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Title page

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The impact of Clinical Leadership in Teams' course on quality, efficiency, responsiveness of health care services and collegial trust in the Emergency Department: Study protocol: Evaluation using trailing research

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Abstract

Introduction Clinical leadership has long been recognised as critical for optimizing patient safety, quality of care and inter-professional teamwork in busy and stressful health care settings. There is a need for competencies in clinical leadership to conduct professional roles effectively at the frontline due to the absence of role models such as experienced medical doctors and nurses, sicker patients, a shift in patient expectations of health care and lack of focus in healthcare education. Thus, the purpose of the paper is to present and discuss the study protocol of clinical leadership in a course for teams that aims to improve quality, efficiency, responsiveness of health care services and collegial trust in the Emergency Department.

Methods and analysis The study employs a trailing research design using multiple quantitative and qualitative methods in the summative (pre- and post-test) and formative evaluation. Quantitative data have been collected from a patient questionnaire, the Emergency database and by observation of team performance. Qualitative data have been collected by shadowing healthcare professionals and through focus group interviews. To ensure trustworthiness in the data analysis, we will apply member checks and analyst triangulation; in addition to providing contextual and sample description to allow for evaluation of transferability of our results to other contexts and groups.

Ethics and dissemination The study is approved by the Norwegian Social Science Data Services. The study is based on voluntary participation and informed written consent. Informants can withdraw at any point in time. The results will be disseminated at research conferences, peer review journals, and through public presentations to people outside the scientific community.

Keywords: clinical leadership, intervention, study protocol, emergency department, inter-professional teamwork

Strengths and limitations of this study

- The strengths of trailing research design is the flexible use of knowledge collected through participation and dialogue in combination with knowledge acquired and interpreted through traditional scientific methods.
- Participatory validity will be obtained by participant confirmation of the "shadowing" transcription and feedback on results in the dialogue meetings**.** Rigour will be achieved by the transparency with which the data are generated and how events are questioned and interpreted in the formative and summative evaluation**.**
- The pre-test post-test design used in this study has several weaknesses. Other events (history) between the pre- and post-test, which represent a threat to internal validity, may also cause an effect that has alternative explanations.
- The effectiveness of training programs is more difficult to measure because a wide range of variables unrelated to the training intervention can mediate both the training process and the outcome.
- Several factors may influence the effectiveness of the intervention (CLT course).

Introduction

Clinical leadership (CL) has long been recognised as critical for optimizing patient safety, quality of care and inter-professional teamwork in busy and stressful healthcare settings. [1 2] Effective CL is a prerequisite for understanding the complex system of care for the benefit of patients and ensuring healthy workplaces. [3 4] Conversely, ineffective CL has a negative impact on health care workers and standard of care and can lead to adverse events. [4 5] There is an increasing need for competencies in CL to conduct professional roles effectively at the frontline due to the absence of role models such as experienced medical doctors and nurses, sicker patients, a shift in patient expectations of health care and a lack of focus on health care education. [6-9] Nevertheless, opportunities in everyday clinical practice to acquire, practise and receive feedback on CL skills remain scarce. [10] Strategies to promote CL skills should include clinical supervision programmes, inter-professional collaboration and the development of skills. [11-13] Previous CL programs have demonstrated development of self- and observer-reported behaviours of CL competencies [14], improved safety and quality of care [11], development of individual skills and influence on workplace culture. [15 16] The training programs have centred on leadership behaviours/traits and competencies; however, evidence of the impact of such programs on the operational level is scarce. [4 17]

CL is a poorly understood concept that lacks a standard definition. [4 17] Mannix et al. [4] suggested there exists an almost taken-for-granted stance about how CL can be characterized. Others [18] have stated that CL is fostered in an environment where staff are empowered and where there is a vision for the future. Cook and Holt [19] concluded that effective CL requires leadership skills for team building, confidence and respect for others. A review presents a definition of CL that emphasizes attributes such as a drive toward improved service and management of teams to provide excellence in patient care. [17] In Mannix et al. [4], only two studies have developed a definition of CL from their respective findings. One of the studies [20] refers to Harper [21], who is describing a clinical leader as one who possesses clinical expertise in a specialty practice area and who uses interpersonal skills to enable nurses and other health care providers to deliver quality patient care.

According to Howieson and Thiagarajah [17], although the CL literature in healthcare programmes seems to be extensive, problems exist. Research on CL has focused on studying trait- and behavioural-based competency models. Howieson and Thiagarajah [17] claim there are several concerns with this approach, such as centredness on recommended behaviour/traits and competencies, losing sight of the contextual and situational nature of CL, gaps between the perceptions of leadership embodied in competency frameworks and the perceptions of leaders themselves. This approach does not inform what constitutes effective CL behaviours in different contexts. Consequently, the social influence process of CL cannot be fully understood unless a more discursive approach is applied.

Hence, there is a need for more research to determine if a course in clinical leadership in teams (CLT) improves the quality of healthcare services in the emergency department (ED). To address this need, our study aims to evaluate the impact of a CLT course in terms of quality, efficiency, responsiveness of healthcare services and inter-professional trust in the ED.

Theoretical concepts

To address the aim of the hospital improvement process related to clinical quality in the ED and CL, in the context of taking responsibility for conducting medical and nursing practice with a patient-centred perspective, CL needs to be redefined. The working group responsible for developing the course decided that the following four bedside values would underpin the theoretical foundation of the curriculum and evaluation of the course's impact [22]: trust, quality, responsiveness, and efficiency. These values were considered to provide the necessary platform for the translation of principles combining the values of the hospital with the concept of CL to address the needs of the ED. Definitions of these values are outlined elsewhere. [13]

Methods and analysis

Study design

The current study employs a trailing research design with pre- and post-test, using quantitative and qualitative methods in the evaluation. [22] Trailing research is a dialogue-based process analysis and an appropriate research method when the purpose is to have a constructive dialogue with the participants and stakeholders. [23 24] They will be able to influence not only what is evaluated, but also the methods and how the data are interpreted and applied. [25] In trailing research, the role of a researcher is not intervention, but more to engage as a partner in dialogue. The objective is learning and evaluation created through participants' and researchers' reflections (table 1).

Please insert Table 1 here

In phase 1, the planning of the study and the CLT course, it was important to clarify the study design and outcomes in cooperation with the ED. [24] A pilot test of the CLT course was conducted and was followed with an evaluation and refinement of the course. [22] Additionally, parts of the CLT course were tested in a simulation setting. In phase 2, the CLT course was executed and the first author gave feedback on the preliminary findings in dialogue meetings. The objective of these meetings was to reflect and gain experiential learning based on the preliminary findings. [24] The objective of the formative evaluation was to improve the course as it happens, based on the quantitative and qualitative data. In the next phase, the CLT course was adjusted, and the last phase was a summative evaluation of the course and the consequences of the intervention.

Setting

The current study takes place in the ED at a university hospital in the southwestern part of Norway. The ED at the hospital is located in an urban setting and triages approximately 30,000 patients per year. Every week the ED delivers emergency care to 600 patients per week from 18 municipalities with a population of about 350,000. The ED staff consists of 120 Intensive Care and Registered Nurses, 40 attending physicians on rotation from medical, surgical and neurological departments, and various support personnel. The ED is divided into two major care areas; the triage area with 14 beds and the treatment area with 22 beds.

The regional office of the Norwegian Board of Health Supervision conducted a follow-up evaluation of ED services at the hospital in the spring of 2013. [26] The report concluded that there was an insufficient number of qualified medical personnel (doctors) in the ED. The hospital responded to these conclusions by establishing a steering committee involving the hospital's top leadership. This committee established several working groups, each with a specific mandate to address the challenges the report highlighted. As a result of the proceedings of one of these groups it was concluded that there was a need to initiate a process to secure CL skills among key health personnel in the ED. The response to this conclusion was the development and implementation of the CLT course.

Study participants and ethics

Twelve nurses in charge, 40 doctors on call, 30 nurses and 400 patients admitted to the ED in the hospital were invited to participate in the pre- and post-test, respectively. The pre-test was conducted in August and September 2013 and the post-test was planned for 2016. The data of the formative evaluation were collected from December 2013 to September 2015.

The ethics committee of the western part of Norway and the hospital have approved the study. Participants received written and oral information about the study, and all participants willing to participate signed an informed consent form before they were enrolled in the study. Confidentiality is guaranteed. Patients admitted to the ED will be asked to participate by nurses in the medical, surgical and neurological units one day after admission to the ED (table 2).

Insert table 2 here

Research procedures

The current study comprises the following three components: 1) The summative evaluation, 2) the formative evaluation, and 3) the CLT course (figure 1). Table 3 describe concepts, operationalization of the concepts, sample and data collection in the summative and formative evaluation.

Please insert Figure 1 here

Please insert Table 3 here

Summative evaluation

The summative evaluation includes quality of care and quality of team performance, responsiveness, efficiency and inter-professional trust.

Quality is evaluated from the patient's perspective, and by observing inter-professional team performance. Quality of care is measured by the "Quality from the Patient's Perspective (QPP) questionnaire". [27 28] Patients' perceptions of what constitutes quality of care are formed by their encounters with an existing care structure and by their system of norms, expectations and experiences. The questionnaire has four dimensions: medical-technical competence of the caregivers, physical-technical conditions of the care organization, degree of identity-orientation in the attitudes and actions of the caregivers, and socio-cultural atmosphere of the care organization. [27] A short version of the QPP developed and tested by Larsson and Larsson [27] has been used. The original version in Swedish has been translated into Norwegian. [29]

The quality of multidisciplinary team performance is observed by the «Team Emergency Assessment Measure» (TEAM). [30] TEAM is constructed to measure non-technical skills in teamwork and has three subscales: the team leader (two items), the team (seven items) and task management (two items). The items are rated from "Never/Hardly ever" (0) to "Always/Nearly always" (4). TEAM has 12 items, the last of which is an overall rating scale from one (lowest) to ten (highest).

Responsiveness deals with the patients' expectations and perceptions of existing care structures in health care and will be measured by a subscale (four items) from the "World Health Survey – Health System Responsiveness" (WHSHSR) (subscale Importance 7.4-7.5, Q7100-Q7107). [31]

Efficiency is measured by flow, crowding, and providers' perception of managing high workflow crowding, and a variety of time variables in the ED. [32] Time variables have been collected from the database of Emergency. During each shift, the doctor on call and nurse in charge will simultaneously rate the level of crowding on a 5-point Likert scale, from "not busy" (1) to "extremely crowded" (5). If they consider the ED crowded, the level to which crowding compromises patient safety is indicated, from strongly disagree (1) to strongly agree (5). In order to compare the provider's ability to recognize crowding, the mean ED crowding rating of the two raters will be correlated. [33] To assess how the providers perceive their ability to manage several patients at the same time, the providers will rate the level of multitasking on a 5-point Likert scale from "not managing the number of patients" (1) to "managing the number of patients very well (5)".

Inter-professional trust will be explored by conducting focus group interviews (FGI) in the pre- and post-test to obtain a picture of how healthcare providers in the ED perceive and experience inter-professional trust. [34] A convenience sample of doctors on call and nurses in charge will be invited to participate in three FGIs. The group format is efficient for generating dialogue, and group interaction facilitates access to the participants' thoughts and perceptions. [34]

Formative evaluation

The formative evaluation includes the dialogue meetings, efficiency and characteristics of how CL is performed by nurses in charge and doctors on call after participating in the CLT course. Data from the dialogue meetings that describe organizational processes taking place and changes during the period will be analysed using document analysis. [35]

Shadowing nurses in charge and doctors on call, respectively, from the medical, surgical and neurological units has been conducted to explore how CL is performed. [36] Shadowing is a research technique that involves a researcher closely following a member of an organization over an extended period of time. [36] The method can "produce the sort of first-hand, detailed data that gives the researcher access to both the trivial or mundane and the difficult to articulate". [36] To gain validity of the data, all participants read the field notes and give feedback. [36]

Efficiency includes the number of patients admitted to the ED and a variety of time variables of length of stay (i.e., arrival at triage, arrival at provider and arrival at doctor). [32] The time variables have been retrieved from the database of Emergency.

Intervention: Clinical leadership in team course

The overarching vision of the CLT course is to establish bedside values and an understanding of excellent day-to-day CL in teams, executing CL with existing resources and within the organisational structure. The development of the CLT followed the seven factors outlined by Salas et al. [37] cf. [13] The didactic model of relation [38] has guided the design of the course (figure 2). Further, the goals of the intervention have been linked to the vision and overarching goals of the hospital. [37 39]

The CLT course encompasses the six factors Hiim and Hippe. [38] All factors are mutually dependent; changes in one feature have consequences for the other features.

Please insert Figure 2 here

Required resources and time commitment were secured by the Steering Committee and the decision to allocate three days for the pilot course plus four group meetings and a facilitated session over a two-month period. [37]

Competence was ensured by a faculty consisting of individuals with a background in medicine, leadership, paramedics, pedagogy, emergency-care nursing and research. [38] Three faculty members had long experience as simulation facilitators and Train the Trainers instructors (EUSim). To ensure understanding and relevance, the faculty also reviewed adverse events reports in the ED and took observational shifts prior to designing the workshops and scenarios. To guarantee a sustainable course and relevance to clinical practice, buy-in and ownership were secured by recruiting former course participants as future trainers. [37]

The overarching vision of the CLT course is to establish bedside values and an understanding of excellent day-to-day CL in teams, executing CL within existing resources and organisational structure. The specific objectives of the CLT for participants are to 1)

function as skilled operative leaders and clinical supervisors within their clinical everyday setting, 2) understand and improve patient safety and quality, 3) understand the dynamics of patient flow, and critically and efficiently use available resources, and 4) improve trust between health personnel.

In developing the course content, both in materials and subject matter, five main contextualized topics were established: basics, behaviour, team, safety and tools. From these, subtopics were then derived. The CLT course is structured in four steps comprising introduction, theory, workshop/simulation and implementation. [13] The simulation scenarios focus on limited trauma with chest pain, lack of resources and overcrowding, prolonged length of stay in the ED, unclarified patients, bullying at work, and medication error with consequences (for details, see Olsen et al. 2015). [13] The simulation sessions were developed by analysing challenging clinical settings and patient scenarios relevant to the department in question. These were identified through pre-course discussions and the active use of the hospital incident reporting system.

Pedagogical methods include workshops, simulation, group counselling and peer-to-peer dialogue, all of which emphasize guided reflection. [40-43] The last two methods were chosen to support the implementation of CL (table 1) and to facilitate the application of trained CL skills on the job. [37]

Statistical analysis

Multilevel analysis will be performed to analyse the results. Common descriptive statistics with frequencies, percent, mean and standard deviation will be conducted to describe the study sample on the cluster level. The differences in the outcomes measures will be evaluated on a team or individual level. Differences in the distribution of sex, age groups, level of education etc. and results from the QPP questionnaire between pre and post-test will be analysed by *t*-test, the Mann-Whitney test and analysis of variance (ANOVA). To identify differences between the percentages of patients admitted to the different specialties and triage codes, the chi-square test will be used. The chi-square test will also be conducted to identify differences between the pre- and post-test in time variables. Correlations will be used to analyse the difference in assessment of crowding from doctors and nurses. All analyses will be carried out using the Statistical Package for Social Sciences, SPSS v.20. A p-value <0.05 is regarded as statistically significant.

Qualitative data analysis

To ensure trustworthiness in the analysis, analyst triangulation and member checks will be applied. [44] The research team will discuss and refine the analysis according to the research questions and themes emerging in the data. The FGI will be analysed by conducting content analysis. [45] The summary of the dialogue meeting will be analysed using document analysis. [35] The summaries will act as important data material in the formative evaluation of organizational processes taking place and changes during the study period.

The analysis of shadowing doctors and nurses will be conducted by the first author. The method described by Coffey and Atkinson [46] will be used to analyse and interpret the data.

Dissemination

Results of the CLT course study will be reported according to a pre-determined publication policy approved by all members of the research team. Study results will be disseminated via scientific conferences and publications; presentations to health care providers, and meetings with stakeholders.

Study status

The CLT course study run-in period began in August 2013. Data collection will continue until June 2016.

Discussion

The discussion of the study protocol has been structured in three parts, including discussion of the study design, outcome criterion and the CLT course (the intervention).

Study design

The strengths of trailing research design is the flexible use of knowledge collected through participation and dialogue in combination with knowledge acquired and interpreted through traditional scientific methods. [47] Another advantage of trailing research is the capacity to follow up changes in the project through monitoring, feedback and feed-forward loops. [47] To improve validity and achieve rigour in trailing research data, the data in this study will be assessed from different sources. The quality of observations will be achieved by prolonged and persistent observations in the ED. [48] Participatory validity will be obtained by participant confirmation of the "shadowing" transcription and feedback on results in the dialogue meetings. [48] Rigour will be achieved by the transparency with which the data are generated and how events are questioned and interpreted in the formative and summative evaluation.

The challenges with trailing research revolve around the performance of the intervention, finding a good balance between the content of the intervention and the advice given to adjust the intervention based on the results, and the values that guide the advice based on the dialogue meetings. Evaluation will always have a relationship with values. Therefore, it is important to reflect on one's own role as a researcher when entering social processes and how the researcher influences processes. [49]

The literature in trailing research answers questions regarding "technical" issues, but not how difficult questions linked to researcher relations and roles should be solved in the clinical field. The researcher should be aware of the challenge of shifting between closeness and distance regarding the research as well as feelings related to personal and ethical issues. [23 50] Usually, this is strengthened if the researcher knows the field, but can, of course, result in confusion if the researcher witnesses unethical practices and acts. The ways the researchers solve difficult situations have consequences for them, the research and the participants.

The study design used in this study has several weaknesses. [51] Firstly, the monitoring of time variables, such as length of stay, may be atypical and apart from the mandate. To eliminate some alternative explanations for change in time variables, data have been collected every six months over an extended period of one-and-a-half years. Secondly, any other events (history) between the pre- and post-test, which represent a threat to internal validity, may cause an effect that has alternative explanations. Implementations of similar courses and changes in routines and organization in the intervention period will be monitored and evaluated as historical threats. [52] The current design is considered practical in a natural setting, but difficult or impossible to deliver as a random intervention to some people but not to others in the ED. Thus, results are usually less conclusive because causal inferences cannot be made. [51]

Outcome criteria

Establishing the outcomes of the intervention was challenging, partly due to the length and complexity of the causal chains linking interventions with outcomes. [53] Additionally, the effectiveness of training programs is more difficult to measure because a wide range of variables unrelated to the training intervention can mediate both the training process and the outcome. Dreschner et al. [54] suggest that these variables need to be considered if it is to be established whether an outcome is due to the training interventions or other unrelated factors.

The outcome of this study is linked to four values outlined in the theoretical framework. Since the main purpose of the intervention is to improve quality of care and patient safety in the ED, it is critical patient-centred outcomes such as experience and quality of care should be taken into account. [53] A number of instruments exist to measure patient-reported outcomes, such as the Patient Judgements of Hospital Quality. [55] In Norway, only a few instruments measuring patient-reported outcomes have been translated and validated. Instruments measuring satisfaction/quality of care for patients admitted to the ED are rare. [56] Therefore, the QPP survey [28] was considered appropriate for acutely ill patients 24 hours after admission in the ED. Although TEAM [30] was constructed to observe critical emergency teams, the instrument was considered manageable and suitable for observing quality of team performance in all teams in the ED. The fact that a variety of time variables have been used to measure efficiency in the ED helped decide how to measure efficiency. [56 57] Inter-professional trust is not a well-studied phenomenon in the ED [58], which implies a qualitative, explorative design to capture the experiences of inter-professional trust among doctors on call and nurses in charge. [51]

The intervention

Several factors may influence the effectiveness of the intervention. [59] Consequently, several aspects of the intervention need to be assessed and evaluated. [52] The aspects include assessment of learning needs, duration of educational activity, group composition, active participants and use of opinion leaders. [59]

Previous research demonstrates a mixed picture regarding the impact of assessment of learning needs, from no consistent effect to significant effect on learning. [59] The content and

format of the CLT course have been developed by the faculty based on the evidence-based factors [37], which emphasizes organisational goals more than individual learner goals. With reference to previous research, the result of the study can go both ways. In this regard, the participants' motivation can be significant in the explanations of the study results. [60]

The duration and frequency of the CLT course will have an influence of effectiveness. One review [61] demonstrates that continuing education lasting one day is less effective than education lasting several days, but little difference exists between education of two days and education of longer duration. The process of reflection is considered critical for learning in clinical practice. [62] To meet the recommendations for the duration of the program, the CLT course facilitates further reflection in group counselling lasting three months. A sustainable change in how CL is performed by doctors and nurses will be demonstrated by the study results. Nevertheless, to create a successful, large-scale improvement program in the long term requires administrative and organizational implementation strategies in the hospital. [59]

Group composition has an impact on the effect of the CLT course, where participants from one organization are preferable. [59] The departmental management selects the participants in the CLT course. Doctors represent the medical, surgical and neurological department, while all nurses represent the ED. Future evaluation will demonstrate whether the selection process and participants from different cultures with different motivations will have an impact on the results. Another factor that has an impact on the effectiveness of the intervention is active participants. [59] Participants are active in large parts of the CLT course, and the educational activities are therefore consistent with existing knowledge.

The last factor that may have a moderate influence on the results is the use of opinion leaders. [59] Opinion leaders have different roles, and structured methods are available to identify them. Since departmental management selects the participants in the CLT course, this factor has not been carefully considered. In future, such consideration may decide which faculty members are chosen to conduct new courses.

The results of the study will allow a greater understanding of whether the intervention is effective and how the CLT course tailored for the ED will have an impact on changes in the course curriculum, changes in the study protocol and in procedures in the ED and other units. Finally, our results will be useful to the Steering Committee and the top leadership of the hospital in future decisions and the distribution of the CLT course in the departments of medicine and surgery. The results will contribute to the bank of available research data that can be used to develop better health care services for patients admitted to hospitals.

Contributorship statement SEH drafted the manuscript. SEH and ØEO participated in the design of the study and performed the qualitative analysis, and SEH performed the quantitative analysis. SEH and ØEO have provided input, protocol and study design revision. All authors read and approved the final manuscript.

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Data sharing statement Additional unpublished data from the study will only be available for the authors of the manuscript.

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Table 1 Characteristics of trailing research (Segaard, 2007)

Researcher	Not intervening Not responsible Dialogue partner
Focus and objective	Scientific knowledge Learning and evaluation
Respondent- researcher relationships	Often formal contract based Division of roles (researcher/participants/stakeholders)
Timeframe	Contemporary

View on data and knowledge	Humanistic, created through participants' reflections

Table 2 Inclusion and exclusion criteria

Inclusion criteria

Patients admitted to the ED must be:

-Norwegians 18 years or older

-able to read and write

-transferred from the ED to surgical, medical or neurological units

-admitted to the hospital a minimum of 24 hours ago.

Healthcare professionals:

-Doctors on call, nurses in charge, and other doctors and nurses that work daily in the ED, both in ad hoc teams and in permanent positions.

Exclusion criteria

-Patients with severe illness who have been transferred from the ED to other acute care units (i.e., intensive care units, cardiac units and operating theatres)

-Patients who have been diagnosed as demented or depressed by a health care professional and incapable of being medically fit to answer the questionnaire.

Table 3 Concepts, operationalization of the concepts, sample and data collection in the summative (pre- and post-test) and formative evaluation.

Summative evaluation (pre- and post-test)		
Concepts	*Operationalization of the concepts*	*Sample and data collection*
Quality	Quality from the patient's perspective Quality of team performance	Randomized sample; 'Quality from the Patient's Perspective' (QPP) Questionnaire (Larsson & Larsson, 2002) Convenience sample on team level; "Team Emergency Assessment Measure (TEAM)" Observation (Cooper et al., 2012)
Responsiveness	Responsiveness from the patient's perspective	Randomized sample; WHO "World Health Survey - Health System Responsiveness" subscale 7.4-7.5 (Q7100-Q7107) Questionnaire
Efficiency	Flow, length of stay, crowding and reasons for crowding, providers' perception of managing high workflow	The numbers of patients and a variety of time variables of length of stay will be retrieved from the database of Emergency. How nurses in charge and doctors on call perceive their abilities in managing several patients at the same time (Doyle et al., 2012)
Inter-professional trust	Characteristics of inter-professional trust	Purposeful sample; focus group interviews with doctors on call and nurses in charge
Formative evaluation		
Reflection and learning	Dialogue meetings	Document analysis of dialogue meetings
Quality	Performance of clinical leadership	Convenience sample; shadowing doctors on call and nurses in charge
Efficiency	Flow and length of stay	The numbers of patients and a variety of time variables of length of stay will be retrieved from the database of Emergency.

Figure 1 Components in the current study

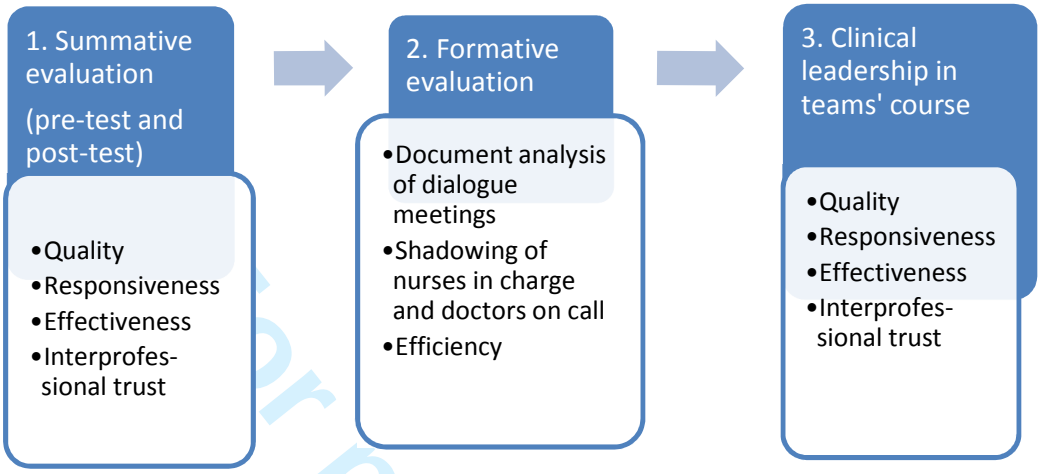
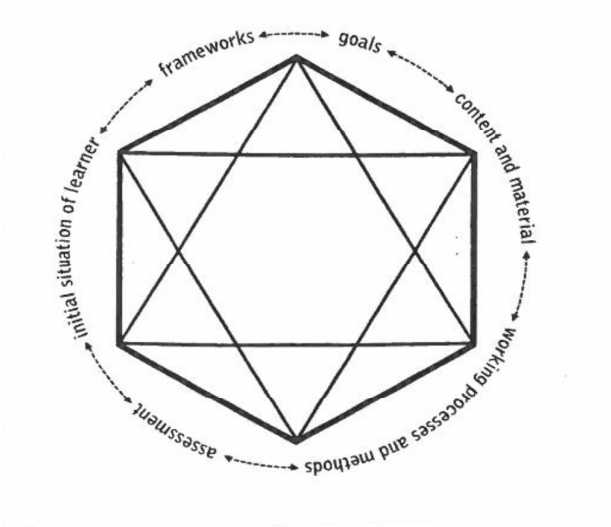


Figure 2. Illustration of the the didactic model of relation (Hiim & Hippe, 1998)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Yes/ No	Description
Administrative information		
Title	Y	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	N	Trial identifier and registry name. If not yet registered, name of intended registry
	N	All items from the World Health Organization Trial Registration Data Set
Protocol version	N	Date and version identifier
Funding	Y	Sources and types of financial, material, and other support
Roles and responsibilities	Y	Names, affiliations, and roles of protocol contributors
	Y	Name and contact information for the trial sponsor
	Y	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	Y	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	Y	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	N	Explanation for choice of comparators
Objectives	Y	Specific objectives or hypotheses
Trial design	Y	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	Y	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	Y	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	Y	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	N	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	N	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	N	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	Y	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	Y	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	Partially	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	Y	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:		Not relevant
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	Y	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	N	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	N	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	Y	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	N	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	N	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	N	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	No	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	No	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	Y	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	Y	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	Y	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	Y	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	Not relevant	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	Y	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	Y	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	Y	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	Not relevant	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	Y	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	Y	Authorship eligibility guidelines and any intended use of professional writers

	Not relevant	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	Y	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	Not relevant	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

The impact of Clinical Leadership in Teams' course on quality, efficiency, responsiveness and trust in the Emergency Department: Study protocol of a trailing research study

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Title page

Title:

The impact of Clinical Leadership in Teams' course on quality, efficiency, responsiveness and trust in the Emergency Department: Study protocol of a trailing research study

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Abstract

Introduction Clinical leadership has long been recognised as critical for optimizing patient safety, quality of care and inter-professional teamwork in busy and stressful health care settings. There is a need to compensate for the absence of the conventional mentor-to-apprentice transfer of clinical leadership knowledge and skills. While young doctors and nurses are increasingly proficient in medical, surgical and technical skills, their training in, and knowledge of clinical leadership skills, is not adequate to meet the demands for these non-technical skills in the Emergency Department. Thus, the purpose of the paper is to present and discuss the study protocol of clinical leadership in a course for teams that aims to improve quality, efficiency, responsiveness of health care services and collegial trust in the Emergency Department.

Methods and analysis The study employs a trailing research design using multiple quantitative and qualitative methods in the summative (pre- and post-test) and formative evaluation. Quantitative data have been collected from a patient questionnaire, the Emergency database and by observation of team performance. Qualitative data have been collected by shadowing healthcare professionals and through focus group interviews. To ensure trustworthiness in the data analysis, we will apply member checks and analyst triangulation; in addition to providing contextual and sample description to allow for evaluation of transferability of our results to other contexts and groups.

Ethics and dissemination The study is approved by the ethics committee of the western part of Norway and the hospital. The study is based on voluntary participation and informed written consent. Informants can withdraw at any point in time. The results will be disseminated at research conferences, peer review journals, and through public presentations to people outside the scientific community.

Keywords: clinical leadership, intervention, study protocol, emergency department, inter-professional teamwork

Strengths and limitations of this study

- The strengths of trailing research design is the flexible use of knowledge collected through participation and dialogue in combination with knowledge acquired and interpreted through traditional scientific methods.
- Participatory validity will be obtained by participant confirmation of the “shadowing” transcription and feedback on results in the dialogue meetings**.** Rigour will be achieved by the transparency with which the data are generated and how events are questioned and interpreted in the formative and summative evaluation**.**
- The pre-test post-test design used in this study has several weaknesses. Other events (history) between the pre- and post-test, which represent a threat to internal validity, may also cause an effect that has alternative explanations.
- The effectiveness of training programs is more difficult to measure because a wide range of variables unrelated to the training intervention can mediate both the training process and the outcome.
- The content, duration and frequency of the CLT course may influence the effectiveness of the intervention.

Introduction

Clinical leadership (CL) has long been recognised as critical for optimizing patient safety, quality of care and inter-professional teamwork in busy and stressful healthcare settings. [1 2] Effective CL is a prerequisite for understanding the complex system of care for the benefit of patients and ensuring healthy workplaces. [3 4] Conversely, ineffective CL has a negative impact on health care workers and standard of care and can lead to adverse events. [4 5] There is a need to compensate for the absence of the conventional mentor-to-apprentice transfer of clinical leadership knowledge and skills. While young doctors and nurses are increasingly proficient in medical, surgical and technical nursing skills, their training in, and knowledge of clinical leadership skills, is not adequate to meet the demands for these non-technical skills in the Emergency Department (ED) and other wards and work environments in a modern hospital. [6-9] Nevertheless, opportunities in everyday clinical practice to acquire, practise and receive feedback on CL skills remain scarce. [10] Strategies to promote CL skills should include clinical supervision programmes, inter-professional collaboration and the development of skills. [11-13] Previous CL programs have demonstrated development of self- and observer-reported behaviours of CL competencies [14], improved safety and quality of care [11], development of individual skills and influence on workplace culture. [15 16] The training programs have centred on leadership behaviours/traits and competencies; however, evidence of the impact of such programs on the operational level is scarce. [4 17]

CL is a poorly understood concept that lacks a standard definition. [4 17] Mannix et al. [4] suggested there exists an almost taken-for-granted stance about how CL can be characterized. Others [18] have stated that CL is fostered in an environment where staff are empowered and where there is a vision for the future. Cook and Holt [19] concluded that effective CL requires leadership skills for team building, confidence and respect for others. A review presents a definition of CL that emphasizes attributes such as a drive toward improved service and management of teams to provide excellence in patient care. [17] In Mannix et al. [4], only two studies have developed a definition of CL from their respective findings. One of the studies [20] refers to Harper [21], who is describing a clinical leader as one who possesses clinical expertise in a specialty practice area and who uses interpersonal skills to enable nurses and other health care providers to deliver quality patient care.

According to Howieson and Thiagarajah [17], although the CL literature in healthcare programmes seems to be extensive, problems exist. Research on CL has focused on studying trait- and behavioural-based competency models. Howieson and Thiagarajah [17] claim there are several concerns with this approach, such as centredness on recommended behaviour/traits and competencies, losing sight of the contextual and situational nature of CL, gaps between the perceptions of leadership embodied in competency frameworks and the perceptions of leaders themselves. This approach does not inform what constitutes effective CL behaviours in different contexts. Consequently, the social influence process of CL cannot be fully understood unless a more discursive approach is applied.

Hence, there is a need for more research to determine if a course in clinical leadership in teams (CLT) improves the quality of healthcare services in the ED. The CLT course is an institutionalized approach to improve value based non-technical skills of clinical personnel. It takes a horizontal and operational approach, focusing on clinical management and coordination of the inter-professional team in a realistic, routine based patient centred context. A teams approach to CL has been taken because all clinical personnel operate in an

environment in which they are influenced by, and influence others through their actions and decisions. Patient safety is highly dependent on the level of collaboration between clinical personnel in all settings. CL therefore requires leadership skills for interdisciplinary team building, confidence in and respect for others and a combination of expertise and communication skills.

The aim of the study is to evaluate the impact of a CLT course in terms of quality, efficiency, responsiveness of healthcare services and inter-professional trust in the ED.

Theoretical concepts

To address the aim of the hospital improvement process related to clinical quality in the ED and CL, in the context of taking responsibility for conducting medical and nursing practice with a patient-centred perspective, CL needs to be redefined. The working group responsible for developing the course decided that the following four bedside values would underpin the theoretical foundation of the curriculum and evaluation of the course's impact [22]: trust, quality, responsiveness, and efficiency. These values were considered to provide the necessary platform for the translation of principles combining the values of the hospital with the concept of CL to address the needs of the ED. Definitions of these values are outlined elsewhere. [13]

Methods and analysis

Study design

The current study employs a trailing research design with pre- and post-test, using quantitative and qualitative methods in the evaluation. [22] Trailing research is a dialogue-based process analysis and an appropriate research method when the purpose is to have a constructive dialogue with the participants and stakeholders. [23 24] They will be able to influence not only what is evaluated, but also the methods and how the data are interpreted and applied. [25] In the current study, trailing research was considered suitable because the researcher had no explicit stake in the outcome of the change or responsibility in any way for securing successful results. PAR, in comparison, assumes the researcher is also influencing and involved in the change process. [23] The objective is learning and evaluation created through participants' and researchers' reflections (table 1).

Please insert Table 1 here

In phase 1, the planning of the study and the CLT course, it was important to clarify the study design and outcomes in cooperation with the ED. [24] A pilot test of the CLT course was conducted and was followed with an evaluation and refinement of the course. [22] Additionally, parts of the CLT course were tested in a simulation setting. In phase 2, the CLT course was executed and the first author gave feedback on the preliminary findings in dialogue meetings. The objective of these meetings was to reflect and gain experiential learning based on the preliminary findings. [24] The objective of the formative evaluation was to improve the course as it happens, based on the quantitative and qualitative data. In the next phase, the CLT course was adjusted, and the last phase was a summative evaluation of the course and the consequences of the intervention.

Setting

The current study takes place in the ED at a university hospital in the southwestern part of Norway. The ED at the hospital is located in an urban setting and triages approximately 30,000 patients per year. Every week the ED delivers emergency care to 600 patients per week from 18 municipalities with a population of about 350,000. The ED staff consists of 120 Intensive Care and Registered Nurses, 40 attending physicians on rotation from medical, surgical and neurological departments, and various support personnel. The ED is divided into two major care areas; the triage area with 14 beds and the treatment area with 22 beds.

The regional office of the Norwegian Board of Health Supervision conducted a follow-up evaluation of ED services at the hospital in the spring of 2013. [26] The report concluded that there was an insufficient number of qualified medical personnel (doctors) in the ED. The hospital responded to these conclusions by establishing a steering committee involving the hospital's top leadership. This committee established several working groups, each with a specific mandate to address the challenges the report highlighted. As a result of the proceedings of one of these groups it was concluded that there was a need to initiate a process to secure CL skills among key health personnel in the ED. The response to this conclusion was the development and implementation of the CLT course.

Study participants and ethics

Twelve nurses in charge, 40 doctors on call, 30 nurses and 400 patients admitted to the ED in the hospital were invited to participate in the pre- and post-test, respectively. The pre-test was conducted in August and September 2013 and the post-test was planned for 2016. The data of the formative evaluation were collected from December 2013 to September 2015.

The ethics committee of the western part of Norway and the hospital have approved the study. Participants received written and oral information about the study, and all participants willing to participate signed an informed consent form before they were enrolled in the study. Confidentiality is guaranteed. Patients admitted to the ED will be asked to participate by nurses in the medical, surgical and neurological units one day after admission to the ED (table 2).

Insert table 2 here

Research procedures

The current study comprises the following three components: 1) The summative evaluation, 2) the formative evaluation, and 3) the CLT course (figure 1). Table 3 describe concepts, operationalization of the concepts, sample and data collection in the summative and formative evaluation.

Please insert Figure 1 here

Please insert Table 3 here

Summative evaluation

The summative evaluation includes quality of care and quality of team performance, responsiveness, efficiency and inter-professional trust.

Quality is evaluated from the patient's perspective, and by observing inter-professional team performance. Quality of care is measured by a short form of the "Quality from the Patient's Perspective (QPP) questionnaire". [27 28] Patients' perceptions of what constitutes quality of care are formed by their encounters with an existing care structure and by their system of norms, expectations and experiences. The questionnaire has 50 items and four dimensions: medical-technical competence of the caregivers, physical-technical conditions of the care organization, degree of identity-orientation in the attitudes and actions of the caregivers, and socio-cultural atmosphere of the care organization. [27] The original version in Swedish has been translated into Norwegian. [29]

The quality of multidisciplinary team performance is observed by the «Team Emergency Assessment Measure» (TEAM). [30] TEAM is a measure of team performance during medical emergencies and is constructed to measure non-technical skills in teamwork. The authors have adapted TEAM for use in non-emergency medical setting in the ED. TEAM has three subscales: the team leader (two items), the team (seven items) and task management (two items). The items are rated from "Never/Hardly ever" (0) to "Always/Nearly always" (4). TEAM has 12 items, the last of which is an overall rating scale from one (lowest) to ten (highest).

Responsiveness deals with the patients' expectations and perceptions of existing care structures in health care and will be measured by a subscale (four items) from the "World Health Survey – Health System Responsiveness" (WHSHSR). [31]

Efficiency is measured by a variety of time variables in the ED. [32] Doctor on call and nurse in charge will simultaneously rate the level of crowding on a 5-point Likert scale, from "not busy" (1) to "extremely crowded" (5). If they consider the ED crowded, the level to which crowding compromises patient safety is indicated, from strongly disagree (1) to strongly agree (5). In order to compare the provider's ability to recognize crowding, the mean ED crowding rating of the two raters will be correlated. [33] To assess how the doctor on call and nurse in charge providers perceive their ability to manage several patients at the same time, they will

rate the level of multitasking on a 5-point Likert scale from "not managing the number of patients" (1) to "managing the number of patients very well (5)".

Inter-professional trust will be explored in the pre- and post-test to obtain a picture of how healthcare providers in the ED perceive and experience inter-professional trust. [34] Doctors on call and nurses in charge will be invited to participate in three FGIs. The group format is efficient for generating dialogue, and group interaction facilitates access to the participants' thoughts and perceptions. [34]

Formative evaluation

The formative evaluation includes the dialogue meetings, efficiency and characteristics of how CL is performed by nurses in charge and doctors on call after participating in the CLT course. Data from the dialogue meetings that describe organizational processes taking place and changes during the period will be analysed using document analysis. [35]

Shadowing nurses in charge and doctors on call, respectively, from the medical, surgical and neurological units has been conducted to explore how CL is performed. [36] Shadowing is a research technique that involves a researcher closely following a member of an organization over an extended period of time. [36] The method can "produce the sort of first-hand, detailed data that gives the researcher access to both the trivial or mundane and the difficult to articulate". [36] To gain validity of the data, all participants read the field notes and give feedback. [36]

Efficiency includes the number of patients admitted to the ED and a variety of time variables of length of stay (i.e., arrival at triage, arrival at provider and arrival at doctor). [32] The time variables have been retrieved from the database of Emergency.

Intervention: Clinical leadership in team course

The overarching vision of the CLT course is to establish bedside values and an understanding of excellent day-to-day CL in teams, executing CL with existing resources and within the organisational structure. The development of the CLT followed the seven factors outlined by Salas et al. [37] cf. [13] The didactic model of relation [38] has guided the design of the course (figure 2). Further, the goals of the intervention have been linked to the vision and overarching goals of the hospital. [37 39]

The CLT course encompasses the six factors Hiim and Hippe. [38] All factors are mutually dependent; changes in one feature have consequences for the other features.

Please insert Figure 2 here

Required resources and time commitment were secured by the Steering Committee and the decision to allocate three days for the pilot course plus four group meetings and a facilitated session over a two-month period. [37]

Competence was ensured by a faculty consisting of individuals with a background in medicine, leadership, paramedics, pedagogy, emergency-care nursing and research. [38] Three

faculty members had long experience as simulation facilitators and Train the Trainers instructors (EUSim). To ensure understanding and relevance, the faculty also reviewed adverse events reports in the ED and took observational shifts prior to designing the workshops and scenarios. To guarantee a sustainable course and relevance to clinical practice, buy-in and ownership were secured by recruiting former course participants as future trainers. [37]

The overarching vision of the CLT course is to establish bedside values and an understanding of excellent day-to-day CL in teams, executing CL within existing resources and organisational structure. The specific objectives of the CLT for participants are to 1) function as skilled operative leaders and clinical supervisors within their clinical everyday setting, 2) understand and improve patient safety and quality, 3) understand the dynamics of patient flow, and critically and efficiently use available resources, and 4) improve trust between health personnel.

In developing the course content, both in materials and subject matter, five main contextualized topics were established: basics, behaviour, team, safety and tools. From these, subtopics were then derived. The CLT course is structured in four steps comprising introduction, theory, workshop/simulation and implementation. [13] The simulation scenarios focus on limited trauma with chest pain, lack of resources and overcrowding, prolonged length of stay in the ED, unclarified patients, bullying at work, and medication error with consequences (for details, see Olsen et al. 2015). [13] The simulation sessions were developed by analysing challenging clinical settings and patient scenarios relevant to the department in question. These were identified through pre-course discussions and the active use of the hospital incident reporting system.

Pedagogical methods include workshops, simulation, group counselling and peer-to-peer dialogue, all of which emphasize guided reflection. [40-43] The last two methods were chosen to support the implementation of CL (table 1) and to facilitate the application of trained CL skills on the job. [37]

Statistical analysis

Multilevel analysis will be performed to analyse the results. Common descriptive statistics with frequencies, percent, mean and standard deviation will be conducted to describe the study sample on the cluster level. The differences in the outcomes measures will be evaluated on a team or individual level. Differences in the distribution of sex, age groups, level of education etc. and results from the QPP questionnaire between pre and post-test will be analysed by *t*-test, the Mann-Whitney test and analysis of variance (ANOVA). To identify differences between the percentages of patients admitted to the different specialties and triage codes, the chi-square test will be used. The chi-square test will also be conducted to identify differences between the pre- and post-test in time variables. Correlations will be used to analyse the difference in assessment of crowding from doctors and nurses. All analyses will be carried out using the Statistical Package for Social Sciences, SPSS v.20. A p-value <0.05 is regarded as statistically significant.

Qualitative data analysis

To ensure trustworthiness in the analysis, analyst triangulation and member checks will be applied. [44] The research team will discuss and refine the analysis according to the research questions and themes emerging in the data. The FGI will be analysed by conducting content analysis. [45] The summary of the dialogue meeting will be analysed using document analysis. [35] The summaries will act as important data material in the formative evaluation of organizational processes taking place and changes during the study period.

The analysis of shadowing doctors and nurses will be conducted by the first author. The method described by Coffey and Atkinson [46] will be used to analyse and interpret the data.

Dissemination

Results of the CLT course study will be reported according to a pre-determined publication policy approved by all members of the research team. Study results will be disseminated via scientific conferences and publications; presentations to health care providers, and meetings with stakeholders.

Study status

The CLT course study run-in period began in August 2013. Data collection will continue until June 2016.

Discussion

The discussion of the study protocol has been structured in three parts, including discussion of the study design, outcome criterion and the CLT course (the intervention).

Study design

The strengths of trailing research design is the flexible use of knowledge collected through participation and dialogue in combination with knowledge acquired and interpreted through traditional scientific methods. [47] Another advantage of trailing research is the capacity to follow up changes in the project through monitoring, feedback and feed-forward loops. [47] To improve validity and achieve rigour in trailing research data, the data in this study will be assessed from different sources. The quality of observations will be achieved by prolonged and persistent observations in the ED. [48] Participatory validity will be obtained by participant confirmation of the "shadowing" transcription and feedback on results in the dialogue meetings. [48] Rigour will be achieved by the transparency with which the data are generated and how events are questioned and interpreted in the formative and summative evaluation.

The challenges with trailing research revolve around the performance of the intervention, finding a good balance between the content of the intervention and the advice given to adjust the intervention based on the results, and the values that guide the advice based on the dialogue meetings. Evaluation will always have a relationship with values. Therefore, it is important to reflect on one's own role as a researcher when entering social processes and how the researcher influences processes. [49]

The literature in trailing research answers questions regarding "technical" issues, but not how difficult questions linked to researcher relations and roles should be solved in the clinical field. The researcher should be aware of the challenge of shifting between closeness and distance regarding the research as well as feelings related to personal and ethical issues. [23 50] Usually, this is strengthened if the researcher knows the field, but can, of course, result in confusion if the researcher witnesses unethical practices and acts. The ways the researchers solve difficult situations have consequences for them, the research and the participants.

The study design used in this study has several weaknesses. [51] Firstly, the monitoring of time variables, such as length of stay, may be atypical and apart from the mandate. To eliminate some alternative explanations for change in time variables, data have been collected every six months over an extended period of one-and-a-half years. Secondly, any other events (history) between the pre- and post-test, which represent a threat to internal validity, may cause an effect that has alternative explanations. Implementations of similar courses and changes in routines and organization in the intervention period will be monitored and evaluated as historical threats. [52] The current design is considered practical in a natural setting, but difficult or impossible to deliver as a random intervention to some people but not to others in the ED. Thus, results are usually less conclusive because causal inferences cannot be made. [51]

Outcome criteria

Establishing the outcomes of the intervention was challenging, partly due to the length and complexity of the causal chains linking interventions with outcomes. [53] Additionally, the effectiveness of training programs is more difficult to measure because a wide range of variables unrelated to the training intervention can mediate both the training process and the outcome. Dreschner et al. [54] suggest that these variables need to be considered if it is to be established whether an outcome is due to the training interventions or other unrelated factors.

The outcome of this study is linked to four values outlined in the theoretical framework. Since the main purpose of the intervention is to improve quality of care and patient safety in the ED, it is critical patient-centred outcomes such as experience and quality of care should be taken into account. [53] A number of instruments exist to measure patient-reported outcomes, such as the Patient Judgements of Hospital Quality. [55] In Norway, only a few instruments measuring patient-reported outcomes have been translated and validated. Instruments measuring satisfaction/quality of care for patients admitted to the ED are rare. [56] Therefore, the QPP survey [28] was considered appropriate for acutely ill patients 24 hours after admission in the ED. The lack of patients' experience of their illness in the survey may have increased the risk of bias. Although TEAM [30] was constructed to observe critical emergency teams, the instrument was considered manageable and suitable for observing quality of team performance in all teams in the ED. The fact that a variety of time variables have been used to measure efficiency in the ED helped decide how to measure efficiency. [56 57] Inter-professional trust is not a well-studied phenomenon in the ED [58], which implies a qualitative, explorative design to capture the experiences of inter-professional trust among doctors on call and nurses in charge. [51]

The intervention

Several factors may influence the effectiveness of the intervention. [59] Consequently, several aspects of the intervention need to be assessed and evaluated. [52] The aspects include assessment of learning needs, duration of educational activity, group composition, active participants and use of opinion leaders. [59]

Previous research demonstrates a mixed picture regarding the impact of assessment of learning needs, from no consistent effect to significant effect on learning. [59] The content and format of the CLT course have been developed by the faculty based on the evidence-based factors [37], which emphasizes organisational goals more than individual learner goals. With reference to previous research, the result of the study can go both ways. In this regard, the participants' motivation can be significant in the explanations of the study results. [60]

The duration and frequency of the CLT course will have an influence of effectiveness. One review [61] demonstrates that continuing education lasting one day is less effective than education lasting several days, but little difference exists between education of two days and education of longer duration. The process of reflection is considered critical for learning in clinical practice. [62] To meet the recommendations for the duration of the program, the CLT course facilitates further reflection in group counselling lasting three months. A sustainable change in how CL is performed by doctors and nurses will be demonstrated by the study results. Nevertheless, to create a successful, large-scale improvement program in the long term requires administrative and organizational implementation strategies in the hospital. [59]

Group composition has an impact on the effect of the CLT course, where participants from one organization are preferable. [59] The departmental management selects the participants in the CLT course. Doctors represent the medical, surgical and neurological department, while all nurses represent the ED. Future evaluation will demonstrate whether the selection process and participants from different cultures with different motivations will have an impact on the results. Another factor that has an impact on the effectiveness of the intervention is active participants. [59] Participants are active in large parts of the CLT course, and the educational activities are therefore consistent with existing knowledge.

The last factor that may have a moderate influence on the results is the use of opinion leaders. [59] Opinion leaders have different roles, and structured methods are available to identify them. Since departmental management selects the participants in the CLT course, this factor has not been carefully considered. In future, such consideration may decide which faculty members are chosen to conduct new courses.

The results of the study will allow a greater understanding of whether the intervention is effective and how the CLT course tailored for the ED will have an impact on changes in the course curriculum, changes in the study protocol and in procedures in the ED and other units. Finally, our results will be useful to the Steering Committee and the top leadership of the hospital in future decisions and the distribution of the CLT course in the departments of medicine and surgery. The results will contribute to the bank of available research data that can be used to develop better health care services for patients admitted to hospitals.

Contributorship statement SEH drafted the manuscript. SEH and ØEO participated in the design of the study and performed the qualitative analysis, and SEH performed the quantitative analysis. SEH and ØEO have provided input, protocol and study

design revision. All authors read and approved the final manuscript.

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Data sharing statement Additional unpublished data from the study will only be available for the authors of the manuscript.

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Table 1 Characteristics of trailing research (Stensaker 2013, p.152)

Objective	Scientific knowledge Provide real-time feedback to organizations Enable learning and collaborative knowledge generation
Role of researcher	Critical outsider yet integrated insider Not an active change agent and has no explicit stake in change outcomes Dialogue partner and trustful relationship with "insiders"
Respondent- researcher relationships	Often formal contract based Division of roles (researcher/participants/stakeholders)
Timeframe	Contemporary

Table 2 Inclusion and exclusion criteria

Inclusion criteria

Patients admitted to the ED must be:

-Norwegians 18 years or older

-able to read and write

-transferred from the ED to surgical, medical or neurological units

-admitted to the hospital a minimum of 24 hours ago.

Healthcare professionals:

-Doctors on call, nurses in charge, and other doctors and nurses that work daily in the ED, both in ad hoc teams and in permanent positions.

Exclusion criteria

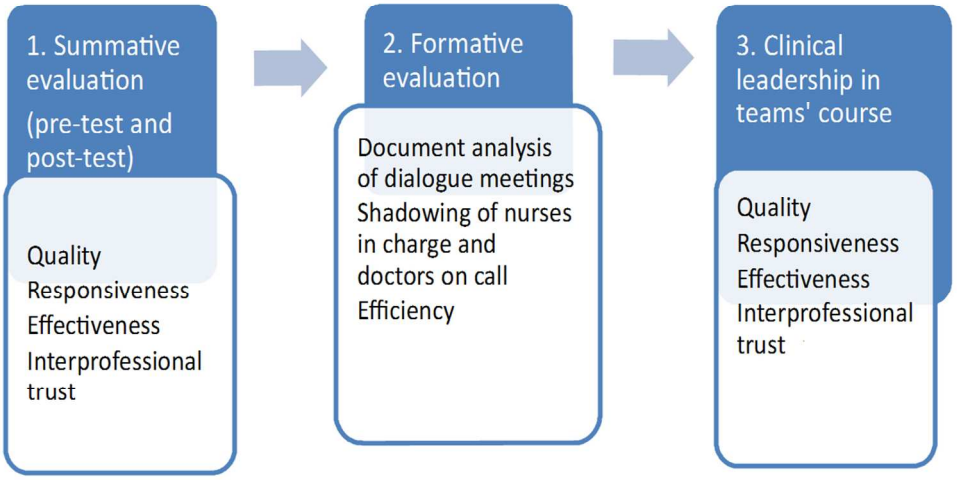
-Patients with severe illness who have been transferred from the ED to other acute care units (i.e., intensive care units, cardiac units and operating theatres)

-Patients who have been diagnosed as demented or depressed by a health care professional and incapable of being medically fit to answer the questionnaire.

Table 3 Concepts, operationalization of the concepts, sample and data collection in the summative (pre- and post-test) and formative evaluation.

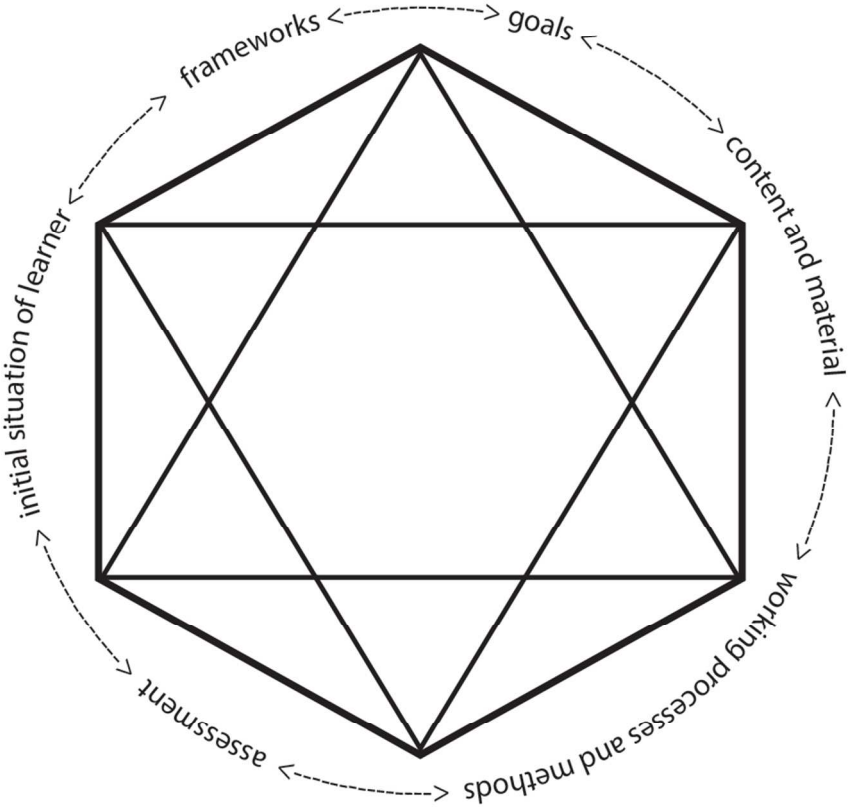
Summative evaluation (pre- and post-test)		
Concepts	*Operationalization of the concepts*	*Sample and data collection*
Quality	Quality from the patient's perspective	Randomized sample; 'Quality from the Patient's Perspective' (QPP) Questionnaire (Larsson & Larsson, 2002)
	Quality of team performance	Convenience sample on team level; "Team Emergency Assessment Measure (TEAM)" Observation (Cooper et al., 2012)
Responsiveness	Responsiveness from the patient's perspective	Randomized sample; WHO "World Health Survey - Health System Responsiveness" subscale 7.4-7.5 (Q7100-Q7107) Questionnaire
Efficiency	Flow, length of stay, crowding and reasons for crowding, providers' perception of managing high workflow	The numbers of patients and a variety of time variables of length of stay will be retrieved from the database of Emergency. How nurses in charge and doctors on call perceive their abilities in managing several patients at the same time (Doyle et al., 2012)
Inter-professional trust	Characteristics of inter-professional trust	Purposeful sample; focus group interviews with doctors on call and nurses in charge
Formative evaluation		
Reflection and learning	Dialogue meetings	Document analysis of dialogue meetings
Quality	Performance of clinical leadership	Convenience sample; shadowing doctors on call and nurses in charge
Efficiency	Flow and length of stay	The numbers of patients and a variety of time variables of length of stay will be retrieved from the database of Emergency.

Figure 1 Components in the current study



110x63mm (300 x 300 DPI)

Figure 2 Illustration of the didactic model of relation (Hiim & Hippe, 1998)



92x91mm (300 x 300 DPI)