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ABSTRACT

Introduction Patients with cancer having minor children experience particular burden and strains. Being patient and parent at the same time is associated with specific needs of support. Therefore, the communication of child-related and family-related issues plays an important role in patient care. This study aims at testing the feasibility of a training to improve the situation of patients with cancer having minor children and their families by enhancing the competencies of healthcare professionals (HCPs, eg, physicians, nurses, psychologists) in caring for patients with cancer having minor children. Moreover, the study aims at testing the study design and outcomes of the evaluation concept and preliminary effects of the training.

Methods and analysis We will conduct a randomised controlled pilot trial with three arms (face-to-face training versus web-based training versus waitlist control group) to investigate the study aims. Primary outcome will be the competency to approach child-related and family-related topics in patients with cancer measured using comprehensive case vignettes. Secondary outcomes will be communication and attitudes regarding child-related and family-related topics and self-efficacy in clinical communication skills. Outcomes will be assessed prior to the training and after the training as well as 3 months after the training. Data will be analysed using descriptive analyses, group comparisons and linear mixed models.

Ethics and dissemination The study was approved by the Local Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf (LPEK-001). At the end of the study, a web-based training and a face-to-face training intervention to enhance the competencies of HCPs in caring for patients with cancer having minor children will have been systematically developed and the study design and evaluation concept will have been evaluated. The results of the study will be disseminated through peer-reviewed journals and conference presentations.

Trial registration number DRKS00015794.

Strengths and limitations of this study

- This will be the first randomised controlled pilot study to evaluate the effects of an interprofessional training to enhance health professionals' competencies in caring for patients with minor children.
- The rigorous development of case vignettes as primary outcomes and the range of secondary outcomes will provide a base for larger evaluation studies of the training programme on clinically relevant outcomes.
- Since this is a pilot study, we can only provide preliminary evidence on effects of the training. Using case vignettes instead of simulation patients for practical reasons, we will not be able to conclude on the changes in the actual behaviour of healthcare professionals when interacting with patients and families.

INTRODUCTION

Patients with cancer parenting minor children experience particular challenges and burden during the disease trajectory. Cancer and its consequences can have a great impact on the patients themselves as well as their closest relatives.¹ According to current estimates, between 14% and 18% of patients with cancer live with minor children.² Parents with cancer are concerned about the impact of the disease and its treatment on their children.^{3,4} They experience exhaustion and feelings of guilt, as they struggle to fulfil their parental role while being patients.⁵ In a phase when children need the emotional support of their parents, high risk treatments, toxicity, fatigue or other long-term physical and mental consequences of cancer may impede

parents' emotional and physical availability for their children.⁶ Hence, children may have to deal with changes in daily routines (eg, loss of activities or varying carers) and emotional consequences such as fears or guilt.⁷ Also, the non-ill parent is challenged by the situation and encounters multiple demands such as caring for the patient and organisation of daily life, for example, caring for the children, household requirements and job demands.⁸

According to international guidelines, psycho-oncological support is understood as an integral part of comprehensive cancer care.^{9–10} Patients with cancer and their relatives should receive psycho-oncological/psycho-social support where needed. While adult relatives, mostly partners of patients with cancer, are regularly included in supportive care, support offers for minor children have scarcely been implemented into routine care.¹¹ In a population-based study with cancer survivors up to 6 years postdiagnosis with minor and young adult children, 73% of the survivors retrospectively reported an information need on parenting issues related to the disease or a need for family-focused/parent-focused psychosocial support during the course of the disease.¹² However, only 9% reported to have used a specific support offer.¹² A study on outpatient psychosocial counselling services in Germany reports that only about 50% of the services systematically assessed parental status in their patients.¹³ Main reasons were presumed deficits in competencies and capacities of the staff.¹³ A current study on healthcare professionals' (HCPs) perspective on barriers to communicate about their patients' children illustrates that structural barriers (eg, time pressure, no systematic registration or lack of training) and emotional barriers (eg, distress, professional distance) impact the communication of child-related and family-related topics.¹⁴

However, guidelines recommend that patient-centred communication with patients with cancer and their relatives with regard to individual needs and preferences during cancer treatment should be carried out by all professions in oncology.^{9–15} Only few patients proactively address psychosocial issues to HCPs.¹⁶ Also, patients with cancer having minor children scarcely bring up child-related or family-related concerns unsolicited.¹³ At the same time, physicians and other medical staff rarely broach the issue of emotional or psychosocial topics proactively, but wait for the patients to take the initiative and disclose their psychosocial burden.^{17–19} Missing routines in talking about psychosocial issues and in revealing psychosocial difficulties as well as a lack of competencies in talking about such aspects seem to be central reasons for HCPs to neglect psychosocial topics.²⁰ Current findings illustrate that more than 50% of the HCPs do not regularly discuss child-related aspects (eg, explanation of the disease to the child/communicating with children about the disease/disclosing cancer-related information to children) with their patients.²¹ However, a recent systematic review identified the medical staff, in particular the attending physician, as a major way to access preventive family-centred or child-centred interventions.¹¹

The main aim of this study is to test the feasibility of a newly developed training programme for HCPs from different professions (eg, physicians, nurses, psychologists) working with patients with cancer having minor children. The training aims at increasing the competencies to approach child-related and family-related topics during the course of the disease. For the preliminary evaluation of the effectiveness of the training, we apply Kirkpatrick's framework for training evaluation. The model is widely used²² and comprises following levels: (1) reaction (satisfaction with the training), (2) learning (change of attitudes, improvement of knowledge and increase in skills), (3) behaviour (changes in behaviour) and (4) results (eg, improvement in patient-oriented healthcare).²³ Since the fourth level can rather be understood as improvements on organisational/system level, we refrain from evaluating the training on this level.

As the study can be considered a Phase I and Phase II study concerning the framework for design and evaluation of complex interventions,²⁴ a further aim is to test the feasibility of the evaluation concept including, for example, the applied outcome parameters and the measurement time points. Moreover, we explore the tendency with regard to the effectiveness of the training programme regarding the competencies to approach child-related and family-related topics, HCPs communication and attitude and self-efficacy regarding child-related and family-related topics. The intervention will be delivered either as face-to-face training or as a web-based training.

METHODS AND ANALYSIS

This study protocol is written according the SPIRIT guidelines and addresses applicable recommended items for clinical trial protocols.²⁵

Study setting

The study will be conducted at the Department of Medical Psychology of the University Medical Centre Hamburg-Eppendorf in Germany.

Study design

The study is designed as a three arm randomised controlled trial (RCT). HCPs will be randomised to a face-to-face training (intervention 1), a web-based training (intervention 2) or a waitlist control group (control). Assessments will be performed at baseline (T0, before randomisation), after the training (T1) and 3 months after the training (T2) (only intervention groups). Follow-up assessment in the waitlist control group will be performed 6 weeks after baseline assessment (T1). After the intervention period, participants of the control group will be offered to participate in the web-based training or the face-to-face training. An overview of the study design and the measurement time points is displayed in [figure 1](#).

Eligibility criteria

Eligible for the RCT are all HCPs, independent of setting (inpatient or outpatient), profession (eg, physicians,

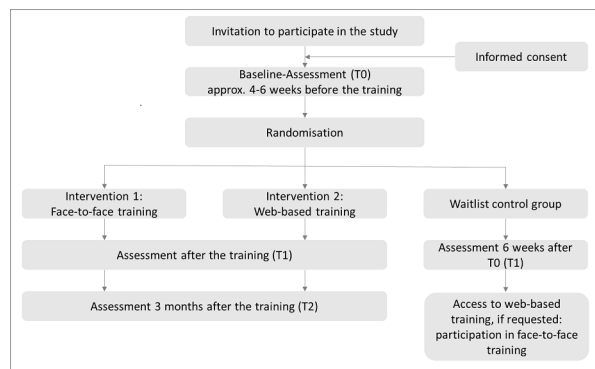


Figure 1 Flowchart of participant flow through RCT.

nurses, psychologists) or amount of work experience in the field, who provide written informed consent for study participation and work with patients with cancer. Additionally, HCPs need any available internet connection in case of being randomised to the web-based training intervention group. No further inclusion or exclusion criteria are defined.

Interventions

The interventions were developed based on a review of the recent literature as well as semistructured interviews with patients with cancer having minor children, HCPs (eg, physicians, nurses, psychosocial staff) and experts in the field of counselling families affected by parental cancer.

Face-to-face training

The face-to-face training (intervention 1) was developed based on the theoretical and empirical findings of the literature on parental cancer and the results of semistructured interviews with patients with cancer having minor children, HCPs (eg, physicians, nurses, psychosocial staff) and experts in the field of counselling families affected by parental cancer. The training consists of three modules: (1) incidences, burden and supportive care needs of patients with cancer having minor children, (2) children of patients with cancer: age-specific illness and death concepts, age-specific reactions to parental cancer, influencing factors for age-appropriate development, (3) communication in the family and communication as a HCP with the family (figure 2).

The face-to-face training will be provided in small groups (5–8 participants) by two trainers (at least one of them with expertise in the field of parental cancer and comprehensive experience in communication skills trainings) with a duration of about 3 hours. The training will be conducted as an interprofessional training to allow synergy effects by the means of different experiences and perspectives. The training adopts several didactic techniques from continuing education: lecture, video sequences of experts, group discussion and role play.²⁶ Participants will be encouraged to provide own examples or cases from their work experience. All participants will receive written information material

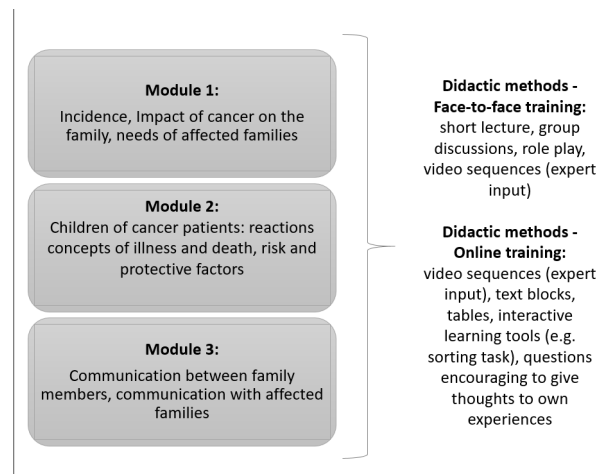


Figure 2 Content and didactic methods of the training to enhance health professionals' competencies in caring for patients with minor children.

for the training. The trainers will follow a manual which describes and defines the content and didactic elements of each module and is supported by standardised presentation material.

Web-based training

The content of the web-based training (intervention 2) was developed concordantly to the face-to-face training. The training is a self-directed web-based training that provides psychoeducational modules, exercises and questions to examine the individual level of knowledge. The web-based training includes video sequences of experts in the field of parental cancer providing commentaries or case examples. The completion of the entire web-based training will take approximately 3 hours and can be conducted in any chosen location with a PC and internet connection.

Correspondent to the face-to-face training, detailed content of the modules are conceptualised based on the results of the semistructured interviews and findings from the literature review about communication training for HCPs regarding parental cancer (figure 2).

Outcomes

Regarding the feasibility of the intervention, number of participants and dropout rates will be monitored. Training fidelity of the web-based training will be assessed by completion rates for each module and descriptive information regarding the profile of usage. Additionally, outcome parameters will be evaluated with regard to feasibility (eg, missing values, psychometric properties). Demographic data as well as professional background will be obtained.

Applying the levels of Kirkpatrick's model of evaluation (table 1), the participants will complete the measures at baseline (T0), after the intervention (T1) and 3 months after T1 (T2) (figure 1, table 2).

Table 1 Level of Kirkpatrick's model and study outcome parameter

Level of Kirkpatrick's model	Outcome parameter
<i>Level 1: Reaction</i> Description: satisfaction with the training	Feedback concerning the training
<i>Level 2: Learning</i> Description: change of attitudes, improvement of knowledge and increase in skills	Competency to approach child-related and family-related topics, knowledge and relevance Communicative competency and self-efficacy
<i>Level 3: Behaviour</i> Description: changes in behaviour	Competency to approach child-related and family-related topics Communication and attitudes regarding child-related and family-related topics in daily practice

Primary outcome

The primary outcome competency to approach child-related and family-related topics in patients with cancer will be measured using comprehensive case vignettes developed with elements of situational judgement test (SJT) and knowledge assessment. Case vignettes have been used in several settings to evaluate training programmes and to assess the transfer of knowledge and competency in the clinical practice.^{27 28}

Hence, we developed clinical case vignettes to assess in which way HCPs address child-related and family-related topics in their routine care, how they apply their knowledge about for example, age-appropriate communication to the case vignettes and how relevant they perceive child-related and family-related topics. Additionally, each case vignette comprises an element of construct driven SJTs to assess empathic reaction towards affected parents.

We developed two case vignettes for each measurement point. All six case vignettes cover typical case constellations and situations of patients with cancer having minor children. They contain a concise presentation of the case and the inclusion of hints indicating a family-related or child-related difficulty for the patient or family. The indicators of the child-related or family-related difficulty vary with regard to explicitness and clarity. The case vignettes were developed to apply to different professions working with patients with cancer (eg, physicians, nurses, psychosocial staff). Based on SJTs from assessment centres, for example, for medical students, in each vignette participants need to answer open-ended questions, multiple choice questions (eg, most appropriate reaction and importance of reaction) and forced choice questions.^{29–31}

Each vignette captures four domains: (1) transfer of knowledge into clinical practice, (2) empathic behaviour towards affected parents, (3) integration of child-related and family-related topics into clinical practice, (4) perceived relevance of integrating child-related and family-related topics into clinical practice.

Each participant will receive a sum score in each domain based on the two vignettes of each measurement point.

Table 2 Study measurements and measurement points

Assessment	Baseline (T0)	After the training (IG)/6-week follow-up (CG) (T1)	3-month follow-up (T2)
Sociodemographic and occupational variables	●		
Changes in sociodemographic or occupational situation		●	●
Primary outcome			
Competency regarding child-related and family-related topics (case vignettes/SJT)	●	●	●
Secondary outcomes			
Communicative competency and self-efficacy	●	●	●
Knowledge regarding child-related and family-related topics	●	●	●
Communication and attitudes regarding child-related and family-related topics in daily work	●	●	●
Covariates			
Professional fulfilment Index	●	●	●
Interprofessional teamwork	●	●	●
Feedback concerning the training*		●	

*Only in the intervention groups.

CG, waitlist control group; IG, intervention groups; SJT, situational judgement test.

Comparisons of the scores between the three measurement points illustrate positive or negative changes. The developed case vignettes were discussed within the research team (including several team members with clinical experience in the field) with regard to comprehensibility, relevance, fairness, level of difficulty and authenticity. In a second step, the case vignettes were pilot tested by 2–3 HCPs and afterwards finalised.

Secondary outcomes

Communicative competency and self-efficacy

Communicative competency will be measured with the translated version of a questionnaire on self-efficacy in HCPs' clinical communication skills (SE-12).³² Additionally, specific communication competencies concerning child-related and family-related topics will be assessed with questions inspired by items of the self-efficacy questionnaire regarding communication skills about existential issues in cancer care by Hvidt and colleagues³³ and a self-efficacy questionnaire for clinical communication skills with parents of childhood patients with cancer.³⁴ All items were translated into German following the TRAPD translation protocol.^{35 36}

Knowledge about child-related and family-related topics

To assess the knowledge about child-related and family-related topics, we developed items based on the information provided in the training. Questions are based on findings from scientific publications on the topic of parental cancer and cover, for example, incidence of parental cancer, the impact of cancer on affected parents and their children and risk factors for maladjustment in children.

Communication and attitudes regarding child-related and family-related topics in daily practice

HCPs' attitudes and behaviours during daily work routines will be assessed using self-developed items. The items include questions such as 'How often do you ask your patients about the needs of their children or family?' and can be answered on a 4-point-likert scale (never, sometimes, often and always).

Covariates

Professional fulfilment

HCPs' professional fulfilment will be assessed using the translated version of the Professional Fulfilment Index, a 16-item instrument with three subscales for professional fulfilment, work exhaustion and interpersonal disengagement.³⁷ The questionnaire was translated using the TRAPD translation protocol.^{35 36}

Interprofessional teamwork

To assess attitudes towards interprofessional teamwork, we developed task specific items based on HCPs' attitude about HCPs' responsibilities concerning child-related and family-related topics, for example, identifying supportive care needs of patients' families.

Participants' feedback

To assess the feedback and evaluation concerning content and organisation of the training, we use self-developed items with regard to the content related to clinical practice, overall impression of the content, organisation and structure of the training, the evaluation of single components of the training and atmosphere during the training. Items are adjusted for kind of intervention (face-to-face training or web-based training). Additionally, participants have the opportunity to comment on the training (open question: general/additional comments).

Sample size

As we cannot assume any effects a priori, we use the approach for pilot studies by Viechtbauer and colleagues³⁸ to determine the sample size. The calculation implicates the identification of unforeseen problems such as incomplete data sets or ambiguous inclusion criteria or misinterpretation of questionnaire items. Assuming a 10% probability for an unforeseen problem to occur and a 95% CI to detect these problems, a sample size of n=30 participants in each group is required. Considering a dropout rate of 30%, n=108 participants (n=36 per group) need to be included in the study.

Recruitment

HCPs working with patients with cancer will be identified through existing and re-established collaborations with clinics and other (psycho-) oncological institutions (eg, practices of haematology and oncology or psycho-oncological outpatient counselling services) in Hamburg and the surrounding area. Eligible HCPs will be contacted and informed about the study by email, letter or telephone. If interested in participation, a member of the research team will contact the HCPs and will send a detailed information letter and informed consent form. HCPs participating in the study will be informed that there is an equal chance to be assigned to one of the three groups (intervention 1, intervention 2, control). HCPs of the waitlist control group can participate in one of the interventions after completion of the T1 questionnaire.

The research team can be contacted in case of questions regarding the study. HCPs who do not react after receiving the information letter/email will be followed-up by an additional contact (telephone, email or letter) and asked about their interest to participate. In case of consent to participate, HCPs will be enrolled into the study and receive the baseline assessment.

Randomisation and blinding

Participants will be randomised in a 1:1:1 ratio into the three study groups. As we follow a continuous enrolment strategy, each newly enrolled HCP will be randomly assigned based on a computer-based randomisation protocol using the statistical programme R. Randomisation will be stratified with regard to profession to ensure a well-adjusted representation of the different professions between groups. A collaborator from the statistical



methods-research group of the Department of Medical Psychology of the University Medical Center Hamburg-Eppendorf, who is otherwise not involved in the study in any way, will perform the randomisation and intervention allocation to ensure independency from recruitment of the HCPs and realisation of the intervention. Following the randomisation, blinding of the participants and the research team cannot be implemented due to the nature of the intervention.

Data management and monitoring

The members of the research team will continuously document the data collection and manage the data collection at the different measurement points. Questionnaires will be entered in a SPSS database by research assistants. To assure high data quality, double entry will take place for some questionnaires (20%) and checked for mistakes. Data are only accessible to members of the research team. Using a data-cleaning protocol based on syntax, the plausibility of the data will be checked for example, with regard to value range or inconsistencies.

As the training will involve HCPs and comprises an intervention with no known/minimal risks, a data monitoring committee was not included. Adverse events will be monitored, documented and the necessity of adaptation in the study process will be discussed within the research team.

Analyses

Descriptive statistics will be used to analyse the parameters regarding the feasibility and the appraisal of the intervention (eg, organisation, content). Moreover, psychometric properties of the questionnaires in the study sample will be analysed. Descriptive statistics will be reported to characterise the sample. Mean and SD will be reported for continuous data and frequencies and percentages for categorical data. Group comparisons will be conducted using χ^2 , U or t-tests, depending on the scale level. We will use linear mixed models to analyse the outcomes with time and study group (intervention group 1, intervention group 2, control group; baseline, postintervention, 3-month postintervention) as fixed factors. Preliminary effects will be calculated for all outcome measures. All analyses will be performed using the intent-to-treat approach. Additionally, exploratory predictor analyses using regression analyses will be conducted.

Patient and public involvement statement

We did not involve patients or the public in our work.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

The study was approved by the Local Psychological Ethics Committee of the Center for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf (LPEK-001). Informed consent will be obtained from each HCP prior to participation in the study.

Confidentiality

Data protection is assured by pseudonymisation and restricted access authorisation. The code list can only be decrypted by an authorised associated member of the study team without any research interest in the presented study. The code list will be destroyed after the end of the data collection.

Availability of data and material

The research team will have full access to the dataset. However, availability of these data will be restricted and data will not be publicly available. Data are, however, available from the authors on reasonable request and with permission of Local Psychological Ethics Committee (LPEK) and the data protection officer of the University Medical Center Hamburg-Eppendorf.

Dissemination

The findings of our study will be presented on national and international conferences and published in scientific journals. Publications will address the main aims of the study. Moreover, analyses of detailed aspects with data derived from the study will be published.

The results of our study will allow conclusions on the feasibility of similar trials and study designs. Moreover, we will systematically investigate the preliminary effects of an interprofessional training with focus on patients with cancer having minor children.

DISCUSSION

Psycho-oncological support for patients and their relatives is an integral part of comprehensive cancer care.^{9 15 39} Patients with cancer parenting minor children have specific concerns and encounter specific challenges as they experience a double burden of being a patient and being a parent.^{3 5} Still, support services for affected parents and their children are not routinely implemented in cancer care.^{11 13} HCPs should support patients and their families to receive healthcare according to their psychosocial needs. This means that HCPs should identify psychosocial needs by assessing and communicating these topics openly and proactively. If specific psychosocial support is indicated to maintain mental health or reduce disruptions in daily life (eg, child care), referral to psycho-oncological treatment, child-centred counselling or social legal advice is necessary. The content of the developed training was conceptualised based on the results of semistructured interviews with patients, HCPs with different professions and experts in the field of parental cancer. This approach allowed to design the content of the training based on the working experience of the target group.

With this pilot study, we will evaluate a newly developed training for HCPs to enhance their competencies regarding child-related and family-related topics and examine preliminary effects of a face-to-face training and a web-based training. The results of the pilot study will

provide relevant information on feasibility and preliminary evidence on the effect of the training. These information may provide a base for further interventional studies for the developed training.

The trial has several limitations. Due to the nature of the intervention, HCPs are not blinded for their intervention, which may impact the results. Moreover, the training is not mandatory and HCPs who are motivated and interested in the topic will possibly participate more frequently. Randomisation will be conducted on an individual level, which may lead to contamination if colleagues who participate are randomised to a comparison group. To evaluate the competencies, we use case vignettes instead of simulation patients for practical reasons. Hence, we will not be able to conclude on the changes in the actual behaviour of HCPs interacting with patients and families.

However, to the best of our knowledge, this is the first randomised controlled pilot trial for a training for HCPs in oncology to enhance their competencies in caring for patients with minor children. So far, only few studies have focused on this topic and have not included any control group.^{17 40}

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