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What matters in clinical trial decision-making

a systematic review of interviews exploring cancer patients' experiences

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What matters in clinical trial decision-making. A systematic review of interviews exploring cancer patients' experiences

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What matters in clinical trial decision making

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What matters in clinical trial decision-making: A systematic review of interviews exploring cancer patients' experiences

Abstract

Background: Being diagnosed with cancer is an existential challenge and involves difficult treatment decisions, including treatment in clinical trials. Therapy for advanced cancer is potentially life-prolonging and only rarely cures advanced cancer, which often renders these patients in a special situation where dealing with end of life, hope and meaning, become an important part of life.

Many existing reviews include both patients with advanced cancer and patients undergoing adjuvant cancer treatment, and there are a lack of reviews with consistent study designs and methods.

Aim: To systematically review and thematically synthesize the experiences of patients and relatives when they have to decide whether or not to participate in a clinical oncology trial and to provide knowledge about the decision-making process.

Method: A qualitative systematic literature review was conducted based on methods for thematic synthesis by Thomas and Hardens.

Results: Eleven full text articles were included in this study. Six descriptive themes appeared and were grouped under two analytical themes: *Individualised decisions* and *Hope and existential matters*, which, through discussion, developed into the synthesis of *What matters in treatment-related decisions close to the end of life?* This review has shown that existential matters are important in the decision-making and that addressing these might be of great importance in medical decision-making, whether it concerns the existential matters of the patients, of their relatives or of the health-care professionals.

Conclusion: This review points to existential issues as important contributors in making decisions about treatment. It can be beneficial if health-care professionals address the role of existential matters in patients' decision-making in terms of clinical trial participation and involve the relatives more directly to increase individualised decisions. Future research should include the health-care professionals' experiences when going in depth with decision-making, with a focus on the existential matters and uncertainties of the health-care professionals.

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Keywords: Decision-making, communication, treatment, advanced cancer, qualitative studies, literature review, existential issues, whole person care, patient communication.

1. Introduction

From a historical perspective, patients' desire for information and health-care professionals' ways of supplying this information have changed over the last decades (1, 2). The healthcare system has undergone substantial development moving from paternalism to focus on more patient-centred healthcare and approaches to improve this environment (3).

Internationally shared decision-making (SDM) is promoted as a part of patient-centred care and a way to help patients and health-care professionals make informed decisions together (4-6). There is a request for SDM in health policy documents and statements from different patient organizations (7, 8), and there are many different approaches and opinions about how to accommodate this type of decision-making (9). Great efforts have been made to facilitate and improve SDM, e.g., decision aids to facilitate the process, methods to improve the communication skills of health-care professionals and methods to empower patients. Nevertheless, there are several challenges with SDM, especially regarding the health-care culture and implementation (10). The recent literature on SDM suggests that medical decision-making in the future should focus more on the person and the entire process of decision-making and not on a single medical encounter itself (11, 12). Furthermore, the literature reveals that one of the main barriers is that many health-care professionals often struggle with addressing existential issues (13) and that implementing shared decision-making requires helping doctors to acknowledge these existential issues (14).

Cancer patients are faced with a wide variety of difficult challenges, including physical and existential challenges (15, 16), and difficult treatment decisions, where they often must decide whether they want to participate in a clinical trial, whether they prefer to undergo standard treatment or whether they want to decline treatment (17). Clinical trials are one of the final stages of a long and careful research process. For safety purposes, clinical oncology trials start with small groups of patients to determine whether a new approach causes any harm. In later phases, researchers learn more about the risks and benefits of the new treatment or approach and compare the new treatment with the standard treatment that would otherwise be considered the best (18). Decisions about participating in these trials can be particularly difficult because patients have to choose between a well-known and accepted treatment and a treatment where both the effects and side effects are less documented (12, 17).

To protect patients and to ensure reliable study results, clinical trials follow strict scientific standards. One of these procedures is informed consent (19, 20). Informed consent involves the patients' understanding of and willingness to participate in the clinical trial. It is the health-care professionals' responsibility to ensure that the patients understand the purpose, the procedures, the potential risks, the benefits, and the alternatives to participating in a clinical trial. This consent process places a great demand on the health-care professionals' ability to involve and advise patients in the decisions, and it takes time to sufficiently inform patients. Furthermore, in many cases, this process happens at a time when the patients and their relatives have just been informed that the disease has spread and is incurable, making it a very vulnerable situation (21).

In many cases, the difference between harms and benefits of treatment options and clinical trials is small or unknown, and, today, it is generally agreed that the choice should be based on the patient's preferences (22, 23) and that relatives are a valued support for the patient and an active part in treatment decisions (24, 25).

Questions that remain include how patients and their relatives experience communication with health-care professionals and whether or not health-care professionals are capable of accommodating the individual needs of patients. Understanding the experiences of patients when engaging in the decision-making process may help identify ways of improving their experiences with healthcare.

In a preliminary literature search, we found a relatively small body of literature regarding the experiences of cancer patients with decision-making when offered to participate in a clinical trial. We identified several quantitative studies showing barriers and facilitators for participation, without the possibility to go in-depth with the patients' underlying experiences because of the limitations of the study design. Furthermore, the existing reviews were found to be inadequate as they did not distinguish between patients with curable

cancer (adjuvant therapy) and patients with advanced cancer. Adjuvant therapy is given to lower the risk of relapse after a curative treatment compared with palliative treatment to patients with advanced cancer, where therapy is only potentially life-prolonging. Patients with advanced cancer are faced, to a great extent, with existential issues, such as dealing with the end of life and powerlessness (15, 16, 26); therefore, to identify the underlying experiences, it is important to separate these two groups of patients in a qualitative review.

The aim of this review is as follows:

To systematically review and thematically synthesize the experiences of patients and relatives when they have to decide whether or not to participate in a clinical oncology trial and to provide knowledge about the decision-making process.

2. Method

A qualitative systematic literature review was conducted based on methods for thematic synthesis by Thomas and Hardens (27).

Search strategies and selection criteria

The literature search included English and Scandinavian peer-reviewed articles, reports from the Danish Health Authority and scientific literature. We searched the following electronic databases from their inception until the end of 2017: PubMed, CINAHL, Embase and Bibliotek.dk (a Danish library database). The literature search was conducted by using a block search strategy combining keywords, free text words, MeSH terms, or database equivalents. The included articles were reviewed for additional keywords and synonyms, and a manual search of the reference lists of the included articles was conducted. The keywords used were search terms and synonyms based on the population (cancer patients), health condition (advanced cancer), setting (clinical trial), type of study (qualitative interview), and activity (shared decision-making). Table 1 shows the inclusion and exclusion criteria for the selection of studies for this review. See appendix A for the PubMed search strategy.

Data collection and analysis

Selection of the studies, description of the included articles and assessment of the quality

Initially, the first author independently applied the inclusion criteria to the identified records. During this process, uncertainties were discussed with the co-authors. The review was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)(28). Descriptive data were

then extracted from the included articles to provide an overview of essential content and ease of comparison of the studies (Table 2). A modified version of Critical Appraisal Skills Programme (CASP) was used to assess the methodological quality of the included articles (Table 3). Three issues (2, 3 and 5) of the original CASP checklist were deselected because these were part of the inclusion criteria. Based on the seven remaining CASP criteria, two reviewers (TAG and MLN) independently assessed the quality of the included articles based on the following seven CASP criteria:

- Was there a clear statement of the aims of the research?
- Was the recruitment strategy appropriate to the aims of the research?
- Has the relationship between the researcher and participants been adequately considered?
- Have ethical issues been taken into consideration?
- Was the data analysis sufficiently rigorous?
- Was there a clear statement of findings?
- How valuable was the research? (Discussion in relation to, e.g., current practice or policy, relevant research-based literature, transferability to other populations or consideration of other ways the research may be used).

Thematic synthesis

The systematic literature review was based on the thematic synthesis described by Thomas and Harden (27). Data were extracted from the results section of the articles, and the synthesis was carried out in three phases: 1) free line-by-line coding, 2) development of descriptive themes and 3) generation of analytical themes. To some degree, phases 1 and 2 merged into each other, and descriptive themes were developed across findings from the articles before analytical themes were generated in phase 3. For an overview of the phases, see Table 4.

Line-by-line coding and descriptive themes

In phase one, the result sections from the articles were entered verbatim into NVivo 11 software and coded line-by-line. The study findings were extracted and synthesized via inductive line-by-line coding and then according to our review aim regarding the experiences of patients and their relatives. After completing this phase of the synthesis, we examined the codes and checked the text for consistency of interpretation. This created a total of 49 initial codes. Differences and similarities between codes were identified and then grouped into hierarchical structures, creating new codes capturing the meaning of each of these groups. This process resulted in six descriptive themes, combining findings from each study as a whole describing patient experiences with clinical trial decision-making. The six descriptive themes were discussed by two of

the reviewers (TAG and RB) who agreed upon a final version. In these two first phases, the synthesis was kept close to the findings in the included articles, and thus far, it has summarized existing knowledge without further interpretation.

Generating analytical themes

Generating analytical themes and constructing the synthesis is described in the discussion section. In this last phase, the analysis of the findings was conducted beyond the content of the included articles and applied the approach described in “Whole Person Care - A New Paradigm for the 21st Century” by Tom A. Hutchinson. Whole person care is an approach to patient care that combines curing and healing with well-being as the overall goal of patient care (29). Well-being is defined as ‘a state in which the individual has the best possible life and level of activity’ (30, 31). This approach was chosen for the analytical framework because it includes both curing and healing, clarifies the need for both and describes why curing and healing should be united. Healing is understood as practices aimed at helping the sick person return to the highest possible level of well-being with a focus on suffering, being healed and growth (29, 31), and curing is described as the focus on the disease, symptoms, being cured and survival. Whole person care combines these two perspectives as the way to patient care (29). This approach is of high relevance when working with people with advanced cancer because there is a focus on curing the cancer disease, and, at the same time, the life-threatening nature of the disease places the patient in a vulnerable situation where existential issues, such as dealing with end of life, hope and meaning, become an important part of communicating about treatment choices (14).

3. Results

3.1 Included articles

The literature search identified 982 articles and resulted in 11 full text articles as shown in the PRISMA diagram (Figure 1). Included articles were published from 2000-2016. Six articles originated from the USA, three from the UK, one from Sweden and one from Japan. Relatives’ experiences were only investigated in two of the 11 articles. The CASP-based quality assessment showed that all of the included articles had a clear statement of the research aim and the study findings (Table 3). All articles described fundamental or basic ethics as approval from an ethical committee and with informed consent. However, only two articles elaborated on the psychological aspect of interviewing people with a life-threatening disease. Furthermore, none of the articles adequately described the relationship between the researcher and participants, and, in four studies, participants were informed by the clinic staff and not by the researcher. One article included

both patients who were offered a trial and patients who were never offered a trial. For this review, only the results regarding patients who were offered a trial were included.

3.2 Descriptive themes

The following six themes provide an overview of the first two phases in the analysis, presented here as a part of the results and organized under two analytical themes, *Individualised decisions* and *Hope and existential matters*, which will be described in the discussion section.

3.2.1 Individualised decisions

Experiences with the health-care professionals - Faith in our doctor

One of the key issues in the process of decision-making was trust in the physician and the medical institution (32-34). Patients based their trial decision on the physician recommendation, and the warnings of negative health outcomes dissuaded patients to enrol in trials. However, many trial refusers would participate if a physician recommended it and if standard treatment failed (35). Most patients preferred guidance and direction from the health-care professionals, and some patients were influenced by the health-care professionals through direct or indirect messages (36). Patients felt they had enough information from the oncologist to make trial decisions and felt comfortable asking questions (36). Some patients felt that the physician sold the product but left the decision to the patient (34). The role of the nurse was unclear in the decision-making process, but patients described their interactions with the nurse as important (34).

Importance of preferences even though options are limited

In this descriptive theme, the patients' approach to decision-making reflects two different patient perspectives: 1) *Acceptors* (patients who decide to participate in a clinical trial) and 2) *Decliners* (patients who said no to clinical trial participation).

Acceptors

Many of the patients knew they had a choice but felt that they had no other options than to participate in the trial because they would not accept death and the standard treatment did not offer them a cure (32, 37-39). Some relatives also expressed that they felt like they had no choice (37, 38). Acceptors believed they would make the same decision again (32), they felt that trial participation gave them the best treatment available (40), and they felt that trial participation was an easy decision (32). Patients knew that they had options, and being able to make their own decisions was very important, even though options

were limited (34). However, patients expressing regret with trial participation felt they had wasted valuable time (40).

Decliners

Decliners felt that rejecting a trial gave them control over their life (33, 35), and they equated the randomising process with loss of control (36). Patients often considered their own medical history, illness history and health events in the decision-making process. Lifestyle and life concerns (such as work and family) favoured certain treatments (36). Some patients stated that they or their family members preferred standard treatment and did not support trial participation (33). Others were afraid of hearing about a clinical trial because it sounded similar to a death sentence or having no other options (35).

Decliners prioritised having time to do what they wanted to do before it was too late rather than spending that time on an ineffective treatment, knowing their disease would not be curable (41). A relative felt that she would have said no to participating in the trial if she could decide, and instead she valued better quality in life (38).

Information overload at a difficult and emotional time

Several studies showed that patients were well informed and satisfied with the trial information (34, 36). However, at the same time, many patients felt overloaded with information provided by numerous different health-care professionals at a difficult and emotional time (36, 37, 42). Many patients relied both on the formal information from health-care professionals (32, 37, 42) as well as information from the internet, previous patients, and relatives with a medical background (36, 42). One study showed that patients had a good understanding of the trial and randomisation procedure (36). Nevertheless, other studies revealed that the information was unclear for quite a few patients. Misunderstanding the principle of allocation, confusion about trial setup, potentially equal risks and benefits (42) and trial purpose (32) were common problems.

Relatives matters

The personal and family history of cancer can play a central role in patients' decision-making. Approval of a family member's point of view or a desire to reduce their burden was very important for the patients in the decision-making process (33), and some felt obligated to participate in a trial because of their family (37). Some patients preferred to make the decision on their own, while some made the decision in dialogue with their relatives (32). For some patients, their relatives' reactions towards the trials meant more than the experiences with past treatment and the doctors' positive explanation of trial participation (41).

3.2.2 Hope and existential matters

Life with cancer - Clinical trials sound like hope

Some patients described that there was a sense of hope associated with clinical trial participation but that, along with hope, there was a feeling of fear, and they were afraid to take a chance. Some patients felt that because clinical trials test and develop new cures, they sound like hope (35), and thus saying no to a trial equates to giving up hope. Patients knew they could say no to treatment, but they felt that their situation gave them no choice (40) and that maintaining hope meant trying everything (32, 40). Patients who agreed to participate in a trial lived with the hope of a therapeutic benefit (41), and some of them expressed that they had to play to win (32, 41).

Wanting a cure

In general, wanting a cure was the primary motivation of patients to participate in a clinical trial (32, 37, 39, 42). Several patients were willing to try anything that was suggested to them (40-42), and even though the treatment had proved ineffective on previous occasions, they were willing to try it again (38). Patients who had previously refused a trial said that they would consider participating in a trial if there was no other option (35). Hope was a great motivator for trial enrolment, which became evident in a study where patients in a phase 1 trial (no standard treatment available) expressed their hope for personal benefit, although they knew the trial aim was to determine the safe dose and toxicities (34). Other patients believed that participating in the trial and thinking positively would influence their treatment benefit (32). Patients' current situation and not past values or attitudes appeared to be a main factor in their decision-making (40). Many patients expressed altruistic reasons for participation (32, 42) and valued helping future patients (34, 36, 37, 39, 40, 42). Nevertheless, altruism was not what came first in the decision-making (34); for some patients, the primary reason for trial participation was the intense and frequent monitoring that is inherent in participating in trials (32, 40, 42) as well as feeling cared for and being in safe hands (32, 39).

4. Discussion

From exploring patients' and relatives' experiences with trial participation, it appears that individualised communication about treatment decisions and communication about the patients' and relatives' hope and other existential matters are of great importance. This is discussed below, where the descriptive themes are grouped under two analytical themes: *Individualised decisions* and *Hope and existential matters*. Through this discussion, these themes are developed into a synthesis of *What matters in treatment-related decisions close to the end of life*.

4.1 Individualised decisions

Patients described their preferences as important for the decision-making process, even though treatment options were limited (34, 36). Although patients felt well informed about treatment options (34, 36), there was a considerable risk of patients experiencing information overload at a difficult and emotional time (36, 37, 42). Through the analysis, it became clear that each patient has a history of his or her own and preferences that matter in the decision-making process. Nevertheless, experiences of the patient reflect a primary focus on information about treatment and at curing the disease. In the book “Whole Person Care”, the authors describe the approach to patients’ care and well-being combines curing and healing (29). The authors define *curing* as the best curative modern medicine (29) and *healing* as a practice aimed at helping the sick person return to the highest possible level of well-being (29, 31). Taking these definitions into account, this approach might be a way of individualising decisions as it paves the way for decisions that are based on a dialogue about what is most important in the patient’s life.

4.2 Hope and existential matters

A cure is the key topic discussed in the included articles when patients decide whether or not to participate in a trial. *Acceptors* were motivated by finding a cure (32, 34, 35, 37-42), whereas *decliners* gave priority to having time to do what they wanted to do while understanding the disease was incurable (41). The results showed that patients commonly participate in clinical trials because they hope for a cure (16-19, 21, 23-26), even though finding a cure was not the purpose of the trial. Consequently, clinical trials equals hope for the patients (35), and, for many patients, treatment becomes the meaning in life, a way to try to live and a hope to the end (32, 40-42). In patients’ experiences, hope and fear seem to be closely connected when making treatment decisions (32, 35, 40, 41). In the context of whole person care, healing can be described as a transition from anxiety and suffering towards a sense of integrity, completeness and inner peace. This transition helps sick individuals experience a better quality of life and helps them feel more similar to themselves and more alive (29, 30, 43). Whole person care describes how people can move from suffering to a sense of integrity and wholeness often independently of objective improvement (29, 30). In view of this approach, patients with advanced cancer might have a meaningful end-of-life experience regardless of the opportunities of treatment and finding hope in life beyond survival. This experience is a contrast to the patients’ experiences described in the included articles, where hope was connected with a cure and treatment opportunities, even though the offered treatment did not provide a cure and was life-prolonging at best.

From a patient perspective, it could seem as if the health-care professionals were reluctant to inform the patients of the limited survival benefit of treatment for advanced cancer, even though this reluctance might

be unconscious. Although the missing information might give some patients hope, it may also prevent the ability to reflect upon the consequences of the course of the disease and thereby also hinder decisions that take the reality into account (29). If health-care professionals are to help patients in this process, they need to have a clear understanding of the patient's suffering as it is experienced by the patient and not as assessed by the health-care professionals (13, 14, 44).

4.3 A synthesis: What matters in treatment-related decisions close to the end of life?

Hope, death anxiety and other existential issues are of great importance for patients who need to make decisions about end-of-life cancer treatment, which emerged from the analyses of the included articles. In the approach “whole person care”, death anxiety contains challenges and opportunities, and it influences the medical decision-making of patients, their relatives and the health-care professionals. Denial of death can be self-preservation and can help patients manage existential crises (29). However, it can be a challenge for health-care professionals to relate to and to talk about existential issues if they are not used to relating to and talking about their own feelings with regard to, e.g., their own death (13, 29). Consequently, one of the main challenges when involving patients in treatment-related decisions close to end of life seems to be the health-care professionals' ability to adjust the information and communication about the treatment and cure at a time when the patient is going through an existential crisis. From the perspective of this review, whole person care, or combining healing and curing, can be an important approach when discussing decision-making in the future. Whole person care might help us move the focus from curing exclusively to curing and healing via cultivating individualised treatment decisions based on the assumption that the patients are not able to make a treatment decision without discussing and considering what is important in (the rest of) their lives.

4.4 Strengths and limitations

This review applied rigorous inclusion and exclusion criteria, systematic search strategy, systematic data extraction and quality assessment, and the process of the review was carefully performed by several researchers. Nevertheless, there are some limitations that need to be mentioned. The well-documented method by Thomas and Harden led us through the process of synthesizing data from qualitative studies, even though this is a research field where the methods are not as well-defined as for other review methods. However, the data analysis and synthesis were supervised by a qualified qualitative researcher. The experiences of relatives were only described in one study (38), although other studies also focused on the experiences of relatives but did not report the experiences because of a lack of consent from the relatives.

4.5 Implications for practice and future research

This review suggests several implications for research involving clinical trials and related communication practice. Patient experiences depend on their life situation and stage of disease.

There are still many unanswered questions about the experiences of patients, relatives and health-care professionals and the preferences of patients when they have to decide whether or not to participate in a clinical oncology trial. For instance, how do health-care professionals experience the process? Are health-care professionals equipped to discuss existential issues? How do the health-care professionals' own approaches to life-threatening disease and death impact their ability to go into such conversations? Therefore, it could be beneficial to include health-care professionals' experiences with decision-making in future research. In addition to exploring health-care professionals' experiences through qualitative methods, the next step approaching whole person care in treatment decision-making could be intervention studies working with health-care professionals' existential issues via self-reflection exercises (13) and coaching (45).

5. Conclusion

In this review, it appears that patients' experiences with deciding whether or not to participate in a clinical trial depend on each individual patient's life situation. The experiences of patients and relatives can be different despite being in the 'same decision situation'. Involving the relatives more directly in decision-making can be an advantage and increases individualised decisions, considering the patients' preferences. The review also shows that it is an existential decision to make decisions about treatment and that the focus is primarily on a cure. Therefore, it might be beneficial if health-care professionals are able to address the role of existential issues in patients' decision-making for clinical trial participation. Considering each person's existential issues might be of great importance in medical decision-making to help patients make treatment decisions on the preferences of the patients instead of those of the health-care professionals.

6. References

1. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ (Clinical research ed)*. 2012;345:e6572.
2. Wind A, Uhrenfeldt L. Det informerede samtykke: Træk af kræftpatienters historiske oplevelser. *Klinisk Sygepleje*. 2013;27(1):4-14.

3. McCormack B, Dulmen AMv, Eide H, Skovdahl K, Eide T. Person-centred healthcare research. 1st ed. Hoboken, NJ: John Wiley & Sons, Ltd; 2017.
4. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ (Clinical research ed)*. 2010;341:c5146.
5. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *The New England journal of medicine*. 2012;366(9):780-1.
6. Politi MC, Wolin KY, Legare F. Implementing clinical practice guidelines about health promotion and disease prevention through shared decision making. *Journal of general internal medicine*. 2013;28(6):838-44.
7. Coulter A, Collins A. Making shared decision making a reality. No decision about me without me. The King's Fund. 2011.
8. Sundhedsstyrelsen. Styrket Indsats På Kræftområdet 2010.: Sundhedsstyrelsen; 2010. Available from: <http://sundhedsstyrelsen.dk/publ/Publ2010/PLAN/Kraeft/StyrketindsatsPaaKraeftomraadet2010.pdf> . Accessed October 3, 2018.
9. Gulbrandsen P, Dalby AM, Ofstad EH, Gerwing J. Confusion in and about shared decision making in hospital outpatient encounters. *Patient education and counseling*. 2014;96(3):287-94.
10. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them - a scoping review. *Implementation science : IS*. 2018;13(1):40.
11. Clayman ML, Gulbrandsen P, Morris MA. A patient in the clinic; a person in the world. Why shared decision making needs to center on the person rather than the medical encounter. *Patient education and counseling*. 2017;100(3):600-4.
12. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient education and counseling*. 2014;94(3):291-309.
13. Ammentorp J, Wolderslund M, Timmermann C, Larsen H, Steffensen KD, Nielsen A, et al. How participatory action research changed our view of the challenges of shared decision-making training. *Patient education and counseling*. 2017.

14. Gulbrandsen P, Clayman ML, Beach MC, Han PK, Boss EF, Ofstad EH, et al. Shared decision-making as an existential journey: Aiming for restored autonomous capacity. Patient education and counseling. 2016;99(9):1505-10.
15. Missel M, Birkelund R. Living with incurable oesophageal cancer. A phenomenological hermeneutical interpretation of patient stories. European journal of oncology nursing : the official journal of European Oncology Nursing Society. 2011;15(4):296-301.
16. Seibaek L, Hounsgaard L, Hvidt NC. Secular, Spiritual, and Religious Existential Concerns of Women with Ovarian Cancer during Final Diagnostics and Start of Treatment. Evidence-based complementary and alternative medicine : eCAM. 2013;2013:765419.
17. Mills EJ, Seely D, Rachlis B, Griffith L, Wu P, Wilson K, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. The Lancet Oncology. 2006;7(2):141-8.
18. Institute NC. Phases of Clinical Trials 2018 [cited 2018 19. April]. Available from: <https://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/phases>. Accessed October 3, 2018.
19. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. Jama. 2013;310(20):2191-4.
20. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? Jama. 2000;283(20):2701-11.
21. Schaeffer MH, Krantz DS, Wichman A, Masur H, Reed E, Vinicky JK. The impact of disease severity on the informed consent process in clinical research. The American journal of medicine. 1996;100(3):261-8.
22. Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. BMJ (Clinical research ed). 2007;335(7609):24-7.
23. Coulter A. Engaging patients in healthcare. Milton Keynes: Open University Press; 2011.
24. sundhedsvæsenet Vfbi. Pårørende ViBis.dk2014 [Available from: <https://danskepatienter.dk/om-danske-patienter/publikationer/tema-om-paaroerendeinddragelse>. Accessed October 3, 2018.
25. Sundhedsstyrelsen. Bilag til Kræftplan II - Pårørende.pdf: Sundhedsstyrelsen; 2005. Available from:

http://sundhedsstyrelsen.dk/publ/Publ2005/PLAN/Kraeftplan2/bilag/Bilag_11_2_Paaroerende.pdf.

Accessed October 3, 2018.

26. van der Spek N, Vos J, van Uden-Kraan CF, Breitbart W, Tollenaar RA, Cuijpers P, et al. Meaning making in cancer survivors: a focus group study. *PloS one*. 2013;8(9):e76089.
27. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol*. 2008;8:45.
28. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of internal medicine*. 2009;151(4):264-9.
29. Hutchinson TA. *Whole Person Care: A New Paradigm for the 21st Century*. 1st edn ed. New York, NY. : Springer Science+Business Media, LLC, ; 2011.
30. Cassell EJ. Suffering, whole person care, and the goals of medicine. In: Hutchinson T, editor. *Whole person care: a new paradigm for the 21st century*. New York, NY: Springer Science and Business Media, LLC; 2011. p. 9-22.
31. Cassell EJ. *The nature of Healing: The modern practice of medicine*. Oxford: Oxford University Press; 2012.
32. Godskesen T, Nygren P, Nordin K, Hansson M, Kihlbom U. Phase 1 clinical trials in end-stage cancer: Patient understanding of trial premises and motives for participation. *Supportive Care in Cancer*. 2013;21(11):3137-42.
33. Quinn GP, Pratt CL, Bryant-George K, Caraway VD, Paternoster B, Roldan T, et al. Lung cancer patients' decisions about clinical trials and the theory of planned behavior. *Journal of cancer education : the official journal of the American Association for Cancer Education*. 2011;26(4):641-8.
34. Schutta KM, Burnett CB. Factors that influence a patient's decision to participate in a phase I cancer clinical trial. *Oncology nursing forum*. 2000;27(9):1435-8.
35. Quinn G, Koskan A, Wells K, Gonzalez L, Meade C, Pozo C, et al. Cancer patients' fears related to clinical trial participation: a qualitative study. *Journal of Cancer Education*. 2012;27(2):257-62.
36. Harrop E, Kelly J, Griffiths G, Casbard A, Nelson A. Why do patients decline surgical trials? Findings from a qualitative interview study embedded in the Cancer Research UK BOLERO trial (Bladder cancer: Open versus Laparoscopic or RObotic cystectomy). *Trials*. 2016;17:35.

37. Shannon-Dorcy K, Drevdahl DJ. "I had already made up my mind": patients and caregivers' perspectives on making the decision to participate in research at a US cancer referral center. *Cancer nursing*. 2011;34(6):428-33.
38. Drevdahl DJ, Dorcy KS. Transitions, decisions, and regret: order in chaos after a cancer diagnosis. *Advances in Nursing Science*. 2012;35(3):222-35.
39. Kvale EA, Woodby L, Williams BR. The Experience of Older Patients With Cancer in Phase 1 Clinical Trials: A Qualitative Case Series. *American Journal of Hospice & Palliative Medicine*. 2010;27(7):474-81.
40. Moore S. A need to try everything: patient participation in phase I trials. *J Adv Nurs*. 2001;33(6):738-47.
41. Kohara I, Inoue T. Searching for a way to live to the end: decision-making process in patients considering participation in cancer phase I clinical trials. *Oncology nursing forum*. 2010;37(2):E124-32.
42. Harrop E, Noble S, Edwards M, Sivell S, Moore B, Nelson A. "I didn't really understand it, I just thought it'd help": exploring the motivations, understandings and experiences of patients with advanced lung cancer participating in a non-placebo clinical IMP trial. *Trials*. 2016;17(1):329.
43. Mount B, Kearney M. Healing and palliative care: charting our way forward. *Palliative medicine*. 2003;17(8):657-8.
44. McNamara H, Boudreau JD. Whole person care: a new paradigm for the 21st century. . In: T. H, editor. New York, NY:: Springer Science and Business Media, LLC; 2011. p. 183-200.
45. Pollak KI, Nagy P, Bigger J, Bilheimer A, Lyna P, Gao X, et al. Effect of teaching motivational interviewing via communication coaching on clinician and patient satisfaction in primary care and pediatric obesity-focused offices. *Patient education and counseling*. 2016;99(2):300-3.

References

1. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ (Clinical research ed)*. 2012;345:e6572.
2. Wind A, Uhrenfeldt L. Det informerede samtykke: Træk af kræftpatienters historiske oplevelser. *Klinisk Sygepleje*. 2013;27(1):4-14.
3. McCormack B, Dulmen AMv, Eide H, Skovdahl K, Eide T. *Person-centred healthcare research*. 1st ed. Hoboken, NJ: John Wiley & Sons, Ltd; 2017.
4. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ (Clinical research ed)*. 2010;341:c5146.
5. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *The New England journal of medicine*. 2012;366(9):780-1.
6. Politi MC, Wolin KY, Legare F. Implementing clinical practice guidelines about health promotion and disease prevention through shared decision making. *Journal of general internal medicine*. 2013;28(6):838-44.
7. Coulter A, Collins A. Making shared decision making a reality. No decision about me without me. *The King's Fund*. 2011.
8. Sundhedsstyrelsen. *Styrket Indsats På Kræftområdet 2010.*: Sundhedsstyrelsen; 2010. Available from: <http://sundhedsstyrelsen.dk/publ/Publ2010/PLAN/Kraeft/StyrketindsatsPaaKraeftomraadet2010.pdf>. Accessed October 3, 2018.
9. Gulbrandsen P, Dalby AM, Ofstad EH, Gerwing J. Confusion in and about shared decision making in hospital outpatient encounters. *Patient education and counseling*. 2014;96(3):287-94.
10. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them - a scoping review. *Implementation science : IS*. 2018;13(1):40.
11. Clayman ML, Gulbrandsen P, Morris MA. A patient in the clinic; a person in the world. Why shared decision making needs to center on the person rather than the medical encounter. *Patient education and counseling*. 2017;100(3):600-4.

12. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient education and counseling*. 2014;94(3):291-309.
13. Ammentorp J, Wolderslund M, Timmermann C, Larsen H, Steffensen KD, Nielsen A, et al. How participatory action research changed our view of the challenges of shared decision-making training. *Patient education and counseling*. 2017.
14. Gulbrandsen P, Clayman ML, Beach MC, Han PK, Boss EF, Ofstad EH, et al. Shared decision-making as an existential journey: Aiming for restored autonomous capacity. *Patient education and counseling*. 2016;99(9):1505-10.
15. Missel M, Birkelund R. Living with incurable oesophageal cancer. A phenomenological hermeneutical interpretation of patient stories. *European journal of oncology nursing : the official journal of European Oncology Nursing Society*. 2011;15(4):296-301.
16. Seibaek L, Hounsgaard L, Hvidt NC. Secular, Spiritual, and Religious Existential Concerns of Women with Ovarian Cancer during Final Diagnostics and Start of Treatment. *Evidence-based complementary and alternative medicine : eCAM*. 2013;2013:765419.
17. Mills EJ, Seely D, Rachlis B, Griffith L, Wu P, Wilson K, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *The Lancet Oncology*. 2006;7(2):141-8.
18. Institute NC. Phases of Clinical Trials 2018 [cited 2018 19. April]. Available from: <https://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/phases>. Accessed October 3, 2018.
19. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Jama*. 2013;310(20):2191-4.
20. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *Jama*. 2000;283(20):2701-11.
21. Schaeffer MH, Krantz DS, Wichman A, Masur H, Reed E, Vinicky JK. The impact of disease severity on the informed consent process in clinical research. *The American journal of medicine*. 1996;100(3):261-8.
22. Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ (Clinical research ed)*. 2007;335(7609):24-7.
23. Coulter A. *Engaging patients in healthcare*. Milton Keynes: Open University Press; 2011.

24. sundhedsvæsenet Vfbi. Pårørende ViBis.dk2014 [Available from: <https://danskepatienter.dk/om-danske-patienter/publikationer/tema-om-paaroerendeinddragelse>. Accessed October 3, 2018.
25. Sundhedsstyrelsen. Bilag til Kræftplan II - Pårørende.pdf: Sundhedsstyrelsen; 2005. Available from: http://sundhedsstyrelsen.dk/publ/Publ2005/PLAN/Kraeftplan2/bilag/Bilag_11_2_Paaroerende.pdf. Accessed October 3, 2018.
26. van der Spek N, Vos J, van Uden-Kraan CF, Breitbart W, Tollenaar RA, Cuijpers P, et al. Meaning making in cancer survivors: a focus group study. *PloS one*. 2013;8(9):e76089.
27. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol*. 2008;8:45.
28. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of internal medicine*. 2009;151(4):264-9.
29. Hutchinson TA. *Whole Person Care: A New Paradigm for the 21st Century*. 1st edn ed. New York, NY. : Springer Science+Business Media, LLC, ; 2011.
30. Cassell EJ. Suffering, whole person care, and the goals of medicine. In: Hutchinson T, editor. *Whole person care: a new paradigm for the 21st century*. New York, NY: Springer Science and Business Media, LLC; 2011. p. 9-22.
31. Cassell EJ. *The nature of Healing: The modern practice of medicine*. Oxford: Oxford University Press; 2012.
32. Godskesen T, Nygren P, Nordin K, Hansson M, Kihlbom U. Phase 1 clinical trials in end-stage cancer: Patient understanding of trial premises and motives for participation. *Supportive Care in Cancer*. 2013;21(11):3137-42.
33. Quinn GP, Pratt CL, Bryant-George K, Caraway VD, Paternoster B, Roldan T, et al. Lung cancer patients' decisions about clinical trials and the theory of planned behavior. *Journal of cancer education : the official journal of the American Association for Cancer Education*. 2011;26(4):641-8.
34. Schutta KM, Burnett CB. Factors that influence a patient's decision to participate in a phase I cancer clinical trial. *Oncology nursing forum*. 2000;27(9):1435-8.

35. Quinn G, Koskan A, Wells K, Gonzalez L, Meade C, Pozo C, et al. Cancer patients' fears related to clinical trial participation: a qualitative study. *Journal of Cancer Education*. 2012;27(2):257-62.
36. Harrop E, Kelly J, Griffiths G, Casbard A, Nelson A. Why do patients decline surgical trials? Findings from a qualitative interview study embedded in the Cancer Research UK BOLERO trial (Bladder cancer: Open versus Lapararoscopic or RObotic cystectomy). *Trials*. 2016;17:35.
37. Shannon-Dorcy K, Drevdahl DJ. "I had already made up my mind": patients and caregivers' perspectives on making the decision to participate in research at a US cancer referral center. *Cancer nursing*. 2011;34(6):428-33.
38. Drevdahl DJ, Dorcy KS. Transitions, decisions, and regret: order in chaos after a cancer diagnosis. *Advances in Nursing Science*. 2012;35(3):222-35.
39. Kvale EA, Woodby L, Williams BR. The Experience of Older Patients With Cancer in Phase 1 Clinical Trials: A Qualitative Case Series. *American Journal of Hospice & Palliative Medicine*. 2010;27(7):474-81.
40. Moore S. A need to try everything: patient participation in phase I trials. *J Adv Nurs*. 2001;33(6):738-47.
41. Kohara I, Inoue T. Searching for a way to live to the end: decision-making process in patients considering participation in cancer phase I clinical trials. *Oncology nursing forum*. 2010;37(2):E124-32.
42. Harrop E, Noble S, Edwards M, Sivell S, Moore B, Nelson A. "I didn't really understand it, I just thought it'd help": exploring the motivations, understandings and experiences of patients with advanced lung cancer participating in a non-placebo clinical IMP trial. *Trials*. 2016;17(1):329.
43. Mount B, Kearney M. Healing and palliative care: charting our way forward. *Palliative medicine*. 2003;17(8):657-8.
44. McNamara H, Boudreau JD. Whole person care: a new paradigm for the 21st century. . In: T. H, editor. New York, NY:: Springer Science and Business Media, LLC; 2011. p. 183-200.
45. Pollak KI, Nagy P, Bigger J, Bilheimer A, Lyna P, Gao X, et al. Effect of teaching motivational interviewing via communication coaching on clinician and patient satisfaction in primary care and pediatric obesity-focused offices. *Patient education and counseling*. 2016;99(2):300-3.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• Qualitative studies• Published studies• English and Scandinavian literature• Patients with advanced cancer• Patients point of view• Focus on treatment decision making for clinical trial participation• Adults > 18 years	<ul style="list-style-type: none">• Studies testing decision aids• Surveys and questionnaires• Clinical trials without treatment• Studies focusing on improving enrolment in clinical trials• Articles that did not present original material

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Table 2

First author, year, country, ref	Objectives/focus	Interview method	Health condition(s)	Sample	Participant characteristics	Time from information to interview.	Before/after decision. Yes/no to trial participation	Trial specifications	Relatives
Moore, 2000, UK, (40)	Explore: patients perceive any benefits from participation and whether they view experience as worthwhile.	Semi-structured interviews, open-stem questionnaire. Longitudinal study design	All types of cancer. Metastatic. Progression and stable disease	13 patients. 6 of them interviewed twice	Male and female.	n.a.	13 Before 6 After Yes	Phase 1	No
Harrop, Noble et al 2016, UK, (42)	Patient motivations, understanding and experiences of participation in the FRAGMATIC trial.	Up to three times	Lung cancer Advanced	10 participants from control and intervention arm	1 female, 9 male	Within 18 weeks of joining the trial	After Yes	Phase 3 Non-placebo clinical IMP trial. RCT	Companions present during the interview
Kohara, 2010, Japan, (41)	Reveal the decision making process in patients considering participation.	Semi-structured interviews. Unstructured observations	All / different types	25 patients	Age ≥ 18 Male and female	In the time between information and starting treatment	After Both yes and no	Phase 1	Yes: observations when patients discussed the trial with their families

Harrop, Kelly et al 2016, UK, (36)	Exploring why patients decline randomization.	Semi-structured interviews	Bladder cancer	10 patients 2 recruiting research nurses	8 male and 2 female. Age range 44-74 Mean age 63,5	n.a.	After No (Patients declined randomization).	Open versus Lapararoscopic or RObotic cystectomy. 2 pt. without option of robotic surgery.	No
Drevdahl, 2012, USA, (38)	Exploring how individuals with hematologic malignancies made the decision to enroll.	Interviews. Face to face and telephone (2. and 3. interview). Longitudinal.	Hematologic malignancie. Relapsed cancer.	25 patients and 20 caregivers	Patients: Male and female. Age 22-69	1 interview pre-treatment. 2 follow up: day 80, 1 year.	After Yes	Phase II HSCT clinical trials. Experimental stem cell transplant	Yes
Quinn, 2012, USA, (35)	The role of fear in patients' perceptions of participating in clinical trials and what role clinicians play in addressing or perpetuating this.	Semi-structured in-depth interviews	All / different types.	48	Patients: Male and female. Age 32-75. Mean age 66.	n.a.	Patient who agreed to participate. Patients who declined and patients who were never asked to participate	n.a.	No
Kvale, 2010, USA, (39)	Describe the social processes characterizing the phase 1 chemotherapy experience.	Semi-structured, open-ended, face to face interview	All types of cancer Advanced	4 patients	Older patients Mean age 63. 3 male, 1 female	n.a.	After Yes	Phase 1	No
Quinn, 2011,	Utilize the <i>theory of</i>	Semi-	Lung cancer	12 patients +	≥ 18 years	n.a.	After	Any phase of	No

USA, (33)	<i>planned behavior framework</i> to better understand the clinical trial decision making process.	structured, open-ended, Interview		9 patients			Yes/no: 12 Previously participated and 9 declined to participate	treatment clinical trial	
Godskesen, 2013, Sweden, (32)	Explore and describe patients' reasons for participation, their experiences related to their participation and issues associated with the information-consent process at trial entrance.	Semi-structured interview Cross-sectional design	All / different types. (prostate, melanoma, lung, pancreas) Advanced	14 patients	Age range 51-81. Median age 63. Male and female.	2 finished the trial 1 and 4 month earlier. 12 were actively participating in the trial.	After Yes	Phase 1	Allowed to bring along a support person
Schutta, 2000, USA, (34)	Factors that influenced patients' decision to participate	Two focus groups	All / different types	8 patients	Age range 42-72 Male and female.	Earlier been asked to participate	After n.a.	Phase 1	No
Shannon-Dorcy, 2011, USA, (37)	Examine how patients and their caregivers decide to participate.	Semi-structured. Face to face and telephone (2. and 3. interview)	Advanced cancer	25 patients and 20 caregivers	Age \geq 18 years	1 interview pre-treatment. 2 follow up: day 80. 3 follow up: 12-18 month	After Yes	Phase 2 Hematopoietic cell transplant	Yes

Table 3. Quality assessment of included articles. CASP Qualitative Research Checklist modified version.

Point 2, 3 and 5 of the original CASP checklist are deselected because these points are a part of the inclusion criteria.

* informed by clinic staff and not by researcher.

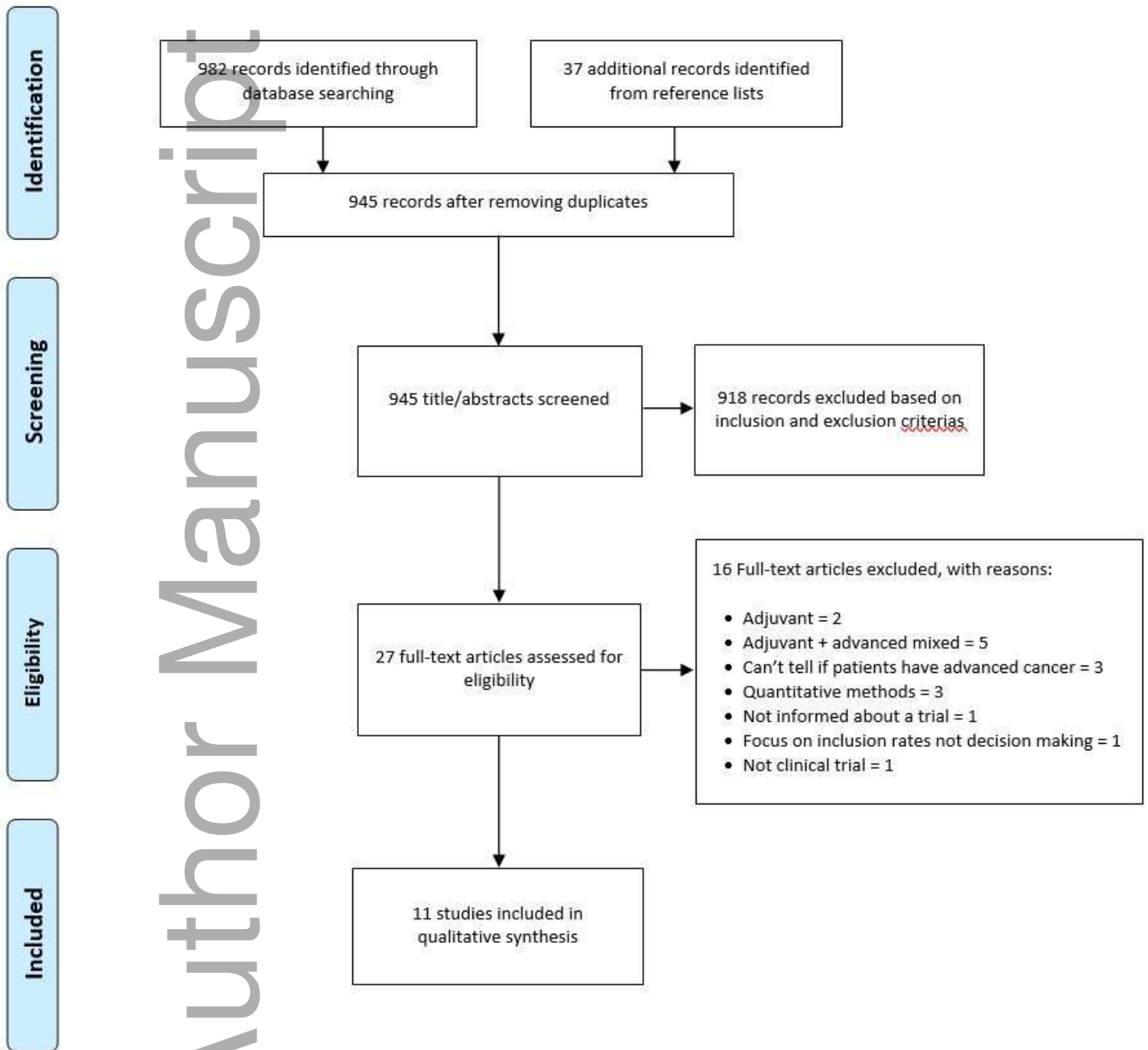
** Ethical approval and consent, but not ethical consideration about doing research with sick persons.

Yes/No/Can't tell	Moore, 2000 (Ref 40)	Harrop, Noble 2016 (Ref 42)	Kohara 2010 (Ref 41)	Harrop, Kelly 2016 (Ref 36)	Drevdahl, 2012 (Ref 38)	Quinn, 2012 (Ref 35)	Kvale, 2010 (Ref 39)	Quinn, 2011 (Ref 33)	Godskesen, 2013 (Ref 32)	Schutta, 2000 (Ref 34)	Shannon- Dorcy (Ref 37)
1) Was there a clear statement of the aims of the research?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4) Was the recruitment strategy appropriate to the aims of the research?	Yes	Yes	Yes	Yes	Yes *partly	Yes	Yes *partly	Yes *partly	Yes	Yes	Yes *partly
6) Has the relationship between researcher and participants been adequately considered?	No	No	No	No	No	No	No	No	No	No	No
7) Have ethical issues been taken into consideration?	Yes	Yes	Yes **partly	Yes **partly	Yes **partly	Yes **partly	Yes	Yes **partly	Yes	Yes **partly	Yes **partly
8) Was the data analysis sufficiently rigorous?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
9) Is there a clear statement of findings?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10) Describes how valuable the research is?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 4

Phase 1	Phase 2	Phase 3	
Line-by-line coding	Descriptive themes	Analytical themes	Synthesis
<p>“In the end we made this decision because we had faith in our doctor, and she told us this may be our only hope” (35).</p>	<p><i>Experiences with the health care professionals - Faith in our doctor</i></p>	<p><i>Individualized decision</i></p>	<p><i>What matters in treatment-related decisions close to end of life</i></p>
<p>“It was the only decision, which made it the right decision” (38). “Previous cancer chemotherapies were not effective for me. So, I assume that the next chemotherapy will be less effective than previous therapies. . . So, it is better for me to go where I want to go before it is too late” (41).</p>	<p><i>Importance of preferences even though options are limited</i></p>		
<p>It was almost at the time I was just starting chemo, so I had a load of information from the lung nurse, from the doctor... the specialist, uh, which quite honestly was almost an overload. Then I had this trial, which is another load of information, and it’s quite a bit of an overload when your mind is in [turmoil anyway] (42).</p>	<p><i>Information overload at a difficult and emotional time</i></p>		
<p>“You know, the family really wanted me to do it” (37).</p>	<p><i>Relatives matters</i></p>	<p><i>Hope and existential matters</i></p>	
<p>“clinical trials are a way to test and develop new cures. So they sound like hope” (35).</p>	<p><i>Life with cancer - Clinical trials sounds like hope</i></p>		
<p>"I can lay down and die, or I can make myself available to the therapies that are available to me" (34).</p>	<p><i>Wanting a cure</i></p>		

Figure 1



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