed consent are also criteria for inclusion. Patients that participate in other trials that interfere with the intervention or data collection will be excluded.

Procedures

Recruitment

Nurse coordinators identify and screen potential candidates for initial eligibility according to the inclusion and exclusion criteria. In connection with initial cycles of chemotherapy, immunotherapy and/or antibody therapy in the outpatient clinic, eligible patients are informed and invited to participate in the study by a trained nurse or study nurse. Eligible patients are provided with written and oral information about the study objectives procedures. Signed consent is obtained from those willing to participate. Consent must be given within 12 weeks from treatment start, that is, at the fourth cycle of treatment at the latest. Recruitment continues until the defined sample size is reached. For optimisation of the selection bias analysis, patients declining to participate will be encouraged to complete a questionnaire on sex, age, type of cancer and treatment purpose (curative or palliative).

Randomisation

On signed consent, patients complete baseline questionnaires on demographic data, cancer diagnosis and stage, oncology treatment, QoL, degree of anxiety and depression, two top concerns, decision regret as to anticancer treatment and their attitude towards and possible use of CAM. The clinical trial unit using OPEN Randomise (https://open.rsyd.dk/), an online central randomisation service, subsequently performs randomisation. Patients are randomised 1:1 to the intervention and control groups with no further stratification. OPENs Randomise ensures allocation concealment, as it will not release the randomisation code until the patient has been enrolled in the study. Thus, randomisation will be performed when all baseline measurements have been completed.

Blinding

This is a non-blinded study. Neither participants nor staff can be blinded to the allocation due to the nature of the intervention. The principal investigator is blinded to the allocation and not involved in the treatment and care of the patients. Results data are entered in separate sheets allowing for analysis without revealing allocation status. All statistical analyses will be performed blinded to group allocation and results will be interpreted prior to disclosure.

Interventions

Eligible patients are randomised in equal proportions between OD-CAM and SC and SC with referral to www.kabcancer.dk

Intervention group: OD-CAM

OD-CAM has been developed and described in our previous study (CAMONCO 1).[32] As in CAMOCO 1, patients in the intervention group will receive SC and participate in one or two sessions on OD-CAM facilitated by a nurse-specialist, who has completed the programme Fellowship in Integrative Medicine at The University of Arizona, USA. This programme trains health professionals in empowering individuals and communities to optimise health and well-being through evidence-based, sustainable and integrative approaches.[34] In the OD-CAM, the nurse specialist is inspired by the principles of Integrative Medicine. Based on the patients' individual experiences, values, beliefs, concerns and needs, the nurse specialist provides evidence-based information as to which CAM modalities are recommendable or should be avoided. A primary caregiver may participate, if preferred by the patient. The number of OD-CAM sessions depends on the individual patient. The OD-CAM is exclusively a dialogue between the nurse-specialist and the patient. The nurse-specialist does not offer CAM treatments. The guideline for OD-CAM is presented in table 1, and was developed in our previous study (CAMONCO 1).[32]

Control group: SC

Patients randomised to the control group receive SC that is, conventional oncology treatment and care, including antineoplastic drugs. SC also involves continuous assessment of performance status, adverse events, symptoms and their management by specialist doctors and nurses. The patients are given a pamphlet describing and referring to a website, www.kabcancer.dk. Based on systematic reviews, this website presents research-based information on effects and outcomes of specific CAM interventions, that is, acupuncture, antioxidant supplements, mindfulness, herbs, massage, etc.[35]

No concomitant medications or consultations are prohibited during the study.

Primary outcome measure

The primary outcome measure is the difference in level of patient reported QoL, specifically with regard to emotional well-being, between the two groups 8 weeks^{t1} after enrolment. The patient reported data will be registered according to the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire computerised adaptive test (EORTC QLQ CAT Core). The EORTC QLQ CAT core is a translated and validated instrument, which encompasses 15 domains with pools of validated questions. Within each pool of questions, the EORTC CAT Core selects and presents the question that is the most informative for the individual patient. The instrument lists questions assessing QoL, including functional scales, symptom scales, global health status and psychosocial scales.[36]

Secondary outcome measures

The secondary outcome measure is the change from baseline to post intervention 8 t1, 12 t2 and 24 t3 weeks after enrolment. Difference between the two groups will be assessed in the following outcomes.

- Patient reported anxiety and depression evaluated by the Hospital Anxiety and Depression Scale (HADS). HADS is a translated and validated self-assessment questionnaire detecting states of anxiety and depression in the setting of hospital outpatient clinics.[37]
- Patient reported level of top concern evaluated by Measure Yourself Concerns and Well-being (MYCaW). MYCaW is an individualised questionnaire scoring patients concerns, problems and well-being and collecting qualitative data about other major events in a patient's life and what has been most important to the patient.[38]
- Patient-reported level of decision regret regarding conventional oncology treatment evaluated by the Decision Regret Scale (DRS). The DRS is a validated measurement tool measuring the distress or remorse after a healthcare decision.[39]
- Patient-reported QoL 12 and 24 weeks after enrollment evaluated by the EORTC QLQ CAT Core.[36]

Overall survival will be measured 12 months after enrolment of last patient.

Process measures

Variables likely to mediate the effect of OD-CAM will be measured twice during follow-up (at baseline^{t1} and 24 t3 weeks):

- Attitude of CAM.
- Use of CAM including type.

Flow chart and participant timeline are presented in table 2 and figure 1, respectively. All questionnaires are administered electronically. If questionnaires are not completed within 2 weeks, a reminder is sent.

Data management

Cooperation and a license agreement have been established with the OPEN organisation (Odense Patient data Explorative Network). All sensitive data will be registered and stored in OPEN Analyse and handled in REDCap (Research Electronic data Capture), a mature, secure web application for building and managing online surveys and databases. REDCap provides logging at the transaction level and may therefore store and process any person identifiable data. Thus, congruent with guidelines, sensitive data about the patients are stored and handled securely.[40]

STATA software, version 16 (Texas, USA) will be used as a platform for statistical analysis. Since STATA only provides logging at the file level, participant data will be pseudonymised by assigning a unique ID number to each participant. The list of ID numbers and the pertaining

Table 2 Participant timeline

	Study period				
	Enrolment	Allocation	Post-allocation		
Timepoint	$-t_1$	0	t_1 8 weeks	t_2 12 weeks	t_3 24 weeks
Enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions					
SC+OD-CAM			⟷	⟷	
SC			⟷	⟷	
Assessments					
Baseline variables					
Demographic data	X				
QoL	X				
Anxiety and depression	X				
Top concerns	X				
Decision regret	X				
Attitude and use of CAM	X				
Outcome variables					
QoL			X	X	X
Anxiety and depression			X	X	X
Top concerns			X	X	X
Decision regret			X	X	X
Mediators					
Attitude and use of CAM					X

CAM, complementary and alternative medicine; QoL, quality of life; SC, standard care.

key will be kept separately. Information on user and time of data processing in STATA will be logged.

Only persons involved in the project are allowed to access data. In accordance with the license agreement principal investigator (Mette Stie) controls access and rights and the OPEN data manager provides the access.

Research nurses in the clinical trial unit will only have the right to enter data into REDCap. Data collected on paper (baseline data) will be registered in REDCap. The electronic questionnaires are completed by the patients directly in REDCap, which promotes data quality.

Statistical analysis plan

Sample size

The sample size is calculated on the basis of the primary endpoint. A 10-point difference or more in the QoL EORTC QLQ CAT Core scale from baseline to 8 weeks between the two study groups is considered of clinical importance. We plan a randomised controlled study of a continuous response variable in independent control and experimental subjects with one control per experimental subject. In a previous study, the response within each subject group was normally distributed with an SD of 24.2. If the true difference in the experimental and control means is 10, the number of subjects required in each group is 93 to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The type I error probability associated with this test of the null hypothesis is 0.05. With an expected loss of 10%, the total number of patients to be enrolled is 207.

Statistical methods

The intervention arm (OD-CAM) will be compared against the control arm (SC plus referral to www.kabcancer.dk) in all primary analyses. Demographic data will be presented as counts (n) and proportions (%), respectively, means and SD with 95% CI. χ^2 test or a Fisher's exact test will be applied where appropriate to detect differences between the two groups in relation to QoL. The EORTC QLQ CAT Core, HADS scores, DRS and MYCaW will be reported as means and SD compared between the two groups by using Student's t-test or Mann Whitney's U test, depending on normality of the data checked by quantile-quantile plots.

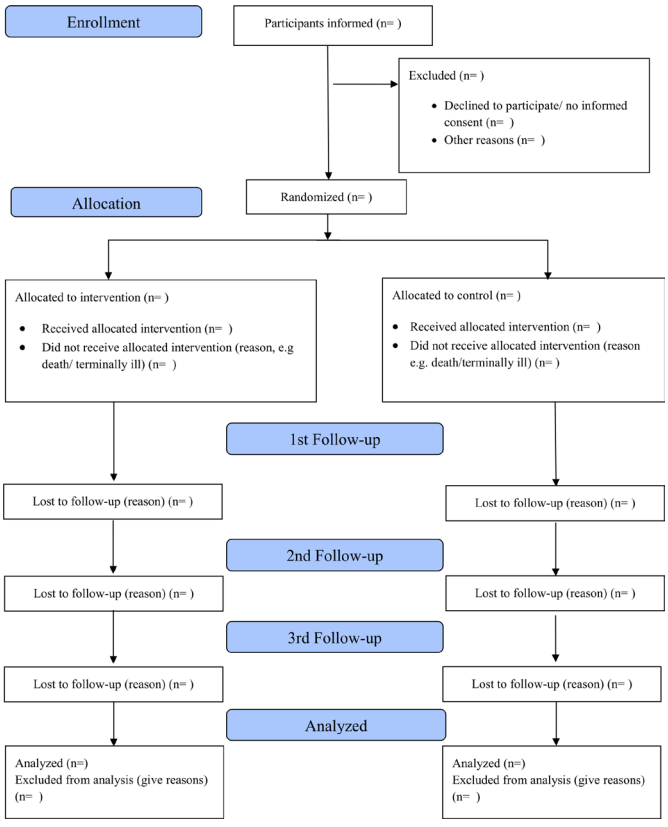

Figure 1 Study flow chart.

P-values will be reported to three decimal places with p values less than 0.001 reported as <0.001. Two-sided p values with a 0.10 level of significance will be used for all tests. Kaplan-Meier survival analysis will be applied to detect potential difference in overall survival between the two group. A professional academic, statistician blinded to the study group assignment will conduct all analyses. For potential subgroup analyses, appropriate regression methods will be applied, for example, in case of a great variety in number of OD-CAM sessions

Patient and public involvement

The Patient and Relative Council Board at Lillebaelt Hospital has initiated the CAMONCO 1 and 2 studies. Before submission, this research protocol was developed and reviewed by the CAMONCO steering group, a joint initiative of patients with cancer, health professionals and staff representing medical oncology, oncology nursing and nurse managers. Furthermore, Danish Cancer Society is represented in the CAMONCO steering group. Patients in the CAMONCO steering group were in particular involved in development of the intervention OD-CAM and time required to participate in the study. Also, patients' priorities, experiences and preferences informed some of the outcome measures (EORTC-CAT core and MYCaW). The steering group will continuously provide feedback on interim findings and advise on dissemination of results and output of the study. Patients from the steering group are pivotal partners in the dissemination of the CAMONCO 1 and 2 studies to relevant stakeholders.

Ethics and dissemination

According to the Committee on Health Research Ethics for Southern Denmark, ethics approval of this study is not required (S-20202000-5, 20/1019). The Region of Southern Denmark (Journal no. 20/11100) approved the storing and handling of data. The procedures in this study adhere to the principals of the Declaration of Helsinki. Thus, patients are informed about the purpose of the study, including the right to withdraw, the guarantee of anonymity, and the confidentiality of the data. Trained nurses or study nurses will introduce and discuss the trial with the patients. If needed, patients will be able to have an informed discussion about the trial with the principal investigator. The trained nurses or study nurses will obtain written consent from patients willing to participate in the trial (see patient consent form in online supplemental file). Subsequently, demographic data and questionnaires regarding patients' QoL, depression and anxiety, concerns and well-being, and decision regrets will be collected, preserved and shared only by researchers involved in this trial.

It is estimated that the study does not involve any risk to the patients, and the potential benefits clearly outweigh the theoretical risks involved in participating in OD-CAM and completing questionnaires.

The results of the study, whether positive, negative or inconclusive, will be disseminated through open-access, peer-reviewed publications, stake-holder-reporting and presentations at relevant conferences.

DISCUSSION

The need for OD-CAM as an integral part of oncology care becomes increasingly urgent with the increasing number of patients using CAM as an adjunct to conventional oncology treatment. To the best of our knowledge, this is the first randomised controlled trial that aims to evaluate the efficacy of OD-CAM integrated in conventional oncology care versus SC in patients undergoing anticancer treatment, by the EORTC QLQ CAT Core, the HADS, the MYCaW and the DRS questionnaires. The current study will shed light on the effect of OD-CAM on patients receiving outpatient oncology treatment for cancer and provide foundation for guidelines on how to meet patients' needs for guidance in safe and health promoting use of CAM. It will also add to the evidence-based knowledge on communication about CAM between patients and health professionals in clinical practice. Only few studies have exclusively explored the effects OD-CAM integrated in conventional oncology care.[26] Most of them include both open dialogue and the provision of CAM and mainly assess patient satisfaction. According to our knowledge, only one study other than our previous trial (CAMONCO 1), has investigated the effects of OD-CAM on patients' symptoms, QoL and well-being.[33] The present

CAMONCO 2 study will therefore be an important contribution to the sparse knowledge on the issues as integrated in conventional oncology care.

Strengths and limitations

One limitation of this study may be that since little is known about the effects of OD-CAM, the pragmatic choice of including patients with different cancer diagnoses and prognoses may be too broad. On the other hand, these patients have much in common including the need for self-care, self-control and empowerment, which are some of the main reasons for using CAM.[41–43] The randomisation secures the even distribution of different diagnoses and prognoses. Only the researchers are blinded to the allocation, which is a limitation but necessary due to the nature of the intervention. The complexity of the intervention also makes it difficult to determine the potential effects, but the same nurse specialist conducts the OD-CAM throughout the study, which secures a homogeneous intervention.

The prospective, randomised design with a control group and the use of validated patient-reported questionnaires is a strength of the study. Strengths also include the use of the EORTC QLQ CAT CORE questionnaire, it increases measurement precision, flexibility, question relevance to the individual patients and reduces respondent burden.

Study status

The first participant was enrolled on 11 Ma 2020. A total of 181 patients were enrolled at the time of preparation of this manuscript.

Author affiliations
[1]Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark
[2]Oncology, Lillebaelt Hospital - University Hospital of Southern Denmark, Vejle, Denmark
[3]Department of Public Health, Research Unit for Nursing and Healht Care, Aarhus Universitet, Aarhus, Denmark
[4]Department Public Health, University of Southern Denmark, Odense, Denmark

Twitter Birgitte Nørgaard @BRgaard

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Contributors All authors, MS, CD, BN and LHJ, contributed to the study planning, conception and design. MS and LHJ perform material preparation, data collection and analysis. MS wrote the first draft of the manuscript and CD, BN and LHJ revised it critically for important intellectual content. MS, CD, BN and LHJ approved publication of the final version and agree to be accountable for all aspects of the work.

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ORCID iD
Mette Stie http://orcid.org/0000-0002-5254-9359

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Deltagerinformation og samtykkeerklæring ved deltagelse i et videnskabeligt projekt

Effekten af åben dialog om komplementær og alternativ behandling integreret i kræftbehandlingen. Patientoplevet livskvalitet og velvære

Engelsk titel:
The efficacy of open dialogue about complementary alternative medicine integrated in conventional oncology care. Patient reported quality of life and well-being

Version 1
2. marts 2020

Deltagerinformation

Vi ønsker at fremme åben dialog mellem patienter og sundhedsprofessionelle om komplementær og alternativ behandling, når patienter har et behandlingsforløb i Onkologisk Afdeling. Det alternative kan f.eks. bestå af kosttilskud, akupunktur, massage mm. De, der bedst kan hjælpe os, er patienter som dig, der er i kræftbehandling. Derfor vil vi spørge, om du vil deltage i et videnskabeligt forsøg, der udføres på Onkologisk Afdeling.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad det går ud på. Vi vil derfor bede dig om at læse denne deltagerinformation igennem. Ved din næste samtale eller behandling i Onkologisk Ambulatorium vil forsøget blive uddybet og du kan stille spørgsmål. Du er velkommen til at tage et familiemedlem, en ven eller en bekendt med til samtalen. Herefter har du ret til betænkningstid på mindst et døgn.

Sammen med denne deltagerinformation har du også fået udleveret folderen "Før du beslutter dig", som vi opfordrer dig til at læse. Her kan du få yderligere oplysninger om deltagelse i forsøg.

Det er frivilligt at deltage og du kan når som helst og uden grund trække dit samtykke tilbage. Det vil på ingen måde få indflydelse på din videre behandling.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive samtykkeerklæringen vedhæftet denne information. Hvis du ikke ønsker at deltage, håber vi, du vil udfylde sidste side.

Baggrund for projektet

Mange patienter med kræft anvender såkaldt komplementær og alternativ behandling (KAB) som et supplement til kemoterapi eller immunterapi. I nogle tilfælde er disse behandlinger ikke forenelige, hvilket kan betyde, at man enten ikke får gavn af kemoterapien og immunterapien eller, at man får unødige bivirkninger. På den anden side kan visse former for KAB øge livskvaliteten og velværet hos patienter med kræft. Derfor er det vigtigt, at patienter og sundhedsprofessionelle taler åbent med hinanden om både fordele og ulemper ved KAB som et supplement til kemoterapi eller immunterapi.

Baseret på vores tidligere, lignende projekt tyder det på, at åben dialog om KAB kan forbedre patientens livskvalitet og velvære. Denne undersøgelse skal derfor vise, om samtaler om KAB som en integreret del af kræftbehandlingen kan forbedre patientens livskvalitet og velvære og bidrage til, at patienten er tilfreds med sit valg om at modtage kræftbehandling.

Hvad går projektet ud på?

Vi inviterer 207 patienter til at deltage i undersøgelsen. Halvdelen tilbydes en samtale om KAB med en specialuddannet sygeplejerske. De patienter, der ikke tilbydes samtale om komplementær og alternativ behandling, følger Onkologisk Afdelings vanlige forløb, der består af samtaler om kemoterapi og/eller immunterapi samt henvisning til en hjemmeside om komplementær og alternativ behandling (www.KABcancer.dk). Udvælgelsen foregår ved computerbaseret lodtrækning.

Få dage efter underskrivelse af samtykkeerklæringen får man besked på, om man er blevet tildelt en samtale om KAB.

Samtalen foregår i starten af behandlingsforløbet i Onkologisk Afdeling og varer 1 time. Den tager udgangspunkt i patientens værdier, ønsker og præferencer med hensyn til KAB og indeholder råd og vejledning i forhold hertil. Hvis der er behov for det, tilbydes en opfølgende samtale.

For at kunne undersøge effekten af disse samtaler vil vi bede dig om at udfylde et spørgeskema 4 gange i løbet af behandlingsforløbet. Det første skema modtager du på papir i forbindelse med tilmeldingen til forsøget. De næste får du i eBoks 8, 12 og 24 uger senere til udfyldelse elektronisk.

Hvad betyder forsøget for dig selv eller andre?

Hvis du bliver udvalgt til at deltage i en samtale om KAB, er det muligt, at du vil drage nytte deraf. Resultaterne af forsøget forventes dog primært at være nyttige i forhold til fremtidige patienter med kræft.

Eventuelle bivirkninger, risici eller ulemper

Du udsættes ikke for øget risiko eller ubehag. Det kan føles som en ulempe ved forsøget, at du skal bruge tid på at besvare spørgeskemaer og at du muligvis vil skulle møde en ekstra gang i Onkologisk Ambulatorium.

Hvem kan få oplysninger?

Alle oplysninger om dig i dette projekt opbevares fortroligt i henhold til dansk lovgivning (databeskyttelsesloven og databeskyttelsesforordningen). Personale, der er involveret i projektet, vil få adgang til oplysningerne i indtil 5 år efter forsøgets afslutning. Tavshedspligt er gældende for alt personale, og din identitet bliver ikke afsløret, når vi offentliggør resultaterne af projektet. Vi registrerer en række oplysninger om din sygdom fra din elektroniske patientjournal, men kun de oplysninger, der er nødvendige for at opgøre forsøgsresultaterne.

Projektet gennemføres i et samarbejde mellem Onkologisk Afdeling, Vejle Sygehus og Syddansk Universitet. Resultaterne af undersøgelsen forventes at kunne gøres op i år 2021 og vil i anonymiseret form blive søgt offentliggjort i et internationalt, videnskabeligt tidsskrift og være tilgængelige på www.ClinicalTrials.gov. Du er også velkommen til at kontakte undertegnede til den tid for at få et uddrag af resultaterne.

Godkendelse og økonomi

Patient- og Pårørenderådet ved Vejle Sygehus har taget initiativ til undersøgelsen, som er godkendt af Region Syddanmark. Studiet finansieres delvist af Fondation Idella. Øvrige fonde vil blive søgt om midler til aflønning af projektsygeplejerske og statistiker.

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutning om din eventuelle deltagelse.

Med venlig hilsen

Lars Henrik Jensen
Klinisk lektor, overlæge, PhD
Onkologisk Afdeling
Vejle Sygehus

Mette Stie
Klinisk Sygeplejespecialist, cand.cur., PhD-studerende
E-mail: mette.stie@rsyd.dk
Tlf.: 7940 6060

Patientens kopi

Samtykkeerklæring

Effekten af åben dialog om komplementær og alternativ behandling integreret i kræftbehandlingen. Patientoplevet livskvalitet og velvære. CAMONCO 2
(The efficacy of open dialogue about complementary alternative medicine integrated in conventional oncology care. Patient reported quality of life and well-being, CAMONCO 2)

Erklæring fra forsøgsdeltageren

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til at deltage i forskningsprojektet og til at forskningsgruppen må hente oplysninger i min journal om mit behandlingsforløb i Onkologisk Afdeling til brug i projektet.

Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Patient navn: _____
BLOKBOGSTAVER

Jeg ønsker at besvare spørgeskemaer elektronisk (sæt X) ___JA ___NEJ

Mailadresse _____

Dato og patientunderskrift: _____
Dato Underskrift

Erklæring fra den informerende sygeplejerske/læge

Jeg erklærer, at forsøgsdeltageren har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål til mig. Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Informerende sygeplejerske/læge: _____
BLOKBOGSTAVER

Dato og underskrift, informerende sygeplejerske/læge:

_____
Dato Underskrift

Sygeplejerskens/lægens kopi

Samtykkeerklæring

Effekten af åben dialog om komplementær og alternativ behandling integreret i kræftbehandlingen. Patientoplevet livskvalitet og velvære, CAMONCO 2
(The efficacy of open dialogue about complementary alternative medicine integrated in conventional oncology care. Patient reported quality of life and well-being, CAMONCO 2)

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Patient navn: _____
BLOKBOGSTAVER

Jeg ønsker at besvare spørgeskemaer elektronisk (sæt X) ___JA ___NEJ

Mailadresse _____

Dato og patientunderskrift: _____
Dato Underskrift

Erklæring fra den informerende sygeplejerske/læge

Jeg erklærer, at forsøgsdeltageren har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål til mig. Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Informerende sygeplejerske/læge: _____
BLOKBOGSTAVER

Dato og underskrift, informerende sygeplejerske/læge:

_____
Dato Underskrift

Udfyldes af Forskningsenheden

Patientnummer ☐☐☐ **Patient-initialer** ☐☐☐

Jeg ønsker ikke at deltage

Tak fordi du tog dig tid til at blive informeret og forholde dig til projektet. Din beslutning om ikke at deltage, får på ingen måde indflydelse på din videre behandling og pleje.

Vi vil dog sætte pris på at få dine svar på nedenstående få spørgsmål.

1) Hvad er dit køn? (sæt x) ____Mand ____Kvinde

2) Hvad er din fødselsdato og år?_____

3) Hvilken type kræft er du i behandling for (sæt X)

- ○ Brystkræft
- ○ Prostatakræft
- ○ Lungekræft
- ○ Tarmkræft
- ○ Æggestokkræft
- ○ Livmoderkræft
- ○ Bugspytkirtelkræft

4) Hvad er målet med behandlingen? (sæt x) ____Helbredelse ____Lindring

Mange tak for din besvarelse.