FORTEe

An exercise intervention for children and adolescents undergoing anti-cancer treatment

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D2.4 Analysis and publication of findings

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Executive Summary

This deliverable presents the **analysis and dissemination of findings** generated within Work Package 2 (WP2: Ethical and Legal Issues) of the FORTEe project. Building on prior deliverables documenting data collection and preparation, the present report synthesises qualitative and mixed-methods results and outlines their scientific and stakeholder-oriented dissemination.

WP2 investigated the ethical and experiential dimensions of a structured exercise intervention for children and adolescents undergoing cancer treatment. The analysis is based on a multi-source dataset, including semi-structured interviews with patients and families, participant observations and a multi-centre survey of healthcare professionals. This approach enabled a comprehensive, multi-perspective assessment of the intervention in clinical settings.

The findings demonstrate that the FORTEe exercise intervention is **widely perceived as beneficial and acceptable**, with positive effects including psychological well-being, sense of normalcy and patient empowerment. At the same time, WP2 identified several **recurring ethical challenges**, particularly in relation to child autonomy and assent, parental influence, perceived burden, fairness of randomisation and emotional and moral strain among healthcare professionals.

Importantly, these challenges arise primarily during **practical implementation**, rather than from the study design alone, highlighting the need for continuous ethical reflection in paediatric clinical research. Cross-centre analyses further indicate that experiences of the intervention are shaped by contextual and cultural factors, underlining the importance of context-sensitive implementation strategies.

WP2 findings have been disseminated through **peer-reviewed publications** (see Annex 1)**, conference presentations** (see Annex 2) **and a lay summary** (see Figure 1, ensuring communication across scientific, clinical and public audiences.

Overall, WP2 contributes to the FORTEe project by providing **contextualised, ethically informed insights** into the implementation of exercise interventions in paediatric oncology, supporting the development of patient-centred and ethically robust supportive care strategies.

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1 Introduction

This deliverable presents the **analysis and publication of findings** generated within Work Package 2 (WP2: Ethical and Legal Issues) of the FORTEe project. Building on prior deliverables documenting data collection (D2.2) and transcription and preparation of qualitative material (D2.3), the present report focuses on the **interpretation, integration and dissemination** of WP2 results.

WP2 employed a qualitative research approach to investigate ethical and experiential aspects of the FORTEe exercise intervention for children and adolescents undergoing cancer treatment. The primary data sources comprised semi-structured interviews with patients and their families, participant observations conducted during intervention sessions and additional contextual field notes. These data, summarised as “textual data”, enabled an in-depth exploration of participants’ perspectives and the ethical dimensions of trial implementation.

The main objective of the FORTEe interviews was to generate narrative data on patients’ self-assessments, lived experiences and perceptions of the exercise intervention. In line with the ethical monitoring function of WP2, qualitative data collection was initially restricted to participants in the intervention group. Participant observations complemented interview data by capturing situational, relational and non-verbal aspects of the intervention context. Together, these approaches provided a comprehensive qualitative understanding that extends beyond standardised outcome measures.

In addition to patient-centred qualitative research, WP2 incorporated a dedicated ethical monitoring component, including a multi-centre survey of healthcare professionals involved in the FORTEe trial. This enabled the systematic assessment of ethical challenges arising in clinical practice, such as issues related to child autonomy, informed consent, burden-benefit evaluation and moral distress.

The qualitative and mixed-methods findings generated within WP2 complement the standardised data collected in WP3 by providing contextualised insights into how the intervention is experienced, interpreted and implemented in clinical settings. This integrated perspective is essential for understanding not only the effectiveness of the intervention but also its ethical acceptability and practical feasibility.

The present deliverable synthesises these findings and documents their dissemination through peer-reviewed publications, conference contributions and stakeholder-oriented outputs, including lay summaries. In doing so, it demonstrates how WP2 contributes to the broader objectives of the FORTEe project by informing ethically sound, patient-centred and context-sensitive implementation of exercise interventions in paediatric oncology.

2 Data Basis and Analytical Approach

This chapter provides an overview of the qualitative and mixed-methods data underlying the WP2 findings, as well as the analytical strategies applied.

2.1 Data Sources

The analyses presented in this deliverable are based on a multi-source qualitative dataset generated within WP2. The primary data sources include:

- **Semi-structured interviews** with children and adolescents participating in the FORTEe exercise intervention, as well as with parents or caregivers
- **Participant observations** conducted during exercise sessions
- **Contextual field notes and contact protocols**, capturing situational and non-verbal aspects of the intervention
- **A multi-centre survey of healthcare professionals (HCPs)** involved in the FORTEe trial, including both quantitative and qualitative components

The qualitative interview and observation data were collected between June 2022 and February 2024 at the Childhood Cancer Center of the University Medical Center Mainz. The HCP survey was conducted between September and October 2024 across all participating FORTEe recruitment centres.

An overview of the data sources included in the present analyses is provided in Table 1.

The qualitative interview dataset comprises narrative accounts of patients' and families' experiences with the intervention, while observational data provide insight into interactional dynamics and the practical implementation of the exercise programme. The HCP survey complements these perspectives by capturing ethical challenges and experiences from the professional viewpoint across multiple European study sites.

In addition, subsequent collaborative qualitative analyses were conducted together with the Copenhagen study site (University Hospital Copenhagen - Rigshospitalet, Denmark), extending the originally planned analytical scope of WP2 Task 3. These exploratory cross-centre analyses incorporated additional interview data from both intervention and control group participants and aimed to generate comparative insights into participant and family experiences across different healthcare and cultural settings. As these analyses were developed as a later collaborative extension of the original WP2 programme, parts of the resulting data are currently being further prepared for scientific publication.

Together, these sources constitute a **comprehensive dataset**, enabling analysis of the intervention from patient, family and healthcare professional perspectives.

Table 1. Overview of data sources included in the analyses

Data source	Participants / material	Sample size	Study sites	Methodological approach	Source
Semi-structured interviews	Children and adolescents participating in the FORTEe intervention	**n = 6 patients**	**University Medical Center Mainz, Germany**	Qualitative open interviews	Wilke, Paul, Dreismickenbecker, et al. (2025)

Semi-structured interviews	Parents of participating patients	**n = 5 parents**	**University Medical Center Mainz, Germany**	Qualitative open interviews	Wilke, Paul, Dreismickenbecker, et al. (2025)
Participant observations	Exercise sessions during intervention participation	**n = 10 participant observations**	**University Medical Center Mainz, Germany**	Ethnographic participant observation	Wilke, Paul, Dreismickenbecker, et al. (2025)
Contextual field notes and contact protocols	Interview field notes, observation protocols and contextual documentation	**Generated throughout data collection (June 2022 – February 2024)**	**University Medical Center Mainz, Germany**	Qualitative field documentation	Wilke, Paul, Dreismickenbecker, et al. (2025)
Multi-centre HCP survey	Healthcare professionals involved in the FORTEe trial, including exercise professionals, physicians, nurses, psychologists and allied professionals	**n = 79 respondents**	**10 FORTEe centres across Germany, Italy, Spain, France, Denmark, Slovenia and the United Kingdom**	Mixed-methods browser-based survey including quantitative and qualitative items	Alt, Dreismickenbecker, et al. (2026)
Cross-centre semi-structured interviews	Children, adolescents and parents from intervention and control groups	**n = 14 participants (7 patients, 7 parents)**	**University Hospital Copenhagen - Rigshospitalet, Denmark**	Qualitative semi-structured interviews; comparative cross-centre analysis using reflexive thematic analysis and Framework Method	Alt, Neu, et al. (2026)/ ongoing joint publication

2.2 Scope and Sampling Considerations

Qualitative data collection within WP2 was primarily focused on participants in the **intervention group**, reflecting the objective of capturing in-depth experiences of the exercise programme. This design allowed for detailed exploration of perceived benefits, burdens and ethical considerations associated with active participation.

The HCP survey was conducted across **multiple FORTEe recruitment centres**, involving a broad range of professional groups, including physicians, nurses, exercise professionals, psychologists and other allied healthcare staff. This ensured representation of diverse roles and responsibilities within the trial.

Subsequent exploratory cross-centre analyses additionally incorporated qualitative interview data from further FORTEe sites, thereby broadening the analytical perspective beyond the original intervention-focused dataset.

2.3 Analytical Approach

The qualitative data were analysed using established interpretative methods, including:

- **Reflexive thematic analysis** for the identification of patterns and themes within interview data
- **Framework-guided qualitative content analysis** for structured evaluation of survey free-text responses

These approaches allowed for both **inductive identification of emergent themes** and **deductive structuring of ethically relevant domains**, such as autonomy, burden-benefit balance and fairness.

Quantitative components of the HCP survey were analysed descriptively, using frequencies and proportions to summarise key response patterns. Integration of qualitative and quantitative findings was conducted at the interpretative level, enabling a comprehensive understanding of ethical challenges in the implementation of the FORTEe intervention.

2.4 Methodological Considerations

The WP2 approach is characterised by:

- **Exploratory and interpretative design**, allowing in-depth understanding of experiences
- **Multi-perspective data collection** (patients, families, healthcare professionals)
- **Context-sensitive analysis**, capturing implementation conditions in clinical settings

At the same time, several limitations should be acknowledged. The qualitative focus and relatively small sample sizes limit generalisability. Furthermore, initial data collection was restricted to intervention participants and findings may therefore not fully reflect experiences of control group participants. The integration of additional cross-centre data partially addresses this limitation.

3 Synthesis of WP2 Findings

This chapter integrates the qualitative and mixed-methods findings generated within WP2, drawing on patient and family interviews, participant observations and the multi-centre survey of healthcare professionals. Rather than presenting results by individual study, findings are synthesised across data sources to identify **key thematic domains relevant to the ethical and experiential dimensions of the FORTEe intervention**. The synthesis presented in this chapter is based on the scientific publications, conference presentations and exploratory cross-centre analyses generated within WP2. An overview of related publications is provided in Annex 1, while dissemination activities including conference contributions and presentations are summarised in Annex 2.

3.1 Perceived Benefits and Meaning of Exercise

Across all data sources, exercise was consistently experienced as **beneficial beyond physical outcomes**.

Patients and families described improvements in:

- physical strength and endurance
- daily functioning
- overall well-being

Importantly, exercise was also associated with **psychological and existential effects**, including:

- creating distance from the illness experience
- providing structure and routine during treatment
- restoring a sense of normalcy

Participants frequently emphasised that exercise allowed them to experience themselves as **active individuals rather than passive patients**, highlighting its relevance for identity and self-perception.

These findings were corroborated by healthcare professionals, who reported a predominantly positive overall **burden-benefit balance** of trial participation, while acknowledging situational burdens.

3.2 Patient-Centred Experience and Autonomy

A central theme across WP2 was the importance of **patient-centred implementation and the role of autonomy**.

Qualitative findings indicate that:

- children and adolescents valued being actively involved in the exercise programme
- individualisation of training contributed to feelings of safety and motivation
- interactions with exercise professionals supported a sense of being recognised as an individual person

At the same time, both interview and survey data revealed **tensions in decision-making**, particularly in the context of:

- child assent versus parental consent
- fluctuating willingness to participate during treatment
- communication challenges in vulnerable situations

Healthcare professionals reported difficulties in interpreting children's preferences, especially in younger patients or during emotionally demanding phases of illness. These findings underscore that autonomy in paediatric research is **relational, dynamic and context-dependent**, rather than purely procedural.

3.3 Burden, Vulnerability and Acceptability of Participation

While the intervention was largely perceived as acceptable, WP2 findings highlight that **burden remains a relevant and multifaceted issue**.

Reported sources of burden included:

- logistical demands of study participation
- questionnaire load and timing during intensive treatment
- emotional strain associated with illness and decision-making

Importantly, the data suggest that:

- much of the perceived burden cannot be attributed solely to the intervention

- rather, it emerges from the **interaction between research procedures and the broader clinical context**

Despite these challenges, the majority of healthcare professionals considered the overall burden-benefit ratio to be appropriate, indicating general ethical acceptability of the intervention.

3.4 Ethical Tensions in Trial Design and Implementation

WP2 identified several recurring ethical tensions inherent to conducting a randomised controlled trial in a vulnerable population.

A key issue was **fairness in control group allocation**:

- patients and families sometimes experienced disappointment or frustration when not receiving the intervention
- healthcare professionals reported ethical discomfort when withholding an intervention perceived as beneficial

In addition, challenges were reported regarding:

- explaining randomisation processes
- managing expectations of benefit
- maintaining engagement among control group participants

Cross-centre qualitative findings further demonstrated that **experiences of control group allocation varied**, ranging from perceived exclusion to acceptance or even relief from participation burden. This variability highlights the importance of **context and communication** in shaping ethical perceptions.

3.5 Emotional and Moral Dimensions of Clinical Research

The WP2 findings emphasise that ethical challenges are not limited to formal procedures but include **emotional and relational dimensions**.

Healthcare professionals reported experiences of:

- emotional strain related to patient deterioration, relapse or death
- moral distress when balancing research requirements with perceived patient needs
- difficulties in trial-related decisions, such as discontinuation or non-re-enrolment

In parallel, professionals perceived **emotional distress among patients and families**, particularly in situations involving:

- disease progression
- uncertainty about outcomes
- conflicts between hope and clinical reality

These findings illustrate that conducting research in paediatric oncology involves **ongoing ethical negotiation in emotionally demanding contexts**, extending beyond protocol-level considerations.

3.6 Contextual and Cross-Centre Influences

Extended qualitative analyses revealed that experiences of the intervention are shaped by **contextual and cultural factors.**

Cross-centre comparisons identified:

- differences in how families integrate exercise into daily routines
- the role of family health beliefs in shaping engagement
- variability in experiences related to control group participation

At the same time, core experiences were shared across settings, including:

- perceived physical and psychological benefits
- the importance of normalcy and routine
- the value of being treated as an individual

These findings highlight the need for **context-sensitive implementation strategies**, particularly in multi-centre and international trials.

3.7 Summary of Key Findings

Taken together, WP2 demonstrates that:

- The FORTEe exercise intervention is **widely perceived as beneficial and acceptable**
- Ethical challenges arise primarily in **real-world implementation**, not in principle
- Key areas of ethical relevance include:
    - autonomy and assent
    - burden and vulnerability
    - fairness and randomisation
    - emotional and moral dimensions of care and research

Importantly, the findings across interviews, participant observations and healthcare professional perspectives consistently indicate that ethical challenges emerged less from the existence of the intervention itself than from its implementation within the complex realities of paediatric oncology care. Ethical tensions were particularly associated with fluctuating patient conditions, questions of child assent and parental influence, experiences related to control group allocation, emotional burden during intensive treatment phases and the integration of research procedures into everyday clinical care. These findings therefore suggest that **ethically sound study designs** require **continuous reflection, contextual sensitivity** and **adaptive implementation strategies** throughout the conduct of the study, particularly in **vulnerable populations** such as children and adolescents undergoing cancer treatment.

4 Dissemination and Publication of Findings

This chapter summarises the dissemination activities and publication outputs generated within WP2. The dissemination strategy aimed to ensure that findings on ethical and experiential aspects of the FORTEe intervention are communicated across **scientific, clinical and public audiences**, thereby supporting both academic impact and practical implementation.

4.1 Peer-Reviewed Scientific Publications

The primary findings of WP2 have been disseminated through peer-reviewed journal articles addressing complementary dimensions of the ethical and experiential landscape of the FORTEe trial.

First, a qualitative interview study by Wilke, Paul, Dreismickenbecker, et al. (2025) explored the experiences of children and adolescents participating in the exercise intervention, as well as perspectives of their families. This study provides in-depth insights into how patients perceive and

integrate exercise into their daily lives during cancer treatment, highlighting themes such as physical recovery, psychological relief and identity beyond the patient role.

Second, a mixed-methods multi-centre survey by Alt, Dreismickenbecker, et al. (2026) examined the ethical experiences of healthcare professionals involved in the FORTEe trial. This study identified key ethical challenges arising in clinical practice, including issues related to child autonomy, parental influence, burden-benefit evaluation, fairness of randomisation and moral distress. Overall, the ethical climate of the trial was perceived as positive, although tensions emerged in the clinical implementation.

In addition, earlier conceptual work by Wilke, Paul, Neu, et al. (2025) provided the theoretical and ethical foundation for the empirical studies conducted within WP2, informing the development of interview guides and analytical frameworks.

Together, these publications represent a **coherent body of work**, covering:

- conceptual ethical considerations
- patient and family perspectives
- healthcare professional perspectives

A detailed list of the scientific publications is provided in Annex 1.

4.2 Conference Contributions and Scientific Dissemination

WP2 findings were further disseminated through international scientific conferences, enabling engagement with the broader research community.

A conference poster presenting preliminary qualitative findings from patient interviews was presented at the 55th Annual Meeting of the Société Internationale d'Oncologie Pédiatrique (SIOP), held in Ottawa, Canada (October 11-14, 2023; DOI: 10.1002/pbc.30748). This contribution reported first insights from a single-centre qualitative analysis within the FORTEe trial, based on participant observations, interviews with patients aged 6–21 years and their parents and ethnographic field notes. Preliminary results indicated predominantly positive effects of the structured exercise programme on patients' well-being, coping, and self-image, including enhanced physical awareness, increased confidence and the experience of agency during treatment.

A conference poster based on the healthcare professional survey presented key results on ethical challenges in the FORTEe trial, including tensions related to autonomy, fairness and moral distress. This work was presented at the 3rd Pediatric Exercise Oncology Congress (PEOC × FORTEe), held in Mainz, Germany (April 16-17, 2026), and was based on a multicentre survey across ten European study sites involving 79 healthcare professionals. The poster emphasised that ethically sound study designs may still generate challenges in practice and highlighted the importance of integrating ethical reflection into clinical research processes.

In addition, a cross-centre qualitative analysis comparing patient and parent experiences across German and Danish study sites was presented as both a conference abstract and poster. Also presented at PEOC × FORTEe 2026 in Mainz, this study included data from both intervention and control group participants and applied reflexive thematic analysis to explore cross-country differences in experiences and contextual influences. This work incorporated perspectives from intervention and control group participants and provided novel insights into contextual influences, including family health beliefs, activity strategies and experiences of randomisation.

These conference contributions extend the scope of WP2 dissemination by:

- presenting preliminary and ongoing analyses
- enabling international exchange

- supporting the development of future publications

A detailed list of conference contributions, including full author lists and titles, is provided in Annex 2.

4.3 Stakeholder-Oriented Dissemination and Lay Summary

In addition to academic dissemination, WP2 placed strong emphasis on communicating findings to **non-scientific audiences**, including patients, families and healthcare providers.

A lay summary was developed based on the qualitative interview study, translating key findings into an accessible and visually structured format. The summary highlights core themes such as improved physical capability, psychological relief from the illness context and the importance of being perceived as a person beyond the patient role.

Furthermore, the lay summary emphasises the relevance of exercise interventions for emotional well-being and patient empowerment, demonstrating how tailored and participatory approaches can support both patients and their families.

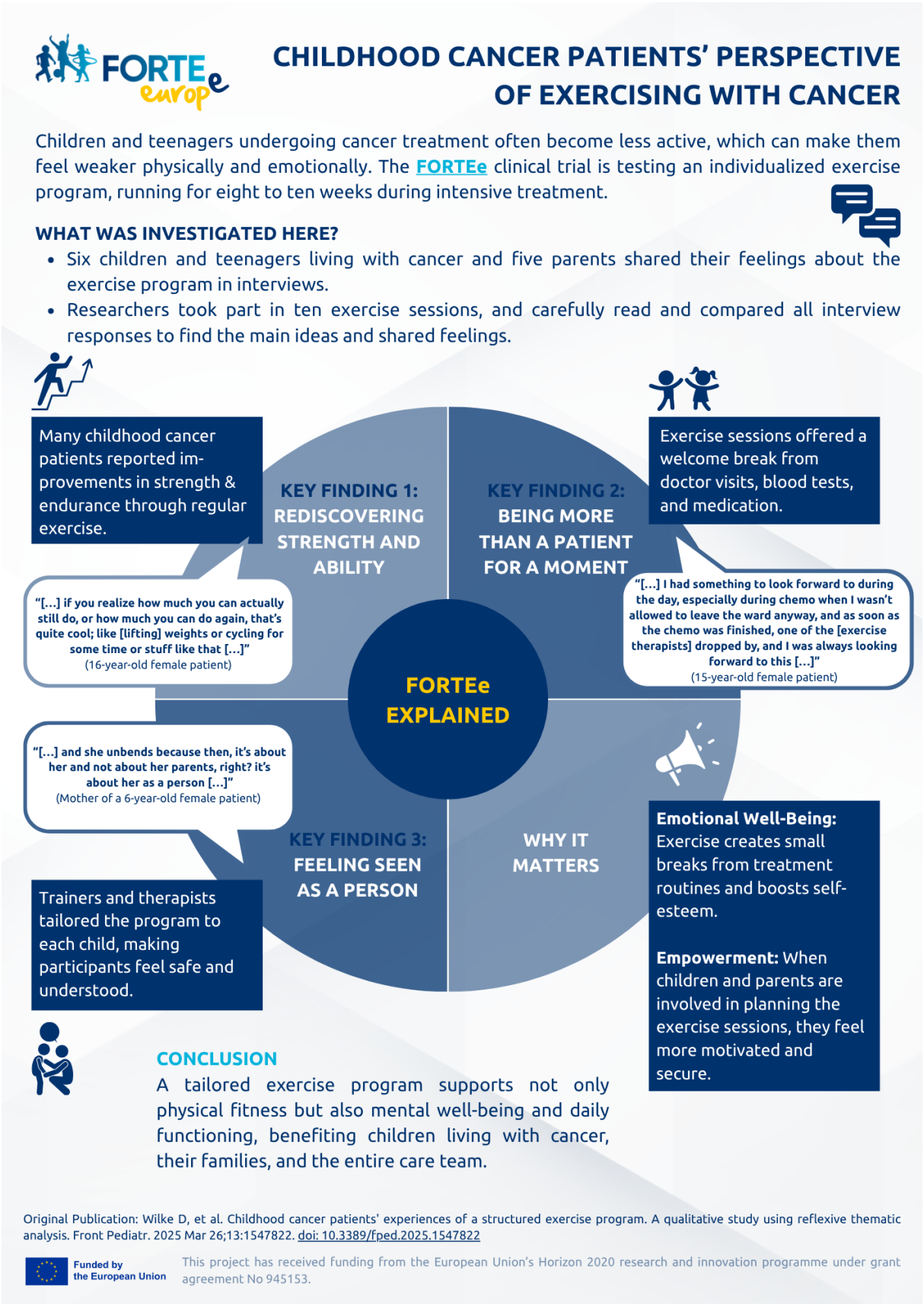

Figure 1: Lay summary of qualitative findings on childhood cancer patients' experiences with a structured exercise intervention (based on Wilke, Paul, Dreismickenbecker, et al. (2025)). The figure

illustrates key themes including improvements in physical capability, psychological relief from the illness context and the importance of being perceived as a person beyond the patient role.

This form of dissemination contributes to:

- enhancing public understanding of research findings
- supporting patient engagement
- facilitating knowledge translation into clinical practice

4.4 Ongoing and Future Dissemination Activities

Beyond completed publications and conference contributions, WP2 includes ongoing dissemination efforts.

A full manuscript based on the cross-centre qualitative analysis (Germany and Denmark) is currently in preparation. This planned publication will further expand the evidence base by systematically analysing contextual and cultural influences on patient and family experiences within the FORTEe trial.

In addition, WP2 findings continue to inform internal project communication and contribute to interdisciplinary exchange within the FORTEe consortium, particularly in relation to the interpretation of clinical outcomes and implementation strategies.

4.5 Summary of Dissemination Impact

The dissemination activities within WP2 demonstrate a **multi-level strategy**, including:

- peer-reviewed publications targeting the scientific community
- conference presentations supporting academic exchange
- lay summaries addressing patients and the broader public

This comprehensive approach ensures that WP2 findings contribute not only to scientific knowledge but also to the **ethical, patient-centred and context-sensitive implementation** of exercise interventions in paediatric oncology.

5 Acknowledgement and Disclaimer

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Wilke, D., Paul, N. W., Dreismickenbecker, E., Alt, F., Neu, M. A., & Faber, J. (2025). Childhood cancer patients' experiences of a structured exercise program. A qualitative study using reflexive thematic analysis [Original Research]. *Frontiers in Pediatrics*, *Volume 13 - 2025*. https://doi.org/10.3389/fped.2025.1547822

Wilke, D., Paul, N. W., Neu, M. A., & Faber, J. (2025). Sources of vulnerability and ethical challenges in qualitative research with pediatric cancer patients. *Childhood*, *32*(2), 267-284. https://doi.org/10.1177/09075682251316855

7 Attachments

Please see attached to this report:

Annex 1: List of scientific publications in WP2

Annex 2: List of conference contributions in WP2

Annex 1: Scientific Publications (WP2)

1. Wilke, D., Paul, N. W., Dreismickenbecker, E., Alt, F., Neu, M. A., & Faber, J. (2025). Childhood cancer patients' experiences of a structured exercise program. A qualitative study using reflexive thematic analysis. *Frontiers in pediatrics, 13*, 1547822. https://doi.org/10.3389/fped.2025.1547822

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3. Wilke, D., Paul, Neu, M. A., & Faber, J. (2025). Sources of vulnerability and ethical challenges in qualitative research with pediatric cancer patients. *Childhood, 32(2), 267-284*. https://doi.org/10.1177/09075682251316855

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Childhood cancer patients' experiences of a structured exercise program. A qualitative study using reflexive thematic analysis

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Introduction: Undergoing cancer treatment as a child, adolescent or young adult involves decreased physical activity and fitness, which may further compromise the bodily and psychosocial well-being of young patients. As an element of supportive care, exercise interventions may counteract these adverse effects. However, knowledge about the impact of such interventions, and of patients' and parents' experiences of participation, is only beginning to emerge.
Objectives: To explore patients' and parental experiences of participating in a structured, individualized exercise program lasting 8–10 weeks during intensive treatment in a German childhood cancer center as part of the clinical trial *FORTEe – Get strong to fight childhood cancer*.
Methods: We conducted open qualitative interviews ($n = 11$) with children and adolescents ($n = 6$) and parents ($n = 5$), as well as participant observation during exercise sessions ($n = 10$). We used reflexive thematic analysis, as developed by Braun and Clarke, as our method of analysis.
Results: We generated three themes: 1. *Feeling better in my body and experiencing my physical capabilities*; 2. *Gaining distance from illness and treatment*; and 3. *Being recognized and involved as a vulnerable and individual patient*. Moreover, we gained insights, regarding the burdensome impact of childhood cancer, and limitations of the exercise intervention. Participants reported almost exclusively positive experiences of participating in the program, which yielded benefits for the patients' physical fitness and capabilities, their bodily and psychological well-being and everyday life situation.
Conclusion: This study supports the suitability and importance of making exercise therapy an integral element of supportive care for childhood cancer patients. Its insights may be helpful for health care professionals who plan on implementing, or who are involved in providing exercise interventions, as well as for scientists who accompany such interventions with qualitative research.

KEYWORDS

childhood cancer, exercise therapy, pediatric exercise oncology, physical activity, qualitative study, reflexive thematic analysis

1 Introduction

Cancer treatment in children, adolescents and young adults is accompanied by burdensome side-effects as well as by decreased mobility and physical activity (1–3). The latter can have additional adverse effects such as impaired cardiorespiratory fitness (4), muscle strength and quality of life (5, 6), which may lead to a "downward spiral" of inactivity (7). Thus, adverse late effects of childhood cancer may be exacerbated (8).

In recent years, researchers have increasingly examined the effects of physical activity and exercising on the health and well-being of childhood cancer patients, establishing the field of *pediatric exercise oncology*. While evidence is still emerging, studies have shown that physical activity may be beneficial for childhood cancer patients, with regard to endpoints such as functional mobility, strength, cancer-related fatigue, or quality of life, and that exercise interventions are appreciated by patients (9–17). In their qualitative study, Götte et al. (18) found for example that patients reported predominantly positive attitudes towards physical activities during treatment. However, knowledge gaps regarding the effects and limitations of exercise interventions remain, and authors have called for larger (multisite) studies to be conducted to enhance evidence (19–21).

The International Pediatric Oncology Exercise Guidelines (iPOEG) (22) recommend that exercise prescription be guided by professionals with expertise in both cancer and exercise. To ensure safety and effectiveness, qualified staff are crucial to delivering exercise interventions appropriately and maintaining clear communication with patients and families, including assessing their preferences and potential barriers. In addition, Wurz et al. (20) have argued for greater adoption of patient-oriented research approaches that center and "activate the voices of end users", as well as for the use of "alternative" and "varied" study designs in pediatric exercise oncology, and other researchers from this field have recommended "[…] physical exercise interventions be delivered according to the preferences and wishes of children and adolescents." [(23); see also (14, 24)]. By drawing on the subjective perspectives and lived experiences of patients or families, qualitative approaches may contribute precisely to these recommendations. Qualitative methods are established both in research with childhood cancer patients (25), as well as in (health-related) physical activity and exercise research (26, 27), and authors have emphasized the relevance of qualitative methodology for the latter (28).

However, qualitative insights on childhood cancer patients' perspectives and experiences regarding exercise interventions are still rare. Using semi-structured interviews and grounded theory analysis, Götte et al. (18) have examined patients' attitudes to physical activity and to an exercise program during cancer treatment. While some barriers were identified, patients were motivated to participate in the exercise program and reported positive effects on physical and mental well-being. Grimshaw et al. (7) have conducted semi-structured interviews with parents to explore reasons for, and effects of physical inactivity during acute treatment, identifying the aforementioned "spiral" of inactivity and highlighting the need for support by the oncology team. Thorsteinsson et al. (29) have interviewed childhood cancer patients about their motivations to participate in a physical activity program during treatment. As part of the same overarching project, Petersen et al. (30) have examined the participation experiences of childhood cancer survivors and their parents, as well as their perspectives on physical activity both during hospitalization and after treatment. These studies highlight the significance of social support by classmates, parents, and professionals, of noticeable physical and psychological effects, and of adapting interventions to the individual situation of each patient. As a final example, within a study on a rehabilitation intervention for preschool children undergoing cancer treatment (including structured active play), Pouplier et al. have examined both the embodied participation of these patients (31), and the perspectives of their parents (32), reporting positive experiences among both.

Notwithstanding the insights gained from the articles cited above, several gaps remain as a function of the limited qualitative insights available. Thus, the purpose of the present study was to examine the perspectives and experiences of childhood cancer patients and their parents, respectively, regarding their participation in a structured and individualized exercise intervention.

2 Methods

2.1 Research approach

The present study represents a subproject within the multi-center randomized-controlled trial *FORTEe*[1], which aims to evaluate both physiological and psychosocial effects of a structured and individualized exercise intervention for children and adolescents undergoing cancer treatment. The *FORTEe* trial was registered on ClinicalTrials.gov with the identifier NCT05289739 and in the German Clinical Trials Register with the identifier DRKS00027978. Participants randomized to the exercise group received an 8–10-week exercise intervention supervised by an exercise professional during the intensive cancer treatment phase. The intervention included both in-patient exercise sessions and supervised online sessions (if the patient was at home) and could be supplemented by the use of digital tools. The exercise protocol consisted mainly of age-appropriate, moderate-intensity combined strength and aerobic exercise, as well as flexibility and balance training. Participants in the control group received usual care according to the local standard.

The objective of this subproject was to examine patients' perspectives and lived experiences of participating in the exercise intervention by generating narrative and descriptive data that would complement the standardized data generated in the clinical trial. For that purpose, we conducted qualitative

[1]Full title: *Get strong to fight childhood cancer – An exercise intervention for children and adolescents undergoing anti-cancer treatment.*

interviews and participant observations with a subset of patients and parents at the Childhood Cancer Center of the University Medical Center of the Johannes Gutenberg University Mainz, Germany (UMC Mainz), one of the ten clinical centers participating in the *FORTEe* trial.

2.2 Recruitment and participants

Initially, all patients aged 6–21 years with sufficient command of German language and eligible for participation in the *FORTEe* clinical trial at UMC Mainz were informed about the subproject by the exercise team. After that, the qualitative researcher (D. W.) introduced himself and resolved any questions. With these separate steps, we aimed to reduce the amount of study information given at one time, as childhood cancer patients have to process a great deal of information alongside burdensome treatment experiences and disruptions of their lives (33). Families received printed information and assent/consent forms in age-group specific designs; both patients and parents needed to give written assent/consent. After assenting/consenting, patients were randomized into the intervention group or the control group. As the qualitative subproject focuses specifically on the experiences and perspectives regarding the exercise intervention, only patients from the intervention group were eligible. Patients could also choose to participate only in the intervention without participating in the subproject, and parents could decide independently whether or not they wanted to participate.

2.3 Data generation

We employed two qualitative methods of data generation. First, we conducted *participant observations* during exercise sessions (34, 35). Prior to each observation, we asked the patients whether they agreed with the qualitative researcher joining and observing the session. Usually, the exercise team and the researcher met on the ward, picked up the patient from their room and went to the exercise room together. When it seemed appropriate and feasible, the researcher assumed an active role by participating in exercises or competitive games, and this was sometimes even asked for by the patients. No notes were taken during the observations, as this would have conflicted with this active role, as this may have evoked the false impression of "evaluating" the patients' performance. We also avoided recording the observations, as this would not have been practical during the sessions and may have felt intrusive for some participants. Thus, observations were written immediately afterwards. These observations comprised a detailed description not only of the exercises done, but also of social interaction between participants, exercise therapists and the researcher, of participants' statements referring to their current experience, and of situations that appeared ethically significant.

Second, we conducted *qualitative interviews* with patients and parents (36). Following recommendations for qualitative research in pediatric oncology (33), we aimed to give participants as much control as possible regarding the interview setting (time, place, duration, presence of parents), although this was limited given the institutional restrictions and the health status of the patients (37, 38). An interview guide was developed, but used flexibly in view of the individual situation. Interviews with parents also focused on their child's experiences and on the perceived effects of the exercise intervention. To be able to contextualize the interview data, field notes were written after each interview, capturing aspects of the meeting that could not be audiotaped (e.g., reflections on research practice and relationships; atmospheres and moods; events before and after the interview). Interviews were audiotaped (except one interview conducted in the waiting area of the ward, which was not recorded due to privacy reasons) and transcribed in detail.

2.4 Data analysis

We chose *reflexive thematic analysis* (RTA) as our method of analysis. RTA, developed by Braun & Clarke (39, 40) and colleagues (41), is a particular version of *thematic analysis* (TA), a qualitative approach "[…] for identifying patterns ("themes') in a dataset, and for describing and interpreting the meaning and importance of those." (42). These authors have promoted RTA as a suitable approach to data analysis in research on exercise (42, 40) and on health (43). RTA's flexibility and its orientation towards deep interpretive engagement with the data appeared especially suitable in view of our small and heterogeneous sample. We have used the RTA Reporting Guidelines (RTARG) published by Braun and Clarke (44) when preparing and reviewing this manuscript.

RTA's flexibility requires researchers to actively make and transparently communicate methodological decisions, adopting a stance of "reflexive openness" (44). One key decision involves the epistemological framework. We adopted an experiential orientation, treating participants' accounts as *reflective* of their lived experiences, rather than analyzing them through the lens of social construction. Another methodological decision concerns the layer of meaning on which the analysis takes place. We analyzed both *semantic* (more explicit, "surface") and *latent* (more implicit, "hidden") meaning; sometimes, experiences were discussed quite explicitly, whereas other parts of the data required deeper interpretation. Finally, our analysis was primarily *inductive,* i.e., grounded in the data, rather than *deductive* (i.e., starting with predefined codes).

We used the recursive six-step process developed by Braun, Clarke, and colleagues (42). *Familiarization* consisted of detailed interview transcription, reviewing transcripts in anticipation of further interviews, followed by data reading, coding and theme generation. For *coding*, we used the analysis software MAXQDA (2020). We started coding the first data items while data generation was ongoing. We wrote analytical notes for data segments which appeared pertinent, or which required a deeper analysis. Multiple (three) rounds of coding proved valuable. Initially, our codes were too abstract and resembled themes rather than remaining close to the data. To maintain an

inductive approach, we refined our coding in the subsequent rounds, ensuring that the codes were more data-driven before moving toward theme development.

Braun and Clarke note that *themes* ("patterns of shared meaning underpinned by a central organizing concept" (40), should be distinguished from *domain summaries* ("summaries of the range of meaning in the data related to a particular topic or 'domain' of discussion.", (40). Drawing on this distinction, we purposefully created four domain summaries in MAXQDA as a first tool to group our codes: *Positive experiences and effects of exercise therapy*; *Limitations of exercise therapy*; *Perspectives and needs regarding the implementation of exercise therapy*; *Impact of illness and treatment*. This was a helpful intermediate step towards *development of themes*, which started systematically as coding was mostly finished. Here, we used a mind-mapping tool, which fostered the creative and flexible visualization of interrelations between codes and themes. We inserted and clustered our codes (as contained in the four domain summaries) and developed themes from them. We maintained recursiveness by returning to the data whenever needed, and by rearranging, rephrasing, merging or discarding codes as well as themes. Once we had generated a set of candidate themes, we proceeded to the fourth phase, *reviewing potential themes,* although these phases cannot be separated strictly from each other. Rather, developing and reviewing themes was a recursive process. *Defining and naming themes* began after we had finalized our themes, although this phase, too, is grounded in the previous two. Refining themes continued even in the final step, *writing* this report. Two peculiarities of our approach to RTA were that we related a few codes to more than one theme, and that we used multiple *central organizing concepts* to grasp the shared meaning of the codes within one theme.

2.5 Reflexivity

Reflexivity is integral to our method of analysis and is increasingly regarded as a core value of qualitative research in general (45, 46). We aimed to practice reflexivity from the beginning by writing reflective notes (47) focusing on relationships to the participants and other ethical aspects of the research, as part of the case-related field notes.

Reflecting on positionality, one aspect of our study is the *generational asymmetry* between our adult researcher and our minor patients. This asymmetry entails a power imbalance, as adult researchers usually control most parts of a study (48). However, acknowledging this should not lead to attributing a "victim role" of powerlessness to patients, who may exert their own agency when participating in research (49, 50). A second aspect of positionality is that our researcher was not one of the exercise professionals who saw the patients on a regular basis. This may have influenced the relationship with the patients, and, subsequently, their answers in the interviews. However, we gained the impression that participating in the exercise sessions was an appropriate measure for building trust and for gaining additional insights into patients' experiences.

While we perceive it as important to introduce minors' perspectives into research on pediatric exercise oncology, we refrain from presenting these as allegedly "authentic voices", in line with our orientation towards critical childhood studies (51) and RTA (39). Thus, the perspectives presented here should be understood as relational products of situated interactions, and within the boundaries of their interpretation by adult researchers, as participants have not been involved in data analysis.

3 Results

Between April 2022 and December 2023, six patients (3 male, 3 female) and five parents (3 mothers, 2 fathers) were enrolled (Table 1 shows participants' characteristics). Four more patients would have been eligible, but did not participate because of non-compliance, refusal or withdrawal of consent. Data generation started in June 2022 and ended in February 2024. We conducted 11 interviews (ranging from 7 to 50 min), as well as 10 participant observations, ranging from 45 to 60 min.

The interviews frequently developed beyond the limits of the thematic focus into conversations about other illness and treatment experiences or life beyond illness, and such conversations also happened during the observations. This seemed important to most participants, whereas some of their answers regarding the experience of the intervention were quite succinct. Thus, there was a great variety in the thoroughness of answers. The information generated from participant observations did not differ from the interviews but rather reinforced and contextualized the findings.

We generated three fully developed themes: 1. *Feeling better in my body and experiencing my physical capabilities;* 2. *Gaining distance from illness and treatment;* 3. *Being recognized and involved as an individual and vulnerable patient*. Figure 1 shows a simplified map of the three themes and their codes and central organizing concepts. We provide a Supplementary Table in which further data extracts are listed together with their assigned codes, from which the respective themes have been generated.

We have deliberately not constructed *themes* from the two domain summaries *Impact of and impairments due to illness and*

TABLE 1 Characteristics of study participants.

Patient characteristics	*n* (%)	Mean ± standard deviation	Range
Age at enrolment (years)		11,67 ± 4,19	6–16
Sex			
Female	3 (50)		
Male	3 (50)		
Diagnosis			
Leukemia (ALL)	4 (66,67)		
Hodgkin lymphoma	1 (16,67)		
Osteosarcoma	1 (16,67)		
└ Thereof relapses	1 (16,67)		
Parent characteristics			
Mother	3 (60)		
Father	2 (40)		

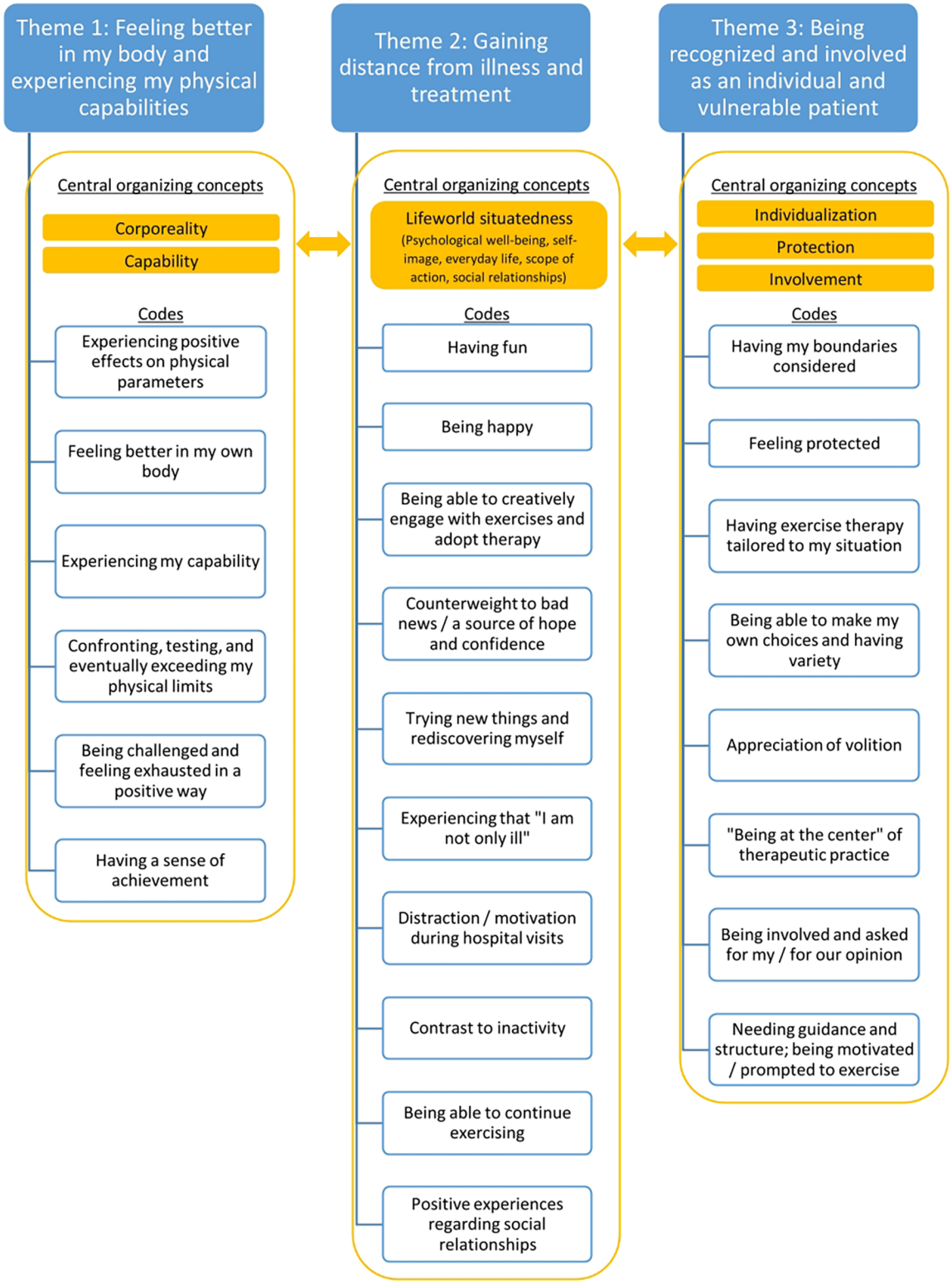

FIGURE 1
Simplified map of themes, codes and central organizing concepts.

treatment and *Limitations of exercise therapy*. This is because we believe both the burdens and limitations mentioned by the participants or witnessed by us can hardly be united in relation to a *shared meaning* [Braun & Clarke explicitly mention "Drawbacks of […]" as a typical domain summary which is *not* a theme; (40), p. 593]. However, we present the insights from these domains as two additional result sections: *Background: Impact of and impairments due to illness and treatment* and *Limitations of exercise therapy*. All data excerpts in the following paragraphs have been translated from German specifically for this publication by D. W. and were independently reviewed by M. N. and F. A. (however, the analysis was still conducted in German).

3.1 Background: impact of and impairments due to illness and treatment

Throughout our data collection, the impact of illness and treatment on the patients' physical capacities remained palpable. *Physical* symptoms such as pain or fatigue forced patients to reduce or cease their sports activities soon before diagnosis. Consequently, this resulted in impairments on *social* relations:

> "[…] I went to the gym three or four times a week with my friends […] or with my brother, that was our thing, our time together during the week and it sucked to drop that completely."
> (16-year-old female patient)

Especially in the first weeks of treatment, chemotherapy exacerbated or caused further impairments of mobility, strength, and endurance. Together with lifeworld constraints such as repeated hospital stays and absence from physical education, this forced patients to cease their sports activities completely for some time. As a result, patients' fitness further deteriorated – here, the "downward spiral" of physical inactivity identified by Grimshaw et al. (7) became apparent – so that daily activities became arduous or even impossible:

> "[…] in the first weeks and months, he was really lying around a lot; he could hardly do anything […] he couldn't walk up the stairs on his own."
> (Father of a 7-year-old male patient)

Consequently, the first exercise sessions were physically challenging for most patients:

> "[…] I noticed that I hadn't exercised for quite a long time, […] I didn't have good endurance and fitness anymore, and that, well, was extremely exhausting."
> (15-year-old female patient)

As patients made progress both with their cancer treatment and with exercise therapy, side effects or illness events (such as fever, pain, mood changes, and impairments related to specific body parts) situationally compromised their capacities to exercise. In some cases *catheters* limited patients' mobility or access to activities such as swimming.

3.2 Theme 1: feeling better in my body and experiencing my physical capabilities

Due to the overlap between their codes and organizing concepts, themes 1 and 2 are closely intertwined. The central organizing concepts of theme 1 are *corporeality* and *capability*. Our use of the concept *corporeality* is inspired by phenomenological understanding of the body (52–54). From this perspective, corporeality firstly expresses a dual understanding of the human body as a *material body* that a person *has*; and as the *lived body* that a person *is*. While the former results from an objectifying perspective (e.g., when a person receives medical treatment), the latter refers to the body as part of our existence. Corporeality secondly signifies the fact that our (lived) body is a medium of our relation to the world and our possibilities to act upon it. This perspective serves as a link to the second organizing concept, *capability*, which we integrated into theme 1, as this topic was often addressed in close connection to bodily experiences. Corporeality appears as a suitable concept to grasp the shared meaning of the participants' body-related experiences, in which these very two perspectives find expression as fluctuating yet indivisible aspects.

Participants described various positive effects that exercise therapy has had on a bodily level, primarily on their mobility, strength and endurance (some participants also mentioned increased concentration, motor skills, body control, and the possibility to lose weight as positive effects). These effects contributed to patients' rehabilitation in certain *activities of daily living* again:

> "[…] physically, she was reset to zero, and within a few weeks only, she recovered to the point that you can go for normal walks with her; she dashes up and down the stairs on her own again"
> (Mother of a 6-year-old female patient)

This mother expresses her surprise about the rather rapid recovery of her daughter's physical fitness. One father was surprised by the stepwise nature of the recovery, realizing that the patient no longer needs to be confined to physical inactivity:

> "[…] [there] was this transition period, right? from the time when he needed to lay down on the sofa, to [exercise therapy] becoming a routine, and next it was like: "no, you don't need to lay down on the sofa anymore, you can [move] again". and then you noticed how he was able to do quick movements and to be active again during exercising, right? that was hardly conceivable before […]"
> (Father of a 7-year-old male patient)

Apart from mentioning positive effects on their child's capacities to carry out ordinary activities, participants

emphasized their progress *within exercise therapy* as a positive experience in its own right:

> "[…] we always make sure to increase my exercises, and this sense of achievement is really cool, if you notice that you can do more than the week before […]"
> (16-year-old female patient)

> "[…] I was always looking forward to [exercise therapy], because in the beginning, we noticed that I don't have a lot of endurance, but it kept getting better, I was able to do the exercises for longer and longer […]"
> (15-year-old female patient)

These two patients also emphasized the broader positive effects of exercise therapy on their physical well-being, noting that it made them "feel good" or "feel better" and enhanced their physical awareness. While improvements in mobility, strength, and endurance are both experienced and objectively measurable, the focus here shifts to the *lived body* perspective—where "feeling good" and heightened bodily awareness reflect the subjective dimension of *lived experience*.

The improvement of one's fitness goes hand in hand with positive experiences of confronting, testing, and exceeding the perceived limits of one's physical capabilities. These aspects were often linked to each other in the participants' accounts. *Confronting one's limits* may refer to one's inclination regarding certain exercise, as was the case for this participant:

> "Sometimes there are also things which are exhausting and which I don't feel like doing but which I do anyway."
> (6-year-old female patient)

But even more so, it refers to testing one's perceived physical limits, which seemed important to virtually all patients. For example, one mother described the beginning of exercise as a turning point, noting that her physically restricted daughter surprised her by going beyond the expected physical capacities. She interpreted this as a key moment:

> "[…] and I think that was the crucial point for her, right? 'I need to go beyond what I can actually do, and then I can accomplish a lot' […]"
> (Mother of a 6-year-old female patient)

This aspect often became apparent during participant observations, too:

> When he was doing the strength exercise, [the exercise therapist] told him that he should stand up a little straighter in case it got too challenging for him. He answered that he would rather increase the difficulty of this exercise [causing (the exercise therapist) and me to laugh].
> (Participant observation with a 16-year-old male patient)

Experiencing their extant or improving physical capabilities through exercise often yielded a sense of achievement for the patients:

> "[…] if you realize how much you can actually still do, or how much you can do again, that's quite cool; like [lifting] weights or cycling for some time or stuff like that […]"
> (16-year-old female patient)

The fact that patients wanted to "exhaust" their extant or improving physical capacities and the resulting positive experiences did not only become apparent in view of their impaired physical fitness, but also in view of more specific impairments. One patient was affected by considerable vision impairment as a result of cancer treatment. While they needed some assistance in spatial orientation, they still carried out all exercises and handled the situation competently. However, testing one's limits did not automatically result in exceeding them, but also in understanding them precisely *as limits*:

> "[…] but I think that [treating exercise therapy as a challenge] is great because [he/she] always has a motivation for that day, so that [he/she] can say 'one thing I managed, another thing I didn't' […]"
> (Mother; patients' age and sex anonymized to prevent identifiability)

3.3 Theme 2: gaining distance from illness and treatment

While theme 1 and theme 2 are closely connected, bodily experiences and the concept of corporeality play a less prominent role in theme 2. What comes to the fore, are experiences related to the patients' situatedness within their *lifeworld*, understood, from a social phenomenological perspective (55), as the intersubjectively (as well as spatially and temporally) structured world which is the foundation for one's daily life and lived experiences. Illness, treatment, and the pediatric oncology ward or the hospital as institutions characterized by specific social practices and spatial and temporal arrangements become formative factors for this situatedness. More specifically they impact patients' *psychological well-being* and *self-image*, their *everyday life* and *scope of action*, and their *social relationships*. While *corporeality* is fundamental to this situatedness, it is set aside here as it serves as an organizing concept in theme 1. Various experiences of how exercise therapy can mitigate impairments and negative effects resulting from this became apparent in the participants' reports and in our observations. These accounts conveyed how the program attenuated the formative influence that cancer may have on their everyday lives, and its omnipresence within them, and how it thus served as a space in which patients could *gain distance from illness and treatment*.

It became apparent that exercise therapy positively affected their psychological well-being. Besides nonspecific statements about "feeling good/feeling better", two different sensations or affective states can be differentiated in the data in this regard:

having fun and *feeling happy*. *Having fun* is a sensation experienced *during* therapy sessions. As a positive affective state, it has a value of its own for these young patients and may be an important factor for their motivation to participate. Having fun contributed to the participants' anticipation of the next session and made the actual (medical) reason for the next hospital visit fade into the background to some degree.

> "[…] she's having fun and she always craves for the next time, right? so she's actively looking forward to it; of course, we need to go to the hospital because of – [illness and treatment] but she's actively looking forward to it, she plans her outfit to make sure she's wearing sportswear […]"
> (Mother of a 6-year-old female patient)

Play is a key element of children's lives and development that was implemented by combining the exercises with games, doing competitions, enabling patients to engage creatively with the exercises, and handing out small rewards. This element contributed to having fun:

> After they had completed all exercises in the bingo game, [the patient and his brother] were allowed to shoot some hoops, which appeared to be a lot of fun for them. After that, [the patient] was given two stickers (one for this exercise session, one for yesterday's online session), which he and his brother put in his sticker album with great joy.
> (Participant observation with a 7-year-old male patient)

Feeling or *being happy*, in contrast, appeared as a longer lasting affective state that ensues after the exercise sessions. This becomes apparent in one patient's statement: each time she comes back from exercise therapy, her mother welcomes her "as a happy child." In the accounts given independently by two parents (of different children), who explained that their children were "all smiles" when returning from exercise therapy, as well as in the following statement:

> "I'm always happier after exercising. Each time I return from exercising, I'm happy."
> (15-year-old female patient)

With regard to psychological well-being, two patients also explained how the program served as a counterweight to bad news and as a source of hope and confidence. While one patient compared the positive mental effects of exercise therapy with those of social support from her school class and experienced both these aspects as beneficial for her recovery, in the accounts given by another patient this felt benefit was often closely related to experiences of extant or increased physical capabilities (see theme 1):

> "[…] if you realize that you can still do a lot of things, that always [motivates you], like '[…] you'll get well again, everything will fall into place, and you can still do so much.' […] that you're not only presented with the problems you have at the moment, and with what can go wrong, but that you get [to see] some positive aspects […]"
> (16-year-old female patient)

The positive experiences made in exercise therapy potentially affected the patients' *self-image*. As one patient expresses poignantly, exercising helped her realizing that "[…] I am not only ill […]" and that "[…] I am not only this illness." (16-year-old female patient) These statements point to the fundamental, even existential effect that cancer can have on patients' identities – "being one's illness" – and to the potential of exercise therapy to mitigate this effect. Beyond that, the accounts of one young patient and her mother, who felt that her daughter "discovers herself in a new way" and "develops through the exercise program", even implied experiences of *personal development* through testing one's boundaries and trying out new activities:

> "Sometimes there are things which I don't feel like doing, but then I do them anyway, and then I realize that I like them. […]"
> (6-year-old female patient)

This further reflects how exercise therapy served as a space of restored or expanded *scope of action* for these patients. This scope tends to be impaired due to the restrictions imposed by health issues, treatment regimens and by the ward or the hospital as social institutions. What contributed to this scope was the fact that some patients were able to adopt the exercises creatively and to realize their own ideas (see also theme 3). Sometimes this even appeared to stimulate their (especially younger children's) imagination:

> [She] seemed to be in a very good mood, and as it appeared to me, the fact that she 'stepped out of line' during the exercises a few times, using the equipment in a different manner or moving about the room freely, was indicative precisely of this. After this exercise, we removed the course, and [she] hid a small ball […] in the cones and told us that she needed to hide this "gemstone" […]
> (Participant observation with a 6-year-old female patient)

This passage also reflects how children sometimes implemented elements of play on their own. Further, participants highlighted how exercise therapy got them "out of their room/bed" and how it served as an activation or counterbalance to idleness, against the background of imposed physical inactivity. This was also a reason for some patients to participate in the first place:

> "I just wanted to exercise. I didn't just want to sit idle and do nothing – although I do that anyway. But I wanted to exercise, that was the main thing."
> (16-year-old male patient)

Moreover, many participants referred to exercise therapy as an opportunity to *continue sports*, i.e., the role that sport used to play before illness. While this may refer to a bodily need or to maintaining one's physical capacities, it may also concern one's *self-image*: if exercising has been part of a patient's everyday life and even of their "identity", not being able to exercise over a

longer period may be a disruptive experience. Exercise therapy may serve as a space that softens this disruption and fulfils a "bridging function", preventing patients from losing touch with exercising as part of their self-image and lifeworld.

> "I think [by participating in FORTEe] I don't lose joy in exercising. And [I think] that I can resume my own sports activities more quickly, once I'm doing well again, like going to the gym."
> (16-year-old female patient)

> "So the main reason [for participating in FORTEe] was that I had exercised before, I was in a gymnastics team at our turnverein […]"
> (15-year-old female patient)

Against the backdrop of these experiences, exercise therapy became, as one mother (of a 10-year-old male patient) expresses it repeatedly, "an important building block" within the patients' everyday lives with illness and treatment, to the extent that they were actively anticipating and planning their next exercise sessions:

> "[…] I had something to look forward to during the day, especially during chemo when I wasn't allowed to leave the ward anyway, and as soon as the chemo was finished, one of the [exercise therapists] dropped by, and I was always looking forward to this […]"
> (15-year-old female patient)

There were no signs of patients experiencing the sessions as an obligation. One patient appreciated online therapy sessions (performed at home) as a positive "task" that gave structure to her everyday life. Most participants described exercise therapy as a *distraction* from, or as a *counterbalance* to their strenuous treatment routine and life on the ward, which lost their severity to some extent. Consequently, it actually became easier for the families to come to the hospital.

> "[…] when we're having our appointments in the hospital, and we know that we can go to exercise therapy afterwards, that's a good motivation for him to start the day in a good mood […]. then he's already planning, 'oh, but then I could go see [the exercise therapists] afterwards', and anything that needs to be done before isn't such a big hurdle anymore."
> (Mother of a 7-year-old male patient)

Exercise therapy also became a welcome element of everyday life with illness and treatment due to its implementation as a *social* or *shared activity*. First, this social dimension appeared to be appreciated as a value of its own by the participants, who seemed to enjoy the presence and participation of the exercise therapists and the possibility to chat with them or to engage in competitions, as well as the option to invite along parents, siblings or other patients to the sessions:

> "[…] I think it's cool that [the exercise therapists] participate in the exercises, that we get in kind of a 'battle', 'how much can you do, how much can I do?' or that they're like 'we do it as a team now so that you're not being watched all the time on your own […]'."
> (16-year-old female patient)

Second, this implementation of exercise therapy as a social or shared activity enabled more specific positive experiences, such as being encouraged during the exercises, receiving recognition or praise for one's performance, or experiencing the pride of one's parents. These experiences may in turn have had positive effects on the patients' self-image:

> […] [Putting stickers into his FORTEe booklet] seemed to be fun for him, and he eventually said that he would show the booklet to his parents and siblings, adding that "then they are proud of me.'
> (Participant observation with a 10-year-old male patient)

> […] [He] was giving high fives with his dad after he had completed an exercise […] [and] clearly showed his joy when [the exercise therapist] praised him for [completing] an exercise […]
> (Participant observation with a 7-year-old male patient)

On the other hand, some families also reported benefits from decidedly using the exercise sessions as a time-and-space of *separation* from each other. During illness and treatment, parent-child relationships are shaped by increased dependence of children on their parents and by additional time spent together. Time spent apart during the exercise sessions potentially *relieved* these relationships. Some participants considered time spent apart important for facilitating children's *independence* from their parents.

> "[…] I accompany him everywhere, we're together twenty-four-seven, so he needs this independence. […] he goes there on his own and that's okay and important […] for me as a relief to relax, and for him it means independence."
> (Mother of a 10-year-old male patient)

For one young patient (who only allowed her parents to accompany her to a session if her blood levels were not that good), this independence was not merely an abstract concept that parents insist on, but a concrete and important subjective experience:

> "No, [mum] shouldn't come here anymore because I can do that on my own."
> (6-year-old female patient)

3.4 Theme 3: being recognized and involved as an individual and vulnerable patient

We constructed this theme from codes that we had first clustered within the domain summary "*Needs and perspectives regarding the implementation of exercise therapy*". This domain summary concerned questions about how the program should be put into practice, and what needs participants have in this regard. However, we noticed that important information in view of our research interest – the *experience* of participation – is conveyed in these codes, which is why we grouped them in relation to their shared meaning. As a result, we generated three closely related organizing concepts: *individualization, protection,* and *involvement*. Thus, we "promoted" the (*evaluative*) domain summary to a (more *experiential*) theme: *being recognized and involved as an individual and vulnerable patient*.

The three organizing concepts of this theme cannot be disentangled but overlap and refer to each other. However, *individualization* may be regarded as its "superordinate" organizing concept. It refers to the experience of receiving exercise therapy that is responsive to one's individual situation and needs, and of being at the center of therapeutic practice as a patient in a vulnerable life situation. This, in turn, involves *protection against* (or *freedom from*) potential negative experiences or effects, and having exercise therapy conducted, to some extent, in an open, flexible manner that facilitates positive experiences through co-creation, choice, creative adoption and a resulting variety. We have summarized these aspects under the term *involvement*.

Regarding the first aspect, both patients and parents positively emphasized the feeling of being protected against harm during the exercise sessions (as well as when they/their child experienced discomfort during a session), having their boundaries respected in case they/their child did not want to or were unable to participate in a session or perform a specific exercise, and the general volition of the program:

> "[…] so I know that when your colleagues exercise with her, they take care of her, [and] the [exercises] that are being done, they fit the physical state […] so, she's not overchallenged but just exhausted, right?"
> (Mother of a 6-year-old female patient)

> "[…] due to the port, I wasn't able to fully raise my arm for some time, so we dropped the [exercises] on that side or did something else that didn't put as much pressure on the port."
> (15-year-old female patient)

> "[…] they don't force anyone, so it's really – you notice that it's voluntary, that it's an offer, and that it's meant to support you."
> (16-year-old female patient)

As can be seen from these quotes, the patients' physical vulnerability resulting from illness and treatment often formed a (sometimes explicit, sometimes implicit) point of reference when participants talked about positive experiences of feeling protected or having their boundaries considered.

Regarding *involvement*, the participants valued the possibility to co-create the exercise sessions to some extent, the freedom to sometimes choose their exercises according to their individual preferences, mood or physical capacities, and the experienced variety resulting from that. Co-creation was not restricted to choosing or helping to prepare the exercises, but also to the general setting of the sessions, as some patients would turn on their own music or bring their parents or siblings to the sessions when they were visiting. In this way, they integrated familiar elements of their lifeworld into exercise therapy. Involvement was actively encouraged by the exercise therapists but also happened through spontaneous and creative initiative by the patients themselves. This personal initiative and the concomitant experiences became much more tangible through participant observation than through explicit thematization in interviews:

> After some time, [he] […] suggested that he could shoot some hoops while cycling, whereupon I positioned the basketball hoop. Throwing the ball seemed to visibly distract him from the physical effort, which involved pain in his legs, and he continued until he had scored fifteen times.
> (Participant observation with a 10-year-old male patient)

Two parents even mentioned the accompanying research (which included questionnaires and half-structured interviews in addition to the open qualitative interviews) as a valuable feature of the clinical trial. In this regard, one mother described it as a positive experience that her daughter's perspectives are actively asked for, but also referred to the need to advance scientific knowledge:

> "[…] it's fun for her that her own opinion is asked for, so that it's not mum or dad saying 'exercising is good' or 'go sit on your bike, that's great' or something, but that she can say 'how do I feel when I do that?', 'am I having fun or am I not having fun?', so that she herself is getting asked. […] and the interviews are part of it because that includes research as a topic, right? so that [this topic] can move forward […]"
> (Mother of a 6-year-old female patient)

Taken together, it appears that these experiences of protection and involvement have contributed to the positive feeling of *being at the center* of therapeutic practice:

> "[…] I really like that all the people [i.e., the exercise team] really focus upon me […]"
> (16-year-old female patient)

This feeling was sometimes expressed in view of timing, in that participants welcomed the fact that exercise therapy was provided regularly and flexibly. However, it was also expressed in view of gratitude for the time that therapists took with them. Putting the individual patient at the center of therapeutic practice was also implied as an important element by two mothers who talked about their children going to exercise therapy without them.

They deemed this situational separation necessary so that exercise therapy could really focus on their children:

> "[…] and she unbends because then, it's about her and not about her parents, right? it's about her as a person […]"
> (Mother of a 6-year-old female patient)

> "[…] and that's important for you [i.e., the exercise team] in that moment, so that you can calmly work with him alone […]"
> (Mother of a 10-year-old male patient)

While individualization and its more specific aspects such as unrestraint and involvement appeared to be experienced positively, some patients also voiced appreciation of *being prompted* to exercise and of *receiving clear input* and *targets* from the therapists:

> "[…] I think if [the exercise therapists] wouldn't come up to me, I would exercise less and would rather let myself go and fall into a lazy mode, that's why I appreciate their commitment and the impulse behind it."
> (16-year-old female patient)

> "[…] my concern with exercising is that I have a coach, and they tell me how to do it."
> (10-year-old male patient)

> "[…] sometimes I would do what I like, but sometimes one should simply do what [the exercise therapists] say."
> (16-year-old male patient)

3.5 Limitations of exercise therapy

We have divided the identified limitations into three different categories: (1.) Factors limiting participation in exercise therapy; (2.) Discomfort caused by exercise therapy; (3.) Limitations of positive effects of exercise therapy.

(1) Most obviously, the bodily and emotional impacts of illness and treatment limit patients' physical as well as motivational capacities to participate in exercise therapy, and this has become apparent in all six cases. Pain, "not being in the mood", fatigue, and side effects have been the main reasons for patients to be reluctant whether they should participate or not, or to decide to not participate after all:

> "[…] this week I actually told [the therapists] that I don't feel like exercising, and last week I cancelled it once as well, because I couldn't do it because I was pretty exhausted."
> (16-year-old female patient)

In view of such situations, patients valued having their boundaries respected (see theme 3), but sometimes, when they agreed to participate in a session despite previous reluctance (after therapists and/or parents had tried to motivate them), they were also happy about it afterwards. While not explicitly talking about it in terms of "fear", the youngest participant also recounted that she did not want to exercise in the beginning of her participation and that she cried because of that, but that she lost this aversion after the first few sessions.

(2) There were very few situations in which the patients' vulnerable health condition interfered with exercising, causing temporary physical discomfort or stress (abdominal pain; headache or vertigo; nausea; one fall resulting in a minor bruise) during and after the exercise sessions. Referring to an online training session, one patient recounts:

> "[…] that day, I wasn't feeling so well and we needed to stop [the session] because I started to feel queasy […]"
> (15-year-old female patient)

Depending on the severity of these situations, the exercise therapists informed the physicians who either looked after the patient directly or ordered further examinations after the session. In view of this, participants reported feeling that they were in good hands. The patients themselves also occasionally referred to their vulnerability during the exercise sessions by explaining that they cannot carry out a specific exercise or that they need to go slow or be careful when doing so. The reciprocal relation between *experienced discomfort* and *barriers to (further) participation* also became visible when one patient reported that, following a fever and an infection, she reduced exercising within the program because she had recently felt very exhausted by it.

(3) There were only two instances in which participants explicitly reported limitations of positive psychoemotional effects, highlighting how these effects are situationally overshadowed by the burdensome nature of cancer and cancer treatment. As one patient expressed it,

> "[…] on days when everything is crap, even [exercise therapy] doesn't help."
> (15-year-old female patient)

Similarly, looking back at an especially burdensome phase of treatment, a father explained that the positive impact the exercise therapy had on his son's mood would be of limited duration, until awareness of that burdensome phase prevailed. Beyond these limitations, when being asked explicitly, most participants had no criticisms or suggestions for improvement of the program, apart from ideas to incorporate certain types of sport and from spatial aspects such as having a larger exercise room or exercising outside.

4 Discussion

4.1 Discussion of results

This study expands the emerging knowledge of childhood cancer patients' experiences of exercise therapy during treatment. Participants reported, and we witnessed mostly beneficial effects

on well-being and life situations, as well as positive experiences with the implementation of the program, in contrast to the minor limitations we observed in terms of barriers to participation, experienced discomfort during exercise sessions and limited psychoemotional benefits.

Patients experienced positive effects on the level of *corporeality*, i.e., on their physical capacities such as strength, endurance and mobility, as well as on their physical awareness and well-being (theme 1). Exercise therapy served as a space in which they were able to train and experience these capacities – an experience that is usually severely restricted by cancer treatment and the institutional environment (7, 18, 29). Confronting and potentially exceeding the perceived limits of one's physical capacities appeared to be a positive experience for patients. Thus, exercising contributed to a gradual improvement of the ability to carry out activities of daily living again and yielded a sense of achievement. These results are relevant in view of the impact that impaired physical functioning can have on childhood cancer patients' quality of life and self-esteem (56).

Exercise therapy further became an important element of the patients' *lifeworld* and their situatedness within it, and enabled them to step back from ever-present illness and treatment (theme 2). It allowed for positive sensations such as having fun – not least through elements of play – and feeling happy, became a source of confidence and personal development, and even enabled one patient to revise her self-image as a person who *has* cancer, but who defies being reduced to their illness. This is relevant in view of the significant impact that a cancer diagnosis can have on a child's or adolescent's identity and its formation (57). The program provided patients with a scope of action and served as a counterweight to inactivity, as an opportunity to maintain their relations to exercising, and as a distracting and motivating element of their hospital visits. Moreover, participants appreciated exercise therapy as a shared activity, which appears valuable given the fact that illness and treatment may impair social functioning and relationships of some childhood cancer patients (58, 59). Some participants valued the time apart during exercise therapy as a relief in their parent-child relationships and an opportunity to foster children's independence. Finally, participants appreciated the program in view of *individualization, protection* and *involvement* as "pillars" of its implementation (theme 3). They welcomed participating in a program that was tailored and open to their individual needs and interests, feeling safe in view of their vulnerability, having their boundaries considered, and being able to co-create the sessions and contribute their perspectives.

There were a few minor limitations to these positive results. First, illness events and fluctuating health status and mood sometimes impeded participation in exercise therapy, and one young patient reported initial reluctance to participation. These factors reflect aspects of acceptability, as patients' willingness and motivation to engage in exercise therapy might be influenced by their physical and emotional status. Second, the patients' vulnerable health status occasionally interfered with exercising. Leading to rare instances of physical discomfort. One patient reported reducing participation after experiencing exhaustion due to a prior fever and infection. These challenges relate to feasibility, as they highlight practical constraints in maintaining consistent participation. Third, the burdensome nature of illness and treatment occasionally overshadowed the experienced psychoemotional benefits.

These results are in line with existing qualitative research on physical activity interventions in childhood cancer patients, which has also reported largely positive experiences (18, 7, 30–32). Some specific aspects have also been identified by these studies, e.g., the sense of achievement through challenging one's limits (31); the significance of having fun (18, 31, 32); the role of activity interventions as a motivating counterweight in everyday hospital life (18, 31); the appreciation of such interventions as social activities (29, 30); and positive effects on parent-child-relationships (31, 32). Positive experiences have also been shown in qualitative studies with adult cancer patients (60–62), although different populations should be distinguished from one another according to their specific burdens and needs.

4.2 Strengths and limitations

Our study has specific methodological strengths. The combination of qualitative interviews (with both patients and parents) and participant observations generated rich and insightful data. Keeping the interviews *open* enabled participants to report on aspects important to them and build rapport with the researcher. Participant observation turned out to be a fruitful method of data generation, as pediatric exercise oncology is a setting of *embodied and performative practice*, and some important phenomena and experiences related to it may elude retrospective verbalization in interviews. Further, participant observations enabled us to gain insights into the patients' *situated* participation experience (and practices) which may have otherwise been obscured. At the same time, the researcher's active role in some exercises may have influenced interactions with patients. While this approach helped build a relationship and encouraged engagement, it may also have introduced an observer effect, which should be considered when interpreting the findings. Regarding the analysis, using RTA produced a comprehensive and nuanced interpretation of the data.

There are also limitations of this work. The small sample of participants who all received care in the same German hospital means that results might not be generalized to the wider childhood cancer population. Beyond the single-center setting, sociocultural differences—such as attitudes toward physical activity during illness, the perceived role of rehabilitation in pediatric oncology and the integration of structured exercise programs into supportive care—may further limit the transferability of our findings. Additionally, differences in healthcare infrastructure, available resources, access to specialized exercise professionals and family expectations regarding medical and supportive care may influence how such interventions are received and implemented in other settings. Moreover, the patients' answers varied greatly in their detailedness (here, it should also be noted that one interview couldn't be recorded because it took place in a waiting area, so that

a protocol had to be written from memory). Consequently, the perspectives of individual patients are represented unequally in our study. There are also sources of bias in our data. First, participants may have been inclined to emphasize positive experiences or give socially desirable answers because our researcher, albeit not an exercise scientist, was a member of the study team, which possibly made it more difficult to talk openly about limitations. Second, the predominantly positive responses may partly be a result of a selection bias, as the families who agreed to participate in the study may be those who have already had an affinity for exercising, and as all patients reported that they had done sports before their illness. Thus, the potential of the program to positively influence a patient's basic attitude towards physical activity needs to be further investigated. Third, our position as professionals working in the field of pediatric exercise oncology may have influenced interpretation and coding of the data, and thus the presented results. However, we attempted to maintain a critical distance by using a strongly reflective method of data analysis and by highlighting possible limitations of this subproject above.

4.3 Implications for practice and research

The results of our study suggest that an expansion of exercise therapy as part of their standard care could be beneficial for many childhood cancer patients. We are aware, however, that this is a matter of resources – both in terms of funding and material and spatial prerequisites, as well as of culture, as such an expansion requires a general positive attitude towards physical activity within institutions (7). Incorporating exercise therapy as a crucial element of supportive care in policies such as the World Health Organization's *CureAll* framework (63) could foster change to that effect. Efforts are also being made at a national level, in Germany, to provide quality-assured, i.e., guideline-based (64), exercise therapy in all pediatric oncology centers and to raise awareness among treatment teams, specialists and families for the general promotion of physical activity (64).

Regarding its implementation, our findings indicate that exercise therapy is best put into practice as a flexible offer that is sensitive to the needs and vulnerabilities of individual patients and that leaves room for them to creatively make the sessions "their own", while at the same time providing structure and consistency so that patients can reliably benefit from it in the long run. This is in line with existing results and recommendations (7, 18, 23, 24). As indicated above, *individualization, protection* and *involvement* may serve as helpful guiding principles informing the implementation of future interventions. They are also relevant in view of the minor limitations we noted. Involved professionals should identify barriers to participation and work with families to overcome them where possible. However, while motivating patients is important, their boundaries must always be respected, and reluctant patients should be given time to get used to interventions. Furthermore, exercise therapists should be sensitive to potential experiences of discomfort and stay in close contact with medical team members.

In future research in the field of pediatric exercise oncology, qualitative methods should be incorporated as an integral part, as they allow for in-depth explorations of the *lived experiences* of those affected. This is crucial because exercise therapy is not only a matter of physiological parameters (24). Future qualitative studies could broaden the knowledge by involving further agents (e.g., other family members; health care professionals) as participants and by integrating additional ("creative") methods of data generation that are responsive to the needs of different patients, as well as participatory approaches that involve families in the design of studies and interpretation of results (20).

5 Conclusion

This qualitative study revealed predominantly positive experiences of childhood cancer patients (and their parents) regarding their participation in a structured and individualized exercise intervention. Participants reported and we observed significant positive effects on their physical and psychological well-being, on their physical capabilities and capacity to act, and on their everyday life with illness and treatment. These positive effects and experiences highlight the appropriateness of expanding exercise therapy or other physical activity interventions as crucial elements of supportive care of childhood cancer patients. Such interventions should be implemented as flexible, socially responsive activities that are tailored to each patient's individual situation and needs.

Data availability statement

The datasets presented in this article are not readily available because qualitative research data contain personal information of participants and cannot be fully anonymized, and in order to comply with the European and national data protection regulations applicable for this project. Requests to access the datasets should be directed to Dennis Wilke, denwilke@uni-mainz.de.

Ethics statement

The studies involving humans were approved by Ethics Committee of the Rhineland-Palatinate Chamber of Physicians (application number 2021-15904). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin. Written informed consent was obtained from the individual (s), and minor(s)' legal guardian/next of kin, for the publication of any potentially identifiable images or data included in this article.

Author contributions

DW: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing, Visualization. NP: Supervision, Writing – review

& editing, Conceptualization, Methodology. ED: Writing – review & editing, Data curation, Project administration. FA: Writing – review & editing, Supervision. MN: Conceptualization, Funding acquisition, Project administration, Supervision, Writing – original draft, Writing – review & editing, Data curation, Formal analysis. JF: Funding acquisition, Project administration, Supervision, Writing – review & editing, Conceptualization.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that no Generative AI was used in the creation of this manuscript.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fped.2025.1547822/full#supplementary-material

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RESEARCH

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Navigating ethical challenges in the FORTEe randomised controlled trial: a multi-centre staff survey on exercise intervention for children and adolescents undergoing cancer treatment

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Abstract

Background The FORTEe randomised controlled trial (NCT05289739) investigates an exercise intervention for children and adolescents undergoing cancer treatment. Conducting research with this vulnerable population poses unique ethical challenges, including participant burden, child autonomy, and parental decision-making. This study explored the ethical experiences of healthcare professionals (HCPs) involved in the trial.

Methods A multicentre survey was conducted across ten clinical sites in Europe using a structured, browser-based questionnaire comprising both closed and open-ended questions. Domains included burden and benefits assessment, informed consent, child autonomy, parental influence and moral distress. Quantitative responses were analysed descriptively, while qualitative data underwent content analysis.

Results Seventy-nine HCPs participated, including exercise professionals ($n=30$), physicians ($n=19$), nurses ($n=8$), psychologists ($n=5$), social workers ($n=3$), one social scientist, one medical ethicist and 12 individuals in other roles. A large majority of respondents (86.1%) agreed or strongly agreed that the overall burden-benefit balance of trial participation was appropriate, while 11.4% were unsure and 2.5% disagreed. Open-text responses described perceived challenges related to questionnaire burden, logistical demands, and emotional discomfort associated with control-group allocation. Informed consent procedures were generally perceived as appropriate. However, some respondents reported situations in which parental influence appeared to outweigh children's expressed preferences,

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and difficulties were noted in assessing children's evolving decision-making capacity. Among HCPs who described prognosis-related events ($n=45$), 68.9% described experiences they associated with moral distress, particularly in relation to communication and decisions regarding continuation of participation.

Conclusion The trial's ethical climate was largely perceived as positive, though emotional and logistical burdens were noted. Reports of emotional discomfort and moral distress among staff highlight the ethical tensions between research integrity and individual well-being. Furthermore, divergent views on children's capacity to give consent suggest the need for clearer guidance on paediatric autonomy and shared decision-making.

Implications Ethically sound paediatric research must address real-world burdens and emotional dynamics beyond procedural compliance. Findings from the FORTEe trial staff survey highlight the importance of flexible, child-centred approaches, sustainable access to beneficial interventions, and institutional structures that promote ethical reflection.

Trial registration Registered on ClinicalTrials.gov (NCT05289739, 21 March 2022) and in the German Clinical Trials Register (DRKS00027978, 28 January 2022).

Keywords Childhood Cancer, Exercise intervention, Randomised controlled trial, Supportive Care, Child autonomy, Informed consent in paediatrics, Vulnerability in research, Moral distress, Burden-benefit assessment

Introduction

Clinical research in paediatric oncology involves unique ethical challenges, as investigators must protect vulnerable patients while advancing therapies [1]. Children with cancer not only face life-threatening illness, but also the long-term consequences of intensive treatments, ranging from cardiopulmonary dysfunction to profound psychosocial burdens [2]. These challenges highlight the need for integrated supportive care.

Exercise therapy has been shown to improve both physical recovery and psychosocial well-being in this population [3, 4]. "FORTEe-Get strong to fight childhood cancer " trial investigates such interventions, which may enhance recovery beyond conventional treatment. While the therapeutic benefits of exercise are well documented [5], the ethical dimensions associated with implementing them in paediatric randomised controlled trials (RCTs) remain underexplored.

RCTs involving children must navigate unique challenges related to informed consent, autonomy and child protection [6, 7], while balancing scientific rigour with respect for young participants´ decision-making. Ethical guidelines emphasise securing both parental consent and child assent which require careful assessment of a child's capacity to comprehend the research aims and implications [8]. In exercise-based therapy, these challenges may be further nuanced. Exercise is often perceived as a safe and beneficial component of supportive care rather than a "research procedure", potentially leading to misconceptions about the purpose, the likelihood of benefit and participation [9]. Additionally, exercise protocols consisting of multiple sessions may demand considerable physical effort from children undergoing intensive cancer treatment [10] underscoring the need for clear communication about the time and physical commitments [11]. Because exercise is often perceived as low-risk and beneficial within supportive care, the ethical justification of randomisation and temporary non-access to the intervention requires explicit consideration. In paediatric exercise-oncology trials, equipoise may be experienced differently by families and HCPs when an intervention is viewed as inherently helpful rather than experimental. The use of control conditions, including delayed or no access to exercise, can therefore generate ethical tension related to fairness, expectations of benefit, and post-trial access, particularly in the context of serious illness.

Pragmatic RCTs, such as the FORTEe trial, which test effects in real-world settings, bring additional complexities. As these trials integrate into clinical care, distinctions between research and standard care must be clearly defined alongside robust ethical oversight [12]. Recent evidence underscores that supportive care interventions, including exercise, mitigate treatment-related fatigue and improve health-related quality of life [13], highlighting the importance of rehabilitation and tailored training strategies that address both physical and psychosocial recovery [14, 15].

As the field evolves, it is essential to refine our approaches to paediatric cancer care, ensuring that therapeutic advancements are accompanied by a focus on the holistic needs of young patients. These ethical concerns are compounded by the emotional and moral challenges experienced by healthcare professionals (HCPs) involved in paediatric oncology trials. HCPs often face moral distress when navigating difficult decisions about trial participation, particularly when balancing the scientific goals of the trial with the potential harm or burden to participants. For example, the inclusion of control groups, the decision to discontinue trials after relapse, and concerns regarding post-trial access to beneficial interventions can contribute to significant emotional strain. These dilemmas highlight the importance of providing robust institutional support and creating ethical frameworks that prioritise the welfare of both participants and HCPs.

Given the heightened vulnerability of paediatric cancer patients, adherence to ethical principles, such as beneficence, non-maleficence, autonomy, and justice, is essential to uphold research integrity and participant welfare [6].

Against this background, the present study reports a quantitative and qualitative survey of HCPs involved in the FORTEe trial. The survey explores ethical challenges encountered in practice, with particular attention to child assent and parental influence, perceived burden, fairness of control-group allocation, sustainability of access to exercise, and moral distress. By centring HCPs' perspectives, the study aims to clarify how ethical principles are negotiated in real-world paediatric exercise-oncology research.

Methods

Informed consent and data protection

Before starting the survey, participants were informed about the survey aims, terms of use, data protection and the voluntary nature of participation. They were also explicitly informed that proceeding with the questionnaire constituted informed consent. The introductory screen further explained that the survey focused on HCPs ethical experiences related to their involvement in the FORTEe trial and that participants could skip any question. Demographic data (profession, gender, age range) and further questionnaire answers were collected, processed and stored using a pseudonym (Study ID) in accordance with the EU General Data Protection Regulation (GDPR) and local legislation.

Research approach and Ethical approval

This mixed-methods staff ethics substudy was embedded within the randomised controlled, multi-centre FORTEe trial (NCT05289739) [16], which investigated an exercise intervention for children, adolescents and young adults (aged 4- 21) undergoing cancer treatment. The present manuscript reports a cross-sectional, browser-based survey of HCPs conducted between 2nd September and 11th October 2024 at ten FORTEe recruitment centres in Germany, Italy, Spain, France, Denmark, Slovenia and the United Kingdom. The survey was disseminated to HCPs involved in the FORTEe trial across participating sites, including physicians, nurses, psycho-oncologists and exercise professionals. Participants' involvement in the trial varied, ranging from direct delivery of the exercise interventions and patient care to indirect roles such as clinical oversight or coordination. Including professionals with differing levels of trial involvement allowed for the capture of a broad range of perspectives, including those not directly responsible for applying detailed protocol or eligibility criteria. This substudy surveyed HCPs only; children and parents participating in the FORTEe trial were not surveyed in this study.

The FORTEe trial was prospectively registered in the German Clinical Trials Register (DRKS00027978) on 28 January 2022 and on ClinicalTrials.gov (NCT05289739) on 21 March 2022. Ethical approval was first granted by the Rhineland-Palatinate Chamber of Physicians (lead committee; application no. 2021–15904) on 4 August 2021, with subsequent approvals obtained from local committees at each recruitment centre in accordance with national and local requirements.

To support understanding of the ethical context in which the trial was conducted, key procedural safeguards are briefly outlined here. Given the vulnerability of the study population, the FORTEe trial was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. Before enrolment, age-appropriate informed consent or assent was obtained and documented. Because minors cannot provide legally binding consent, written consent was obtained from a parent or guardian, while children were involved in discussions whenever appropriate. A two-step consent approach, including the use of age-appropriate materials and a minimum reflection period of 24 h, was implemented to minimise coercion. The protocol further stipulated that exercise sessions were to be paused or discontinued immediately if a child expressed resistance or showed signs of distress, regardless of parental consent. Detailed eligibility criteria are provided in Supplementary Material 1.

All trial personnel received standardised training delivered by the coordinating centre, covering Good Clinical Practice and age-appropriate communication techniques for consent and assent. Training also addressed recognition of medical or psychological contraindications and available support mechanisms for ethical or safety concerns. Ongoing refresher sessions, site-specific webinars, and site visits ensured consistent implementation across centres.

In this paper, *moral distress* refers to the psychological and emotional discomfort experienced when professionals feel constrained from acting in ways they believe to be ethically appropriate, consistent with established definitions in paediatric oncology research [17]. While this definition guided the analytic framework, the survey intentionally relied on participants' self-reported interpretations of morally distressing experiences. As a result, responses reflect how HCPs themselves used and understood the term 'moral distress' in practice, rather than a strictly delimited theoretical construct.

Recruitment and survey participants

The survey was distributed across all ten FORTEe centres and circulated by the designated site contacts to reach

as many involved professionals as possible. To reflect the realities of multidisciplinary care, survey participation was not restricted to core FORTEe research staff but included wider clinical personnel such as nurses, psycho-oncologists, and other allied professionals. Involving these groups aimed to provide a more representative account of the ethical, practical, and clinical challenges of implementing the intervention in routine care.

Data collection

The survey was conceptualised and developed by the multi-professional FORTEe ethics working group, with the aim of capturing HCPs perspectives on ethical aspects, perceived responsibilities, and role-specific challenges encountered during exercise interventions in paediatric oncology. The survey was developed around a set of predefined domains, which informed both the structure of the questionnaire and the subsequent analysis. An overview of the survey domains and their corresponding survey items is provided in Supplementary Material 3. These domains included: familiarity with inclusion and exclusion criteria; informed consent and parent–child decision-making dynamics; ethical issues during exercise testing and training; perceived burden-benefit balance; sustainability of the intervention and post-trial access; fairness in group allocation; and experiences of moral distress.

Survey instrument

The survey questionnaire combined single-choice items, multiple-choice Likert scale items and open-text items, enabling both quantitative description and qualitative exploration of ethical experiences. The questionnaire was piloted with four HCPs from different disciplines to assess clarity, relevance, and interpretability of items; minor refinements in wording were made based on their feedback.

Participants could skip any question. Conditional follow-up questions were displayed depending on prior responses; consequently, not all items were viewed by all participants. Items not viewed reflect the survey's skip-logic rather than active non-response. The full English version of the questionnaire is available as Supplementary Material 2. Survey items were organised into predefined descriptive domains; a detailed mapping of domains to survey items is provided in Supplementary Material 3.

The survey was administered electronically in English via a secure browser-based platform across all participating sites and disseminated through project-specific and institutional mailing lists. Questionnaire Data were collected via a web-based interface using the open-source NUM COMPASS web application [18]. The application was deployed on institutional infrastructure at the local study site. Each participant accessed the survey through a unique, non-personalised QR code; 175 QR codes were distributed. Participating sites were located in Germany, Italy, Spain, France, Denmark, Slovenia and the United Kingdom, where the primary local languages include German, Italian, Spanish, French, Danish, Slovene and English.

Data analysis

Quantitative data were analysed descriptively using frequencies and percentages, calculated based on the number of valid responses per item. Missing responses were excluded on an item-by-item basis.

Qualitative free-text responses were analysed using a framework-guided descriptive approach [19, 20]. The predefined domains that structured the survey served as the initial deductive framework. Qualitative coding was conducted manually by the investigators using Microsoft Excel 2016 to organise responses within the predefined domains and to support inductive identification of recurring concerns and experiences. Free-text responses were independently coded by two investigators (F.A. and M.N.) with discrepancies discussed and resolved through reflexive dialogue.

For each domain, narrative summaries were developed and representative quotations selected to illustrate key findings. Overlapping issues across domains were subsequently grouped into higher-order, cross-domain themes. The predefined survey domains that structured data collection and analysis are summarised in Supplementary Material 3. These themes informed the integrative interpretation presented in the Discussion. Integration occurred at the interpretive level by relating quantitative patterns to qualitative findings within shared domains, rather than through formal statistical integration. This analytic approach enabled structured exploration of predefined domains while allowing for the identification of emergent patterns across participants' narratives.

Results

A total of 79 professionals participated in the survey, corresponding to a response rate of 45% (79 of 175 HCPs who were invited via distributed QR codes). Response rates were high for core demographic and consent-related items (up to 97.5%), but lower for ethically nuanced or open-ended items (59.5% to 97.5%).

Cross-domain thematic synthesis

The integrative analysis of the eight a priori domains produced seven overarching themes, each reflecting recurrent concerns raised by HCPs: (1) ethical complexity in trial decision-making, (2) respect for child autonomy and valid assent, (3) burden-benefit balance and participant distress, (4) long-term sustainability of intervention

benefits, (5) fairness in control-group allocation, (6) moral distress among staff in response to patient outcomes, and (7) perceived moral distress in patients and families.

These themes reflect patterns across survey domains and informed the organisation of the Results section.

Respondent demographics

Seventy-nine professionals ($n = 79$) completed the survey, representing a range of clinical, research, and therapeutic backgrounds. Of the 78 respondents reporting gender, 57 (73.1%) identified as female and 21 (26.9%) as male. Professions represented included 30 exercise professionals (38.0%), 19 physicians/oncologists (24.1%), 8 nurses (10.1%), 5 psychologists (6.3%), 3 social workers (3.8%), with one social scientist (1.3%) and one bioethicist (1.3%). Twelve participants (15.2%) reported interdisciplinary roles and were coded as "other" (e.g. physiotherapy, neuropsychomotor therapy, clinical research coordination, education, osteopathy, and sports therapy). Most were aged 26–35 years ($n = 46$, 58.2%), followed by 36–50 years ($n = 15$, 20.3%), 9 (11.4%) aged 50 + years, and 8 (10.1%) aged 18–25. A summary of participants' demographic and professional characteristics is presented in Table 1.

Ethical awareness related to inclusion and exclusion criteria

Of the 79 respondents, 64 (81%) reported familiarity with the FORTEe trial's inclusion and exclusion criteria. Among the 67 who evaluated their adequacy, 59 (88.1%) considered them ethically appropriate, while 8 (12%) reported concerns regarding clarity. Qualitative comments ($n = 10$) referred to barriers such as insufficient training, unclear role expectations, and insufficient information.

Table 1 Respondent demographics ($n = 79$)

Characteristic	Category	n (%)
Survey participation	Completed survey	79 (100%)
Professional background	Physicians/oncologists	19 (24.1%)
	Nurses	8 (10.1%)
	Social workers	3 (3.8%)
	Psychologist	5 (6.3%)
	Exercise professionals	30 (38.0%)
	Social scientist	1 (1.3%)
	Bioethicist	1 (1.3%)
	Other/interdisciplinary roles*	12 (15.2%)
Gender	Female	57 (73.1%)
	Male	21 (26.9%)
Age group (years)	18–25	8 (10.1%)
	26–35	46 (58.2%)
	36–50	15 (20.3%)
	≥ 50	9 (11.4%)

*Includes interdisciplinary roles such as physiotherapy, neuropsychomotor therapy, clinical research coordination, education, osteopathy, and sports therapy

Knowledge of and experiences with informed consent

Sixty-six (83%) reported familiarity with the FORTEe informed consent process, while 13 (17%) did not. Of the 50 respondents who completed the follow-up items on experiential aspects of the informed consent process, 39 (78%) perceived little or no burden for patients or families. Five respondents (10%) reported burden on a single occasion, five (10%) reported recurrent burden, and one respondent was unsure (2%). Narrative responses described challenges related to parental influence on children's willingness to participate, information overload and communication challenges related to cognitive or linguistic factors.

Parent–child decision-making dynamics

This item was intended to capture ethically relevant tensions in shared decision-making about trial participation (e.g. assent, refusal, or continuation), rather than decision-making about clinical treatment.

Of 75 respondents, 14 (18.7%) reported encountering situations they considered ethically relevant regarding the relationship between patients and their parents in the context of trial participation. Two respondents (2.7%) reported such situations once and 12 (16.0%) on multiple occasions. Nine respondents (12.0%) were unsure, and 52 (69.3%) reported no such experiences.

Narrative responses illustrated situations in which parents encouraged participation despite initial reluctance expressed by the child, as well as situations in which children wished to participate but parental concerns led to refusal of consent. Respondents also noted instances of divergent views or communication difficulties between children and caregivers. One respondent stated:

> *"[There were] noticeable differences of opinion between patients and their parents."*

Ethical events during exercise testing and training

Of the 77 respondents who answered this item, 62 (80.5%) reported no ethically relevant events during exercise testing or training. Ten respondents (13.0%) reported having witnessed at least one such situation, while five (6.5%) were unsure.

Written accounts ($n = 5$; 6.5%) commonly described difficulties interpreting children's willingness to participate during physical assessments, particularly in younger children with fluctuating behaviour or motivation. In some cases, testing was discontinued due to uncertainty regarding assent. One exercise professional reported:

"It was difficult to evaluate to which degree a young kid (6 years) wanted or did not want to be tested. He kept switching mood.., thus the testing was stopped."

Perceived burden during trial participation

This section reports HCPs' reports of perceived burden and their ratings of the burden-benefit balance of trial participation, focusing on burden experienced by children and families during the FORTEe trial, as perceived and reported by staff. For the purposes of analysis, perceived burden was defined a priori as any instance in which trial participation was perceived by HCPs to cause distress, compromise autonomy or privacy, or interfere with wellbeing.

Seventy-seven respondents commented on perceived burden among trial participants or their families. Of these, 51 (66.2%) reported observing no burden, three (3.9%) reported burden on a single occasion, 18 (23.4%) reported burden on multiple occasions, and five (6.5%) were unsure.

Open-text responses identified three reported sources of perceived burden. First, questionnaire volume and frequency were described as burdensome, particularly in the context of intensive treatment schedules. Respondents reported fatigue or emotional strain associated with repeated or lengthy questionnaires. One respondent noted:

"Several families told me that the amount of questionnaires was too big and too frequent."

Second, sensitive or intrusive questionnaire content was described as distressing for some families, particularly questions addressing personal or socio-economic circumstances during periods of heightened emotional vulnerability:

"We had a few patients who did not appreciate the socio-economic questions because we referred to sensitive family situations."

Third, respondents reported difficulties related to children's comprehension of questionnaire items and the timing of assessments, particularly during intensive treatment phases:

"Few parents reported that the child was uncomfortable in answering certain questions. Other parents complained that the child could not understand the meaning of the question."

In a subsequent item assessing the perceived balance between burden and benefit, all 79 respondents provided a rating. Twenty-six respondents (32.9%) strongly agreed and 42 (53.2%) agreed that the overall burden-benefit balance of trial participation was appropriate (86.1% combined); nine (11.4%) were unsure and two (2.5%) disagreed.

Long-term sustainability of the exercise intervention

This section reports HCPs' assessments of post-trial exercise provision following completion of the FORTEe intervention.

Of the 63 respondents, 21 (33.3%) strongly agreed and 33 (49.2%) agreed that participants' exercise needs were adequately met after completing the trial- a combined 82.5% ($n = 52$) expressing a positive view.

Qualitative responses indicated that structured exercise programmes were available beyond the trial period at their sites. These were described as having been integrated into routine care and, in some cases, extended beyond former trial participants. Respondents most frequently referred to the presence of local infrastructure, such as on-site exercise facilities, trained staff, or video-based exercise options. At some sites, this infrastructure was described as having been established or strengthened during the FORTEe trial. One respondent stated:

"We have implemented [exercise] therapy in standard care … even after participation in the study has ended."

In contrast, sustainability concerns were reported at sites with fewer resources. Eight respondents (12.7%) disagreed and three (4.8%) strongly disagreed that post-trial exercise needs were adequately met. Reported barriers included limited staffing, lack of institutional embedding, and the absence of exercise programmes outside the trial context. One respondent noted:

"Outside of the FORTEe project there is no standard exercise programme for children or families within our hospital or community setting."

In addition, 25 respondents (31.7%) reported difficulties explaining the discontinuation or absence of post-trial exercise opportunities. Among these, 12 respondents (15.2%) indicated that such situations occurred frequently or occasionally.

Fairness for control group participants

Among respondents, 26 (32.9%) reported no difficulties related to control group allocation, while 28 (35.4%) reported encountering ethically or practically challenging situations on multiple occasions and nine (11.4%) reported such situations once. A further 16 respondents (20.3%) were unsure or did not provide a clear response.

In open-text responses, respondents described emotional reactions among some children and families following allocation to the control group. These accounts most commonly referred to disappointment or frustration, particularly among children who were highly motivated to participate or who associated exercise with perceived benefit. In some cases, respondents reported reduced engagement with trial procedures or decisions not to participate. One respondent noted:

> *"Some children were sad to be in the control group or decided not to participate in the study because they didn't want to be in the control group."*

Difficulties were most often described in relation to families whose children had positive experiences during the intervention phase or were allocated to the control group:

> *"It is sometimes hard to tell motivated patients that they are part of the control group, but it helps to tell them that they have the chance to take part after the intervention phase."*

Respondents also described situations in which intervention and control group participants were present in shared spaces. In these contexts, some respondents reported difficulties adhering to trial procedures while providing care to children allocated to the control group. As one respondent stated:

> *"I find it ethically difficult to [exercise] with children if the person in the same room was assigned to the control group and [was] therefore not allowed to take part in [exercise] therapy."*

A small number of respondents explicitly articulated normative ethical concerns regarding the withholding of exercise from control group participants:

> *"It is difficult not to train someone who needs it."*
> *"I personally believe that not training a patient is unethical."*

Additional logistical challenges were reported at centres with limited spatial separation between groups. In response, respondents described strategies such as offering alternative activities, emphasising voluntariness, or maintaining contact with control group participants to reduce feelings of exclusion.

Experience of moral distress

The following findings distinguish between moral distress experienced by HCPs themselves and distress perceived in patients or families, as reported from the HCP perspective. Although moral distress was analytically defined as a professional experience, respondents frequently used the term broadly to describe emotionally and ethically challenging situations encountered in the context of serious illness, including distress arising from close relationships with families or from witnessing patient suffering.

Of the 77 respondents, 52 (67.5%) reported witnessing cancer progression, relapse, or death among FORTEe trial participants on multiple occasions, while four (5.2%) reported such experiences once. Eight respondents (10.4%) had not encountered these situations, and 13 (16.9%) were unsure.

Moral distress among staff in response to prognosis-related events

Fifty-one respondents (64.5%) completed the follow-up question asking whether the prognosis-related events were associated with moral distress. Twenty respondents (39.2%) did not report any associated moral distress. Among the remaining respondents, 12 (23.5%) reported moral distress affecting HCPs themselves, 10 (19.6%) observed distress primarily among patients or families, and nine (17.6%) reported distress affecting both staff and families.

All respondents who completed this item were subsequently invited to elaborate in an open-text field. A total of 45 respondents provided narrative comments. Of these, 31 (68.9% of those providing narrative detail) described experiences they explicitly associated with moral distress in the context of disease progression, relapse, or death. Twelve responses (26.7%) referred to other context-specific concerns not clearly framed as moral distress. Among the 31 respondents who described moral distress, 21 provided sufficiently detailed and concrete accounts of situations they personally experienced as morally distressing. These responses were categorised into five non-mutually exclusive categories (Table 2). The most frequently reported category was emotional distress related to patient relapse or death ($n = 8$; 38.1%), followed by distress arising from emotionally significant relationships with families ($n = 6$; 28.6%), and ethical unease regarding the continuation of trial participation in terminal situations ($n = 5$; 23.8%). Three respondents (14.3%) referred to strain related to witnessing parental suffering, and three (14.3%) reported stress associated with research-related demands during periods of clinical decline. Percentages exceed 100% because multiple categories could be reported. These descriptions illustrate how clinicians operationalised the concept of moral distress in their responses, often encompassing situations of emotional, relational, and ethical strain that extend beyond narrowly defined constraint-based accounts. One respondent reflected:

Table 2 Categories of HCP reported moral distress

Category of moral distress	Description	Frequency (n)	%
Patient relapse or death	Distress related to witnessing relapse or death among enrolled children	8	38.1%
Emotional bonds with families	Distress linked to close emotional relationships with patients/families	6	28.6%
Balancing research with patient well-being	Ethical unease regarding trial participation decisions	5	23.8%
Parental and family distress	Emotional strain related to witnessing patients or parental suffering	3	14.3%
Research-related demands during decline	Stress associated with research procedures or trial requirements during period of clinical deterioration	3	14.3%

Categories of moral distress reported by HCPs ($n = 21$ valid respondents; multiple responses allowed). Percentages sum to more than 100% because respondents could report more than one category

> *"When a child who had previously participated in the [FORTEe] trial relapsed, it was difficult to explain to the family that they would not re-enrol and complete the FORTEe intervention a second time. This was particularly difficult when the child had enjoyed the sessions and found them to be a helpful coping strategy during treatment. While the child and family understood, it was hard to see them disappointed."*

Perceived distress among patients and families (HCP perspective)

A separate survey domain assessed HCPs´perceptions of distress among patients and families during trial participation.

Twenty-six respondents (33%) reported perceiving distress among patients and families during trial participation. Reported sources frequently related to child suffering ($n = 10$; 38.5%), and clinical deterioration during the trial ($n = 3$; 16.7%). Additional concerns included communication difficulties ($n = 4$; 15.4%), uncertainty regarding trial procedures ($n = 3$; 11.5%), and emotional pressure associated with decision-making under stressful circumstances ($n = 3$; 11.5%). Distress during discussions about trial continuation in the context of disease progression was noted by five participants (19.2%), and psychological burden related to reconciling hope with medical reality was also reported by five respondents (26.9%).

Eighteen respondents (22.8%) provided narrative accounts, of which 15 were thematically coded. As multiple themes could be identified per respondent, cumulative percentages exceed 100%. These accounts do not represent direct statements from patients or families but reflect how HCPs´ interpretations of distress experienced by families.

Across these narratives, perceived family distress was most commonly described in situations of severe clinical decline, including bereavement following a child´s death, relapse leading to exclusion from continued participation, and unexpected clinical deterioration during the trial. Respondents also highlighted emotionally demanding situations in which families struggled to reconcile hope associated with the exercise intervention with worsening prognosis. In addition, practical constraints—such as isolation protocols or bone marrow transplantation—were described as exacerbating family strain by limiting participation in exercise sessions. One respondent noted:

> *"They were upset about the prognosis of the disease."*

Discussion

This study explored HCPs´ ethical challenges experienced during their involvement in a multi-centre paediatric exercise-oncology RCT. While the overall ethical climate of the FORTEe trial was perceived as positive, respondents reported recurrent tensions related to informed consent and child assent, perceived burden, fairness of randomisation, post-trial sustainability, and moral distress. Taken together, these findings illustrate how ethical issues were experienced and managed by HCPs in everyday clinical-research practice when working with a highly vulnerable population, and how ethical challenges extend beyond formal protocol adherence.

Child assent, parental influence, and respect for emerging autonomy

A central ethical issue identified in this study concerned the interpretation of children's assent and the role of parental influence in trial participation. Although formal consent procedures were in place, respondents described situations in which children's willingness to participate was difficult to assess, particularly when emotional states fluctuated or reluctance was expressed non-verbally. These challenges were reported most often in the context of diagnosis, intensive treatment phases, or disease progression, where children's capacity to articulate preferences was perceived as variable.

Respondents reported ethically sensitive situations in which parents encouraged participation despite a child's apparent hesitancy, as well as cases in which children expressed interest in joining the study but parental concerns about burden or safety led to refusal of consent. These accounts did not necessarily indicate procedural failures but rather reflected the relational and emotionally charged contexts in which consent and assent decisions were made.

Interpreted in light of paediatric research ethics, these findings underscore the dynamic nature of assent and its close connection to emerging autonomy. Prior scholarship has emphasised that assent should not be understood as a one-time procedural step but as an ongoing process that is responsive to a child's developmental stage, emotional state, and evolving preferences [7, 21, 22].

Several authors have argued that older children and adolescents may, depending on cognitive and emotional maturity, be capable of meaningful autonomous decision-making, warranting a more substantial role in consent processes [22]. The survey responses aligned with this ethical position in that HCPs consistently emphasised the importance of actively involving children in discussions about participation, even when legal consent authority rested with parents.

Within the FORTEe trial, respondents acknowledged the use of age-appropriate information materials, visual aids, and the explicit option to withdraw without consequences as important safeguards supporting children's emerging autonomy.

Perceived burden and the limits of acceptable participation

Importantly, respondents reported both burdens directly attributable to the trial and distress arising from the broader context of paediatric oncology care. While most respondents did not identify participation as substantially burdensome, the reported instances of questionnaire-related and logistical strain illustrate how research-related demands may be experienced alongside intensive clinical care.

Fairness, randomisation, and access to potentially beneficial interventions

Random allocation to the control group emerged as a recurring source of ethical discomfort for both participants and HCPs. Respondents described situations in which children and families expressed disappointment or frustration when assigned to the control arm, particularly when exercise was perceived as beneficial or when intervention and control activities occurred in shared spaces. For some professionals, these situations generated moral unease, especially when caring for highly motivated children who were temporarily excluded from the intervention.

Such accounts reflect a well-recognised ethical tension in supportive care RCTs: although randomisation is methodologically justified, its experiential implications may be difficult to accommodate in vulnerable populations [12]. While the FORTEe trial employed established communication strategies and, where feasible, offered post-trial access to exercise programmes, respondents´ accounts suggest that these measures did not consistently prevent perceptions of unfairness.

Although respondents did not systematically propose specific alternative designs, their accounts of disappointment and perceived unfairness underscore the need for explicit communication and ethical reflection regarding randomisation. While no single design can be regarded as ethically optimal across all contexts, this reinforces the importance of clearly articulating and revisiting the ethical justification for randomisation during trial design, consent processes, and ongoing communication with families [23, 24]. From an ethical perspective, these accounts also point to more general tensions surrounding the use of randomised controlled designs in supportive care research involving highly vulnerable paediatric populations. Several respondents implicitly questioned the ethical acceptability of withholding an intervention perceived as beneficial, particularly when exercise was closely associated with wellbeing, coping, or normalcy during treatment. Such concerns align with broader ethical discussions about RCTs in contexts where equipoise may be difficult to sustain from the participant's or clinician's perspective, especially when interventions are experienced as low-risk and potentially beneficial rather than experimental [12, 25].

In this light, respondents' accounts suggest the importance of considering how trial design choices and post-trial access arrangements are communicated and ethically justified. While alternative design approaches or enhanced post-trial access strategies may help mitigate perceptions of unfairness or moral distress, no single design can be regarded as ethically optimal across all settings. Our findings therefore highlight the need for explicit ethical reflection on these trade-offs during trial design and consent processes, particularly in supportive care research.

Moral distress among HCPs and perceived distress among families

Moral distress was a recurring concern reported by respondents, particularly in relation to disease progression, relapse, or death. Many respondents described emotional strain when continuing trial-related interactions with children whose prognosis had worsened, or when communicating limitations of the intervention to families who had found exercise meaningful. These experiences align with established definitions of moral distress, which describe the psychological discomfort arising when professionals feel constrained from acting in ways they perceive as ethically appropriate [17].

At the same time, the findings suggest that not all distress reported by HCPs was attributed directly to trial participation. Professionals in paediatric oncology routinely encounter suffering and loss as part of their clinical

roles, making it essential to distinguish between distress inherent to oncology care and distress that is intensified or shaped by research-specific decisions. This conceptual ambiguity reflects a well-recognised challenge in moral distress research, where the term is variably used to describe constraint-based ethical conflict as well as broader experiences of emotional and moral strain, particularly in high-burden clinical contexts [26–28].

Situations requiring trial-related judgments—such as discontinuation, non-re-enrolment, or withholding of an intervention—were frequently described as ethically challenging, highlighting the intersection of clinical care and research responsibilities [29].

In addition to their own experiences, respondents reported perceiving emotional and moral distress among patients and families, especially in contexts of relapse, bereavement, or unexpected deterioration. While these observations reflect HCPs' interpretations rather than direct patient or parent reports, they nonetheless underscore the emotional and ethical complexity of conducting research alongside serious illness. Prior work has similarly highlighted the moral burden placed on families when serious paediatric illness coincides with high-stakes decision-making (e.g. parent moral distress) [30], and has also discussed related burdens in paediatric research and end-of-life contexts [31–33]. These findings reinforce calls for institutional structures that support ethical reflection, interdisciplinary communication, and psychosocial care—not only for families, but also for professionals navigating ethically demanding environments. Ethics debriefings, access to ethics consultation, and opportunities for reflective practice have been proposed as key mechanisms to mitigate moral distress and sustain ethical resilience among healthcare teams [34, 35].

Ethical reflection beyond protocol adherence

Taken together, the findings demonstrate that ethical challenges in paediatric exercise-oncology trials extend beyond formal procedural requirements, such as informed consent or safety monitoring, and are shaped by relational dynamics, emotional labour, and structural constraints encountered in everyday practice. By foregrounding HCPs´ perspectives, this study illustrates how ethical considerations arise not only at the level of trial design and regulation, but also in ongoing interactions with children and families under conditions of serious illness.

These observations suggest that attention to ethical conduct in paediatric trials may require consideration of both procedural safeguards and the relational contexts in which research is embedded, particularly when interventions are delivered alongside intensive clinical care [8, 36–38].

Strengths and limitations

This study has several limitations that warrant consideration. The achieved response rate of 45% (79 responses from 175 disseminated QR codes across various HCPs), is comparable to similar surveys among HCPs, but introduces the possibility of participation and selection bias. It is plausible that individuals with particularly strong views, whether favourable or critical, were more inclined to respond, potentially influencing the range of perspectives captured. Furthermore, the sampling frame, based on local trial staff lists, may have excluded professionals with more peripheral or informal involvement in the study. Nevertheless, the survey successfully reached a diverse cohort of HCPs from all ten FORTEe trial sites, enhancing the generalisability of findings across a variety of institutional contexts and healthcare systems.

The inclusion of both core FORTEe investigators and members of the broader clinical team, some of whom did not receive formal training on trial-specific procedures, may have resulted in variability in familiarity with the intervention and interpretation of survey items. While this heterogeneity may limit the comparability of some responses, it also represents a methodological strength. Including respondents with varying degrees of trial involvement provides a more ecologically valid account of the ethical challenges encountered in everyday practice and may have reduced social desirability bias by allowing more candid expressions of concern.

The survey was administered exclusively in English across all participating sites. Although this facilitated uniform distribution and avoided interpretive inconsistencies associated with multiple translations in a multinational study, it may have affected the clarity, nuance, or expressiveness of responses among non-native speakers.

The use of a web-based, time-efficient survey instrument inevitably limited the depth with which complex ethical reasoning could be explored. Compared to in-depth interviews or focus groups, the format may have constrained the expression of nuanced moral positions. However, the mixed-methods design, combining structured Likert-scale items with open-ended questions, enabled respondents to elaborate on salient ethical experiences while minimising response burden, which likely contributed to participation among busy clinical staff.

The cross-sectional design, implemented towards the end of the intervention period, limits insight into how ethical concerns may have evolved across different stages of the trial. At the same time, this timing ensured that most respondents had direct and contemporaneous experience with the intervention and its procedures, enhancing the immediacy and practical relevance of their reflections.

Importantly, several survey items used broad ethical terms, including *"moral distress"* and *"ethically relevant*

situations", without providing formal definitions within the questionnaire. As a result, responses may reflect variation in how participants interpreted these concepts, influenced by professional role, clinical experience, and linguistic background. Accordingly, findings related to moral distress should be understood as reflecting healthcare professionals' self-reported perceptions of ethical and emotional strain rather than a uniform or clinically assessed construct. This limitation is particularly relevant when interpreting distress related to disease progression, which may overlap with the emotional demands of paediatric oncology care more generally. Similarly, reports of perceived burden and distress among patients and families must be interpreted with caution. Although respondents frequently distinguished between burdens directly attributable to trial participation and distress arising from the broader context of paediatric oncology care, the survey design does not allow for a clear causal attribution of distress to trial-related procedures. Consequently, some reported burden or distress may reflect the emotional and clinical realities of serious illness rather than effects uniquely associated with research participation.

Finally, although anonymity was guaranteed, the potential influence of social desirability cannot be entirely excluded. Respondents may have under-reported ethically problematic practices or overstated adherence to institutional policies. In addition, the study did not include the perspectives of patients or parents, limiting the findings to the professional domain. However, this limitation is partially addressed by recent complementary work within the FORTEe project that qualitatively explored the experiences of patients and families [39].

Despite these limitations, this study provides empirical insight into ethical challenges perceived by HCPs involved in a non-invasive behavioural intervention, an area that remains underrepresented in paediatric research ethics. By focusing on exercise oncology rather than pharmacological trials, the study broadens the scope of empirical ethics research and supports more context-sensitive approaches to the ethical conduct of paediatric trials.

Conclusion

The FORTEe staff-survey indicates that HCPs perceived the ethical conduct of the trial predominantly positively. A large majority of respondents (86.1%) agreed or strongly agreed that the overall burden–benefit balance of trial participation was appropriate. However, the findings highlight several recurring ethical challenges encountered in practice, particularly in relation to the interpretation of child assent, parental influence in decision-making, perceptions of burden, fairness of randomisation, post-trial sustainability, and experiences of moral distress among healthcare professionals. Despite the implementation of procedural safeguards, including age-appropriate consent materials and the possibility of post-trial access to exercise support, respondents reported situations in which children and families experienced emotional strain, especially in the context of control-group allocation or disease progression. These observations underscore the importance of ongoing ethical attentiveness throughout trial implementation, rather than reliance on protocol-level safeguards alone.

Respondents also described moral distress among HCPs, particularly where trial-related decisions intersected with clinical deterioration or perceived unmet needs. While such distress must be interpreted in light of the broader emotional demands of paediatric oncology care, the findings suggest that structured opportunities for ethical reflection, communication support, and psychosocial resources may help professionals navigate ethically challenging situations more sustainably.

Abbreviations

HCP Health care professionals
RCT Randomised controlled trial

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

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Data availability
Due to the inclusion of personal and sensitive information, the data underlying this study are not publicly available in accordance with data protection regulations. However, they may be obtained from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval for this study was granted by the local ethics committee of the Rhineland-Palatinate Chamber of Physicians under application number 2021–15904 (dated 04 August 2021). All study procedures were conducted in accordance with the Declaration of Helsinki (1964) and its subsequent amendments.
Before starting the survey, participants were informed about the survey aims, the terms of use, data protection/privacy policy, and the voluntary nature of participation. They were explicitly advised that proceeding with the questionnaire constituted providing informed consent to participate. Accordingly, informed consent was obtained from all participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Sources of vulnerability and ethical challenges in qualitative research with pediatric cancer patients

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Abstract
Qualitative research with children and adolescents with cancer has been gaining momentum since the early 2000s. However, a focused discussion of ethical aspects of qualitative research with this patient group has been largely neglected to date. Applying a relational perspective on vulnerability, in this article we discuss ethical challenges in qualitative research with patients in pediatric oncology. These vulnerabilities and ethical complexities should be acknowledged and call for practical measures, but should not be overemphasized in a way that adds barriers to the inclusion of pediatric cancer patients in qualitative research.

Keywords
Health and illness, pediatric cancer patients, qualitative research, research ethics, vulnerability

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Introduction

Due to the close integration of treatment and research, children and adolescents with cancer (*pediatric cancer patients*[1]) come into contact with research comparatively early and frequently (Boles and Daniels, 2019), as many of them receive their treatment as part of a clinical trial (between one-third and 86 % of patients aged <15 years in the US; Schapira et al., 2020). In addition, they may participate in studies on supportive care or illness experience. In this respect, scholars have emphasized the need to involve patients themselves in research and to expand dominant psychological, quantitative approaches with social-scientific, qualitative methods (Boles and Daniels, 2019; Dixon-Woods et al., 2005; Woodgate, 2000a). *Qualitative research* refers to methodologies in which primarily textual data is generated through engaging with people in everyday life settings. It comprises and often combines methods such as interviews, participant observation / ethnography, focus groups, and the analysis of documents or objects. While quantitative research aims at measurement, qualitative research can be characterized as "[…] an interpretative approach to data collection and analysis that is concerned with the meanings people attach to their experiences of the social world and how people make sense of that world." (Mays and Pope, 2020: 2).

Since the early 2000s, qualitative studies have become increasingly established in research with pediatric cancer patients[2] (see the systematic reviews on different aspects of illness and treatment experience by Comas Carbonell et al., 2021; Jibb et al., 2018; Lin et al., 2020; Paterson et al., 2023; Tomlinson et al., 2016; Werthern et al., 2022; Woodgate, 2000b). While these studies have expanded the body of knowledge on illness experiences of pediatric cancer patients, a dedicated examination of *ethical* aspects of qualitative research with them has been neglected to date. Merely drawing on reflections on ethical issues of *biomedical* research with this patient group (e.g., Alahmad, 2018; Dupont et al., 2016; Unguru et al., 2010) appears to be of limited use, as these are often restricted to formalized aspects of research ethics and as qualitative research partly raises different ethical questions. Most qualitative studies on pediatric cancer patients, however, only mention obtaining ethics approval and orientation towards general ethical principles. Exemplary exceptions are: (1.) Bluebond-Langner's reflections in her pioneering work (1978: 236-255), in which she addresses aspects such as role conflicts, emotions and the ethical justifiability of her research; (2.) Boles' and Daniels' article (2019) on the ethical conduct of experiential research with pediatric cancer patients and on their preferences in this regard; (3.) Norbäck et al.'s (2023) qualitative study on ethical challenges of recruiting patients for research from the perspective of healthcare professionals.

This lack of ethical reflections is surprising, as pediatric cancer patients may be regarded as a "uniquely vulnerable patient group" (Boles and Daniels, 2019: 8), whose "[…] vulnerability is not simply a social construction" (Dixon-Woods et al., 2005: 159). In addition, the emergence of interdisciplinary *childhood studies* since the 1990s has led to an intensified focus on the ethics of research with minors (Kirk, 2007), so that there are plenty of theoretical and empirical reference points. Against this background, a dedicated exploration of ethical aspects of qualitative research with pediatric cancer patients seems expedient (Boles and Daniels, 2019; Norbäck et al., 2023). Pursuing this concern, in this

article we address the question which specific vulnerabilities and ethical challenges may arise in qualitative research with this patient group.[3] First, we introduce our relational perspective on the concept of vulnerability, which aims to analyze interacting factors resulting in particular vulnerabilities, rather than assuming vulnerability as an inherent characteristic of a group of participants. Accordingly, in the second step, we identify three overarching sources of vulnerability in qualitative research with pediatric cancer patients. In the third section, we explore three ethical challenges in this type of research.[4] We conclude with a discussion.

A processual, relational, situational and analytical perspective on vulnerability

Since the publication of the *Belmont Report* in the US in 1979, vulnerability has become a central concept within ethics guidelines and considerations regarding the protection of research participants (Bracken-Roche et al., 2017). It refers to a social group's "[…] *identifiably increased likelihood of incurring additional or greater wrong*" (Hurst, 2008: 195; emphasis in original) as a result of their participation in research. While the concept fulfils important functions, researchers have voiced significant criticism over the years, particularly of its operationalization in formal research ethics reviews (Bracken-Roche et al., 2017; Carter, 2009; Hurst, 2008, 2015; Luna, 2019; Traianou and Hammersley, 2024). Central points of criticism concern the *reduction* of vulnerability to the question of a person's capacity to give informed consent (which ignores other sources of harm); An *extension* of the concept to all kinds of social groups (which ultimately renders it meaningless); The implication that certain groups of people are *inherently* vulnerable (which neglects the situational circumstances which make them vulnerable); And the approach of Institutional Review Boards (IRBs) to 'label' certain social groups as vulnerable (without any analytical procedure), which can be stigmatizing and contribute to their exclusion from research.

In their critique, the authors cited above and others have argued (1.) that the vulnerability of research participants should not be reduced to issues of informed consent but should be understood as a potentiality which runs through the entire research process and therefore has multiple sources; (2.) That vulnerability should be understood as a *relational* and *layered* phenomenon that arises in concrete social situations and should therefore not be misunderstood as an inherent characteristic of certain social groups; And (3.) that concrete vulnerabilities should be identified using *analytical approaches* in ethics reviews, instead of taking them for granted. These suggestions can be integrated into a processual, relational, situational, and analytical understanding of vulnerability as the result of relations and interactions both between people as well as between people and systemically and historically shaped contexts. Thus, vulnerabilities in qualitative research with pediatric cancer patients should be analyzed starting from the *social situations* in which patients and researchers enter social relationships and interact with each other.

However, this concept of vulnerability is not without pitfalls. First, its emphasis on processuality, relationality, and situatedness should not result in fragmented, merely subjective interpretations of vulnerability – concise definitions such as Hurst's (2008)

should remain at the core. Second, researchers should not lose sight of systemic and historical factors shaping vulnerability when focusing on the individual context (see also ten Have's, 2016, critical remarks on situational conceptualizations of vulnerability). Third, established ethical principles and procedures (such as informed consent) should not be neglected, as this may in turn cause other dilemmas. Finally, putting this complex perspective on vulnerability into practice requires sensitivity and skill on the part of researchers.

Sources of vulnerability in qualitative research with pediatric cancer patients

We identify three overarching characteristics of qualitative research with pediatric cancer patients that may cause vulnerabilities and ethical challenges: (1.) patients' disease- and therapy-related burdens; (2.) ethically significant features of qualitative methodology; (3.) minors' psychosocial, physical and cognitive development and power imbalances in their relationships with adults.

Cancer- and treatment-related burdens

Throughout the course of their illness and treatment, pediatric cancer patients are exposed to various burdens and disruptions of their lifeworld. On a bodily level, these include primary disease symptoms (Linder et al., 2018), side effects of chemotherapy such as fatigue (Tomlinson et al., 2016) and problems with eating (Green et al., 2010), as well as unpleasant examinations, treatments, or surgical procedures. The various effects of cancer treatment on physical appearance and body image (e.g., hair loss, weight changes or amputation) can be burdensome for patients, also due to (feared) inappropriate reactions by others (Williamson et al., 2010).

Pediatric cancer patients may experience their diagnosis as shocking and frightening (Mant et al., 2019). They are exposed to ongoing uncertainty (Sisk et al., 2021) resulting from fluctuating health conditions, unforeseen illness events and the overall uncertainty of treatment success, as well as to the life-threatening nature of their illness (Comas Carbonell et al., 2021).

In addition, they may face difficulties in maintaining social contacts as a result of long-term or repeated hospital stays, making them vulnerable to social isolation (Christiansen et al., 2015). Both their social situation and their health status potentially limit the *agency* of pediatric cancer patients (Davies et al., 2018) and reduce their options for action. Increased *dependence* on parents and other caregivers may be particularly problematic for adolescents, as growing independence is important to them (Kim et al., 2018).

These burdens cause the serious impact that pediatric cancer can have on their identity (Posa et al., 2021), relationship to the world and self, psychosocial development and life course, and can result in long-term psychosocial and physiological consequences (Hendriks et al., 2022). As pediatric cancer affects fundamental aspects of existence in their totality, it can be understood as an *existential experience.* This multitude of *manifest*

burdensome experiences as well as *latent* vulnerabilities appears as the most obvious source of ethical challenges in qualitative research with these patients.

Ethically significant features of qualitative research

A discussion of ethically significant features of qualitative methodology in the context of healthcare research requires engagement with the incoherence between epistemological and ethical orientations of qualitative research on the one hand, and IRBs on the other. IRBs still primarily comply with a *biomedical* understanding of science, whose classical methodological repertoire does not include non-standardized methods (Opsal et al., 2016; Pollock, 2012). This lack of fit can lead to an attribution or overemphasis of risks of qualitative research, so that projects may be regarded as "ethically precarious" (Morrow and Richards, 1996: 102) or "'burdensome'" (Woodgate et al., 2017: 4). Although qualitative research is not inherently ethical and entails identifiable risks (Hadjistavropoulos and Smythe, 2001; Taquette and Da Borges Matta Souza, 2022), it should be recognized that these are comparatively low and that even the most obvious risk, emotional or psychological distress, rarely actually occurs (Guillemin and Gillam, 2004; Opsal et al., 2016; Pollock, 2012). Here, we highlight four features that may raise ethical questions:

(1) Qualitative research is *emergent*: its exact design evolves over the course of the research process, as researchers gain further access in their field, adapt data generation[5] methods or pursue other thematic tracks based on initial analyses. This means that researchers cannot fully inform their participants in advance about some elements of the research (Pollock, 2012). As a result, the implications and consequences associated with qualitative research may be difficult for participants to grasp. This may raise concerns about the validity of their informed consent or assent.

(2) Many qualitative methodologies such as ethnography rely on the *establishment of close* or *trustful relationships* between researchers and participants. In research on sensitive topics, as well as with minors, this can even be a prerequisite for its feasibility (Woodgate and Edwards, 2010). However, an increasing entanglement of researchers in these relationships and a concomitant tendency towards blurred roles or role ascriptions may result in further ethical dilemmas (Taquette and Da Borges Matta Souza, 2022).

(3) As many qualitative methodologies rely on an *in-depth thematization* and *narrativization of subjective experiences*, research on sensitive topics such as illness may cause psychological distress to participants. However, a profound thematization of meaningful subjective experiences in research can also serve as a *social recognition* of these experiences. While participation in qualitative research offers no prospects of health benefits, it can thus still be a positive experience for participants (Opsal et al., 2016).

(4) Finally, the *representation of participants' accounts* poses particular ethical challenges in qualitative research (Pickering and Kara, 2017). A more formal issue is that complete anonymization of qualitative data is hardly realistic, so that

there remains a residual risk for participants to be identified. More complex, however, is the question of how qualitative researchers can *write about others* in an ethically adequate manner: How can they 'transfer' participants' self-interpretations or everyday practices into scientific knowledge and how can they represent them without harming individuals or social groups?

Minors' development and generational relations as sources of vulnerability

Minor age of study participants is seen as a factor that principally increases their susceptibility to harm or injustice (Hurst, 2015). There are different explanatory approaches regarding this vulnerability. A rough distinction can be made between a more developmental-psychological explanation and one focusing on generational power relations (although these approaches can overlap). In the former, the vulnerability of minors as research participants is deduced from their ongoing psychosocial, physical and cognitive *development*, from differing linguistic, intellectual, and cognitive capacities, from their dependence on adults, but also from ascribed negative characteristics (such as incompetence or irrationality). In biomedicine and ethics reviews, the assumption of an age- or development-related *inherent* vulnerability has been dominating, and the focus has been on more formalized elements of research ethics such as informed consent, risk-benefit analyses, and confidentiality (Alderson, 2007; Carel and Györffy, 2014; Carter, 2009; Kirk, 2007; Morrow and Richards, 1996; Woodgate et al., 2017).

In the latter approach, the vulnerability of minors as research participants is rather deduced from their position in the generational order. This perspective has been dominant in *childhood studies*. Scholars from this field have increasingly considered vulnerability in its ambiguity and discursive constructedness, conceptualized it as a relational and situational phenomenon, and drawn attention to the social positioning of minors by adults and associated power imbalances (e.g., Andresen, 2014; Carter, 2009; Christensen, 2000; Frankenberg et al., 2000). In this context, authors have criticized that the categorization of minors as an inherently vulnerable population can be stigmatizing and contribute to their exclusion from research (Carel and Györffy, 2014; Hurst, 2015) – which may particularly affect minors in *factually* more vulnerable life situations (Carter, 2009). In addition, the assumption that the ethics of research with minors is fundamentally different from the ethics of research with adults has been critically discussed (Alderson and Goodey, 1996; Punch, 2002).

In our view, both these aspects should be acknowledged. Neither should developmental factors and the dependence of minors on adults be completely negated, nor should they be understood as the sole determinants of vulnerability in research with minors. A relational perspective, as outlined above, opens up the view that even if one recognizes the potential significance of minors' psychosocial and cognitive development for research ethics, the *manifestation of vulnerabilities* still depends on situated interaction and how researchers deal with these peculiarities in their practice – that is, in their (asymmetrical) generational relationships with minors (see Schweiger and Graf's, 2017, perspective on minors' vulnerability that integrates developmental and situational assumptions).

The following ethical challenges have been repeatedly emphasized in literature on qualitative (health) research with minors (Alderson and Goodey, 1996; Alderson and Morrow, 2020; Carter, 2009; Duncan et al., 2009; Harcourt and Sargeant, 2011; Helseth and Slettebø, 2004; Huang et al., 2016; Hurst, 2015; Kirk, 2007; Kousholt and Juhl, 2023; Morrow and Richards, 1996; Punch, 2002; Wright, 2015):

Especially in regulatory ethics, minors are viewed as vulnerable with regard to *informed consent* or *assent*, as it is considered unclear to what extent they are capable of understanding implications of research participation, weighing up advantages and disadvantages and making self-determined decisions. In this respect, they may be exposed to the harm of making decisions without adequate preconditions and thus potentially against their actual will. Contrary to these assumptions, some authors have argued that minors' competences to consent are more dependent on social context and personal experiences (Alderson, 2007; Ashcroft et al., 2003) and have proposed more interaction-oriented understandings of informed consent (e.g., Kousholt and Juhl, 2023).

The capacity to give informed consent can be seen as a case of an overarching ethical issue, namely the unclear capacity of minors to *act self-determined* in relationships with adult researchers and to *exercise their rights as participants*. This includes asking questions about the study, refusing or discontinuing participation, refusing to address certain topics in interviews, or requesting practical or methodological changes. This vulnerability stems from both generational power relations and personal experience. At the same time, powerlessness and the 'incapacity' to act in a self-determined way may be attributions and expectations from adults which impose a victim role on minors that does not do justice to their capacities. In this perspective, scholars have pointed out the fluctuation and negotiation of power in research relationships (e.g., Davidson, 2017).

Building trust can be particularly important in research with minors, who may feel uncomfortable with anonymous or distant research relationships (Woodgate and Edwards, 2010). At the same time, establishing trustful relationships with young participants may be demanding insofar as it takes place less through demonstrating a certain professional status but rather through spending time together and participating in familiar activities (Coyne et al., 2009).

A peculiarity of research with minors is the *special role of parents* and of *the family as a social system.* This begins with the legally justified dependence of researchers on contact with parents for purposes of study information and consent and extends to the concern not to isolate the perspectives of minors from those of their parents or families. The special role of parents and family may have ethical implications insofar as it increases the *complexity of the social fabric* in which researchers operate, in which they become entangled, in which they must justify their actions and in which they may be exposed to divergent demands from different parties.

The *handling of confidentiality* in research with minors also has special features due to their dependency and the unavoidable involvement of other adults. If researchers witness child endangerment, they have a clear obligation to inform other adults. However, they may also encounter situations in which their obligations are more ambiguous, such as when minors disclose less clearly defined experiences of harm, or when researchers are

confronted with demands from parents to share with them what their child has told in interviews. This can lead to loyalty conflicts.

Two further ethical challenges arise from the fact that usually, adult researchers control most parts of the research process. The first concerns the chosen *methods of data generation and analysis*. While all social research should align its methods with the field studied, with its research interest and its participants, in our own research we have gained the impression that, compared to adults, minors are potentially more sensitive to the choice of data generation methods and may already experience an inadequate choice of methods as a 'violation' (e.g., of their trust in the researcher). The second aspect resulting from the unequal distribution of control over the research process concerns the *inadequate handling of accounts* of minor participants by adult researchers, especially in the phases of interpretation and representation. This includes distorting, devaluing, disregarding or attacking perspectives of minors, which in itself constitutes a violation of ethical research and, once published, can have concrete negative consequences for minors, who may have limited resources to counteract inappropriate use of their data. On the other hand, adult practices and claims of representing minors' 'voices' must be challenged, as they presuppose verbality and notions of authenticity, disregarding the *silences* within, and the *relational emergence* of minors' accounts (Carnevale, 2020; Spyrou, 2016).

Vulnerabilities and ethical challenges in qualitative research with pediatric cancer patients

Drawing on the identified sources of vulnerability, we now discuss three ethical challenges in qualitative research with pediatric cancer patients.

Agreeing to participate in qualitative research in an existentially unsettled life situation

At the beginning of their treatment, pediatric cancer patients must process study information simultaneously with a disruption of their lives (Boles and Daniels, 2019). During this phase, they experience various burdens and have many demands on their time. These factors can make it more difficult for them to understand scientific studies and make decisions about participation. This raises questions about the 'validity' of their agreement to participate in research. Researchers should be aware that (younger) children may agree to participate because they mistakenly assume that this has an influence on their treatment or because they feel that they 'owe' something to the treatment team. The latter refers to the dependence of minors on adults, a factor of vulnerability which can be increased in pediatric cancer patients (Norbäck et al., 2023). It can therefore be even more difficult for these patients to make self-determined decisions that potentially run counter to the expectations of involved adults.

A relational perspective, however, opens up the view that the vulnerability of pediatric cancer patients with regard to their agreement to research participation is also the responsibility of the researchers and depends on how adequately they inform their potential participants about the study (Alderson, 2007). In addition, a *processual understanding of*

consent (Klykken, 2022), which recognizes the need to revisit this agreement repeatedly over the course of participation, mitigates the vulnerability mentioned here anyway, because it is no longer tied to a single situation in which resources for adequate decision-making were potentially impaired. Furthermore, it should be considered that pediatric cancer patients *become experienced* with their illness and treatment (Pyke-Grimm et al., 2020), that they develop *self-advocacy skills* through day-to-day decision-making (Pyke-Grimm et al., 2022), and that this may in turn increase their awareness of their own preferences as well as their competence to make well-considered decisions regarding research participation.

The psychological burden of communicating about cancer

An obvious vulnerability of pediatric cancer patients as participants in qualitative research is the potential psychological burden of communicating about their life-threatening illness and associated unpleasant experiences. As Huang et al. (2016: 349) note: "Recollection of events when children experienced pain and fear might result in discomfort and anxiety." This risk appears to be increased in qualitative methods due to the limited possibility (and desirability) to plan interviews in minute detail, so that sensitive topics may arise unexpectedly, and due to the concern to explore meaningful experiences *in depth* (Hadjistavropoulos and Smythe, 2001; Taquette and Da Borges Matta Souza, 2022).

Researchers should take these risks seriously and implement practical measures to detect and respond early to psychological distress in their participants. However, apart from the fact that burdens associated with participating in qualitative health research rarely exceed burdens to which patients are exposed in their everyday lives and that the risk of causing harm is comparatively low, empirical findings pointing in a different direction should also be considered. While (vulnerable) participants may experience the depth that qualitative methods seek to explore as 'stirring', they report positive experiences more frequently than negative ones. This applies to research with minors in general (Crane and Broome, 2017) as well as to research with 'vulnerable groups' or on sensitive topics (Alexander et al., 2018; Opsal et al., 2016). To date, however, there are hardly any insights on how pediatric cancer patients experience participation in experiential research.

Empirical findings on the preferences of this patient group regarding clinical communication should also be considered. Although the preferred extent and forms of disease-related communication and involvement in medical decision-making vary individually and are influenced, for example, by the patient's age and gender, pediatric cancer patients seem to prefer honest, transparent communication that is tailored to their needs and leaves room for hope (Jalmsell et al., 2016; Lin et al., 2020). Researchers should therefore discuss communication preferences with participants and give them control over topics discussed in interviews (Boles and Daniels, 2019).

However, the vulnerability mentioned here can also be thought of in a different way: Pediatric cancer patients can namely be vulnerable to *communication taboos* imposed by adults. In this case, the 'violation' that patients are exposed to consists of restrictions on discussing aspects of their illness experience, which can also pose a psychological burden. Adults may taboo communication due to assumptions that minors do not yet understand the mechanisms and scope of their illness and treatment, that they are not yet

able to communicate about sensitive topics and burdensome experiences, or that they should be protected from doing so. In contrast, even early qualitative studies (e.g., Bluebond-Langner, 1978) have shown that pediatric cancer patients are capable of understanding and communicating about their situation, and subsequent research has underscored this.

Pediatric oncology as a challenging setting for relationship building and data generation

A third ethical challenge of qualitative research with pediatric cancer patients is the conditions that pediatric oncology as a clinical setting provides for relationship building, establishing trust and generating data (Bishop, 2014; Coyne et al., 2009). As mentioned above, disease and treatment trajectories of these patients are characterized by high degrees of uncertainty (Sisk et al., 2021). In addition to the fundamental uncertainty about treatment success and prognosis, there are unplanned events such as spontaneous hospital admissions due to deteriorating health conditions, postponements of therapy phases and inpatient stays, but also patients' fluctuating psychoemotional states. The resulting limited plannability of contact can make it difficult to build trustful relationships with participants and to establish one's role as a researcher – especially if one is not part of the treatment team. While the emergent nature of qualitative research may cause irritations in biomedical ethics reviews, it becomes obvious here that it can in fact be particularly suitable for research in settings characterized by uncertainty, as data generation must often be designed and conducted spontaneously and flexibly anyway. Another aspect that shapes relationship building is the importance of the family, especially of parents, in the care of patients. By assuming a mediating role between their child and the researcher, they can contribute to the ethical quality of the research. On the other hand, their involvement can cause ethical dilemmas if they restrict their child's autonomy to participate or make claims that violate confidentiality.

The research setting poses challenges not only for relationship building in general, but also for data generation. For example, the methodological scope of research with pediatric cancer patients appears to be more limited, as it may be difficult or impossible for some patients to participate in certain methods (e.g., focus groups or methods that require mobility) due to their health status. This results in additional vulnerability, as these challenges may tempt researchers to limit their methodological repertoire *in advance*, even though creative approaches may be especially appropriate for this patient group. The 'violation' to which pediatric cancer patients are exposed here is that they may be denied appropriate opportunities to express their perspectives (on "cascades" of vulnerability resulting from previous vulnerabilities or responses to them, see Luna, 2019).

Finally, limitations in ensuring confidentiality must be acknowledged, as the presence of third parties (parents, other patients, healthcare professionals) may be unavoidable when generating data in the clinical setting (Coyne et al., 2009). Researchers may also face dilemmas if patients disclose negative experiences with the treatment team on which they themselves rely as researchers.

We conceive these aspects not only as *practical* challenges, but as *ethically* significant, as they concern the question of how to responsively shape relationships with research participants. Methodology has an ethical dimension, insofar as it opens up the scope in which participants can appropriately contribute their perspectives. In this perspective, we draw on an understanding of ethics that Guillemin and Gillam (2004) have termed "ethics in practice" and, drawing on Paul A. Komesaroff, "microethics", and that Rossman and Rallis (2010) have adopted as "everyday ethics". In this understanding, research ethics is neither exhausted by adherence to formal criteria in ethics reviews nor does it only become relevant in 'big' dilemmas. Rather, it should be regarded as a *situated* social practice (Kousholt and Juhl, 2023) which unfolds in the relationships between researchers and participants. This understanding continues to be influential in discussions of qualitative research ethics (Pollock, 2012; Taquette and Da Borges Matta Souza, 2022; Woodgate et al., 2017) and may be even more relevant in ethnography, where researchers and participants share their everyday lives to some degree. From our own experience, even seemingly 'banal' situations such as entering a patient's room without knowing whether it is the right moment to approach them can be understood as "ethically important moments" (Guillemin and Gillam, 2004). A relational perspective on challenges to relationship building posed by the research context calls attention to the importance of communicating openly with pediatric cancer patients about their participation and trying to give them as much control over it as they wish (Boles and Daniels, 2019).

Discussion

Qualitative research with pediatric cancer patients can produce particular vulnerabilities and ethical challenges. These should be understood as *relational* phenomena that arise in concrete social situations. Thus, qualitative research with these patients can be ethically more complex and challenging than research in settings in which fewer sources of vulnerability can be identified. At the same time, it shares some issues with research with other 'vulnerable' groups of participants (e.g., minors with other chronic conditions), so that it should neither be considered as a singular case in ethical terms, nor as completely congruent with qualitative research in other settings (Punch, 2002, has presented this argument in reference to the relation between research with adults and research with minors). The same applies to its relation to biomedical research: both forms of research may raise unique ethical complexities as well as some that they share.

What consequences does this diagnosis have for the practice of qualitative research with pediatric cancer patients? First, the identified vulnerabilities and ethical challenges require suitable practical measures. Although these are not the focus of our article (see Boles and Daniels, 2019), we would like to point out three relevant measures that are based on our own experience:

Processual consent, that is, repeated communication about the agreement to participate (Klykken, 2022), is a way to better capture the validity of this agreement, as it is no longer tied to a single situation. In research with pediatric cancer patients, this can be especially relevant, as fluctuating health and emotional states can affect both patients' decision-making capacity and their actual willingness to participate. Thus, consent processes

should be designed in a manner that is responsive to the participants' capacities and life situations.

Participatory research can mitigate power imbalances between pediatric cancer patients and adult researchers insofar as it aims to give participants as much control over their participation as possible and as they desire. In this way, it can counteract the risk of patients experiencing research as a burden and facilitate the building of trustful relationships. Nevertheless, participatory research is not *automatically* 'better' or more adequate, neither in ethical nor in epistemological terms. It is a complex approach whose implications have been challenged (Davidson, 2017; Gallacher and Gallagher, 2008; Horgan, 2017) and whose quality still depends on its implementation in practice, which faces particular challenges in hospital settings (Bishop, 2014). Thus, researchers should engage in an honest dialogue with patients regarding the desired and realistic degree of participation – and acknowledge their demand for guidance.

Collaboration with healthcare professionals and parents is essential not only because they act as gatekeepers for pediatric cancer patients, but also because researchers – especially if they are not part of the treatment team – require knowledge about the patient's psychosocial and health status, course of treatment, and life situation in order to responsively align their research practice with these aspects (Coyne et al., 2009). This collaboration can thus contribute to the ethical quality of research.

However, these measures may also contribute to the ethical conduct of qualitative research with other groups of participants or in other settings. This brings us to a final argument: while it is essential to tailor ethical practice to the respective research setting and its *relational* vulnerabilities, the alleged ethical 'exceptionality' of research in which more vulnerabilities and ethical challenges can be identified should not be overemphasized. Such an overemphasis of (participant) vulnerability can, first, lead both researchers and IRBs to overlook the agency of participants considered 'vulnerable'. However, *agency* and *vulnerability* are not mutually exclusive opposites but can exist simultaneously (Andresen, 2014). Second, this failure to recognize agency can result in additional barriers – for example, when IRBs present inadequate obstacles to research in settings characterized by vulnerability or when researchers themselves shy away from conducting such projects (Traianou and Hammersley, 2024).

This brings us to another type of vulnerability of pediatric cancer patients regarding their participation in qualitative research: the *vulnerability to inadequate exclusion from research*. This exclusion represents a potential 'violation' insofar as it denies them the opportunity to act upon social structures that affect them (Pollock, 2012). In this respect, pediatric cancer patients – like other groups of people in vulnerable life situations – are potentially exposed to *epistemic injustice,* which consists of denying certain groups of people the capacity and the opportunity to act as 'knowers' (Carel and Györffy, 2014; drawing on Miranda Fricker). In contrast, while recognizing their vulnerability, the potential of pediatric cancer patients to exercise agency, both in terms of interpreting and coping with their illness *and* as participants in qualitative research, should be acknowledged.

Conclusion

The purpose of this paper was to address the gap that exists regarding the ethical aspects of qualitative research with children and adolescents with cancer. Proceeding from a relational perspective which understands vulnerability not as an inherent characteristic but as the result of both social relationships as well as relations between people and situational circumstances, we have identified three sources of vulnerability for this type of research: patients' disease- and therapy-related burdens; ethically significant features of qualitative research; and the psychosocial and cognitive development of minors and power relations between them and adults. We then discussed three ethical complexities in which these sources of vulnerability come into effect: the problem of agreeing to participate in research in an unsettled life situation, psychological burdens arising from communication in the context of a life-threatening illness, and challenges for relationship building and data generation when conducting research in pediatric oncology. One limitation of our contribution is that some ethical challenges (e.g., those emerging when research relationships end) as well as some broader ethical discourses (e.g., on the way adults *use* minors as research participants; Spyrou, 2024) had to be excluded.

On this basis, the ethically challenging nature of qualitative research with pediatric cancer patients has become obvious, which is why we have referred to three practical approaches that can mitigate identified vulnerabilities (processual consent, participatory research, collaboration with health professionals and parents). However, recognizing vulnerabilities and ethical challenges in qualitative research with pediatric cancer patients should not result in the construction of this research as an 'exceptional case' and fundamentally precarious undertaking, as this can favor the exclusion of these patients from research.

While our contribution has drawn on the *theoretical foundation* of the question of pediatric cancer patients' vulnerabilities – entailing the limitation that we have not included patients' accounts –, further empirical research on their actual experiences and needs as research participants (Boles and Daniels, 2019), on the perspectives and experiences of involved healthcare professionals (Norbäck et al., 2023) and parents, and a stronger culture of publishing "ethically important moments" (Guillemin and Gillam, 2004) that researchers experience when working with pediatric cancer patients is required. This could help to break down fixed notions of vulnerabilities of this patient group and show that the substantial ethical work is not exhausted in the procedural ethics of institutionalized ethics reviews, but that it unfolds *situationally* in the research encounters with these patients.

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Notes

1. The World Health Organization (2021) defines childhood cancer as cancers affecting patients aged 0-19 years. We use the term pediatric cancer (patients), as it is not linked to a specific phase of life, but to the respective branch of medicine. Therefore, the term seems more suitable to include adolescents treated in pediatric oncology. However, it should be borne in mind that pediatric cancer patients represent a highly heterogeneous group due to their age spectrum, different types of cancer and individual courses of disease. Where it is necessary to group young people of different ages, we usually refer to them as *minors*. When we refer to *parents,* other legal guardians are also included.
2. This is due to increased survival rates (which, however, are unevenly distributed globally; World Health Organization, 2021), as well as due to changes in scientific conceptions of minors stimulated by *childhood studies* and the shift from research *on* minors to research *with* them (Dixon-Woods et al., 2005).
3. Our considerations are based on two empirical research projects which are being conducted at the Department of Pediatric Hematology, Oncology, and Hemostaseology at the Center for Pediatric and Adolescent Medicine at the University Medical Center of the Johannes Gutenberg University in Mainz, Germany.
4. We understand *ethical challenges* as aspects of or situations within research in which researchers are confronted with the vulnerability of their participants, in which they may have to make difficult decisions with uncertain consequences, and in which 'universal' ethical principles must be weighed against each other.
5. Drawing on Spyrou's (2024) recent critique of "extractivism" in childhood studies, we choose the term data *generation* over *collection* to abandon the notion of data as something pre-existing, merely to be gathered by the researcher.

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Annex 2: Conference contributions (WP2)

1. ***Wilke D, Paul NW, Dreismickenbecker E, Neu MA, Faber J.***
   A qualitative analysis of childhood cancer patients' experiences of a structured exercise program.
   Presented at the 55th Annual Meeting of the Société Internationale d'Oncologie Pédiatrique (SIOP), October 11–14, 2023, Ottawa, Canada.
   (2023), Abstracts. Pediatr Blood Cancer, 70: e30748.
   https://doi.org/10.1002/pbc.30748

2. *Alt F, Dreismickenbecker E, Lanfranconi F, Balduzzi A, Watson E, Marriott H, Wiskemann J, Bauer N, Mongondry R, Fridh MK, Lucia A, Fiuza-Luces C, Beller R, Spreafico F, Konda B, Stefanović M, Diel H, Kühn M, Wypyrsczyk L, Paul NW, Neu MA, Faber J.*
   Navigating ethical challenges in the FORTEe randomised-controlled trial: A multi-centre staff survey on exercise intervention for children and adolescents undergoing cancer treatment.
   Presented at the **3rd Pediatric Exercise Oncology Congress (PEOC × FORTEe 2026)**, April 16–17, 2026, Hyatt Regency Mainz, Mainz, Germany.

3. *Alt F, Neu MA, Diel H, Larsen HB, Hansen MB.*
   Cross-Centre Analysis of Childhood Cancer Patients' Experiences within the FORTEe Exercise Trial: Insights from Denmark and Germany.
   Presented at the **3rd Pediatric Exercise Oncology Congress (PEOC × FORTEe 2026)**, April 16–17, 2026, Hyatt Regency Mainz, Mainz, Germany.