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# BMJ Open

## Towards an open and effective dialogue on complementary medicine in oncology. Protocol of patient participatory study 'COMMON'.

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3 **Title page**  
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6 **Towards an open and effective dialogue on complementary medicine in oncology.**  
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8 **Protocol of patient participatory study 'COMMON'.**  
9

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## Abstract

*Introduction.* Approximately half of patients with cancer use some form of complementary medicine alongside conventional cancer treatment. The topic of complementary medicine often remains undiscussed in consultations between patients with cancer and their healthcare providers. This results in increased risks for adverse or interaction effects and decreased access to the benefits of evidence-based complementary medicine for patients with cancer. This paper describes the design of patient participatory study titled ‘COMMON’ that aims to explore and enhance open and effective communication about complementary medicine in oncology. The study is carried out in collaboration with 12 (former) breast cancer patients as co-researchers.

*Methods and analysis.* The study complies with the six steps of the intervention mapping framework. Three non-academic hospitals recruit participants (patients with cancer, oncology healthcare providers and managers) for interviews about the organization, experiences and needs regarding complementary medicine. To assess communication about complementary medicine, recorded oncology consultations are analysed. For an overview of evidence-based complementary medicine available to patients with cancer, a review of systematic reviews is conducted on the evidence on cancer patient-reported outcomes of complementary medicine frequently used by cancer patients. This meta-analysis is supplemented with an online search and survey among organizations and persons providing complementary medicine to patients with cancer. Together, these steps generate input for the development of a toolbox that supports an open and effective discussion on complementary medicine in oncology. In a pilot study, acceptability and usability of the toolbox are assessed among patients with cancer and oncology healthcare providers. Dissemination of the toolbox is covered by the commitment of stakeholder parties.

*Ethics and dissemination.* The Medical Ethics Committee Arnhem-Nijmegen declared the study was exempted from formal approval under the Dutch Medical Research Involving Human Subjects Act. The results will be disseminated through open-access, peer-reviewed publications, stakeholder-reporting and presentations at relevant conferences.

### Strengths and limitations of this study

- The COMMON study is the first to develop a toolbox for improving communication about complementary medicine for patients with cancer and oncology healthcare providers in the Netherlands

- The participation of patients with breast cancer as co-researchers enhances the validity and relevance of the findings
- The study data collection can be carried out entirely online and will not be delayed due to Covid-19 restrictions
- The study specifically involves breast cancer patients, decreasing the generalizability of the results and the toolbox to the entire population of patients with cancer
- The success of the toolbox depends on the support from national stakeholders in the implementation process and on the willingness of healthcare providers and patients to use the toolbox

## INTRODUCTION

The use of complementary medicine among patients with cancer has become increasingly common over the last decades [1]. Nowadays, approximately half of all oncology patients use complementary medicine alongside conventional cancer treatment [1-3]. However, the topic of complementary medicine remains undiscussed in the majority of oncology consultations [4-6].

Complementary medicine in oncology entails health approaches that are not typically part of conventional cancer treatments, but are used to complement them [7, 8]. This contrasts with alternative medicine replacing conventional cancer treatment. Together, complementary and alternative medicine are often referred to as CAM. The current study focuses solely on complementary medicine and adopts a broad definition, encompassing all approaches that complement biomedical treatment of the oncological disease and that aim to contribute to the physical, mental or social well-being of the patient. The definition includes approaches that were previously considered complementary, but are now regularly incorporated in conventional supportive care (e.g. exercise and psychological therapies).

Complementary medicine approaches frequently used by patients with cancer in Western countries are mind-body therapies, massage and nutrition counseling [9]. Patients with cancer state several reasons for using complementary medicine, such as improving physical and emotional well-being, quality of life or reducing side-effects from conventional treatment [10]. In the field of conventional medicine, the added value of complementary medicine is still hotly debated. Complementary medicine is a heterogeneous field and for many approaches neither effectiveness nor safety have been sufficiently proven. Some supplements or herbs can have adverse effects or interact with conventional cancer treatment

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3 [11, 12]. On the other hand, a growing body of evidence shows that particular types of  
4 complementary medicine can be efficacious and safe to use for patients with cancer, such as  
5 acupressure for reducing chemotherapy-induced nausea and vomiting [13]. A few  
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7 complementary medicine approaches receive recommendation in oncology guidelines [14],  
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9 implying sufficient evidence.

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12 However, 20% to 77% of the patients with cancer do not disclose their use of  
13 complementary medicine to conventional healthcare providers [15]. In 2017, the Dutch Breast  
14 Cancer Association administered a survey among 750 members showing that 65% of the  
15 patients use complementary medicine. Of those patients, 29% did not discuss their  
16 complementary medicine use with their healthcare provider [16]. A similar survey among 229  
17 Dutch patients with hematological cancer reported that 43% of the respondents use  
18 complementary medicine, of which 38% did not discuss this with their healthcare provider  
19 [17]. The main reasons for nondisclosure stated by patients with cancer are related to  
20 healthcare providers' disapproval, disinterest, lack of inquiry or inability to provide  
21 information [15]. Conventional healthcare providers often feel uncomfortable discussing  
22 complementary medicine due to limited education and knowledge on the topic [3, 18]. In  
23 view of the frequent use of complementary medicine among cancer patients, not discussing  
24 the topic in oncology is problematic. It increases risks for patients' exposure to misleading  
25 information, adverse effects due to inappropriate use and interactions with conventional  
26 cancer treatment [12, 19]. Additionally, some patients may remain devoid of evidence-based  
27 complementary medicine that could potentially support them.

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30 It is well-known that effective communication, the cornerstone of patient-centered  
31 care, can positively influence physical and psychosocial aspects of a patients' health [20-22].  
32 An effective discussion about complementary medicine consists of exchanging adequate  
33 information, responding to emotional needs and managing uncertainty of patients [19].  
34 Furthermore, the healthcare provider can play a significant role in informed decision-making  
35 about complementary medicine use. In an open dialogue on the topic, both benefits and risks  
36 or the lack of evidence thereof, can be acknowledged [23]. Open communication about  
37 complementary medicine fosters mutual trust between patients and healthcare providers and  
38 encourages patients to discuss their (interest in) complementary medicine use. Both patients  
39 and clinicians are found to report higher satisfaction with the oncology consultation when  
40 complementary medicine was discussed [6].

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43 It seems evident that communication about complementary medicine decreases risks  
44 and potentially maximizes positive outcomes for patients with cancer. In some countries, tools  
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3 have been developed to support oncology healthcare providers in discussing complementary  
4 medicine, such as educational courses or decision-aids [24-27]. A recent study reported on a  
5 complementary therapy education seminar for patients with cancer in Canada [28]. These  
6 supporting tools cannot simply be generalized across countries, given differences in language,  
7 culture and healthcare systems. To the best of our knowledge, there are no nationwide tools  
8 available for healthcare providers or patients with cancer and there is no scientific literature  
9 reporting on communication about complementary medicine in oncology in the Netherlands.

### 15 **Aim**

16 This paper describes the design of this study titled COMMON, in which patients participate as  
17 co-researchers. The study aims to explore communication about complementary medicine in  
18 oncology and to enhance an open and effective dialogue on the topic by the development of a  
19 toolbox for patients with cancer and oncology healthcare providers. This project seeks to  
20 answer the following research questions:  
21

- 22 1. What organisational and process factors hinder or contribute to communication and  
23 implementation of complementary medicine in oncology?
- 24 2. How is complementary medicine currently being discussed in consultations between  
25 healthcare providers and cancer patients?
- 26 3. What are the experiences and needs regarding communication about and access to  
27 complementary medicine in patients with breast cancer and oncology healthcare  
28 providers?
- 29 4. What is the evidence on patient-reported outcomes on complementary medicine  
30 frequently used by patients with (breast) cancer?
- 31 5. What is the acceptability and usability of the developed toolbox?  
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## 44 **METHODS AND ANALYSIS**

### 45 **Setting and participants**

46 This patient participatory multicenter study is conducted in the Netherlands. Three non-  
47 academic hospitals with an oncology department have committed to recruiting participants for  
48 the study. The hospitals differ in the extent to which they implemented (communication  
49 about) complementary medicine in standard oncology care. This contributes to the diversity of  
50 the study participants and provides opportunities to learn from fellow hospitals' experiences.  
51 The study specifically focuses on patients with breast cancer, the most commonly diagnosed  
52 cancer in women worldwide [29]. Breast cancer patients are found to be the most frequent  
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users of complementary medicine compared to patients with other cancers [30, 31]. In total six categories of study participants are included (see Table 1).

**Table 1.** Participant categories

Participant category	Recruitment	Data collection	Expected numbers
Patients with (breast) cancer	Through participating hospitals	Interviews about needs	16 to 20
		Pilot study toolbox	90
Healthcare providers	Through participating hospitals	Interviews about organisation	6 to 9
		Interviews about needs	16 to 20
		Pilot study toolbox	30
Healthcare managers	Through participating hospitals	Interviews about organisation	6 to 9
Complementary medicine providers	Researchers from Nivel	Online survey	Unknown
Patients with advanced breast cancer and their oncologists	Secondary analysis	Observation of consultations	45 patients and 12 oncologists
Patients with cancer and their healthcare provider	Secondary analysis	Observation of consultations	25 patients and 16 healthcare providers

The first three participant categories are recruited by a designated nurse coordinator in each participating hospital:

- 1: Patients with (breast) cancer, currently or during the last 6 months in active treatment, older than 18 years of age, Dutch-speaking.
- 2: Healthcare providers working with cancer patients, such as oncologists and oncology nurses.
- 3: Healthcare managers responsible for or connected to an oncology department.

The nurse coordinator in the hospital informs eligible participants about study aims and methods and provides them with a participant information letter. When a participant is interested in participating, the nurse coordinator asks for consent to share

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3 their contact details with the researcher team. Before study data collection, written  
4 informed consent is obtained.  
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6 The fourth category of participants is recruited by the research team from Nivel:  
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8 4: Persons and organizations providing complementary medicine to cancer patients,  
9 recruited through professional organizations, stakeholder parties and researchers'  
10 networks.  
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13 Data derived from two observational studies in 2018 is used for secondary analysis. Two  
14 categories of participants were recruited from different hospitals in the Netherlands:  
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16 5: Patients with incurable breast cancer, female, >18 years of age, with sufficient  
17 command of Dutch language, scheduled for a test-result/incurable cancer diagnosis  
18 consultation. Patients were approached by the participating hospital via phone and  
19 when interested by the research team. Information was sent by post. Written informed  
20 consent was obtained preceding the consultation [32].  
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23 6: Patients with incurable cancer with, >18 years of age, with sufficient command of  
24 Dutch, with low health literacy (based on a vocational level education or lower and/or  
25 screening questions for health literacy and/or clinician's views). Patients were  
26 approached by the hospital/research team by phone and when interested met by the  
27 research team, prior to the consultation when written consent was obtained [33].  
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### 36 **Patient and public involvement**

37 Before submission, this research protocol was reviewed by the Patient Advocacy Group  
38 (PAG), a joint initiative of the Breast Cancer Research Group (BOOG) and National Breast  
39 Cancer Society (BVN) in the Netherlands. Furthermore, several stakeholder parties in the  
40 Netherlands (Dutch Nursing Society (V&VN), Breast Cancer Research Group (BOOG),  
41 Netherlands Comprehensive Cancer Organization (IKNL) and the online information platform  
42 for Dutch patients with cancer (Kanker.nl) are involved since the beginning of the study to  
43 provide feedback on interim findings and advise on dissemination of results and output of the  
44 study.  
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#### 50 *Patients as co-researchers*

51 For the cancer system to become more responsive to the needs of patients, involvement of  
52 patients with cancer in research is vital. As healthcare users with their own experiential  
53 knowledge, they can more easily extract relevant themes or interpret experiences from fellow-  
54 patients. This unique patient perspective enhances the relevance of the research findings [34].  
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60 Therefore, co-researchers prominently participate in the current study. We aim to recruit

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3 twelve Dutch-speaking patients aged at least 18 years that are diagnosed with breast cancer in  
4 the last two years with a fairly stable health and emotional situation. The recruitment of the  
5 co-researchers is performed by the nurse coordinator of each involved hospital and by means  
6 of an online advertisement on the website of the National Breast Cancer Society (BVN).  
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10 In research, patients can provide input by means of (a) consultation, where patients are  
11 seen as objects of research (b) collaboration, where researchers and patients work in a  
12 partnership and make joint decisions (c) control, where patients have complete decision-  
13 making power [35]. In this study, patients acting as co-researchers collaborate with the  
14 researchers. They are involved in formulating interview questions, conducting interviews,  
15 interpreting the research findings and designing the toolbox. To ensure the privacy of study  
16 participants, the co-researchers sign a confidentiality agreement. Two important conditions  
17 for participatory research were yielded by a previous multiple case study [36]: a good  
18 working environment and good collaboration. These conditions can be achieved by the  
19 organization of training sessions, availability of the researcher, (financial) appreciation and a  
20 clear division of roles. In the current study, an introductory meeting and three half-day  
21 training sessions are organized at the start of the project to prepare the co-researchers for their  
22 role. A follow-up training is provided after one year, next to several evaluation moments  
23 during the study. One of the researchers (MM) is continuously available as contact person and  
24 keeps the co-researchers up-to-date by means of a quarterly newsletter. We aim to create an  
25 open, safe working environment in which co-researchers feel free to ask questions and discuss  
26 their needs. The co-researchers are reimbursed for their participation. The nature of  
27 participation as a co-researcher is voluntary and withdrawal is possible at any time.  
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### 43 **Data collection and analysis**

44 The data collection takes place during the period 2020-2024 (see Figure 1). For development  
45 of the toolbox, the six steps of the intervention mapping (IM) framework are followed: 1)  
46 assessing the needs of the target group, 2) specifying the problem and its determinants into  
47 change objectives, 3) selecting theoretical intervention methods and practical applications for  
48 change, 4) designing and developing the intervention, 5) implementing the intervention, 6)  
49 evaluating the intervention [37] (see Figure 2). The IM framework supports health promotion  
50 program planners in systematically developing an evidence-based intervention. Several  
51 effective interventions in oncology have been developed using the IM framework [38].  
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#### 58 *Step 1: Needs assessment*

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3 In this first step, the needs of the target group regarding communication and access to  
4 complementary medicine are assessed to specify the goals for the intervention. The needs  
5 assessment of this study consists of interviewing healthcare managers and healthcare  
6 providers in oncology and observing previously recorded consultations [32, 33] between  
7 patients with cancer and healthcare providers.  
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11 *Interviews on organizational factors.* By means of semi-structured interviews with  
12 healthcare managers and healthcare providers working in oncology, insight is sought in the  
13 organisational factors that hinder or facilitate communication and implementation of  
14 complementary medicine in oncology (research question 1). The interview guide will be  
15 developed in close collaboration with the co-researchers. Data saturation [39] is expected to  
16 be achieved after interviewing 2 to 3 healthcare managers and 2 to 3 healthcare providers in  
17 each participating hospital (12 to 18 interviews in total). Each interview is conducted by one  
18 of the researchers together with a co-researcher, preceded by a one-on-one meeting to prepare  
19 the co-researcher for the interview. The interviews have a planned duration of 45 minutes and  
20 are held at a time and location convenient for the interviewees (online interviews are an  
21 option given Covid-19 restrictions). With permission of the participants, the interviews are  
22 audio-recorded. The recordings are transcribed verbatim and coded thematically using  
23 MAXQDA. For the analysis of the interview data, we make use of a framework on  
24 implementation of innovations in healthcare [40] and an indicative method for identifying,  
25 analysing and reporting patterns within data [41].  
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37 *Observation of consultations.* By secondary analysis of recorded consultations from  
38 two previous observational studies, we observe how complementary medicine is currently  
39 discussed in consultations between patients and healthcare providers (research question 2). In  
40 the first study, consultations of 45 patients with incurable breast cancer and 12 oncologists in  
41 two hospitals were audio-recorded between August and December 2018. Post-consultation,  
42 the participants completed a self-created questionnaire on socio-demographic and disease  
43 characteristics (for details, see [32, 42, 43]). Given the fact that curative treatment was not a  
44 topic of discussion, complementary medicine is expected to be discussed relatively often, like  
45 previously found in an Australian study [5]. In the second study, consultations between 25  
46 patients with incurable cancer and 16 healthcare providers (medical specialists and nurses)  
47 were video-recorded between April and October 2018. Pre-consultation, background  
48 characteristics were assessed by the research team.  
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58 An observation scheme to code communication about complementary medicine during  
59 the consultations will be developed based on insights from literature on categorizations of  
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3 complementary medicine and guidelines on grading of complementary medicine interventions  
4 [44-46]. Using the observation scheme, one observer codes all recordings. For inter-rater  
5 agreement, a second observer independently codes 10% of the recordings and discrepancies  
6 will be discussed among the observers until consensus is reached. Descriptive statistics (Stata  
7 14.0) are employed for analysing the data.  
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11 *Interviews on experiences and needs.* We investigate experiences and needs (e.g.  
12 timing in treatment program) regarding communication about and access to complementary  
13 medicine by conducting semi-structured interviews with breast cancer patients and healthcare  
14 providers (research question 3). Interview questions are formulated in close collaboration with  
15 the co-researchers. The recommendations of Francis et al [47] for sample size in qualitative  
16 studies are followed. The initial analysis sample consists of 16 interviews with breast cancer  
17 patients and the same number of healthcare providers. The stopping criterion is 3 consecutive  
18 interviews without additional emerging themes in each of the two groups. The interviews last  
19 approximately 45 minutes and are held at a time and location convenient for the interviewees  
20 (online interviews are a possibility given Covid-19 restrictions). The interviews are conducted  
21 by one of the researchers together with one co-researcher. After permission, the interviews are  
22 audio-recorded. The audio-recordings are transcribed verbatim and then thematically coded  
23 using MAXQDA.  
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34 *Step 2 and 3: Specifying determinants, objectives, theoretical methods and practical*  
35 *application*  
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37 The goal of step 2 is specifying what or who changes as a result of the toolbox. By analysing  
38 the input from the needs assessment in step 1, behavioural and environmental determinants  
39 that are changeable are translated into a list of intervention objectives. In step 3, we seek  
40 theory-based methods and practical applications to change the determinants of behaviour and  
41 environment to meet the intervention objectives. The stakeholders parties will be involved in  
42 the selection of strategies. The main criterion is the possibility to integrate the toolbox in daily  
43 clinical practice without interfering in conventional cancer treatment.  
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50 *Step 4: Development of the intervention*  
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52 The goal of this step is to develop the toolbox supporting patient with cancer and oncology  
53 healthcare providers in discussing complementary medicine. The co-researchers are involved  
54 in designing the structure and lay-out of the toolbox. The content is based on the information  
55 gathered in steps 1 to 3, supplemented with a list of available evidence-based complementary  
56 medicine for cancer patients in the Netherlands. This list will be based on a review of  
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3 systematic reviews on the evidence of complementary medicine on patient-reported outcomes  
4 and an online survey amongst persons and organizations providing complementary medicine.

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6 *Review of systematic reviews.* A review of systematic reviews is conducted on the  
7 evidence on patient-reported outcomes (e.g. quality of life, coping skills, general well-being,  
8 perceived psychological and physical symptoms) of complementary medicine that is  
9 frequently used by patients with cancer (research question 4). The search on review studies is  
10 initially developed in Pubmed and adapted to other databases such as Cochrane library,  
11 Psychinfo, CINAHL. For this search, we make use of medical subject heading terms and/or  
12 keywords frequently used in literature on complementary medicine. The search is limited to  
13 systematic reviews published after 2000. Systematic reviews should meet the criteria of  
14 having a methods section that describes a search strategy and an a priori approach to  
15 synthesizing the data. Then, methodological quality is assessed by means of quality criteria  
16 adapted from the Quality of Reporting of Meta-analyses (QUOROM) [48] and the  
17 Assessment of Multiple Systematic Reviews (AMSTAR) [49].

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27 *Online survey.* To gain an overview on what types of evidence-based complementary  
28 medicine are currently available in the Netherlands, an online search accompanied by an  
29 online survey is performed among persons and organizations providing complementary  
30 medicine approaches that are widely used by cancer patients (research question 4). Survey  
31 questions are formulated in close collaboration with the co-researchers, but minimally covers  
32 what kind of complementary medicine is being offered, to whom, with what goal and what the  
33 outcomes are.

#### 34 35 36 37 38 39 *Step 5: Implementation of the intervention*

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41 Planning the implementation of the toolbox begins as soon as the needs assessment has been  
42 performed and is continuously revisited during the study by the involvement of co-researchers  
43 and the stakeholder parties. Following the development the toolbox, we conduct a pilot study  
44 for which 90 patients with cancer (half of them complementary medicine users) and 30  
45 oncology healthcare providers are recruited from the three hospitals. If relevant, informal  
46 caregivers are also recruited. As recommended by the Medical Research Council guidance  
47 [50], the exact selection of instruments and dimensions evaluated in the pilot study will be  
48 adjusted to the eventual design of the toolbox. The toolbox will be at least assessed on  
49 acceptability, usability, layout and transparency using descriptive statistics. The co-  
50 researchers are involved in the design of the pilot study. No risks are expected to be  
51 associated with participation in the pilot study, because the toolbox will not interfere with  
52 conventional cancer treatment.

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3 The results of the pilot study are used to optimize the toolbox before shifting to the  
4 phase where it is made publicly available. We plan to organize an invitational conference to  
5 guarantee proper use and uptake of the toolbox and to report on its development and  
6 evaluation. Dissemination in the intended population is covered by the commitment of the  
7 stakeholder parties. Naturally, the content of the toolbox changes as new insights into  
8 effectiveness and safety of complementary medicine becomes available. To ensure  
9 continuation of the intervention, budget is reserved for biennial updates of the toolbox for at  
10 least 4 years after dissemination.  
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### 13 *Step 6: Evaluation of the intervention*

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15 As described in Step 5, a preliminary evaluation of the toolbox by means of a pilot study will  
16 take place. In the future, we intend to recruit funding for an additional, larger trial to measure  
17 the impact of the toolbox on aspects of communication about complementary medicine (e.g.  
18 initiation, satisfaction) between healthcare providers and patients with cancer. A description  
19 of the trial design for an effect evaluation of the toolbox is beyond the scope of the current  
20 protocol paper that describes the development of the toolbox.  
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### 30 **In conclusion**

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32 To the best of our knowledge, this is the first patient participatory study that aims to explore  
33 and enhance communication about complementary medicine in oncology. Despite the  
34 frequent use of complementary medicine among patients with cancer, the topic often remains  
35 undiscussed in consultation with the healthcare provider [4-6]. This results in risks for adverse  
36 or interaction effects and decreases access to evidence-based complementary medicine for  
37 patients with cancer. To date, it is unknown to what extent complementary medicine is  
38 discussed and implemented in oncology in the Netherlands and what the experiences and  
39 needs of patients with cancer and oncology healthcare providers are in this area. This study  
40 will fill these information gaps by conducting interviews, observations, a survey and a meta-  
41 analysis on complementary medicine in oncology. Perspectives of patients with cancer,  
42 oncology healthcare providers, healthcare managers and complementary medicine providers  
43 are included. The collected data is used for the systematic development [37] of an unique  
44 toolbox supporting the dialogue on complementary medicine in oncology. Preceded by a  
45 pilot-test, the toolbox is disseminated with the support of national stakeholders to the intended  
46 population: patients with cancer and oncology healthcare providers. The use of the toolbox  
47 should result in a more common discussion of complementary medicine in oncology, thus  
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3 minimizing the risks and maximizing the benefits of evidence-based complementary medicine  
4 for patients with cancer.  
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## 8 **ETHICS AND DISSEMINATION**

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10 The Medical Ethics Committee Arnhem-Nijmegen declared the study was exempted from  
11 formal approval under the Dutch Medical Research Involving Human Subjects Act (case  
12 number 2020-6917). No risks are expected to be associated with participation in the study.  
13 Results of this study will be disseminated through open-access, peer-reviewed publications,  
14 stakeholder-reporting and presentations at relevant conferences.  
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### 18 **Author contributions**

19 All authors contributed to, reviewed and approved the article drafts and final manuscript.  
20 SvD, JN, MB and LV designed the study protocol and raised funding, led by SvD. MM was  
21 responsible for writing the manuscript. SvD, JN, AT read several versions of the manuscript  
22 and provided their feedback and suggestions regularly.  
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30  
31

### 32 **Competing interests**

33 None declared.  
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37 **Figure 1.** Time frame of the COMMON study  
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41 **Figure 2.** The six steps of the intervention mapping framework  
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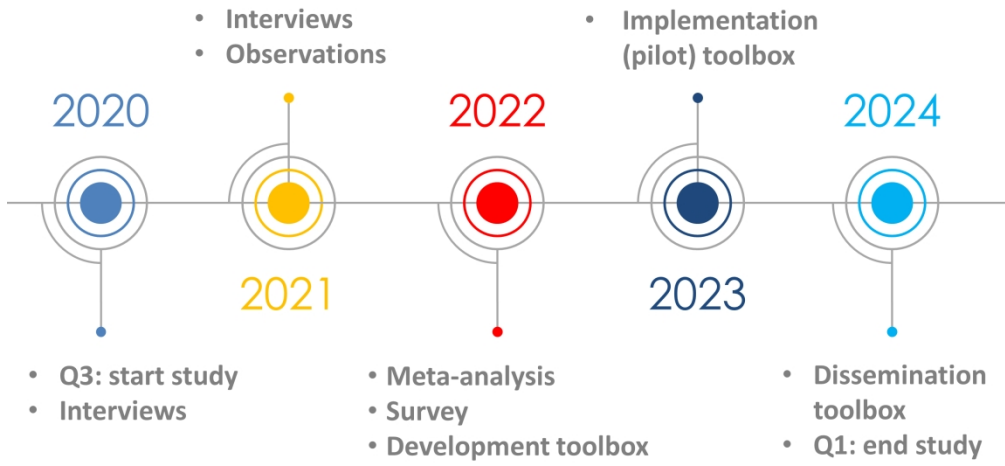


Figure 1. Time frame of the COMMON study  
254x190mm (300 x 300 DPI)

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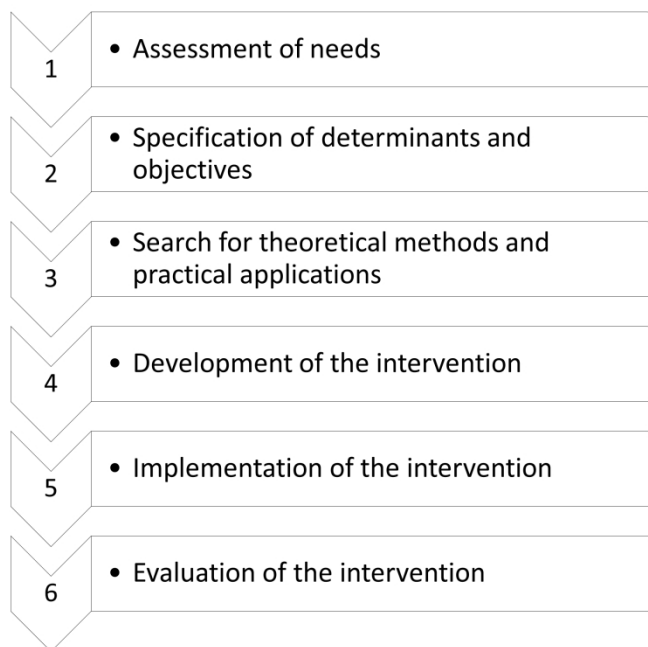


Figure 2. The six steps of the intervention mapping framework

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# BMJ Open

## Towards an open and effective dialogue on complementary medicine in oncology. Protocol of patient participatory study 'COMMON'.

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3 **Title page**  
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6 **Towards an open and effective dialogue on complementary medicine in oncology.**  
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8 **Protocol of patient participatory study ‘COMMON’.**  
9

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## Abstract

*Introduction.* Approximately half of patients with cancer use some form of complementary medicine alongside conventional cancer treatment. The topic of complementary medicine often remains undiscussed in consultations between patients with cancer and their healthcare providers. This results in increased risks for adverse or interaction effects and decreased access to the benefits of evidence-based complementary medicine for patients with cancer. This paper describes the design of patient participatory study titled 'COMMON' that aims to explore and enhance open and effective communication about complementary medicine in oncology. The study is carried out in collaboration with 12 (former) breast cancer patients as co-researchers.

*Methods and analysis.* The study complies with the six steps of the intervention mapping framework. Three non-academic hospitals recruit participants (patients with cancer, oncology healthcare providers and managers) for interviews about the organization, experiences and needs regarding complementary medicine. To assess communication about complementary medicine, recorded oncology consultations are analysed. For an overview of evidence-based complementary medicine available to patients with cancer, a review of reviews is conducted on the evidence on cancer patient-reported outcomes of complementary medicine frequently used by cancer patients, supplemented with an online search and survey among organizations and persons providing complementary medicine to patients with cancer. Together, these steps generate input for the development of a toolbox that supports an open and effective discussion on complementary medicine in oncology. In a pilot study, acceptability and usability of the toolbox are assessed among patients with cancer and oncology healthcare providers. Dissemination of the toolbox is covered by the commitment of stakeholder parties.

*Ethics and dissemination.* The Medical Ethics Committee Arnhem-Nijmegen declared the study was exempted from formal approval under the Dutch Medical Research Involving Human Subjects Act. The results will be disseminated through open-access, peer-reviewed publications, stakeholder-reporting and presentations at relevant conferences.

## Strengths and limitations of this study

- The COMMON study is the first to develop a toolbox for improving communication about complementary medicine for patients with cancer and oncology healthcare providers in the Netherlands

- The participation of patients with breast cancer as co-researchers enhances the validity and relevance of the findings
- The study data collection can be carried out entirely online and will not be delayed due to Covid-19 restrictions
- The study specifically involves breast cancer patients, decreasing the generalizability of the results and the toolbox to the entire population of patients with cancer
- The success of the toolbox depends on the support from national stakeholders in the implementation process and on the willingness of healthcare providers and patients to use the toolbox

## INTRODUCTION

The use of complementary medicine among patients with cancer has become increasingly common over the last decades [1]. Nowadays, approximately half of all oncology patients use complementary medicine alongside conventional cancer treatment [1-3]. However, the topic of complementary medicine remains undiscussed in the majority of oncology consultations [4-6].

Complementary medicine in oncology entails health approaches that are not typically part of conventional cancer treatments, but are used to complement them [7, 8]. This contrasts with alternative medicine replacing conventional cancer treatment. Together, complementary and alternative medicine are often referred to as CAM. The current study focuses solely on complementary medicine and adopts a broad definition, encompassing all approaches that complement biomedical treatment of the oncological disease and that aim to contribute to the physical, mental or social well-being of the patient. The definition includes approaches that were previously considered complementary, but are now regularly incorporated in conventional supportive care (e.g. exercise and psychological therapies).

Complementary medicine approaches frequently used by patients with cancer in Western countries are mind-body therapies, massage, nutrition counselling and acupuncture [9]. Patients with cancer state several reasons for using complementary medicine, such as improving physical and emotional well-being, quality of life or reducing side-effects from conventional treatment [10]. In the field of conventional medicine, the added value of complementary medicine is still hotly debated. Complementary medicine is a heterogeneous field and for many approaches neither effectiveness nor safety have been sufficiently proven. Some supplements or herbs can have adverse effects or interact with conventional cancer

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3 treatment [11, 12]. On the other hand, a growing body of evidence shows that particular types  
4 of complementary medicine can be efficacious and safe to use for patients with cancer, such  
5 as acupuncture for reducing chemotherapy-induced nausea and vomiting [13]. A few  
6 complementary medicine approaches receive recommendation in oncology guidelines [14],  
7 implying sufficient evidence.  
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11 However, 20% to 77% of the patients with cancer do not disclose their use of  
12 complementary medicine to conventional healthcare providers [15]. In 2017, the Dutch Breast  
13 Cancer Association administered a survey among 750 members showing that 65% of the  
14 patients use complementary medicine. Of those patients, 29% did not discuss their  
15 complementary medicine use with their healthcare provider [16]. A similar survey among 229  
16 Dutch patients with haematological cancer reported that 43% of the respondents use  
17 complementary medicine, of which 38% did not discuss this with their healthcare provider  
18 [17]. The main reasons for nondisclosure stated by patients with cancer are related to  
19 healthcare providers' disapproval, disinterest, lack of inquiry or inability to provide  
20 information [15]. Conventional healthcare providers often feel uncomfortable discussing  
21 complementary medicine due to limited education and knowledge on the topic [3, 18]. In  
22 view of the frequent use of complementary medicine among cancer patients, not discussing  
23 the topic in oncology is problematic. It increases risks for patients' exposure to misleading  
24 information, adverse effects due to inappropriate use and interactions with conventional  
25 cancer treatment [12, 19]. Additionally, some patients may remain devoid of evidence-based  
26 complementary medicine that could potentially support them.  
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39 It is well-known that effective communication, the cornerstone of patient-centred care,  
40 can positively influence physical and psychosocial aspects of a patients' health [20-22]. An  
41 effective discussion about complementary medicine consists of exchanging adequate  
42 information, responding to emotional needs and managing uncertainty of patients [19].  
43 Furthermore, the healthcare provider can play a significant role in informed decision-making  
44 about complementary medicine use. In an open dialogue on the topic, both benefits and risks  
45 or the lack of evidence thereof, can be acknowledged [23]. Open communication about  
46 complementary medicine fosters mutual trust between patients and healthcare providers and  
47 encourages patients to discuss their (interest in) complementary medicine use. Both patients  
48 and clinicians are found to report higher satisfaction with the oncology consultation when  
49 complementary medicine was discussed [6].  
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58 It seems evident that communication about complementary medicine decreases risks  
59 and potentially maximizes positive outcomes for patients with cancer. In some countries, tools  
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3 have been developed to support oncology healthcare providers in discussing complementary  
4 medicine, such as educational courses or decision-aids [24-27]. A recent study reported on a  
5 complementary therapy education seminar for patients with cancer in Canada [28]. These  
6 supporting tools cannot simply be generalized across countries, given differences in language,  
7 culture and healthcare systems. To the best of our knowledge, there are no nationwide tools  
8 available for healthcare providers or patients with cancer and there is no scientific literature  
9 reporting on communication about complementary medicine in oncology in the Netherlands.

### 15 **Aim**

16 This paper describes the design of this study titled COMMON, in which patients participate as  
17 co-researchers. The study aims to explore communication about complementary medicine in  
18 oncology and to enhance an open and effective dialogue on the topic by the development of a  
19 toolbox for patients with cancer and oncology healthcare providers. This project seeks to  
20 answer the following research questions:  
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- 22 1. What organisational and process factors hinder or contribute to communication and  
23 implementation of complementary medicine in oncology?
- 24 2. How is complementary medicine currently being discussed in consultations between  
25 healthcare providers and cancer patients?
- 26 3. What are the experiences, needs and expectations regarding communication about and  
27 access to complementary medicine in patients with (breast) cancer and oncology  
28 healthcare providers?
- 29 4. What is the evidence on patient-reported outcomes on complementary medicine  
30 frequently used by patients with (breast) cancer?
- 31 5. What is the acceptability and usability of the developed toolbox?  
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## 44 **METHODS AND ANALYSIS**

### 45 **Setting and participants**

46 This patient participatory multicenter study is conducted in the Netherlands. Three non-  
47 academic hospitals with an oncology department have committed to recruiting participants for  
48 the study. We deliberately selected hospitals that differ in the extent to which they  
49 implemented initiatives regarding complementary medicine in standard oncology care. This  
50 contributes to the diversity of the study participants and provides opportunities to learn from  
51 fellow hospitals' experiences. The study specifically focuses on patients with breast cancer,  
52 the most commonly diagnosed cancer in women worldwide [29]. Breast cancer patients are  
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found to be the most frequent users of complementary medicine compared to patients with other cancers [30, 31]. In total six categories of study participants are included (see Table 1).

**Table 1.** Participant categories

Participant category	Recruitment	Data collection	Expected numbers
Patients with (breast) cancer	Through participating hospitals	Interviews about needs	16 to 20
		Pilot study toolbox	90
Healthcare providers	Through participating hospitals	Interviews about organisation	6 to 9
		Interviews about needs	16 to 20
		Pilot study toolbox	30
Healthcare managers	Through participating hospitals	Interviews about organisation	6 to 9
Complementary medicine providers	Researchers from Nivel	Online survey	Unknown
Patients with advanced breast cancer and their oncologists	Secondary analysis	Observation of consultations	45 patients and 12 oncologists
Patients with cancer and their healthcare provider	Secondary analysis	Observation of consultations	36 patients and 16 healthcare providers

The first three participant categories are recruited by a designated nurse coordinator in each participating hospital:

- 1: Patients with (breast) cancer, currently or during the last 6 months in active treatment, older than 18 years of age, Dutch-speaking.
- 2: Healthcare providers working with cancer patients, such as oncologists and oncology nurses.
- 3: Healthcare managers responsible for or connected to an oncology department.

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3 The nurse coordinator in the hospital informs eligible participants about study aims  
4 and methods and provides them with a participant information letter. When a  
5 participant is interested in participating, the nurse coordinator asks for consent to share  
6 their contact details with the researcher team. Before study data collection, written  
7 informed consent is obtained.  
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11 The fourth category of participants is recruited by the research team from Nivel:

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13 4: Persons and organizations providing complementary medicine to cancer patients,  
14 recruited through professional organizations, stakeholder parties and researchers'  
15 networks.  
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19 Data derived from two observational studies in 2018 is used for secondary analysis. Two  
20 categories of participants were recruited from different hospitals in the Netherlands:  
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22 5: Patients with incurable breast cancer, female, >18 years of age, with sufficient  
23 command of Dutch language, scheduled for a test-result consultation. Patients were  
24 approached by the participating hospital via phone and when interested by the research  
25 team. Information was sent by post. Written informed consent was obtained preceding  
26 the consultation [32].  
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30 6: Patients with incurable cancer, >18 years of age, with sufficient command of Dutch,  
31 with limited health literacy (based on a vocational level education or lower and/or  
32 screening questions for health literacy and/or clinician's views). Patients were  
33 approached by the hospital/research team by phone and when interested met by the  
34 research team, prior to the consultation when written consent was obtained [33].  
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## 41 **Patient and public involvement**

42 Before submission, this research protocol was reviewed by the Patient Advocacy Group  
43 (PAG), a joint initiative of the Breast Cancer Research Group (BOOG) and National Breast  
44 Cancer Society (BVN) in the Netherlands. Furthermore, several stakeholder parties in the  
45 Netherlands (Dutch Nursing Society (V&VN), Breast Cancer Research Group (BOOG),  
46 Netherlands Comprehensive Cancer Organization (IKNL) and the online information platform  
47 for Dutch patients with cancer (Kanker.nl) are involved since the beginning of the study to  
48 provide feedback on interim findings and advise on dissemination of results and output of the  
49 study.  
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### 52 *Patients as co-researchers*

53 For the cancer system to become more responsive to the needs of patients, involvement of  
54 patients with cancer in research is vital. As healthcare users with their own experiential  
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3 knowledge, they can more easily extract relevant themes or interpret experiences from fellow-  
4 patients. This unique patient perspective enhances the relevance of the research findings [34].  
5 Therefore, co-researchers prominently participate in the current study. We aim to recruit  
6 twelve Dutch-speaking patients aged at least 18 years that are diagnosed with breast cancer in  
7 the last two years with a fairly stable health and emotional situation. The recruitment of the  
8 co-researchers is performed by the nurse coordinator of each involved hospital and by means  
9 of an online advertisement on the website of the National Breast Cancer Society (BVN).

15 In research, patients can provide input by means of (a) consultation, where patients are  
16 seen as objects of research (b) collaboration, where researchers and patients work in a  
17 partnership and make joint decisions (c) control, where patients have complete decision-  
18 making power [35]. In this study, patients acting as co-researchers collaborate with the  
19 researchers. They are involved in formulating interview questions, conducting interviews,  
20 interpreting the research findings and designing the toolbox. To ensure the privacy of study  
21 participants, the co-researchers sign a confidentiality agreement. Two important conditions  
22 for participatory research were yielded by a previous multiple case study [36]: a good  
23 working environment and good collaboration. These conditions can be achieved by the  
24 organization of training sessions, availability of the researcher, (financial) appreciation and a  
25 clear division of roles. In the current study, an introductory meeting and three half-day  
26 training sessions are organized at the start of the project to prepare the co-researchers for their  
27 role. A follow-up training is provided after one year, next to several evaluation moments  
28 during the study. One of the researchers (MM) is continuously available as contact person and  
29 keeps the co-researchers up-to-date by means of a quarterly newsletter. We aim to create an  
30 open, safe working environment in which co-researchers feel free to ask questions and discuss  
31 their needs. The co-researchers are reimbursed for their participation. The nature of  
32 participation as a co-researcher is voluntary and withdrawal is possible at any time.

### 47 **Data collection and analysis**

48 The data collection takes place during the period 2020-2024 (see Figure 1). For development  
49 of the toolbox, the six steps of the intervention mapping (IM) framework are followed: 1)  
50 assessing the needs of the target group, 2) specifying the problem and its determinants into  
51 change objectives, 3) selecting theoretical intervention methods and practical applications for  
52 change, 4) designing and developing the intervention, 5) implementing the intervention, 6)  
53 evaluating the intervention [37] (see Figure 2). The IM framework supports health promotion  
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3 program planners in systematically developing an evidence-based intervention. Several  
4 effective interventions in oncology have been developed using the IM framework [38].

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6 *Step 1: Needs assessment*

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8 In this first step, the needs of the target group regarding communication and access to  
9 complementary medicine are assessed to specify the goals for the intervention. The needs  
10 assessment of this study consists of interviewing healthcare managers and healthcare  
11 providers in oncology and observing previously recorded consultations [32, 33] between  
12 patients with cancer and healthcare providers.  
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17 *Interviews on organizational factors.* By means of semi-structured interviews with  
18 healthcare managers and healthcare providers working in oncology, insight is sought in the  
19 organisational factors that hinder or facilitate communication and implementation of  
20 complementary medicine in oncology (research question 1). The interview guide will be  
21 developed in close collaboration with the co-researchers. Data saturation [39] is expected to  
22 be achieved after interviewing 2 to 3 healthcare managers and 2 to 3 healthcare providers in  
23 each participating hospital (12 to 18 interviews in total). Each interview is conducted by one  
24 of the researchers together with a co-researcher, preceded by a one-on-one meeting to prepare  
25 the co-researcher for the interview. The interviews have a planned duration of 45 minutes and  
26 are held at a time and location convenient for the interviewees (online interviews are an  
27 option given Covid-19 restrictions). With permission of the participants, the interviews are  
28 audio-recorded. The recordings are transcribed verbatim and coded thematically using  
29 MAXQDA. For the analysis of the interview data, we make use of a framework on  
30 implementation of innovations in healthcare [40] and an indicative method for identifying,  
31 analysing and reporting patterns within data [41].  
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43 *Observation of consultations.* By secondary analysis of recorded consultations from  
44 two previous observational studies, we observe how complementary medicine is currently  
45 discussed in consultations between patients and healthcare providers (research question 2). In  
46 the first study, consultations of 45 patients with incurable breast cancer and 12 oncologists in  
47 two hospitals were audio-recorded between August and December 2018. Post-consultation,  
48 the participants completed a self-created questionnaire on socio-demographic and disease  
49 characteristics (for details, see [32, 42, 43]). Given the fact that curative treatment was not a  
50 topic of discussion, complementary medicine is expected to be discussed relatively often, like  
51 previously found in an Australian study [5]. In the second study, consultations between 25  
52 patients with incurable cancer and 16 healthcare providers (medical specialists and nurses)  
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3 were video-recorded between April and October 2018. Pre-consultation, background  
4 characteristics were assessed by the research team.  
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6 An observation scheme to code communication about complementary medicine during  
7 the consultations will be developed based on insights from literature on categorizations of  
8 complementary medicine and guidelines on grading of complementary medicine interventions  
9 [44-46]. Using the observation scheme, one observer codes all recordings. For inter-rater  
10 agreement, a second observer independently codes 10% of the recordings and discrepancies  
11 will be discussed among the observers until consensus is reached. Descriptive statistics (Stata  
12 14.0) are employed for analysing the data.  
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18 *Interviews on experiences and needs.* We investigate experiences and needs (e.g.  
19 timing in treatment program) regarding communication about and access to complementary  
20 medicine by conducting semi-structured interviews with breast cancer patients and healthcare  
21 providers (research question 3). Interview questions are formulated in close collaboration with  
22 the co-researchers. The recommendations of Francis et al [47] for sample size in qualitative  
23 studies are followed. The initial analysis sample consists of 16 interviews with breast cancer  
24 patients and the same number of healthcare providers. The stopping criterion is 3 consecutive  
25 interviews without additional emerging themes in each of the two groups. The interviews last  
26 approximately 45 minutes and are held at a time and location convenient for the interviewees  
27 (online interviews are a possibility given Covid-19 restrictions). The interviews are conducted  
28 by one of the researchers together with one co-researcher. After permission, the interviews are  
29 audio-recorded. The audio-recordings are transcribed verbatim and then thematically coded  
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41 *Step 2 and 3: Specifying determinants, objectives, theoretical methods and practical*  
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44 The goal of step 2 is specifying what or who changes as a result of the toolbox. By analysing  
45 the input from the needs assessment in step 1, behavioural and environmental determinants  
46 that are changeable are translated into a list of intervention objectives. In step 3, we seek  
47 theory-based methods and practical applications to change the determinants of behaviour and  
48 environment to meet the intervention objectives. The stakeholder's parties will be involved in  
49 the selection of strategies. The main criterion is the possibility to integrate the toolbox in daily  
50 clinical practice without interfering in conventional cancer treatment.  
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56 *Step 4: Development of the intervention*  
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58 The goal of this step is to develop the toolbox supporting patient with cancer and oncology  
59 healthcare providers in discussing complementary medicine. The co-researchers are involved  
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3 in designing the structure and lay-out of the toolbox. The content is based on the information  
4 gathered in steps 1 to 3. The toolbox will at least consist of a communication guideline to  
5 support patients and healthcare providers in discussing complementary medicine,  
6 supplemented with a list of available evidence-based complementary medicine frequently  
7 used by cancer patients in the Netherlands. This list will be based on a review of systematic  
8 reviews on the evidence of complementary medicine on patient-reported outcomes and an  
9 online survey amongst persons and organizations providing complementary medicine.

15 *Review of reviews.* A review of reviews is conducted on the evidence on patient-  
16 reported outcomes (e.g. quality of life, coping skills, general well-being, perceived  
17 psychological and physical symptoms) of complementary medicine that is frequently used by  
18 patients with cancer (research question 4). The search on review studies is initially developed  
19 in Pubmed/MEDLINE and adapted to other databases such as Cochrane library, PsycINFO,  
20 CINAHL and Embase. For this search, we make use of medical subject heading terms and/or  
21 keywords frequently used in literature on complementary medicine. The search is limited to  
22 systematic reviews and meta-analyses published after 2000, written in English. Two  
23 researchers will independently screen titles and abstracts. Subsequently, a full-text screening  
24 is conducted by two researchers. In case of inconsistencies between the two researchers,  
25 consensus will be reached by discussion. If necessary, a third researcher can be involved. For  
26 inclusion in the review of reviews, articles should meet the criteria of having a methods  
27 section that describes a search strategy and an a priori approach to synthesizing the data.  
28 Then, methodological quality is assessed by means of quality criteria adapted from the  
29 Quality of Reporting of Meta-analyses (QUOROM) [48] and the Assessment of Multiple  
30 Systematic Reviews (AMSTAR) [49]. A comprehensive, detailed protocol of the review of  
31 reviews will be registered in PROSPERO.

34 *Online survey.* To gain an overview on what types of evidence-based complementary  
35 medicine are currently available in the Netherlands, an online search accompanied by an  
36 online survey is performed among persons and organizations providing complementary  
37 medicine approaches that are widely used by cancer patients (research question 4). Survey  
38 questions are formulated in close collaboration with the co-researchers, but minimally covers  
39 what kind of complementary medicine is being offered, to whom, with what goal and what the  
40 outcomes are.

#### 56 *Step 5: Implementation of the intervention*

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58 Planning the implementation of the toolbox begins as soon as the needs assessment has been  
59 performed and is continuously revisited during the study by the involvement of co-researchers  
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3 and the stakeholder parties. Following the development of the toolbox, we conduct a pilot  
4 study for which 90 patients with cancer (half of them complementary medicine users) and 30  
5 oncology healthcare providers are recruited from the three hospitals. If relevant, informal  
6 caregivers are also recruited. As recommended by the Medical Research Council guidance  
7 [50], the exact selection of instruments and dimensions evaluated in the pilot study will be  
8 adjusted to the eventual design of the toolbox. The toolbox will be at least assessed on  
9 acceptability, usability, layout and transparency using descriptive statistics. The co-  
10 researchers are involved in the design of the pilot study. No risks are expected to be  
11 associated with participation in the pilot study, because the toolbox will not interfere with  
12 conventional cancer treatment.  
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20 The results of the pilot study are used to optimize the toolbox before shifting to the  
21 phase where it is made publicly available. We plan to organize an invitational conference to  
22 guarantee proper use and uptake of the toolbox and to report on its development and  
23 evaluation. Dissemination in the intended population is covered by the commitment of the  
24 stakeholder parties. Naturally, the content of the toolbox changes as new insights into  
25 effectiveness and safety of complementary medicine becomes available. To ensure  
26 continuation of the intervention, budget is reserved for biennial updates of the toolbox for at  
27 least 4 years after dissemination.  
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#### 34 *Step 6: Evaluation of the intervention*

35 As described in Step 5, a preliminary evaluation of the toolbox by means of a pilot study will  
36 take place. In the future, we intend to recruit funding for an additional, larger trial to measure  
37 the impact of the toolbox on aspects of communication about complementary medicine (e.g.  
38 initiation, satisfaction) between healthcare providers and patients with cancer. A description  
39 of the trial design for an effect evaluation of the toolbox is beyond the scope of the current  
40 protocol paper that describes the development of the toolbox.  
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#### 48 **In conclusion**

49 To the best of our knowledge, this is the first patient participatory study that aims to explore  
50 and enhance communication about complementary medicine in oncology. Despite the  
51 frequent use of complementary medicine among patients with cancer, the topic often remains  
52 undiscussed in consultation with the healthcare provider [4-6]. This results in risks for adverse  
53 or interaction effects and decreases access to evidence-based complementary medicine for  
54 patients with cancer. To date, it is unknown to what extent complementary medicine is  
55 discussed and implemented in oncology in the Netherlands and what the experiences and  
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3 needs of patients with cancer and oncology healthcare providers are in this area. This study  
4 will fill these information gaps by conducting interviews, observations, a survey and a review  
5 of reviews on complementary medicine in oncology. Perspectives of patients with cancer,  
6 oncology healthcare providers, healthcare managers and complementary medicine providers  
7 are included. The collected data is used for the systematic development [37] of an unique  
8 toolbox supporting the dialogue on complementary medicine in oncology. Preceded by a  
9 pilot-test, the toolbox is disseminated with the support of national stakeholders to the intended  
10 population: patients with cancer and oncology healthcare providers. The toolbox aims to  
11 provide 1) tips and tricks on how to conduct an open and effective discussion about the use of  
12 complementary medicine in oncology, and 2) evidence-based complementary medicine  
13 interventions which patients with cancer can use safely alongside their conventional cancer  
14 treatment. Thereby, we want to minimize the risks and maximize the benefits of evidence-  
15 based complementary medicine for patients with cancer.  
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## 29 **ETHICS AND DISSEMINATION**

30 The Medical Ethics Committee Arnhem-Nijmegen declared the study was exempted from  
31 formal approval under the Dutch Medical Research Involving Human Subjects Act (case  
32 number 2020-6917). No risks are expected to be associated with participation in the study.  
33 Results of this study will be disseminated through open-access, peer-reviewed publications,  
34 stakeholder-reporting and presentations at relevant conferences.  
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### 39 **Author contributions**

40 All authors contributed to, reviewed and approved the article drafts and final manuscript.  
41 SvD, JN, MB and LV designed the study protocol and raised funding, led by SvD. MM was  
42 responsible for writing the manuscript. SvD, JN, AT read several versions of the manuscript  
43 and provided their feedback and suggestions regularly.  
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50 organization played no role in designing the study or writing the manuscript for publication.  
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### 53 **Competing interests**

54 None declared.  
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## 58 **Figure 1.** Time frame of the COMMON study

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3 **Figure 2.** The six steps of the intervention mapping framework  
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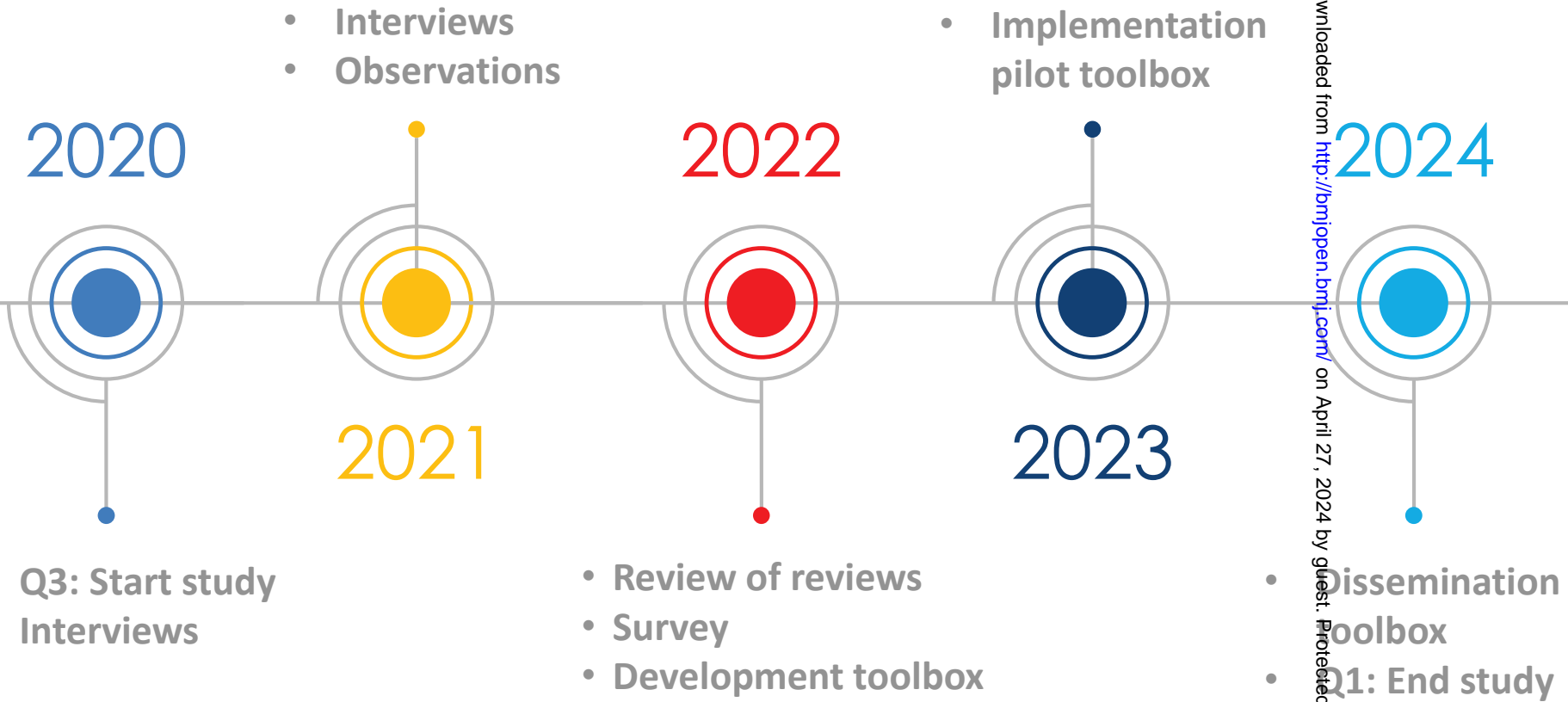
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Figure 2. The six steps of the intervention mapping framework

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