Children with cancer and their families after active treatment: analyses of biopsychosocial needs and implications for healthcare – a study protocol

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ABSTRACT

Introduction Patients and families affected by paediatric cancer experience psychosocial burden not only during active treatment but also during follow-up care. Use of health services during follow-up treatment should be organised according to patients’ and family members’ needs with regard to their physical and mental situation. This study aims (1) at analysing healthcare use (medical and psychosocial) and associated factors in follow-up care of paediatric cancer patients and (2) at investigating the psychosocial situation and support needs of children and their families during follow-up care. Based on the results, recommendations for healthcare planning and for the development of new and the optimisation of existing support offers will be derived.

Methods and analysis We will conduct a prospective observational study using a naturalistic explorative design with quantitative and qualitative methods. Paediatric cancer patients in follow-up care, their parents and siblings will be invited to fill out a questionnaire at three measurement points (baseline, 6 months follow-up, 12 months follow-up; target n=252 complete data sets over all measurement points). Additionally, parents will be interviewed using a semistructured interview guideline (target n=15–20) at baseline. Quantitative data will be analysed using descriptive statistics, linear mixed models and regression models. Moreover, explorative analyses will be conducted. Qualitative data will be analysed using qualitative content analyses.

Ethics and dissemination The study was approved by the Local Psychological Ethics Committee (LPEK-0281). Our findings will be published in scientific, peer-reviewed journals and presented to clinicians and researchers on conferences. To assure that results will be available to affected patients and families, a lay summary will be written and disseminated using several ways (upload on the homepage of the research group, upload on the homepage of the psychosocial working group in the Society for Paediatric Oncology/Haematology in Germany, sending to relevant patient organisations).

Trial registration number DRKS00025289.

INTRODUCTION

In Germany, about 2000 children and adolescents are diagnosed with cancer annually.1 Globally, between 300 000 and 400 000 children and adolescents are affected each year.2,3 Due to improved diagnostics and treatment options, survival rates have increased up to a 5-year survival rate of 85% across all diagnoses during the past decades.4 Nonetheless, childhood cancer is associated with a high physical and mental burden for both patients and their close relatives. Survivorship is associated with intense, long treatment, severe side effects and late effects.5 Hence, limitations in daily activities and integration can occur after successful treatment.

Examples for late effects are limited heart-functioning or liver-functioning, growth hormone deficiency, pain, endocrine disorders or limited cognitive functioning.6 Besides physical late effects, childhood cancer survivorship is associated with worse health-related quality of life, chronic distress and reduced well-being.7,8 Following the end of active treatment, reintegration into daily life can be exhausting and challenging for children with cancer. Visiting school or kindergarten implies normalcy, but may cost lots of energy and resources for the children.9 Additionally, negative psychosocial consequences have been identified in close family members.
such as parents and siblings. Siblings of paediatric cancer patients can show symptoms of post-traumatic stress, worry and fears. Moreover, difficulties in school and in peer-interaction are reported. Parents experience long-term consequences such as anxiety, depressive mood and less stress resilience. Additionally, paediatric cancer can negatively impact parents’ employment and financial situation.

National and international guidelines recommend regular and continuous follow-up care in order to detect late effects timely and to initiate necessary examinations or treatments. Additionally, psychosocial screening should be an integrated part of follow-up care to assess psychosocial issues, which may arise after active treatment. Differences in needs for support in family members, depending on the child’s age and stage of development should be taken into account. Hence, to comprehensively support affected families, assessment of psychosocial issues and needs in all family members should be considered and, if necessary, support offers provided.

Integrated, comprehensive follow-up care should address medical care and psychosocial care routinely. Still, resources providing care are limited and follow-up care routinely integrating medical and psychosocial aspects for affected children and their families is rare. Hence, families are often left alone with regard to identifying their potential needs as well as potential support offers and contact persons.

Due to differences in the organisation of medical and psychosocial follow-up care, results from international studies only partly allow for conclusions for healthcare system in Germany. Data on healthcare use during follow-up care are missing. Moreover, there is no systematic evidence on the healthcare use according to patients’ and families’ needs in follow-up care after paediatric cancer. At the same time, healthcare planning and needs-based allocation of families to support offers is highly needed considering limited resources, for example, regarding manpower and time. Hence, reliable findings on profiles of mental burden in patients and family members as well as supportive care needs during follow-up care are necessary for adequate healthcare organisation.

The overall aim of our study is to analyse the psychosocial situation and the current healthcare of paediatric cancer patients and their families during follow-up care. Based on our findings, strategies and recommendations for the development of new and the optimisation of existing support offers in follow-up care will be developed. We define the following two central study aims and research questions:

Aim 1: Analysis of healthcare use and associated factors in follow-up care of paediatric cancer patients.

- How can the current healthcare and healthcare use of patients and their families in follow-up care be described?
- Considering healthcare and supportive care use and psychosocial situation of patients and families: Is healthcare provision according to the needs of the families?

Aim 2: Analysis of psychosocial situation and supportive care needs of children and their families during follow-up care.

- How is the course of burden in paediatric patients and their families during follow-up care?
- Which are the met and unmet needs of affected families?
- Which factors influence functional and psychosocial parameters and their course?
- Can groups with similar courses and needs be identified?

METHODS AND ANALYSIS

This study protocol is written according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines and addresses recommended items for clinical trial protocols applicable for our study.

Study setting

The study will be conducted at the Department of Medical Psychology of the University Medical Center Hamburg-Eppendorf in Germany. The study is conducted in collaboration with the Clinic of Paediatric Haematology and Oncology.

Study design

The study will be conducted as a prospective observational study using a naturalistic explorative design. The study uses a mixed-methods design with quantitative and qualitative methods to answer the research questions.

In a multiperspective quantitative survey with three measurement points (baseline, 6 months follow-up, 12 months follow-up) patients, their parents as main caregivers and healthy siblings will be included. The study will be conducted according to the guidelines for prospective observational studies.

Complementary, a consecutively selected subsample of parents will be qualitatively interviewed using a semi-structured interview guideline.

Population

Patients (0–17 years) visiting the Clinic of Paediatric Haematology and Oncology for a follow-up appointment as well as their parents and siblings will be included. Patients and their families are eligible during any point of time during a follow-up period up to 5 years after the end of treatment.

Patients will be invited to participate themselves from an age of 11 years. If the patient is <11 years of age, only parents will be asked to participate. In order to avoid feelings of discrimination, siblings ≥11 years will also be invited to participate. All family members of a single family are invited for participation if they meet the inclusion criteria. However, as study participation is voluntarily, also single family members can participate.
In the qualitative study only parents will be invited for an interview.

The following inclusion criteria are further defined: termination of active cancer treatment, age of patient <18 years, sufficient language skills to answer the questionnaires/interview questions, written informed consent (including caregiver consent for child participation). Exclusion criteria are: age of patient ≥18 years, too high physical or mental burden to participate (assessment of study team), refusal.

**Procedure**

Patients, respectively, their caregivers/parents will be informed about the study and invited for participation. If interested, study material will be handed out including questionnaires for all family members, an extensive information sheet, informed consent form and a prepaid return envelope addressed to the Department of Medical Psychology. Participants will be asked for their contact details for (1) sending questionnaires for the two further measurement points and (2) to make an interview appointment, if participating in the qualitative study part.

A member of the research team will contact the parents and make an interview appointment. The questionnaires for the two further measurement points will be mailed to the families from the Department of Medical Psychology. After 4 weeks, a reminder letter will be sent.

**Measures**

**Primary outcomes**

**Study aim 1: healthcare use (medical and psychosocial) during follow-up phase**

Healthcare use will be assessed using self-developed questions on medical healthcare and psychosocial support offers for the patients and psychosocial support offers for family members and frequency of use (eg, Did your child use physiotherapy during the past 6 months?—not at all, once, 2–4 times, 5 times or more). Healthcare offers included are, for example, paediatrician, speech therapy, neuropsychological training, psychotherapy, support group or camp.

**Study aim 2: psychosocial situation and supportive care needs**

The psychosocial situation will be assessed using the KINDL, a questionnaire for health-related quality of life in children (self-report and/or proxy-report) and the Strengths and Difficulties Questionnaire (SDQ) for children. The psychometric properties are reported to be satisfactory for both instruments. The German Ulmer Lebensqualitäts-Inventar für Eltern (ULQIE) will be used for parents to assess quality of life. Reliability and validity of the ULQIE proved to be good to excellent. Additionally to quality of life, anxiety and depressive symptoms of parents will be assessed using the Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder questionnaire (GAD-7). In previous studies, both instruments showed good to excellent psychometric properties. To assess supportive care needs, we modified the supportive care needs survey for caregivers of adult patients for the use in the context of our study (caregivers/parents of children with cancer).

**Additional outcomes**

Additionally to our primary outcomes, we will assess coping using the valid and reliable KIDCOPE for children (self-report only) and the Coping Health Inventory for Parents (CHIP). Reliability and validity of the CHIP were confirmed. Moreover, experiences in oncological healthcare, knowledge about disease and treatment as well as satisfaction with healthcare will be assessed using self-developed questions based on clinical experience.

A full list of the measures is presented in **table 1**. Qualitative interviews will be based on a semistructured interview guideline. The guideline will be developed based on theoretical considerations, the research questions and previous qualitative studies of the research group. The guideline will be pretested in a pilot interview and final adjustments will be made afterwards, if necessary. Themes the guideline will cover among others are: Healthcare use (medical and psychosocial, including barriers and facilitators), needs of patients and families, experiences during follow-up care (**table 2**).

**Data management and monitoring**

Members of the research team will continuously document data collection and manage the data collection at the different measurement points.

Research assistants will enter questionnaires in a SPSS (version 27) database. To assure high data quality, double entry will be conducted for about 20% of the questionnaires and screened for mistakes. Data will only be accessible to members of the research team.

Monitoring and documentation of adverse events during the study will be conducted, and, if necessary, adaptation in the study process will be discussed within the research team.

**Analyses**

**Quantitative data**

Quantitative data will be analysed using the statistic software SPSS (version 27). In order to describe the study sample, we will use descriptive statistics. Mean and SD will be reported for continuous data and frequencies and percentages for categorical data. Differences between subgroups (eg, disease group, age groups) will be analysed using $\chi^2$, U-test or t-tests depending on the scale level. To analyse selection/drop-out bias, we will conduct comparisons between the final sample (participation in all measurement points) and participants dropping out after the first or second measurement. Missing data will be handled according to recommendations of the used outcome measures (eg, mean substitution).

**Study aim 1: healthcare use (medical and psychosocial) during follow-up phase**

To analyse the healthcare situation, use and predictors for healthcare utilisation, we will use descriptive statistics and regression analyses.
Study aim 2: analysis of psychosocial situation and supportive care needs of children and their families during follow-up care

In outcomes with standardised instruments and available norm samples, we will analyse differences between our sample and age- and gender-adapted norm values using one-group t-tests with the norm value as reference. The analyses of the psychosocial situation and supportive care needs will be conducted using descriptive statistics and linear mixed models with time and family as fixed effects. The analyses of predictors of psychosocial outcomes will be analysed using regression models. Exploratively, we will conduct latent class models (growth mixture models) to identify prototypical courses over time.

Qualitative data

Qualitative data will be analysed using qualitative content analyses. Themes and categories will be derived deductively based on theoretical considerations and inductively based on the transcribed data material. We will generate a coding system including definitions and text passages as examples for each category. In order to assure for high validity, the coding system will be applied to at least 25% of the transcripts by two independent coders. In case of ambiguous or unclear categories, the coding system will be modified and finalised. The final coding system will be applied to all data transcripts. The qualitative analysis will be conducted using MaxQDA.

Qualitative and quantitative data will be analysed separately. The results will be related to each other and examined exploratively with regard to convergence and discrepancy regarding the study aims. The qualitative data may allow to increase the understanding and support the results of the quantitative findings.

Sample size

We defined linear mixed models as basis for our sample size calculations. Under the assumptions of three measurement points with medium effects between groups (f=0.25), a high power of w=0.95 and a probability of p<0.05 for alpha error, a sample size of n=260 over all measurement points is necessary. A sample size of n=184 would be necessary to detect medium effects with a power of w=0.80 (G*Power 3.1.9.2).

For qualitative interviews our target sample size is n=15–20 parents to reach saturation of data.
**Patient and public involvement**
We did not involve patients or the public in our work. But the patient’s perspective is explicitly part of our research approach and will be represented in the quantitative and qualitative data.

**ETHICS AND DISSEMINATION**

**Ethics approval and consent to participate**
The study has been approved by the Local Psychological Ethics Committee of the Centre for Psychosocial Medicine of the University Medical Center Hamburg-Eppendorf (LPEK-0281). Parents and children ≥11 years will receive detailed study information. Informed consent will be obtained from caregivers/parents prior to participation in the study. For children ≥11 years informed consent will be obtained by the child and the parent.

**Confidentiality**
Data protection is assured by pseudonymisation during the data collection phase using a unique patient code.

The code list can only be decrypted by members of the research team for managing the study process (sending of the questionnaires at the different measurement points), for matching extracted medical data (eg, diagnosis, treatment, date of diagnosis) and in case of withdrawal from study participation of a patient or family. The code list will be destroyed after the end of data collection. Access to study data will be restricted by authorised access only for members of the research team.

**Dissemination**
We will present our findings on national and international conferences and publish findings in peer-reviewed scientific journals. In order to make the results accessible and available to affected patients and families, a plain language summary will be uploaded on the homepage of the research group and the homepage of the psychosocial working group in the Society for Paediatric Oncology/Haematology in Germany. Moreover, it will be send to relevant patient organisations.

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**Table 2** Guiding questions of the interviews

| Topic | Guiding questions* |
|-------|--------------------|
| **Introduction** | |
| **Sociodemographic and children’s medical characteristics** | |
| Healthcare use | ► Do you know any health care offers you or your child can use during after care?  
► Which health care offers did you or your child use since the end of the active treatment?  
► Did the sibling use any support offers?  
► Did you or your family get any recommendations for supportive therapies, psychosocial support or other health care offers after treatment? |
| Daily life | ► How do you feel—physically and emotionally?  
► Do you experience limitations in your daily life due to the cancer diagnosis of your child?  
► What are your current support needs?  
► How did your social and work life change?  
► How did the diagnosis impact your child’s life for example, with regard to school/kindergarten?  
► How does your child feel?  
► How did the following aspects change?  
  – Ability to concentrate  
  – Physical strength  
  – Peer interaction  
  – Emotional situation  
  – Communication  
► What are your child’s current support needs?  
► How did the diagnosis impact your child’s life, for example, with regard to school/kindergarten?  
► What were particularly challenging situations for your child?  
► What were/are your child’s support needs?  
► Which changes in your family life did you experience from your child’s diagnosis until today?  
► Which changes in your partner relationship did you experience from your child’s diagnosis until today? |
| Parent | ► What was the situation during active treatment which impacted you and your family the most?  
► If you could wish: How would the best possible psychosocial care and health care for your child and your family look like? What should be different? |
| Ill child | |
| Healthy child (if applicable) | |
| Family life | |

*Questions originally in German.*
DISCUSSION

The findings of our study will provide a systematic assessment of the current situation and needs of paediatric cancer patients during follow-up care and their families. The analyses of healthcare service use and potential barriers and facilitators may allow for providing detailed information to optimise follow-up care concerning medical healthcare, but also psychosocial support offers. The multiperspective assessment of the psychosocial situation, including quality of life and mental health outcomes, as well as supportive care needs is essential to derive relevant evidence for comprehensive healthcare planning and implementation. In particular, due to limited financial resources and limited manpower in healthcare, allocation of affected families to healthcare services and psychosocial support offers should be based on specific needs. Based on our findings, recommendations can be derived and will help to improve access to healthcare as well as healthcare services for paediatric cancer patients and their families after active treatment.

Strengths and limitations

This study will comprehensively assess the situation of paediatric cancer patients in follow-up care and their close family members. So far, studies often concentrate on the active treatment phase or long-term survivorship. However, the first years after active treatment can be influenced by persisting physical limitations, difficulties in reintegration or fear of recurrence. Hence, this phase is highly relevant in order to provide comprehensive cancer care. The multiperspective and longitudinal approach of this study allows for elaborated and comprehensive insights into the situation of affected families.

Moreover, aiming at the inclusion of all cancer diagnoses after active treatment, the study will provide a comprehensive overview of follow-up care. This allows conclusions not only for certain diagnoses but for the planning and realisation of follow-up care in paediatric oncology and haematology.

One major limitation of the study is, that the study will be conducted in cooperation with selected study centres. Hence, conclusions may not be applicable for other patients from other clinics. Therefore, recommendations will be developed carefully against the background of possibly different organisation of follow-up care in other clinics or in different healthcare systems.

Another limitation is a potential selection bias in the recruitment or willingness of participation in patients and families, for example, families satisfied with healthcare, patients with little limitations or parents little burdened might be more likely to participate.

Contributors

CB and LJ designed the study. VP, JW, SR and GE were involved in the conception and design of the study. LJ drafted the manuscript, which was modified and supplemented by all other authors. All authors are involved in the management and execution of the study. All authors were involved in revising the manuscript substantively, and read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

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