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Exploring family health, support, self-efficacy and quality of life during the cancer trajectory: a protocol for a longitudinal mixed methods multi-centre cohort study

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ABSTRACT

Introduction A cancer diagnosis not only profoundly impacts individuals but also the very core of their families, reshaping their lives in many ways. However, there is a lack of focus on the well-being and health of the entire family across adult cancer research. This is concerning given that one-third of the Danish population will get a cancer diagnosis before the age of 75, suggesting that many Danes will become caregivers during their lifetime. In addition, identifying vulnerable families is challenging, and the determinant factors for their vulnerability are unknown.

Aims The principal aim of this study is to investigate family health during cancer treatment. This will be done by gathering information on various parameters such as perceived support, quality of life and self-efficacy in patients with cancer and families across the cancer trajectory. Additionally, the study seeks to pinpoint particularly vulnerable families and investigate contributing factors to their vulnerability.

Methods and analysis This mixed-methods study follows a sequential explanatory design, combining patient-reported outcomes in a longitudinal, prospective multicentre survey with interviews conducted with a nested sampling of the participants from the survey. A total of 240 patients diagnosed with prostate-, breast-, gastrointestinal- and lymphoma cancer, and designated adult family caregivers will be recruited from six different sites for the survey. Variables such as family health, needs and perceived support, quality of life, self-efficacy, depression, stress and resilience will be explored. Survey data will be collected at baseline, 3, 6, 12 and 18 months. The interviews (n=12–15) will be conducted twice with patients and caregivers jointly: once during the treatment phase (3 months) and once after completion of treatment (12 months). For the survey part, we estimated a sample size with 90% power and 5% significance to detect a minimal clinically important change in the Family Health Scale. Assuming an SD of $\sqrt{2}\times 22 = 31$, based on a cross-sectional SD of 22, 44 patients per group were required; to allow for dropout, 60 per group (240 total) were included. Patient and caregiver characteristics will be summarised descriptively. Longitudinal patient-reported outcomes will be analysed with linear mixed regression, separately for patients and caregivers. Changes will be reported as mean differences with 95% CIs and compared with published minimal clinically important differences or, if unavailable, 0.3×baseline SD. For the qualitative part, thematic analysis by Braun and Clarke is chosen to extract data, identify patterns and analyse data and themes from the interviews. NVivo will be used for coding interview data.

Ethics and dissemination The study will be conducted in accordance with the Helsinki Declaration. Measures will be taken to ensure confidentiality, data protection and participant safety throughout the study. The results will be published in peer-reviewed journals and conference presentations.

Trial registration number ClinicalTrials.gov: NCT06433349. Protocol version 2.0, June 2024.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ FaCe Cancer is a multi-centre study as it allows for large sample size.
⇒ The mixed-methods longitudinal design explores the needs of families at different stages of the cancer journey.
⇒ Participants may feel burdened due to the extensive number of questions.
⇒ Recruiting both patients and family caregivers to the study may be challenging.

BACKGROUND

Worldwide, an estimated 19.3 million people were diagnosed with cancer in 2020 and the global cancer burden is expected to be 28.4 million cases in 2040.[1] Around 45 000 Danes are diagnosed with cancer each year, with an increasing incidence, and more than 350 000 people are living with cancer.[2]

Depending on the specific diagnosis, the 5-year survival rates range between 67% for men and 69% for women, whereas approximately 15 000 die of cancer each year.[3]

Receiving a cancer diagnosis affects not only the patient but also their family, turning it into a collective journey for the family.[4 5] However, adult cancer research often overlooks the well-being and health of the entire family, despite the fact that about one in five people develop cancer in their lifetime worldwide and one-third of the Danish population will be diagnosed with cancer before the age of 75. This suggests that many will become caregivers for a cancer patient at some point.[6] Adding to this, the Danish Cancer Society recently documented that patients who receive support from family caregivers perform better on all parameters, that is, patients are more aware of signs of relapse and receive more frequent help when needed. Thus, caregiver support is a significant component for getting well through the course of cancer with minimal discomfort,[7] which is also supported by international findings.[8 9]

In addition, there is an increasing political focus on the efficient utilisation of resources in Denmark, which has resulted in fast-track treatments and an increasing number of outpatient clinic visits.[10] This shift from hospital to outpatient settings or even home-based hospitalisation directly involves family caregivers in the care of the individual patient,[11 12] including treatment, physical care and emotional support. Thus, the future healthcare system will increasingly depend on the patient's family and social network to support patients with cancer, ensuring and supporting the health of individuals and communities in multiple interconnected ways.[13] This evident shift from the public to the private sphere has a direct and substantial impact on family function, placing a greater burden and responsibility on family caregivers involved,[14–16] potentially leading to deteriorated overall family health. Additionally, there is growing evidence demonstrating that the health and well-being of family caregivers are affected by higher expectations of active involvement in the care of their ill family member.[17] Families confronted with health challenges are susceptible to stress and disruptions in family functioning, which can lead to additional health problems and further harm within the family system.[18] Equally concerning, evidence shows that caregivers experience high rates (42%) of depression,[19] a disorder associated with multiple concerning outcomes, including premature death, chronic disease courses, self-harm and suicide.[20 21] A recent cross-sectional study carried out among Danish patients with haematological cancer found that caregivers experience impaired sleep, moderate anxiety and reduced quality of life.[22] Recent reviews have documented a general lack of cancer studies including both the patient and the family, and a particular deficiency in studies including more than the spouse.[4 23] Partly due to this lack of research on how cancer affects family health during treatment and survivorship, it is challenging to identify burdened and vulnerable families affected by cancer in the healthcare system.[24] This underscores the need for new research aimed at bridging this gap in understanding by conducting comprehensive studies that not only include the patient but also encompass the broader family unit, using patient-reported outcomes (PROs) and interviews to better identify and support burdened and vulnerable families living with cancer.

The primary objective of this study is to examine family health, perceived support, quality of life, self-efficacy, depression, distress and resilience among patients and caregivers throughout the cancer trajectory by the use of PROs. In addition, the study aims to identify families who are especially burdened or vulnerable and to explore the factors contributing to their vulnerability and support needs through interviews.

METHODS AND MATERIAL

Study design

The FaCe Cancer study is a multi-centre investigation of family health, needs, perceived support, self-efficacy, stress, resilience and quality of life during the cancer trajectory among Danish cancer patients and their adult family caregivers. The study will use mixed methods, including PROs in a longitudinal, prospective multicentre survey combined with family interviews conducted in a subset of participants included in the survey. A sequential explanatory design will be applied involving two phases, wherein the quantitative data collection (survey) and analysis will be followed by qualitative follow-up (interviews).[25] Thus, the qualitative data from the family interviews will help to explain and interpret the context and depth of the mechanisms underlying the survey results. Interviewing families together can provide a fuller picture of the impact of illness and treatment on family health, as their experiences are closely connected. Joint interviews capture shared narratives, highlight differences and allow researchers to observe relational dynamics in real time. They can make participants feel supported and offer more complete information. However, this approach also carries risks as individuals may hold back sensitive views, one voice may dominate and private disagreements may remain hidden. While joint interviews enrich understanding of the caregiving relationship, they may obscure individual perspectives. In this study, the family perspective is prioritised.[26] The researchers are experienced family interviewers from both clinical and research work.

The rationale for applying a mixed-methods approach is to gain a deeper and more comprehensive understanding of the impact of cancer on patients and their families. For data presentation purposes, it will be depicted, by the use of joint display, how the quantitative data are used to inform the qualitative data collection.[27] Thus, the PROs and interview data will be displayed visually side by side, either in a table or figure. Placing the results in direct comparison facilitates combined interpretations, generating new insights into family health during and after treatment. The Checklist of Mixed Methods Elements in

a Submission for Advancing the Methodology of Mixed Methods Research will be used when the results are published.[28] The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines for protocols and the SPIRIT-PRO Extension have been followed.[29 30]

Definitions

Family caregivers

Family caregivers are defined in a broad context and the family is chosen by the patient. This also means that family caregivers in this study can be both blood-related and/or close friends.[31]

Family health

Family health is defined as 'a *resource at the level of the family unit* that develops from the intersection of the health of each family member, their interactions and capacities, as well as the family's physical, social, emotional, economic and medical resources. Family health is greater than the sum of its parts. Positive family health promotes family members' sense of belonging and capacity to develop and adapt, to care for one another and to meet responsibilities'.[13]

Vulnerable families

Due to a lack of a common definition of vulnerable families among adult families, we are inspired by the paediatric literature. Thus, vulnerable families refer to those facing significant challenges or difficulties that may affect their well-being, stability or ability to cope with various stressors. These challenges could include economic hardship, social isolation, health issues, lack of access to resources or support or other factors that increase their susceptibility to negative outcomes or exacerbate existing problems.[32] Vulnerable families often require targeted interventions and support to address their unique needs and mitigate the risk of adverse outcomes. In this specific study, we have chosen the family health scale to inform the vulnerability of the families; see recruitment strategy.

Organisational structure and responsibilities

The principal investigator is responsible for preparing and revising the protocol, organising steering committee meetings and publication of results. A lead investigator, who is also a member of the steering committee, has been identified at each of the six sites. The lead investigators will oversee the recruitment of patients and review the study's progress, also constituting the data monitoring committee. The steering committee comprises three patient and caregiver representatives. Furthermore, a statistician will ensure the correctness of the statistical analysis, and a data manager will help design and maintain the database and ensure that the electronic questionnaires are distributed per protocol.

Patient and public involvement

A user panel that comprises three adults— two cancer survivors, one female and one male, and one female family caregiver—has been established. The patient representatives have been recruited from a larger user panel at Odense University Hospital. The members of the user panel participate in collaborative meetings with the steering group every 6 months. Their knowledge and experiences have been utilised in the design of the study, to qualify information material, such as preparation of informed consent forms for patients and family caregivers, the selection of questionnaires and determining data collection methods. Furthermore, we expect their continued involvement in discussing the results from the quantitative data and analysing the interview data. In the peer-reviewed articles emerging from the project, user involvement will be reported according to the Guidelines for Reporting the Impact of Patient and Public Involvement in Research (GRIPP2).[33]

Setting

Patients and their caregivers will be recruited from six different Danish hospital departments across four hospitals: Odense University Hospital, Lillebaelt Hospital, Copenhagen University Hospital (Rigshospitalet) and Zealand University Hospital. The six sites include three oncology departments and three haematology departments, primarily outpatient clinics, treating and caring for patients receiving various types of anti-neoplastic treatments based on the cancer type and disease stage. Although the hospitals are located in different regions of the country, cancer treatments are similar as they adhere to national guidelines.

Participants

In total, we plan to include 240 patients (see section on statistics), equally divided between four of the most frequent cancer populations treated with curative intent: breast, prostate, gastrointestinal and lymphoma (60 patients in each group). To enhance diversity, the study population will include patients diagnosed with both solid and haematological cancers. In addition, appointed family caregivers will be included. As each recruited patient can appoint one or two caregivers or choose not to recruit any, the number of caregivers is unknown. While patients can participate in the study without a caregiver, the reverse is not possible. Participants must provide written, informed consent before being included in the study.

Inclusion criteria—patients and caregivers

Cancer diagnoses: breast, prostate, colorectal cancer or lymphoma, curative intended treatment, ≥18 years, Danish speaking. Family caregivers over the age of 18 and appointed by the patients.

Exclusion criteria—patients and caregivers

Not able to understand or give written informed consent, not able to speak Danish or complete questionnaires in Danish. No access to electronic mailbox (e-Boks).

Recruitment—survey

Oncology or haematological nurses employed in the respective departments will inform eligible patients about the study and the option of appointing caregivers within 4 weeks of their initial consultation in the cancer department. Eligible patients will receive written study information in paper format. Each site will maintain a screening log of potential candidates, documenting reasons for non-participation. If the patients express an interest in participating in the study, they will receive a secure email in the Danish national electronic mailbox (e-Boks), including a link to the informed consent form for survey participation and access to the questionnaires. They will also be provided with the option of entering the social security number(s) of their appointed caregiver(s), which then triggers an email to the caregiver(s) with a similar link. Accordingly, the links provided to patients and caregivers are personalised and cannot be accessed by third parties. If patients decide not to appoint a caregiver, they will be kindly asked to share the reason for their decision. They can also choose not to provide a reason.

Participants will be recruited using convenience sampling. Recruitment will continue until the target population of 240 patients is achieved. Each of the three oncology departments is expected to enrol 20 patients per cancer diagnosis (breast, prostate and gastrointestinal) and the three haematology departments will enrol 20 patients with lymphoma each. Each diagnosis group will be closed for inclusion after 60 patients have been recruited to avoid overrepresentation of a specific diagnosis.

The enrolment period started in May 2024 and will extend over 18–24 months.

Recruitment—interviews

To recruit vulnerable families for the interviews, data from the survey will be used in accordance with the explanatory sequential design. To identify vulnerable patients and caregivers from the PRO results, 10 items from the Family Health Scale long-form (items 4, 11, 16, 17, 18, 23, 26, 27, 31 and 32), which corresponds to the Family Health short form, will be used. Each participant can have a final family health score between 0 and 10 points. Poor family health=0–5 points; moderate family health=6–8 points; excellent family health=9–10 points.[34] If either the patient or the caregiver has a score indicating poor or moderate family health, the family will be considered a candidate for the interviews.

Compliance

Patients will not be excluded from the study in the event of recurrence. However, data on recurrence will be retrospectively collected from electronic medical records and used in the analysis. Participants can withdraw their consent at any time. To ensure high participation rates, a project coordinator will oversee that participants complete the questionnaire at the selected time points. Participants will receive two reminders in their electronic mailboxes if questionnaires are not completed as scheduled.

Data collection

Patient information will be obtained through a short baseline questionnaire and the electronic health record, including gender, age, marital status, children living at home, educational level, family relations, disease and treatment. Caregivers will be asked to report data based on age, gender, educational level, relationship with the patient (partner, child, friend, etc.) and whether or not they reside with the patient.

Patent-reported outcome measures

Family health, perceived support, quality of life, self-efficacy, depression, distress and resilience in cancer patients and caregivers across the cancer trajectory will be assessed by a number of PROs (table 1). The questionnaires were carefully selected by members of the project group in collaboration with the patient panel, who also reached consensus on their sequencing (online supplemental file 1).

The questionnaires will be administered electronically at treatment initiation (baseline), during treatment (3 months) and at 6, 12 and 18 months after baseline via the electronic mailbox in the patients' homes. The PRO collection is independent of any clinical assessments, and the PRO data are not monitored during the study to inform clinical care for the individual patients. The total number of questions is 74. The patient and caregiver representatives have deemed the number of questions feasible; it is estimated that it takes 20–30 min to complete the questionnaires. If the participants do not respond to the questionnaire, two reminders will be sent out after 7 and 14 days, respectively. If participants do not reply at one of the fixed time points, they will still receive the subsequent questionnaires. Should the patient decide to withdraw from the study, the distribution of the electronic questionnaires will be discontinued.

Statistical analysis

We performed a sample size calculation to be able, with 90% power at a 5% significance level, to detect a minimal clinically important change in the Family Health Scale between two arbitrary time points in the study period. As the SD for change over time was unknown from the literature, we conservatively estimated it as sqrt(2)*22=31, based on a cross-sectional SD of 22. This calculation indicated a requirement of 44 patients in each of the four groups. To take into account the risk of dropout, we increased the target to 60 patients in each group, resulting in a total sample size of 240. During the data analysis, the number of non-compliances will be registered.

We will report descriptive characteristics of the included patients and caregivers as counts and proportions in case of categorical characteristics and as mean with SD or median with IQR for numerical characteristics,

Table 1 Overview of the questionnaires to be applied in the study, including information on the number of questions and if the questionnaires are validated in Danish

Patient-reported outcomes measure	Domains assessed/measured	Number of items
The Family Health Scale (long-form)[34 43]*	Investigates family social and emotional health processes, family healthy lifestyle, family health resources and family external social supports. Higher score indicates better family health	32
Ice Family Perceived Support Questionnaire (ICE-FPSQ)[44]*	Assesses perceived support Higher score indicates a greater perception of support from nurses	14
EuroQol-5 dimensions-5 levels (EQ-5D-5L)[45 46]	Measures health-related quality of life (HRQoL) Higher indicates better HRQoL	6
The General Self-Efficacy Scale (GSE) questionnaire[47]	Investigates the ability to act towards problems in everyday life Higher score indicates higher quality of life (QoL)	10
The Patient Health Questionnaire-9 (PHQ-9)[48]	Measure the degree of depression A higher score indicates a higher severity of depression	9
The National Comprehensive Cancer Network Distress Thermometer (NCCN DT)[49]	Measures the level of distress Higher score indicates a higher level of distress	1
The 2-item Connor-Davidson-Resilience Scale (CD-RISC2)[50]	Assesses resilience Higher score indicates higher resilience	2
	Total number of questions	74

*Validated in Danish.
HRQoL, h; QoL, q.

depending on the Gaussian distribution as investigated by quantile plots.

The longitudinally collected quantitative PRO outcomes will be analysed using linear mixed regression models for repeated measures, including a random normally distributed intercept for each participant. These analyses will be conducted separately for patients and caregivers. Changes over time will be reported as mean differences with 95% CIs and compared with minimal clinically important differences (MCIDs) from literature, if available. If no MCID is available, 0.3 times the baseline SD will be used as an estimate for MCID.

Interviews

Family interviews will be conducted to illuminate how patients and caregivers experience (perceive) vulnerable situations, their family supportive care needs and family support during and after cancer treatment. The groups (n=12–15) will consist of families (one patient and either one or two caregivers) identified in the survey. The interviews will take place longitudinally at two time points at 3 months (during treatment) and 12 months (during follow-up) after completion of baseline questionnaires. The interviews can take place either at the hospital, in the patients' homes or online, depending on the preferences of patients and relatives, and are expected to last approximately 1 hour. We use hermeneutic phenomenology to gain a more thorough understanding of the families' experiences, recognising both their subjective perceptions and the broader cultural and social significance.[35] We will attempt to sustain an open and inductive approach and bracket our pre-understanding, letting the respondents reflect on their own experiences without imposing preconceived notions. An interview guide will be prepared in alignment with this and the family systems theory[36 37] (online supplemental file 2). Purposive sampling will be used to ensure inclusion of families with maximal variation in age, gender and family life situation will be invited. The interviews will be conducted in Danish, with the initial stage of analysis also carried out in Danish. For the final data extraction, the material will then be translated into English. Thematic analysis by Braun and Clarke is chosen to extract data, identify patterns and analyse data and themes.[38] NVivo will be used for coding interview data.

DISCUSSION

The planned study will investigate family health, needs, perceived support, self-efficacy and quality of life among Danish cancer patients and their appointed family caregivers. The results may help identify vulnerable and burdened families and investigate contributing factors to their vulnerability, enabling healthcare providers to provide timely and sufficient support to maintain family health and enhance self-efficacy and resilience for patients and family caregivers in the future.

It is an obvious strength that FaCe Cancer is a multicentre study as it allows for larger sample size, reduces bias and makes it possible to recruit diverse patient populations, enhancing generalisability. Also, the fact

that several investigators are participating will enrich the study with various perspectives and expertise from diverse scientific and clinical backgrounds. On the other hand, it requires careful planning, communication and coordination to ensure consistency, which may be logistically demanding and time-consuming.

Generally, including participants in clinical studies can be challenging due to their resource-demanding nature.[39] The Danish healthcare system is, like other Western healthcare systems, strained and it may be difficult to recruit eligible participants in a busy clinical setting.[40] Moreover, vulnerable patients may be less likely to participate, which represents a clear challenge given that no specific measures were implemented to ensure their inclusion. This limitation is, however, addressed in the qualitative sub-study, where recruitment specifically targets vulnerable patients, as outlined in the recruitment section.

Taking it a step further and recruiting both patients and family caregivers to the study may pose an even bigger challenge. According to Heckel *et al*, the most common reasons for declining participation among cancer dyads were lack of interest, lack of time, not requiring support and finding participation burdensome.[41 2] By examining the reasons for non-participation during the study, we will be able to elucidate if there are patients with certain characteristics that we fail to include. Thus, it is essential to remain vigilant about the potential for selection bias, particularly when studying vulnerable families. There is a risk that certain demographics or characteristics may be overrepresented or underrepresented in the sample, skewing the findings and limiting the generalisability of the results. To mitigate this risk, diverse recruitment strategies must be employed, actively engaging with a wide range of participants to ensure that the study population reflects the diversity of experiences and circumstances within families affected by cancer.

We have also had some concerns regarding the potential burden participants may face due to the extensive number of questions (74) in the survey, which may influence response rates. However, the three patient representatives who are part of the steering committee have expressed that the number of questions is acceptable. The participants are invited to complete the questionnaire five times during 18 months, which means that there are 3–6 months between each completion, which we anticipate is feasible. This aligns with a study involving cancer patients who completed a large number of PROs (n=176 for men and n=180 for women) and interviews. The authors concluded that the patients reported minimal response burden.[42] However, the study also found that patients with lower cognitive functions more often reported a higher response burden. This is important to keep in mind, as there is a risk that patients with low cognitive functioning or otherwise challenged may be more inclined to refuse participation or have lower levels of response rate than patients who are more resourceful, for example, with high levels of health literacy.

A mixed-methods longitudinal study design provides a unique opportunity to comprehensively explore the evolving needs of families at different stages of the cancer journey. Through ongoing assessments and follow-ups, we can explore the multifaceted challenges encountered by patients and caregivers, gaining a nuanced understanding of their experiences and priorities over time. Moreover, by soliciting their perspectives, we may gain valuable insights regarding the types of support and interventions that would be most beneficial. These insights can inform the development of targeted interventions and support services, ultimately improving the quality of care for families facing cancer-related challenges.

Approvals and consent to participate

The study is registered with the Danish Data Protection Agency (23/52139). The study is exempt from ethics approval by the Regional Committees on Health Research Ethics for Southern Denmark (S-20242000 – 44). Informed consent is obtained from all participants included in the study.

ETHICS AND DISSEMINATION

The study will be conducted in accordance with the Helsinki Declaration. Measures will be taken to ensure confidentiality, data protection and participant safety throughout the study. The results will be published in peer-reviewed journals and conference presentations. A lay summary of results will also be prepared for dissemination to participants, patient groups and the broader public to ensure accessibility beyond academic audiences.

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Contributors All authors participated inthe design of the study. KBD, LKT, MS, NH, KJ, MJ and KP took part in collecting data. SM is responsible for the statistical analysis. LKT will collect the qualitative data. KBD, LKT, MS, NH, KJ, MJ, KP and BV will analyse and interprete the qualitative data. All authors took part in writing and rewriting the manuscript and they all read and approved the final manuscript. LKT is responsible for the overall content as the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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