Study Protocol

Name of the project:	International name: PIMPmyHospital (local name: PIMPmyHUG)
Name of the institution:	Geneva Children's Hospital, Geneva University Hospitals
Name of the PI:	Dr Johan N. Siebert
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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
Objective(s)/Aim:	To assess the impact of a newly developed mobile application (PIMPmyHospital) on pediatric emergency physicians and nurses to improve remote collaborative and synchronous communication in a pediatric emergency department (via a chat messaging system) and to reduce the time spent walking/traveling in between destinations (emergency rooms, etc.) when caring for patients, when compared to current methods not using the mobile app. This app aims to provide relevant information in real-time about the patients they care for, as well as a secure chat and messaging platform to virtually connect physicians and nurses caring for the same patients.
Outcome/Endpoints	**Primary outcome** The time taken (in minutes, within a upper time limit set at 120 minutes) for each allocation group to consider new laboratory results, whether accessed through the mobile app or the institutional Electronic Health Record (EHR) patient data system, from the point of availability to participant review on the designated medium (mobile app or EHR). **Secondary outcomes** The time elapsed (in minutes, within a upper time limit set at 120 minutes) from the notification received by the participant through the mobile app or a statement from a study investigator (conventional method), indicating that a nurse needed assistance for a technical procedure, up to the moment when the participant reached the designated nurse.
Project design and procedures	This will be a single-center, non-blind, two-arm, randomized, controlled pilot trial. This study aims to assess two methods for processing laboratory results (specifically, the post-analytical phase) and facilitating collaborative actions in standardized, semi-simulated scenarios mimicking everyday situations within a Pediatric Emergency Department (PED). Participants will be randomly allocated to perform these actions either utilizing the dedicated mobile app PIMPmyHospital (intervention group) or employing conventional methods (i.e., the EHR, control group). The primary hypotheses posited that the use of the mobile app would result in a reduction in both the time taken to access laboratory results and the time required for remote communication with colleagues. The trial will take place in a real-world environment at the Pediatric Emergency Department (PED) of the Geneva Children's Hospital, Switzerland, during caregivers' shifts, but no patients will be enrolled, nor

	their medical data collected. The recordings will not be used for any purpose other than this project. The trial will be registered on Clinicaltrials.gov.
Project population, inclusion and exclusion criteria	A convenience sample of 10 caregivers. Eligible participants will be postgraduate residents pursuing a <6-year residency in pediatrics and registered nurses from the PED of the Geneva Children's Hospital (aged > 18 years). They must have previously completed a standardized 5-minute introductory course on app usage provided by the study investigators on the day of participation. Exclusion criteria encompass participants who have not completed the introductory course. Recruitment of participants adheres to Cohen's calculation, with an anticipated effect size of 2.0, a type I error of 0.05, and a power of 80%.
Recruitment, screening and informed consent procedure	Participants will be recruited from the PED of the Geneva Children's Hospital. On the day of participation, in the presence of the study investigators, participants will provide informed consent, provided they had ample time for consideration and opportunity to ask questions. No financial compensation will be offered to participants.
Involvement of samples or health related data	No patients will be enrolled in this trial. Hence, no patient's samples or data will be collected.
Randomization and Blinding	Participants will be randomized using a single, constant 1:1 allocation ratio determined through web-based software www.sealedenvelope.com. Allocation concealment will be maintained with the use of the allocation software, and it will not be released until participants initiate the scenario. To minimize preparation bias, participants will be kept unaware of the scenario during recruitment. Following randomization at the scenario's commencement, they will be unblinded to their assigned study arm. The study investigators involved in the scenario, assuming the role of a fellow nurse to be located by participants, will be revealed to participants before the scenario begins. All investigators will remain uninformed about the outcomes until all data are unsealed for analysis at the conclusion of the trial.
Intervention	Following randomized allocation, participants will complete a brief demographic survey on the day of participation. Subsequently, they will undergo a standardized 5-minute training session on mobile app usage, designed solely to explain its functionality for the upcoming intervention. To maintain study integrity, the PED signage and layout will remain unaltered, taking into account participants' presumed familiarity with their daily working environment after a minimum of 3 months of common PED assignment. Participants will then encounter a semi-simulated scenario involving a fictitious patient combined with real clinical activities. Retrieving simulated patient laboratory results from the EHR, participants will have the option to use the app or the institutional computerized system without app support. After obtaining results, participants will be tasked with locating a nurse, played by a study investigator, either prompted by an app message or an oral request from a second investigator. Assessing the app's impact on remote communication, this task will address communication challenges in a PED. No nurse location information will be given; participants will have to physically find the nurse, prohibiting virtual contact. Procedures will be standardized to ensure consistent exposure to the same case, minimizing preparation bias. The app will be interfaced on an Apple iPhone X, with identical functionality on Android OS. Data access will be restricted to study investigators. The functionalities of the mobile app have been previously published (PMID: 34734879)

Confidentiality	Information about study subjects will be kept confidential. All data will be entered into a Microsoft Excel spreadsheet where all data on study subjects are assigned an individual identifying code that does not contain identifying information.
Are the samples/data irreversibly anonymized?	YES. Data will be saved in duplicate on secured hard disk drives in a locked cabinet at the Geneva Children's Hospital. All electronic patient data exchanged between the institutional computerized patient record (i.e., the Geneva University Hospital servers) and the app is secured. No patient data will be used as an outcome or for analysis. Only the time taken by participants to access the data will be recorded and analyzed.
Withdrawal and discontinuation	Withdrawal and discontinuation will be limited since this study offers the advantage of taking place in a single center and during a single, short intervention period during a regular working day within the emergency department. In case of withdrawal after informed consent, individual's collected data so far and related to the intervention will be destroyed/deleted. Any withdrawal and/or discontinuation will be justified and reported in final publications in coded form.
Statistics	The Statistical Analysis Plan (SAP) is attached to the study protocol submitted on clinicaltrials.gov
Regulatory aspects and safety	• **Local regulations / Declaration of Helsinki** The research project will be conducted in accordance with the protocol, the Declaration of Helsinki [PMID: 24141714], the principles of Good Clinical Practice [PMID: 10532877]. • **Notification of safety and protective measure** The study investigators anticipate no circumstances that could compromise patient safety, given the project's design, which does not involve patient enrollment and does not expose participants to risks beyond those of their daily practice throughout the course of this study. • **Serious events** No serious events are anticipated. Study investigators do not foresee the need to implement any specific security measures • **Risk-Benefit assessment** Risks to project participants are minimized as the intervention is integrated into their routine clinical practice. The only real difference, devoid of any risk, will be the procedure using a mobile app rather than conventional methods to retrieve lab results and communicate with colleagues. Risk of unauthorized data access and/or unwanted identification of project participants will be guaranteed by using Microsoft Excel software secured by protected access passwords and hosted by the Geneva University Hospitals on secured servers. No direct benefits are anticipated for study participants.
Overall ethical considerations	According to the International Committee of Medical Journal Editors and SwissEthics (i.e., the National Ethic board in Switzerland), the trial protocol received a declaration of no objection by SwissEthics and the Geneva institutional ethics committee (Switzerland) since the purpose of the study will be to assess the effect of the intervention on healthcare providers and not on patients.

Will this project generate generalizable knowledge?	YES. The goal of this study is to generate evidence-based data in order to be able to deploy this mobile app in the near future within the University Hospitals of Geneva, and beyond to other hospitals. To date and to the best of our knowledge, no study has measured such data and for the same purpose as this trial.
Is it solely a quality control for institution-internal purposes	This is a pilot randomized controlled trial to assess the impact of a newly developed mobile app on caregivers' work efficiency, and aimed to improve patient-centered care.
Prior submission to an Ethics Committee?	*The preliminary evaluation study of the app PimpMyHospital via semi-structured interviews was accepted by SwissEthics on July 2nd 2021 (Req-2021-00740).*

Date and signature:

14 July 2021