

Rehabilitation including structured active play for preschoolers with cancer (RePlay)

Statistical Analysis Plan

The collected data is analyzed based on the principle of intention-to-treat (ITT). The treatment effect difference is estimated through constrained longitudinal data analysis that constrains the mean at baseline to be equal between the arms. Constrained linear mixed models are applied in two scenarios. In the 1st scenario, predictors include follow-up time points categorized as T2 (three months after treatment initiation) and T3 (six months after initiation) to account for any non-linear effect and dummy variables representing the intervention group at T2 and T3 follow-ups, respectively. In the 2nd scenario, the time variable is treated as a continuous variable and interaction between groups and the time variable will be included instead. Baseline characters such as age (as a continuous variable) and cancer type (hematologic malignancy, tumors located in the central nervous system (CNS tumor), and extracranial solid tumors) will be included additionally as covariates in both scenarios. Patient identity serves as a random intercept. Likelihood ratio tests based on maximal likelihood is applied for model selection of the fixed effects to determine linear or non-linear associations. We will use a significance level at 0.05.