Implementation of an in Situ Simulation-based Training Adapted from Morbidity and Mortality Conference Cases: Effect on the Occurrence of Aevents – Study Protocol of a Cluster Randomized Controlled Trial

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Study protocol

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Implementation of an *in situ* simulation-based training adapted from morbidity and mortality conference cases: effect on the occurrence of adverse events – study protocol of a cluster randomized controlled trial

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Abstract

Background: Morbidity and Mortality Conferences provides the necessary improvement measures required for patient safety. However, it is an underused resource mainly because the conclusions to be drawn from the discussion and their implications for practice are not always well integrated by inpatient care teams. We therefore propose in this study two interventions to optimise their efficacy; a passive feedback with wide dissemination by e-mail and/or on paper of the results of the Morbidity and Mortality Conference to inpatient care teams, and an active feedback with *in situ* inter-professional simulation-training programme in which scenarios will be based on cases studied in Morbidity and Mortality Conference. In the present study we hypothesise that the greatest reduction the occurrence of adverse event will be in the active feedback arm.

Methods: A cluster randomized controlled study will be performed at four study sites. Passive feedback and active feedback arms will be compared to standard arm in terms of occurrence of adverse events. The trigger tool methodology used to identify adverse events is a retrospective review of inpatient records using "triggers" to isolate potential adverse events.

Discussion: The *in situ* simulation training based on cases processed in Morbidity and Mortality Conference is built according to the main topics identified for the successful implementation of healthcare simulation in patient safety programmes: technical skills,

nontechnical skills, assessment, effectiveness, and system probing. The *in situ* simulation-training programme conducted as part of the study has the potential to improve patient safety during hospitalisation. We therefore expect the greatest reduction in the occurrence of adverse events in patients hospitalised in the active feedback arm. This expected result would have a direct impact on patient safety and would place *in situ* simulation at the highest level of the Kirkpatrick model.

Trial registration: The study has been registered in Clinicaltrials.gov (NCT02771613). Registered on May 12, 2016.

Keywords: Patient safety; *In situ* simulation training programme; Inter-professional teamwork, Cluster randomized controlled trial; Trigger tool; Adverse event; Evaluation; Change management

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BACKGROUND

Any human activity that presents a potential risk develops the analysis of adverse outcomes to learn from mistakes made (1). In the medical field, Morbidity and Mortality Conferences (MMC) have been used for more than 100 years, first in the United States and then around the world, to improve practice by examining medical errors and poor outcomes (2–5). MMC is defined as a collective, retrospective, and systemic analysis of cases involving death, complication, or event that could have caused harm to the patient, with the objective of implementing actions to improve patient care (3). MMCs provide the necessary improvement measures for patient safety and professional learning (6–10). Nowadays, MMCs exist in many healthcare organisations, but is a resource that is used to its full potential mainly because the conclusions to be drawn from the analyses/discussions and their implications for change in practice and behaviour are not always well implemented by inpatient care teams (11,12). In our university hospital federation (*Hospices Civils de Lyon*, Lyon, France), despite the existence of an online procedure to prepare and standardise MMCs, two major obstacles have been identified for optimal efficiency: on the one hand, lack of dissemination of information from return of experience, and on the other hand, the lack of effective implementation of corrective measures, most often due to the absence of a person responsible for the application and monitoring of this experience feedback (13). As a result, there is a need for effective and achievable methods to improve the implementation, monitoring, and effectiveness of MMCs. The MMC Simulation project described herein; *in-situ* simulation-based training adapted from MMC cases) tries to fill these gaps by designing a training programme using innovative methods. This is based on simulation-based teaching, an increasingly applied, evidence-based, teaching method (14); *in situ* simulation-based training is defined as a simulated session in the exact environment in which it is intended to take place, as opposed to simulation centres, and which is particularly adapted for team training within an institution (15). The latter can be an

interesting method to improve care delivery in high pressure situations requiring the coordination of many people, actions and resources; it is inter-professional and aims to raise the team's awareness of the factors that have contributed to local events (16). The goal is the appropriation of corrective measures. However, few studies have evaluated whether such interventions can improve the quality of inpatient care (17,18) and, prior to the trial described herein, no study has evaluated the impact of these interventions on adverse events related to the care provided.

We hypothesise that the greatest reduction the occurrence of adverse event will be in the active feedback arm (*in-situ* simulation-training programme with scenarios adapted to the clinical cases processed in MMC) than in the passive feedback arm (wide dissemination by e-mail and/or paper of the results of the MMC) and standard control arm. In the present report, we describe the methodology, and analytical plan for the MMC Simulation project.

METHODS AND ANALYSIS

Outcomes

The primary outcome is the difference in the occurrence of adverse events between the active feedback arm and the control arm.

Secondary outcomes are the difference in the occurrence of adverse events between the passive feedback arm and control arm, as well as between the active feedback arm and the passive feedback arm, the reduction in the severity of adverse events in both intervention arms as compared to the control arm, and the change over time of the type of contributing factors identified in MMC, more specifically those related to teamwork, classified according to the seven main categories of the Association of Litigation and Risk Management (ALARM) method (19).

Study design

A cluster randomized controlled study constituted by three arms will be conducted. The cluster units will be wards in the participating hospitals. After agreement to participate by the medical head of the wards, the wards will be randomly assigned to a passive feedback, an active feedback, or a standard MMC (control arm) based on computer-generated randomization sequence with a 1:1:1 treatment allocation ratio, stratified by centre. For methodological reasons, wards of the same specialty will belong to different hospitals in order to reduce the risk of contamination. The planned duration of the intervention is 2 years.

Study setting and recruitment

The Lyon university hospital federation (*Hospices Civils de Lyon* [HCL]) is a federation of academic healthcare organisations. The study concerns 4 hospitals (3 multidisciplinary and 1 specialised) located in Lyon (France). Each hospital is separate and has all specialties targeted in the study.

The specialties were chosen in accordance with the legislation of the French National Authority for Health (HAS), which has made mandatory MMC in “at risk” specialties (obstetrics, surgery, emergency, and intensive care) in the context of hospital accreditation (20). Accordingly, surgical and trauma intensive care unit, orthopaedic surgical unit, general and digestive surgical unit, emergency room, and obstetric unit are included in the study. All stays in conventional hospitalisation or week-long adult patients spent in participating wards will be included, regardless of their length of hospital stay. Patients in hospitalisation by day and patients under 18 years of age will be excluded.

Sample size

Number of subjects needed

The estimated sample size is 44024 stays based on the following assumptions: a baseline major adverse events rate of 10% with half reduction in the intervention arm, alpha risk at 5% and power at 80%, intracluster correlation coefficient (ICC) of 0.01, and a mean 5000 number of stays per ward.

Number of subjects expected

Over the entire study period, all stays of patients who stayed in the participating wards will be operated by the coordinating centre in order to measure the evaluation criteria of the trial. In total, we will include approximately 80,000 stays during the 2 years of the intervention phase.

Intervention

As usual in the different hospitals of our institution, the MMC is structured using the guidelines of our federation to prepare and standardise the case analysis. A session should be structured to present the case, identify care problems, investigate the causes, analyse the

recovery process, and finally propose an action plan. For all three study arms, at least 3 MMCs each year will be carried out in each unit during the 2 years of the intervention.

For the control arm, MMCs will be organised during the intervention according to the usual format.

For passive feedback, the local coordinator in charge of MMC will choose the case analysed. A wide dissemination of information will be provided to all health professionals in the unit (medical and paramedical teams) in order to optimise the communication and increase the ownership of the professionals, in order for them to play an active role in error prevention. Therefore, the agenda of the MMC will be widely disseminated by e-mail and/or on paper, then the areas for improvement decided during the meeting, and the regular (monthly) monitoring of progress made. This monthly monitoring will check the implementation of the previous objectives with possible corrections to be made.

For active feedback, it will be first suggested to broaden the choice of adverse events analysed in MMC, which is currently focused on serious events or deaths, by disseminating the list of patients with potential adverse events detected by the triggers. Then the research group will develop an *in situ* simulation training programme with scenarios adapted from the cases analysed in MMC. The content of this training programme is based on the experience acquired in the simulation centre of our institution's medical school. The *in situ* simulation training will be conducted in the ward during working hours in order to make the experience as close as possible to reality. This training programme is designed according to the main topics identified for the successful implementation of healthcare simulation in patient safety programmes: technical skills, nontechnical skills, assessment, effectiveness, and system probing (21). Depending on the case to be treated, the scenario may be clinical using a patient simulator, or an interpersonal communication to learn communication skills through the simulation method. Simulation-based interpersonal communication skills training will be

implemented when the adverse event is due to a communication problem: from the healthcare team to the patient, from the healthcare team to the family, or from a communication problem within the healthcare team. Depending on the case studied in MMC, the most appropriate type of simulation for each session will be discussed by the simulation team, the health services researchers of our institution, the local MMC coordinator, and the health manager of the ward concerned. After discussion between this pedagogical team, the principal investigator (BBX) will write the scenario according to the pedagogical objectives. Each simulation session will have specific objectives to promote the acquisition of appropriate technical and nontechnical skills (stress management, situational awareness, teamwork, and briefing strategies) (22). Participants will receive a standardised briefing for each scenario. Then, an inter-professional simulation will be carried out under the responsibility of a trainer of our local centre for teaching by simulation in healthcare. The principal investigator (BBX) will be responsible for the standardised debriefing formats in order to improve situational awareness (23–25). The debriefing will necessarily be concise with a maximum of 5 key messages for each session. The simulation sessions will be filmed and broadcast live for the entire staff present in the ward. The objective is to involve at least a quarter of the department's staff (participants or observers). At the end of each session, participants and observers will be asked to evaluate and propose solutions to the problems identified.

Measurement tool

To effectively measure adverse events, we use the trigger tool methodology (26). This method is easy to customise and can be easily taught; it is a retrospective review of inpatient records using "triggers" to isolate potential adverse events that provides a consistent measurement of adverse events, and which is reported to provide an effective detection of adverse events (27–30). It is based on critical criteria such as the detection of diagnostic or therapeutic complications, transfer to a higher level of care, abrupt cessation of treatment, or the use of a

narcotic antagonist, for example. Since 2010, this tool is accepted as valid to determine whether adverse events decrease over time as a result of improvement efforts (31). The Institute for Healthcare Improvement (IHI) global trigger tool has been translated into French by our team. The simple nature of its clinical information did not make relevant the use of cross-language translation methods. A local trigger tool, derived from the IHI global trigger tool, was further adapted according to the specificities of each specialty by the department heads: each trigger was adapted to each specialty.

Data collection and management

The data analysed will come from different sources: all the institution's information systems, including emergency, operating room, and biology software, as well as patient records detected by the trigger tool methodology.

Our institution's data management and analysis department (HCL), will extract these triggers from the hospital data warehouse.

The quality of the MMC is verified by the research team, who will attend to each meeting. Five criteria have been defined for this: specific institutional training followed by at least the person in charge of the MMC; at least 3 MMCs/year; multidisciplinary participation (medical and non-medical professionals) at each meeting; systemic analysis of each case; adequacy of the action plan (at least a detailed description of the action, name of the person in charge, and schedule for its implementation). Each point is evaluated during a consensus meeting of two researchers who independently scored the MMC each year, using a yes/no scoring system for each point. The simulation meetings are described in terms of type of professionals, number of professionals, and type of simulation – situational or procedural).

The research team will meet just before database lock. This meeting will provide an opportunity to decide on issues such as possible requests for unresolved corrections, establish

a baseline and check the quality of the data. After this, no changes to the data can be made without unlocking the database.

Data analysis

The occurrence of adverse events detected by the trigger tool methodology is defined as the number of stays with a new potential adverse event divided by the total number of stays. The data management and analysis department (HCL) will carry out data extraction and analysis at the end of the intervention phase. All confidence intervals will be calculated at 95%, and statistical test results will be presented at the 5% threshold. All analyses will be performed using SAS software (SAS Institute Inc., Cary, NC, USA). Tests will be bilateral and based on non-parametric statistics if necessary.

We will successively compare each of the two intervention arms to the control arm. First, the characteristics of the patients and their management will be described (range, interquartile range, frequency, number, mean, median, standard deviation) and compared between the intervention and control arms to ensure that there is no imbalance between them. Comparability of arms will be tested using the Rao-Scott Chi^2 test for qualitative variables and the Wilcoxon non-parametric test for quantitative variables to take into account the hierarchical structure of the data (multiple stays in the same ward). The power of the study as well as the ICC on the main end point will also be calculated.

We will then conduct multivariate analyses to model the effect of the intervention on the primary endpoint by adjusting for the different identified predictors or potential confounding factors. A mixed effects logistic regression model will be developed using the NLMIXED procedure to take into account the two-level hierarchical structure of the data ("stay" level nested within a "ward" level). This type of model will make it possible to measure the degree of similarity between patients of the same cluster and the variability of the endpoint between

clusters. A Generalized Estimation Equation (GEE) model approach will also be tested if relevant using the GENMOD procedure. Quantitative variables will be considered in their continuous form, except if the assumption of linearity with the endpoint studied was not verified. Possible interactions will also be sought and taken into account in the model.

Protocol amendments

Any changes to the protocol that may affect the conduct of the study, including changes to study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects, will require a formal amendment to the protocol and will be reported to relevant parties (e.g. trial registry, ethics committee).

Discussion

The *in situ* simulation training programme conducted as part of the study has the potential to improve patient safety during hospitalisation. This training programme is built according to the key factors identified for change management: a local approach (bottom-up approach) with a systemic analysis based on relevant adverse events specific to each ward, a structured implementation of MMC, and a definition by the moderator of corrective actions and their external monitoring (32). These two interventions are of increasing complexity. The first (Passive feedback) is based on actions that are simple to implement, not yet existent, but whose expected impact is limited; however, the exportability to other institutions is very good. The second (Active feedback) has a more important expected effect, but its exportability is more limited to date: simulation training is nevertheless developing rapidly in other institutions, which justifies the relevance of this research project.

It is important that *in situ* simulations are performed on a continuous and relatively frequent basis. The minimum number of *in-situ* simulation sessions has been set at 6 over the 2 years; this may seem modest, but is justified by the technical and logistical constraints inherent in organising simulation sessions in the patient's clinical environment. Furthermore, because of the rotation, during the same week, of medical and paramedical staff in a ward, rest days, and training days already scheduled, it seems illusory to be able to reach all, and even half of, the staff in a ward. We assumed that simulation training involving a quarter of a ward's staff would be sufficient. This teamwork will encourage active participation and allow teams to identify the factors that may contribute to local adverse events (16). We therefore expect the greatest decrease in the occurrence of adverse events among hospitalised patients in the *in situ* simulation arm. This expected result would have a direct impact on patient safety and improve *in situ* simulation at level 4 of the Kirkpatrick model (33).

In France, the measurement of the occurrence of adverse events relies exclusively on voluntary reporting systems in healthcare facilities (34). This imperfect method does not allow real metrological objectives. Our adaptation, in the wards concerned by this study, of the trigger tool methodology, is an important opportunity to improve knowledge of the risks associated with hospital care in France.

In conclusion passive feedback, if effective, can very easily be implemented, with reinforcement of means, in all private or public hospitals. Active feedback can be extended to many clinical services due to the current multiplication of simulation centres in hospitals and universities. At the end of this study, we will likely be able to make recommendations to best adapt inter-professional simulation education sessions to different types of adverse events.

Trial status

Recruitment is in progress (issue date 1 September 2020). Data collection began in July 2018 and will likely be completed in the spring of 2021.

Dissemination

The findings of the study will be communicated through a comprehensive dissemination strategy. In addition, the results of the study will also be presented at relevant national research congresses and local research symposia. The results will also be disseminated to participating departments.

List of abbreviations

MMC: Morbidity and Mortality Conferences; RMM: Revues de Mortalité et de Morbidité; AE: Adverse Event; HCL (Hospices Civils de Lyon); ALARM method: Association of Litigation and Risk Management method; HAS: Haute Autorité de Santé (French National Authority for Health); ICC: Intracluster Correlation Coefficient; IHI: Institute for Healthcare Improvement; GEE: Generalized Estimation Equation

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Not applicable

Authors' contributions

BBX developed the initial study protocol, while PM, AD, LB, TR, ML, FC and HF supported the first author by reading the manuscript critically and providing very relevant comments. NM and LB drafted the revised manuscript. All authors critically reviewed and approved the final manuscript.

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Availability of data and materials

Not applicable

Ethics approval and consent to participate

The study was approved by the ethical committee (CPP LYON SUD-EST IRB: 00009118) in line with the French law on clinical research. The patient cases used for the simulation session scenarios can only be developed after the patient has been informed of the study and their consent to participate has been indicated in the medical record. An information note has been made available to the departments concerned. This document informs the patients of the implementation of the study and the use of hospitalisation data after anonymisation. The study, by its nature, does not present any additional risk to participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

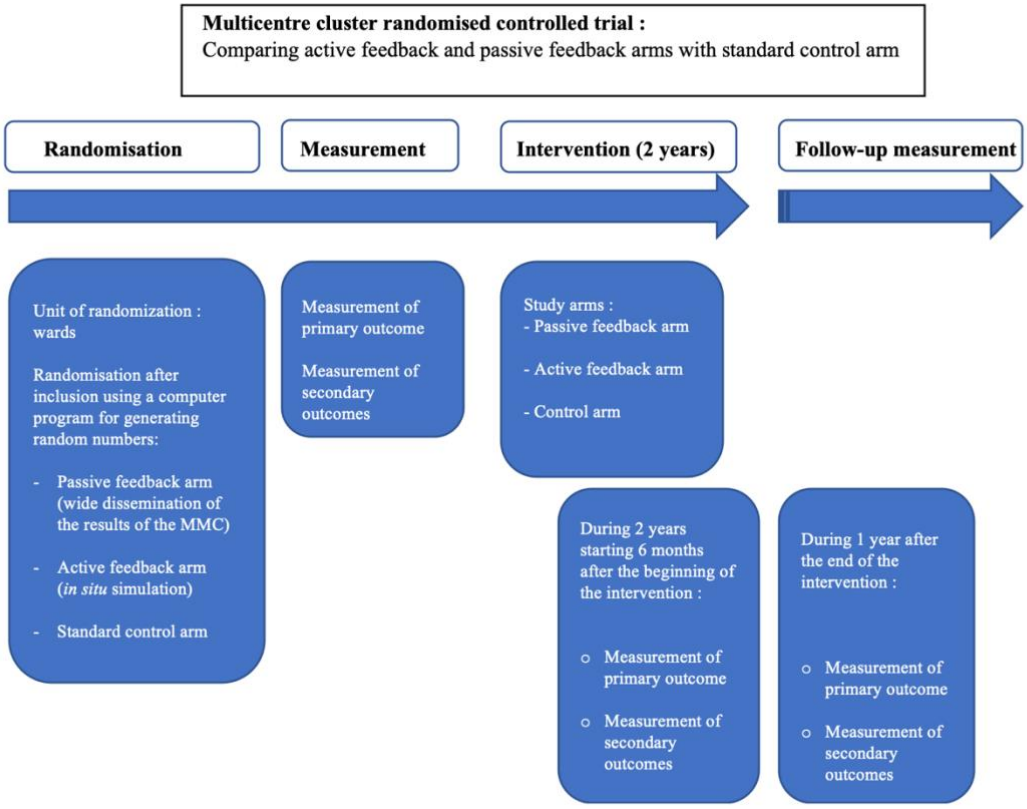

Fig. 1 Study process

	Hôpital Edouard Herriot	Hôpital de la Croix-Rousse	Hôpital de Lyon Sud	Hôpital Femme Mère Enfant
Passive feedback arm	-Orthopaedic surgical unit	-Emergency room -Surgical intensive care unit	-Digestive surgical unit -Obstetrical unit	
Active feedback arm		-Obstetrical unit -Digestive surgical unit	-Surgical intensive care unit -Emergency room -Orthopaedic surgical unit	
Standard control arm	-Surgical intensive care unit -Digestive surgical unit -Emergency room	-Orthopaedic surgical unit		-Obstetrical unit

Fig.2 Distribution of hospital wards in the study arms

	Enrolment	Allocation	Intervention (months)				Post-intervention	Post-intervention
TIME POINT**	$-M_6$	**0**	M_6*	M_{12}	M_{36}	M_{24}	M_{36}	M_{36} - M_{72}
ENROLMENT:								
Eligibility screening	X							
Informed consent	X							
Finalisation of the trigger tool	X							
Preparation of the interventions	X							
Allocation		X						
INTERVENTIONS:								
Passive REX			♦—	—	—	—♦		
Active REX			♦—	—	—	—♦		
Control Group			♦—	—	—	—♦		
ASSESSMENTS :								
Adverse events detected by trigger tool	X			X	X	X	X	X
Severity of adverse events (death, vital threat, prolongation of hospitalization)	X			X	X	X	X	X
Quality of the MMC				X	X	X		

Fig.3 Schedule of enrolment, interventions and assessments ((as per Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure)

Figures

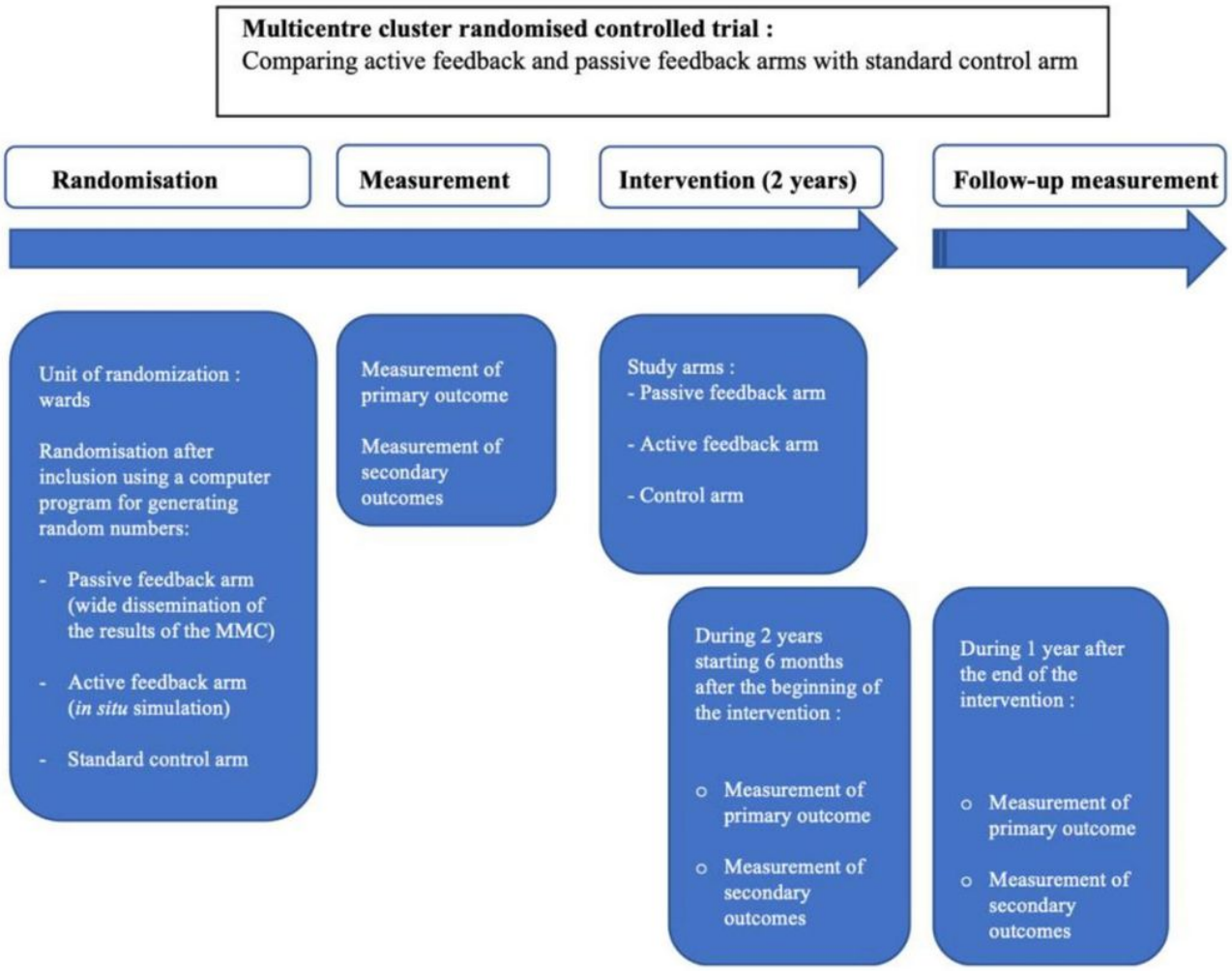

Figure 1

Study process

	Hôpital Edouard Herriot	Hôpital de la Croix-Rousse	Hôpital de Lyon Sud	Hôpital Femme Mère Enfant
Passive feedback arm	-Orthopaedic surgical unit	-Emergency room -Surgical intensive care unit	-Digestive surgical unit -Obstetrical unit	
Active feedback arm		-Obstetrical unit -Digestive surgical unit	-Surgical intensive care unit -Emergency room -Orthopaedic surgical unit	
Standard control arm	-Surgical intensive care unit -Digestive surgical unit -Emergency room	-Orthopaedic surgical unit		-Obstetrical unit

Figure 2

Distribution of hospital wards in the study arms

	Enrolment	Allocation	Intervention (months)				Post-intervention	Post-intervention
TIME POINT**	$-M_6$	0	M_6*	M_{12}	M_{36}	M_{24}	M_{36}	M_{36}-M_{72}
ENROLMENT:								
Eligibility screening	X							
Informed consent	X							
Finalisation of the trigger tool	X							
Preparation of the interventions	X							
Allocation		X						
INTERVENTIONS:								
Passive REX			←	—	—	→		
Active REX			←	—	—	→		
Control Group			←	—	—	→		
ASSESSMENTS :								
Adverse events detected by trigger tool	X			X	X	X	X	X
Severity of adverse events (death, vital threat, prolongation of hospitalization)	X			X	X	X	X	X
Quality of the MMC				X	X	X		

Figure 3

Schedule of enrolment, interventions and assessments ((as per Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRIT2013Checklist.docx