

Statistical Analysis Plan

Name of the project:	International name: PIMPmyHospital (local name: PIMPmyHUG)
Name of the institution:	Geneva Children's Hospital, Geneva University Hospitals
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National Clinical Trial Identifier Number	NCT05203146
Registered on	Jan 21, 2022
Funding	None
Sponsor	None
Version number	v.1.0, Jul 15, 2021
Statistical analyses	<p>For the primary outcome, we will assess the time taken in minutes for each allocation group to consider new laboratory results, whether accessed through the mobile app or the institutional Electronic Health Record (EHR). Normality analysis of continuous variables will be performed using the Shapiro–Wilks test. Given the anticipated non-normal distribution of data, the Mann–Whitney test will be employed for comparing independent groups. No paired data will be compared. Kaplan–Meier curves will be estimated, and bivariate survival analysis will use the log-rank (Mantel–Cox) test.</p> <p>For the secundar outcome, we will assess the time taken in minutes from the participant's notification, either through the mobile app (intervention) or a statement from a study investigator (conventional method), indicating the need for assistance with a technical procedure, to the participant reaching the designated nurse. Similar analyses will be conducted for the secondary outcome.</p> <p>All statistical tests will be two-tailed with a significance level of 5%. Data analysis will be carried out using Prism latest software version (GraphPad software, LLC., San Diego, CA, USA) for MacOS.</p>
Interim analysis	We will not perform interim analyses as our trial has a short duration and no potential serious outcomes.
Handling of missing data	In the case of missing data, a complete case analysis will be conducted. No multiple imputations are planned.
Statistical tests	All statistical tests will be two-sided with a type I error risk of 5%. Data analysis will be carried out using GraphPad Prism latest software version for MacOS (GraphPad software, San Diego, CA, USA) for graph figures, descriptive statistics, and statistical tests.

Date and signature:

14 July 2021

