

## **KULT-SH – A project leveraging telemedicine interventions for children with cancer**

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### **Introduction**

The aim of the project is to analyze the effect of telemedicine on care for children with cancer in phases of intensive chemotherapy. The hypothesis is that a telemedicine intervention is non-inferior in comparison to an on-site visit at the hospital regarding the frequency of serious complications. The study is carried out in a rural area in which patients and their parents often drive large distances to the hospital for on-site visits. This time investment has strong influences on family life and on parents' availability at work, as well as on the childrens' social life. Another potential important factor is the risk of hospital-acquired infections during on-site visits. Thus, the study aims to provide statistical evidence for the non-inferiority of telemedicine in comparison to on-site visits.

### **Study design**

The study is designed as a monocentric randomized controlled trial, relying on a cross-over design, which ensures unbiased patient recruitment. One group will complete the interventional telemedicine phase first and then switch into the on-site visit phase (control). The other group starts with the on-site visit phase and will then receive telemedicine care. Each phase will last 3 months. The study aims to enroll approximately 60 patients in intensive therapy of cancer with ages ranging between 1 and 25 years.

During the telemedicine phase the patient's vital parameters such as heart rate, oxygen saturation and temperature are collected with the help of sensors. The recorded data are automatically transferred to an app via Bluetooth and afterwards to the personal cross-enterprise health record (PEHR). The same app is used for the videocall to facilitate the communication between clinicians and patients during the telemedicine phase. The patient, the physician and other registered physicians (e. g. general practitioners) involved in the care of the patient have access to the PEHR, each one equipped with a different set of rights, managed by the patient.

### **Methods**

Quantitative and qualitative methods will be employed. Quantitative parameters include a cumulative score for adverse events and the time to antibiotic treatment closely associated with the outcome of infectious complications in intensive chemotherapy. Structured questionnaires and validated instruments (e.g. the KINDL, PedsQL etc. questionnaire) are also employed for evaluation of quality of life. These instruments are partly adapted to the specific use case. Additional aspects include an evaluation of for example the quality of life of patients and their families or the user experiences with telemedicine based on qualitative interviews and questionnaires. Also, health economic outcomes are considered. Patients are requested to answer the questionnaires at defined points of time during the intervention.

### **Expected outcomes**

It is expected that KULT-SH will show that telemedicine is non-inferior compared to on-site visits with respect to serious complications. Additionally, it will provide evidence about the impact of telemedicine in the quality of life of the patients and their families. The results will pave the way for the implementation of telemedicine in routine care, not only for the patient population investigated, but also for other vulnerable patient groups in other medical domains.

### **Project partner**

The clinical treatment (both telemedicine and on-site visits) as well as the study lead are located at the Department of Pediatric Hematology/Oncology in Kiel. The evaluation will be lead and performed at the Centre for Population Medicine and Healthcare Research at Lübeck University. The Institute for Medical Informatics and Statistics of Kiel University and UKSH Kiel develops and implements the app and the necessary infrastructure for data collection and interaction between patients and physicians. Furthermore, health insurances are included in the consortium in order to ensure long-term implementation in routine care. Health insurances contribute by providing health economic data.