Effects of Using High-Fidelity Simulation on Nursing Students' Recognition of and Response to Deteriorating Patients

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SUMMARY

Background: Nurses must contend with rapid changes in technology and ways of managing acute patient deterioration events in today's dynamic clinical practice environment. During an undergraduate programme in nursing, it is vital that nursing students learn how to assess, recognise and respond to patients' acute deterioration, but no guarantee exists that their clinical studies will provide sufficient exposure to learning situations needed to achieve full competence as a nurse. Increasing attention to patient safety has decreased the number of clinical placement opportunities for nursing students, and the use of simulated learning in undergraduate nursing education may be a necessary strategy to educate registered nurses who are better prepared for clinical practice.

Aim: The overall aim of this three-year PhD project was to evaluate the efficacy of using high-fidelity simulations in undergraduate nursing education.

Designs, methods and samples: In Study 1, a systematic review and meta-analysis were conducted, comprising 14 journal articles. Study 2 was a feasibility study to develop and validate a questionnaire to measure a high-fidelity simulation intervention's effects on undergraduate nursing students' knowledge and levels of self-confidence. A pre- and postintervention design was used on 107 undergraduate nursing students from two campuses at one university in southern Norway. Embedded within the study, eight undergraduate nursing students participated in individual interviews. Study 3 was a randomised, controlled trial with a pre- and postintervention design. A total of 158 undergraduate nursing students from three campuses at two universities in southern and eastern Norway participated. As part of a process evaluation embedded within the trial, six faculty members and five undergraduate nursing students were individually interviewed. The high-fidelity simulation interventions included in all the studies aimed to improve participants' ability to recognise and respond to deteriorating adult patients, and they included the use of human patient simulators.

Results: The studies included in the meta-analysis reported an increase in knowledge and skill performance among the intervention groups compared with the control groups, though only one out of three interventions showed an increase

in self-confidence in favour of high-fidelity simulation. Most of the knowledge items and all the self-confidence items in Study 2 did not cover the zero value when calculating the difference between the proportion of participants with increased and decreased correct knowledge responses or higher or lower self-confidence levels on each item. Therefore, they identified an increase in knowledge and self-confidence after the intervention. In Study 3, the Wilcoxon-Mann-Whitney rank-sum test adjusted for tied observations, showed a statistically significant increase in the number of total correct responses on knowledge in the intervention group compared with the control group ($p=0.004$). Regarding the three groups of items referring to the knowledge of 'normal values', 'clinical changes' and 'nursing procedures', results showed statistical evidence of intervention effects on items referring to 'clinical changes' ($p=0.04$) and 'normal values' ($p=0.005$). Global levels of perceived self-confidence identified a statistically significant increase in intervention effects on items referring to 'clinical changes' ($p<0.0001$). Undergraduate nursing students in this PhD project identified a safe environment, learning in different roles and fidelity as necessary and important enablers that impact successful implementation of high-fidelity simulation interventions. From the faculty members' perspective, creating a safe environment, promoting reflection and student-centred learning were reported to be important enablers for successful implementation.

Conclusions: The results indicated that knowledge and self-confidence levels in undergraduate nursing students who receive a tailored educational programme that includes high-fidelity simulations will increase compared with nursing students who do not attend high-fidelity simulations on topic recognition and response to acute patient deterioration.

SAMMENDRAG

Bakgrunn: Sykepleiere må håndtere rask teknologisk utvikling i dagens helsetjeneste, som kan medføre endringer i sykepleien til akutt dårlige pasienter. I løpet av bachelorutdanningen i sykepleie er det avgjørende at studenter lærer å vurdere og identifisere tegn til akutt forverring i helsetilstanden til pasienter, og hvordan de kan handle adekvat i slike situasjoner. Det er ikke en garanti at studenter gjennom de kliniske studiene i bachelorutdanningen vil møte situasjoner som kan gjøre de mer rustet til å håndtere akutte situasjoner som ferdig utdannede sykepleiere. Økt fokus på pasientsikkerhet har redusert muligheten for sykepleierstudenter til å være til stede i akutte situasjoner i klinisk praksis. Bruk av fullskalasimulering i bachelorutdanning i sykepleie kan være et godt tilbud for å utdanne sykepleiere som er bedre forberedt til å håndtere akutte situasjoner i klinisk praksis.

Hensikt: Den overordnete hensikten med dette treårige doktorgradsprosjektet var å evaluere effekten av å bruke fullskalasimulering i bachelorutdanning i sykepleie.

Design, metoder og utvalg: Studie 1 er en systematisk kunnskapsoppsummering og meta-analyse, hvor 14 publiserte artikler ble inkludert. Studie 2 er en feasibility studie, der et spørreskjema for å måle kunnskapsnivå og grad av selvtillit hos sykepleierstudenter etter en intervensjon med fullskalasimulering, ble utviklet og validert. Et forskningsdesign med måling før og etter en intervensjon med fullskalasimulering ble brukt, og totalt 107 sykepleierstudenter i bachelorutdanning fra to campuser ved et universitet i Sør-Norge deltok. I tillegg deltok 8 av disse studentene i individuelle intervju. Studie 3 var en randomisert kontrollert studie, der måling ble gjort før og etter en intervensjon med fullskalasimulering. Totalt 158 sykepleierstudenter i bachelorutdanning fra tre campuser ved to universitet lokalisert sør og øst i Norge deltok. Fem av disse studentene og seks lærere på bachelorutdanning i sykepleie deltok også i individuelle intervju som ledd i en prosessevaluering av intervensjonen. Alle intervensjonene med fullskalasimulering inkludert i dette doktorgradsprosjektet hadde som hensikt å forbedre sykepleierstudenters evne til å identifisere og

respondere på akutt forverrelse i helsetilstanden til pasienter, og de inkluderte bruk av en pasientsimulator.

Resultater: Alle studiene som ble inkludert i meta-analysen viste en økning i kunnskapsnivå og ferdigheter hos deltakerne som deltok på en intervensjon med fullskalasimulering sammenlignet med de som ikke gjorde det. Når det gjelder økning i opplevelse av selvtillit, viste meta-analysen derimot bare økning i en av totalt tre studier. De fleste av kunnskapsspørsmålene og alle spørsmålene knyttet til opplevelse av selvtillit i studie 2 overskred ikke nullverdien når forskjellen på prosentpoeng mellom deltakere med forbedret resultat sammenlignet med dårligere resultat etter intervensjonen på hvert spørsmål ble regnet ut. Vi kan derfor si at en økning i både kunnskapsnivå og opplevelse av selvtillit ble identifisert etter intervensjonen. I studie 3 viste Wilcoxon-Mann-Whitney rank-sum test justert for parede data en statistisk signifikant økning i totalt antall korrekte svar på kunnskapsspørsmålene i intervensjonsgruppen sammenlignet med kontrollgruppen ($p=0.004$). I forhold til de tre hoveddimensjonene av kunnskap knyttet til «normale verdier», «kliniske endringer» og «sykepleieprosedyrer», ble det identifisert en statistisk signifikant økning etter intervensjonen både for «normale verdier» ($p=0.005$) og for «kliniske endringer» ($p=0.04$). En statistisk signifikant økning ble også identifisert etter intervensjonen i opplevelse av selvtillit knyttet til «kliniske endringer» ($p<0.0001$). Sykepleierstudenter beskrev et behov for trygt læringsmiljø, å få lære i ulike roller og oppleve realisme i simuleringsscenarioet som viktige faktorer for å lære mest mulig i en intervensjon med fullskalasimulering. Lærere i bachelorutdanning beskrev også viktigheten av å tilrettelegge for et trygt læringsmiljø for å bedre læringsmuligheter for studenter i fullskalasimulering. I tillegg understreket de betydningen av å tilrettelegge for refleksjon og at fullskalasimuleringen har studentene og deres behov i fokus.

Konklusjoner: Resultatene viser at kunnskapsnivå og opplevelse av selvtillit vil øke mer hos sykepleierstudenter som gjennomfører et undervisningsopplegg med bruk av fullskalasimulering, der temaet er hvordan man kan oppfatte og reagere på akutt endring i helsetilstand til pasienter, sammenlignet med sykepleierstudenter som ikke deltar på fullskalasimulering.

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Paper 2

Haddeland, K., Slettebø. Å., Svensson, E., Carstens, P. & Fossum, M. (2019). Validity of a Questionnaire Developed to Measure the Impact of a High-Fidelity Simulation Intervention: A Feasibility Study. *Journal of Advanced Nursing,* 1-10. Doi: 10.1111/jan.14077

Paper 3

Haddeland, K., Slettebø, Å., Svensson, E., Tosterud, R., Wangensteen, S. & Fossum, M. (submitted 7th of November 2019). Recognition of and Response to Deteriorating Patients: A Multi-Center Randomized Controlled Trial and a Process Evaluation. *Nurse Education in Practice*

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1.0 INTRODUCTION

Today's nursing practice environment is complex and dynamic, often producing unpredictable situations. Nurses must contend with rapid changes in technology and provide care to patients with complex health problems who are at a high risk for experiencing acute deterioration events (Eyikara & Baykara, 2018). Much of these deteriorations can be signalled in the patients' physiological parameters, such as changes in respiratory rate, pulse rate, blood pressure, oxygen saturation, temperature or levels of consciousness (Urban et al., 2015). Delayed response to and the mismanagement of patient deterioration has been associated with poor patient outcomes (World Health Organization, 2020; Norwegian Directorate of Health, 2020; Saab et al., 2017), but can be positively influenced by education and experience (Odell et al., 2009). The early detection of patient deterioration is therefore an important focus for evidence-based curriculum development in undergraduate nursing education (Buykx et al., 2011).

Early Warning Systems (EWSs) are designed to facilitate the early detection of clinical deterioration and are based on an aggregate scoring system in which a score is allocated to the patient's key physiological parameters (Saab et al., 2017). Examples of EWSs used include the Modified Early Warning Score (MEWS) (Urban et al. 2015) and the National Early Warning Score (NEWS) (Royal College of Physicians, 2017). NEWS was first produced in 2012 and updated in December 2017 (NEWS2) (Royal College of Physicians, 2017). Although these EWSs can be implemented by ward nurses as part of the clinical assessments of patients, research indicates that EWSs are not always implemented, used or they can be misinterpreted (Stayt et al., 2015; Kelly et al., 2014; Odell, 2014). Failure to recognise and respond appropriately to acute patient deterioration events can include factors such as lack of knowledge, skills and/or self-confidence; failure to seek assistance; inadequate communication; and lack of role clarity (Hart et al, 2014).

During an undergraduate programme in nursing, it is vital that students learn how to recognise and respond to the management of deteriorating patients (Cooper et al., 2010). The government regulates the structure and content of undergraduate nursing education in Norway through a law that manages higher education (Ministry of Education & Research, 2005) as well as national regulations relating to a common curriculum for health and social care education

(Ministry of Education & Research, 2019a). Starting in autumn 2020, new national curriculum laws will regulate nursing education (Ministry of Education and Research, 2019b). In addition to national curriculum regulations, the Norwegian Agency for Quality Assurance in Education (NOKUT, 2020) is an independent expert body under the Ministry of Education and Research that contributes towards quality assurance and enhancement in undergraduate nurse education. Furthermore, nursing education in Norway is regulated by European policies for higher education, such as the Bologna process (Kyrkjebø, Mekki & Hanestad, 2002; Råholm, Hedegaard, Löfmark & Slettebø, 2010), The European Qualification Framework (Ministry of Education & Research, 2011) and The World Health Organization's European standards for nursing and midwifery (Keighley, 2009). The International Council of Nurses (2020) and the Norwegian Nurses' Organization (Norsk Sykepleierforbund, 2020) also play active roles in discussions about the content and quality of nursing education in Norway (Kyrkjebø et al., 2002).

All educational institutions in Norway are required to establish and maintain a study programme containing a plan for the sequence of courses leading to the degree. The study programme also specifies learning outcomes that are aligned with national and international curriculum regulations, comprising the skills and knowledge that students are expected to acquire—if they complete the programme. Out of the 180 credits in the nursing programme, 90 credits comprise theory and 90 credits clinical placements meeting patients (University of Agder, 2020). The clinical placement is mainly supervised by clinical nurses. It aims to integrate theoretical knowledge into practical knowledge in real-life situations and help students develop their critical-thinking and problem-solving skills (Kim, Park & Shin, 2016). However, no guarantee exists that clinical placements will expose nursing students to sufficient learning situations to ensure they acquire the knowledge and skills to manage acute patient deterioration events that a competent nurse requires. Clinical nurses are under pressure, coping with limited resources in clinical practice. At the same time, the demands to improve quality in practice and enhance patient safety are crucial. These conditions present learning challenges and have implications for nursing education (Dahlgren et al., 2019). Increased attention to patient safety has decreased the number of clinical placement opportunities for nursing students (Lee et al., 2017; Shin, Jin-Hwa, & Jung-Hee, 2015), thereby limiting students' hands-on experience and restricting opportunities to engage in acute patient

deterioration events. The extant literature has highlighted the fact that a gap exists between expected learning outcomes for newly graduated nurses and leaders' expectations in clinical practice (Burgess, Buc & Brennan, 2018; Huston et al., 2018). Therefore, increased use of high-fidelity simulation (HFS) in nursing education may be an effective strategy to address this gap (Huston et al., 2018). According to the International Nursing Association for Clinical Simulation and Learning's (INACSL) Standards of Best Practice in Simulation (2016), *simulation* can be defined as '*an educational strategy in which a particular set of conditions are created or replicated to resemble authentic situations that are possible in real life'* (p. 44).

The overall aim of this three-year PhD project was to evaluate the efficacy of using HFS in undergraduate nursing education. First, a systematic review and meta-analysis were undertaken in Study 1, then a feasibility study (Study 2) was conducted to develop and validate a questionnaire before using it in a randomised controlled study (Study 3).

1.1 The disposition of the thesis

After this introduction, Chapter 2 presents the PhD project's various aims. Chapter 3 provides background information concerning HFS used in undergraduate nursing education, and Chapter 4 presents this PhD project's theoretical framework and how it aligns with the simulated context. Chapter 5 presents the PhD project's overall design as well as the methods and results from the three studies in the PhD project. Chapter 6 provides a summary of the PhD project's overall results, and Chapter 7 offers a discussion of the results and provides methodological considerations. Finally, in Chapter 8, conclusions are drawn, and implications for practice and suggestions for further research are presented.

2.0 AIM AND RESEARCH OBJECTIVES

2.1 The PhD project's overall aim

This PhD project's overall aim was to evaluate the efficacy of using HFS in undergraduate nursing education. The HFS intervention evaluated has been used in specific undergraduate nursing programmes for several years, and the PhD student has not been involved in developing the HFS intervention. Evaluating complex interventions, such as HFS interventions in this PhD project, is complicated. The Medical Research Council's (MRC) framework (Craig et al., 2008) for developing, evaluating and implementing complex interventions forms the basis of this PhD project. Complex interventions are described as interventions that contain several interacting components, and the MRC's guidelines emphasise the need for high-quality systematic reviews of relevant existing evidence and theory (Study 1) and feasibility work (Study 2) before embarking on a full-scale evaluation (Study 3) (Craig et al., 2008). The MRC's guidelines also call for process evaluation through qualitative interviews embedded within trials as a means of understanding why an intervention fails or has unexpected results or why a successful intervention works and how it can be optimised (Moore et al., 2015; Craig et al., 2008). A process evaluation embedded within a trial can be used to assess the fidelity and quality of its implementation, clarify causal mechanisms and identify contextual factors associated with various outcomes of trials of complex interventions. However, it is not a substitute for the evaluation of outcomes (Craig et al. 2008). Qualitative interviews in this PhD project were conducted in Study 2 and Study 3 as process evaluations embedded within the trials, not as separate studies.

Study 1's objective in this PhD project was to summarise knowledge and systematically collect and quantify meta-analytical results regarding the effects of HFS in undergraduate nursing education to improve students' ability to recognise and respond to deteriorating patients. The feasibility study's (Study 2) overall aim was to evaluate the validity and responsiveness of a questionnaire developed to measure the impact of an HFS intervention. In Study 3, the overall aim was to examine the effects of an HFS intervention developed to identify how recognising and responding to patient deterioration improve undergraduate

nursing students' knowledge and self-confidence. Figure 1 shows the studies' order and time frames.

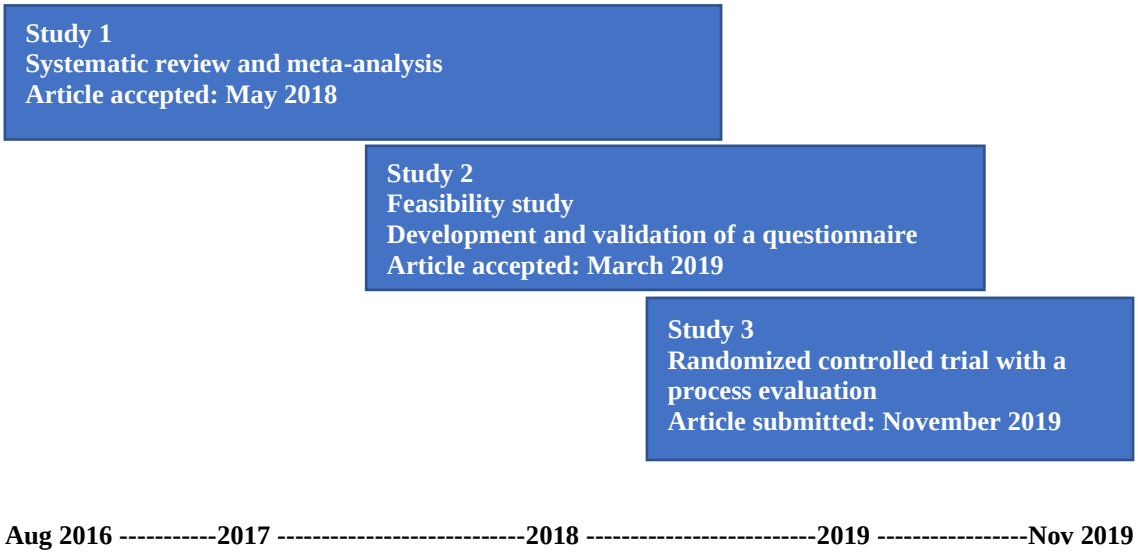


Figure 1. Overview of the research process in this PhD project.

2.1.1 Study 1

The specific research questions in Study 1 were:

1) What are the features of HFS interventions that lead to effective learning?
2) Which instruments are used to measure the outcomes in the intervention studies?
3) What are HFS interventions' effects on students' knowledge, performance and self-confidence?

The study served as important preparation for planning a future randomised, controlled trial.

2.1.2 Study 2

Study 2's specific aims were to:

1) Develop a questionnaire to measure undergraduate nursing students' acquired knowledge and self-confidence regarding an HFS intervention.

2) Evaluate the validity and responsiveness of the items of knowledge and self-confidence.

Responsiveness refers to a questionnaire's ability to detect clinically important changes in outcomes after an intervention (Svensson et al., 2015). The study design's use of identical questionnaires before and after interventions implies evaluations of changes in paired data. As recommended by Craig et al. (2008), process evaluations were embedded within the trial to determine face validity and comprehensiveness. The methodological and statistical approaches used, and the evaluation of the findings, provided useful information for the forthcoming design of the randomised controlled study.

2.1.3 Study 3

Study 3's specific aim was to:

1) Describe and estimate changes in undergraduate nursing students' knowledge and perceived self-confidence after an HFS intervention.

The primary hypothesis was that nursing students who receive a tailored educational programme, including HFS, will experienced increased knowledge compared with nursing students who do not attend HFS in terms of topic recognition and response to acute patient deterioration. Self-confidence was the secondary outcome. As recommended by Craig et al. (2008), process evaluations were embedded within the trial to identify the barriers and enablers that may impact successful implementation of the HFS intervention.

3.0 BACKGROUND

This chapter provides background information concerning HFS used in undergraduate nursing education. Several definitions have been chosen from the INACSL's Standards of Best Practice in Simulation (2016). This is an evidence-based framework to guide simulation design, implementation, debriefing, evaluation and research. The work has been done by numerous INACSL boards of directors, committee members and organisations to provide educators, clinicians and researchers with best practices (INACSL, 2016). The background information is also based on other relevant theory and collaboration with colleagues from the *Michael F. Sorrell Clinical Simulation Lab* at the University of Nebraska Medical Center (University of Nebraska Medical Center, 2020).

3.1 Simulation and fidelity

Simulation is increasingly being used as a pedagogical approach in nursing education (Kim, Park & Shin, 2016). Clinical simulation may be delivered using different modalities, such as actors, standardised patients and human patient simulators (Stayt et al., 2015). There is no universally accepted classification of simulation; however, it may be described as low-, medium- and high-fidelity referring to the degree of realism or authenticity (Stayt et al., 2015). INACSL's Standards of Best Practice in Simulation (2016) define *fidelity* as '*the ability to view or represent things as they are to enhance believability'* (p. 42). Furthermore, the standards say that the fidelity level is determined by the tools and resources used, the environment and other factors associated with the participants, as follows:

1. *Conceptual fidelity*: ensuring that all elements of the scenario or case relate to each other realistically so that the case makes sense to learners (e.g. vital signs reflect the diagnosis).
2. *Physical/environmental fidelity*: ensuring that factors such as environment, manikins, room, moulage, equipment, noise and/or props are realistic.
3. *Psychological fidelity*: entails factors such as participants' emotions, beliefs and self-awareness, i.e., ensuring that the simulated environment evokes the underlying psychological processes that are necessary in real-world settings (INASCL, 2016, p. 42).

This means, for instance, that a low-fidelity technical simulation can elicit a high level of emotional fidelity (Orr et al., 2013) and that simple techniques can boost the level of fidelity in simulations (Nestel, Krogh & Kolbe, 2018). Because all the simulation interventions in this PhD project using full-scale computerised human patient simulators, the simulation experiences are defined as high-fidelity simulation (HFS). However, there is no consistent, agreed-upon definition of *fidelity* or which variables should be taken into consideration when determining fidelity 'levels' (Jeffries, 2016). A simulator that is viewed as low-fidelity in one circumstance might be viewed as high-fidelity in another (Hamstra et al., 2014). Moreover, there is no conclusive evidence to show that there is a minimal level of fidelity that is required to produce significant learning outcomes (Foronda, Liu & Bauman, 2013). While Lubbers and Rossman (2017) state that the higher the fidelity level is in the simulation, the closer the simulation environment will resemble the real situation, studies such as Tosterud, Hedelin and Hall-Lord (2013) have not been able to confirm the association between self-confidence and satisfaction with the use of either low- or high-fidelity simulations. The simulated environment gives the students hands-on opportunities in a safe environment in which they can care for patients without fear of harming anyone. The advantages of simulation-based educational interventions include the ability to provide immediate feedback, repetitive practice learning, the integration of simulations into the curriculum, the ability to adjust difficulty levels, opportunities to individualise learning and the adaptability of diverse types of learning strategies (Kim, Park & Shin, 2016).

3.2 Simulations' historical background

The aviation industry first used simulations as a training method 90 years ago, when Ed Link developed a simulator to train pilots in 1929 (Johnson & Patterson, 2006). The modern aviation industry has since then developed complex, high-fidelity simulators that enable student pilots to transfer their mastery of simulated exercises to flying real aircraft. The aviation industry prepares its workforce so that they can cope with all possible scenarios, including dangerous situations, safely and competently (Murray et al., 2008). However, this approach to training and education is not unique to the aviation industry and is evident within many individual industries and disciplines. The use of simulations in health education has gained momentum over the past 40 years (Wilford &

Doyle, 2006). The first patient simulator, 'Mrs. Chase', was delivered to the Hartford Hospital Training School for Nurses in 1911 so that students could practise injections and other procedures (Jeffries, 2016). The modern era of simulation technology in healthcare began in the 1960s, when Bjørn Lind, a Norwegian anaesthesiologist, persuaded Asmund Laerdal, a maker of soft plastic tools, to develop Resusci Anne, a cardiopulmonary resuscitation mannequin (Olson et al., 2018). In 1966, Abrahamson and Denson developed SimOne, the first full-size, computer-controlled simulator that can reproduce aspects of human physiology and behaviour (Bradley, 2006). The human patient simulators which were used in the HFS interventions in this PhD project are upgraded editions of the SimOne simulator.

3.3 Phases in simulation sessions

To increase opportunities to enhance learning outcomes from simulations, INACSL's Standards of Best Practice in Simulation (2016) support creating each simulation exercise, from prebriefing to scenario to debriefing (p. 8). The HFS interventions in Study 2 and Study 3 in this PhD project included these three phases.

3.3.1 The prebriefing phase

The first phase of the simulation session, *the prebriefing phase*, can be defined as '*an information or orientation session immediately prior to the start of a simulation-based experience in which instructions or preparatory information is given to the participants'* (INACLS, 2016, p. 43). The purpose is to establish a psychologically safe environment for the participants, and suggested activities include reviewing learning objectives; creating a 'fictional contract' with ground rules for the simulation session; and orienting participants to the equipment, environment, simulator, roles, time allotment and scenario (INACLS, 2016). Creating a shared understanding from the outset of what is expected from participating in the simulation activities is important (Kelly et al., 2019). Dieckmann (2009) emphasises the importance of participants getting to know the simulator and the simulated environment through explanations, demonstrations and hands-on time to have sufficient competence to use the simulator as a tool in the scenario. Husebø et al. (2012a) highlight the pedagogical importance of the

briefing as critical in conveying the authenticity and relevance of the simulation, and for creating a framework for understanding what the simulation is actually a simulation of. A foundational part of the briefing is to both explicate the relevant similarities and to problematise the differences of relevance between simulation and clinical practice (Husebø et al, 2012a).

3.3.2 The scenario phase

The next phase of the simulation session is the scenario. INACLS's Standards of Best Practice in Simulation (2016) define a *scenario* as *'a deliberately designed simulation experience (also known as a case), that provides participants with an opportunity to meet identified objectives. The scenario provides a context for the simulation and can vary in length and complexity, depending on the objectives'* (p. 44).

A faculty member can serve as a facilitator or as a simulator operator during the simulation scenario. INACSL (2016) defines a *facilitator* as *'a trained individual who provides guidance, support and structure at some or all stages of simulation-based learning, including prebriefing, simulation and/or debriefing*' (INACSL, 2016, p. 42). The facilitator is often present in the simulation room during the simulation scenario to observe the performance and provide information if required. The *simulator operator* is placed in a control room near the simulation room. The control room houses the computer software, and the simulator operator's role is to control the patient simulator during the scenario, monitoring the scenario's progress and adjusting it. A one-way mirror separates the two rooms and allows the simulator operator to control the simulated scenario and view nursing students' actions. A microphone system is used to communicate between the simulation room and the control room.

3.3.3 The debriefing phase

The debriefing phase is the last phase of the simulation session, and it can be defined as *'a reflective process immediately following the simulation-based experience that is led by a trained facilitator using an evidence-based debriefing model. Participants' reflective thinking is encouraged, and feedback is provided regarding the participants' performance while various aspects of the completed simulation are discussed. Participants are encouraged to explore emotions and*

questions and reflect and provide feedback to one another. The purpose of debriefing is to move toward assimilation and accommodation to transfer learning to future situations' (INACSL, 2016, p. 41).

INACSL (2016) describe the following five criteria for a successful debriefing: it 1) is facilitated by a person(s) competent in the process of debriefing; 2) is conducted in an environment that is conducive to learning and supports confidentiality, trust, open communication, self-analysis, feedback and reflection; 3) is facilitated by a person(s) who can devote enough concentrated attention during the simulation to debrief the simulation-based experience effectively; 4) is based on a theoretical framework that is structured in a purposeful way; and 5) is congruent with the simulation-based experience's objectives and outcomes (p. 21-22).

Structured debriefing has been shown to improve learning outcomes (Cheng et al., 2013), and several methods for debriefings have been identified (Waznonis, 2014). INACLS (2016) recommend using the Promoting Excellence and Reflective Learning in Simulation (PEARLS) framework for debriefing developed by Eppich and Cheng (2015). The authors highlight that learning in the debriefing phase should be active, collaborative, self-directed and learner-centred. The PEARLS framework outlines four distinct phases of the debriefing, including *reactions, description, analysis* and *application* (Eppich & Cheng, 2015). In the *reactions* phase, participants have the opportunity to briefly share reactions and how they are feeling immediately after the simulation scenario. In the *description* phase, the participants describe what happened during the simulation scenario. The description phase ensures that all learners and educators have a shared understanding of the main elements of the scenario. In the *analysis* phase, the participants systematically examine the simulation scenario and what aspects they managed effectively and others that seemed more challenging. Once issues have been identified by the participants, the educator can selectively use focused facilitation techniques to promote more in-depth discussion or strive to close performance gaps through directive feedback and teaching as appropriate (Eppich & Cheng, 2015). Finally, during the *application* phase, the participants consider which courses of action they wish to include in their own future clinical practice with an emphasis on the best practice (Eppich & Cheng, 2015).

Another theoretical framework for debriefing was developed by Steinwachs (1992) and comprises descriptive, analytic and application phases, approximately as described in the PEARLS debriefing framework. Steinwachs

(1992) presents several suggestions for questions the facilitator can ask in each phase in the debriefing, and she underscores that the facilitator's job in debriefings is not to lecture or expound but to maximise idea development and group interchange. According to Steinwachs (1992), the facilitator must concentrate on how best to encourage the participants to reflect on their experiences and articulate their perspectives so that the group can explore these understandings and learn from them.

3.4 Nursing simulation research

To gain more knowledge on HFS simulation used in undergraduate nursing education and identify needs for further research in this area, literature searches were conducted. An overview of some of the research identified in the first part of this PhD project (before 2017) on what is known about the effects of using HFS in undergraduate nursing education and what is needed for further research is displayed in Table 1.

Table 1. An overview of some of the research identified at the start of this PhD project on what is known about the effects of using high-fidelity simulation (HFS) in undergraduate nursing education, and what is needed for further research.

What do we know about the effects of using high-fidelity simulation (HFS) in undergraduate nursing education?

- *Participants perceive high satisfaction from participating in HFS*
  (Mariani & Doolen, 2016; Au et al., 2016; Stayt et al., 2015; Stroup, 2014; Thidemann & Söderhamn, 2012)
- *Nursing students' experiences to identify enablers and barriers to the use of simulation have been explored*
  (Walton, Chute & Ball, 2011; Howard, Englert, Kameg & Perozzi, 2011; Parsh, 2010)
- *Increases in knowledge, performance skills and/or self-confidence have been identified after participating in HFS*
  (Kim & Kim, 2015; Stayt et al., 2015; Hart et al., 2014; Merriman, Stayt & Ricketts, 2014; Kelly et al., 2014; Lindsey & Jenkins, 2013; Thidemann & Söderhamn, 2012; Wood & Toronto, 2012; Shinnick & Woo, 2012; Liaw et al., 2011; Burns, O'Donnell & Artman, 2010; Ackermann, 2009)
- *Significant differences in assessment methods have been identified and led to a wide range of measurement outcomes*
  (Doolen et al., 2016)

What is needed for further research on this topic?

- *High-quality research that can establish a cause-and-effect relationship between HFS and learning outcomes*
  (Doolen et al., 2016; Mariani & Doolen, 2016; Fisher & King, 2013; Yan, Williams & Fang; 2011; Perry, 2011)
- *Validation of measurement instruments used in HFS*
  (Doolen et al., 2016; Yan, Williams & Fang, 2011)
- *Multi-site studies to measure the effects of HFS*
  (Doolen et al., 2016; Mariani & Doolen, 2016)
- *Evidence of the effects of HFS used specifically to prepare nursing students to recognise and respond to the deteriorating patient*
  (Stayt et al., 2015; Fisher & King, 2013)
- *Longitudinal studies to explore the effects of HFS transferability to clinical environments*
  (Mariani & Doolen, 2016; Doolen et al., 2016; Stroup, 2014; Fisher & King, 2013; Yuan, Williams & Fang, 2011)
- *Research on fidelity level, how many students should participate and in what roles, the preparation or support of faculty and simulation designs, why some things work and why it is important to include certain elements in the design of a simulation*
  (Mariani & Doolen, 2016; Page-Cutrara, 2014; Neill & Wotton, 2011)
- *Research that examines the participant's self-confidence as a co-variable*
  (Mariani & Doolen, 2016)
- *Research that measure simulations' influence on patient outcomes and safety*
  (Mariani & Doolen, 2016; Berndt, 2014; Shearer, 2013; Blum & Parcells, 2012)
- *Research that include simulations with vulnerable populations, such as mental health patients*
  (Mariani & Doolen, 2016)

After all the results in this PhD project were analysed and presented, a new updated literature search for peer-reviewed studies, written in English and published in the period from 2000 to 2020, was completed on the 27th of March (2020) in CINAHL and Medline (EBSCOhost). The search was conducted based on Study 1 in this PhD project and is displayed in Table 2.

Table 2. Literature search conducted in "CINAHL & MEDLINE (EBSCOhost)".

#	**Query**	**Results**
S1	nurs* N3 (student* OR educat* OR graduat* OR undergraduat* OR baccalaur*)	85518
S2	Simulat*	64054
S3	Self-confidence OR knowledge OR deteriorat*	231629
S4	**S1 AND S2 AND S3**	**1535**

In total, 1535 studies were identified. All the included articles in Study 1 in this PhD project were identified, 11 through the search and 3 through reference lists checks, and one additional study was identified (Williams & Spurlock, 2019). William and Spurlock (2019) tested the effects of HFS on knowledge acquisition among a total of 98 undergraduate nursing students. They found that the overall knowledge scores increased from pre-test to post-test after participating in HFS; however, this difference was not statistically significant. The sample was limited to one nursing school in the USA, and the authors recommend multi-site studies with larger sample sizes to measure the effect of HFS (Williams & Spurlock, 2019).

Based on the need for further research on simulation, as displayed in Table 1, this PhD project focuses on measuring nursing student learning outcomes. The planned research will take into account the limitations and design issues of earlier studies in this area of interest and include large sample sizes with participants recruited from different undergraduate nursing programmes. In addition, it will utilise high quality trial methodologies, that is, randomisation and tested evaluation measures. To clarify and explain the quantitative findings, process evaluations were embedded within the trials.

4.0 THEORETICAL FRAMEWORK

This chapter presents the theoretical framework and the outcomes measures that form the basis for the PhD project. Theoretical frameworks help to explain why different interventions might work and help faculty select the right intervention to achieve certain learning outcomes (Dieckmann & Reigsted, 2013). All theories on learning and knowledge development are based on fundamental assumptions about the person, the world and the person's relations to the world (Lave & Wenger, 1991). Learning theories that explain how students gain knowledge and self-confidence through HFS can broadly be categorised as *behaviourist*, *cognitivist, constructivist* and *social learning theories* (Bearman, Nestel & McNaughton, 2018; Dieckmann & Ringsted, 2013).

Behaviourist learning theories align most easily with worldviews that are concerned with objective truths and measurements. Learning is seen as a result of external influences. These theories are less concerned with the internal mechanisms of students, such as mental state or consciousness, and more with their behaviours, which can be observed (Bearman, Nestel & McNaughton, 2018). As a reaction to behaviourism, cognitivist learning theories are interested in the mental processes involved in learning. Within the cognitivism paradigm, the learner is viewed as an active participant in which actions are a consequence of thinking. This view is related to the constructivism paradigm, which emphasises learning as grounded in the potential for human growth, recognising humans' responsibility and wish for self-realisation and autonomy. Social learning theories emphasise that learning occurs in the interaction with other people and the environment (Dieckmann & Ringsted, 2013).

Most of the data in this PhD project are quantitative, based on measurements of the students' knowledge and levels of self-confidence after participating in HFS. Measurable outcomes and behavioural learning objectives align to the behaviourist learning theories, which embrace a pedagogy built upon precision, rigour, analysis, measurements and outcomes (Battista & Nestel, 2019; Bearman, Nestel & McNaughton, 2018). Nursing practice is full of simple and complex practices, which should occur automatically without thinking deeply about how to complete the tasks when doing them. These activities can include measuring the patients' vital signs, such as blood pressure and pulse rate, and knowing how to respond to acute patient deteriorating events, as in this PhD

project. These activities are often well taught in HFS due to the emphasis on repetitive practice to ensure automaticity (Bearman, Nestel & McNaughton, 2018). A learning theory that draws from behaviourist principles and has relevance to HFS is *deliberate practice* (Ericsson, Krampe & Resch-Römer, 1993).

However, the results of learning in this PhD project are based on the students' self-assessments after active involvement in HFS. Learning how to recognise and respond to the management of deteriorating patients requires mental processes while the students are in interaction with others in the simulated environment. The HFS intervention is complex, and the learning objectives include more than psychomotor skill acquisition. According to Dieckmann (2009), a simulation setting should be considered as a social practice (s. 41). Two influential theoretical contributions to simulation in healthcare focus on the students' individual mental processes (Kolb, 1984) and learning as a dimension of social practice (Lave & Wenger, 1991). The theories of *deliberate practice*, *experiential learning* and *situated learning* will be presented in the following sections, as a combination of them is seen as beneficial in this PhD project. A concept based on these three learning theories, *patient-focused simulation* (Nestel & Kneebone, 2010), will serve as a summary. At the end of this chapter, the chosen learning outcomes in Study 2 and Study 3 in this PhD project will be presented.

4.1 Deliberate practice in the context of simulation

Deliberate practice was conceptualised by Anders Ericsson, a cognitive psychologist who sought to understand how elite performers achieve excellence (Ericsson, Krampe & Resch-Römer, 1993). From this empirical basis, he concluded that a necessary part of excellence was the notion on focused, repetitive practice. He identified a set of conditions in which practice had been uniformly associated with improved performance. Significant improvements in performance were realised when individuals were given a task with a well-defined goal, motivated to improve, provided with immediate feedback and provided with ample opportunities for repetition and gradual refinements of their performance (Ericsson, 2008). Like many approaches, this is not purely behaviourist in its approach, but there are key elements, such as defined learning

objectives and rigorous, precise measurements of demonstrated behaviours, that align with behaviourism (Bearman, Nestel & McNaughton, 2018).

In a critical review, McGaghie et al. (2011) noted a number of best practices in simulation that draw from behaviourist principles, and deliberate practice was one of these. Wayne et al. (2006; 2005) found that skill acquisition increased under more stringent deliberate practice among internal medicine residents using simulation. Liou, Chang, Tsai and Cheng (2012) examined the effects of a deliberate practice programme on nursing students' perception of clinical competence. They found that participants who practiced skills by watching videos exhibited a significantly higher post-test competence and suggest providing deliberate skill-practice programmes to help students increase their competence. Smallheer, Hunt and Smith (2018) used deliberate practice as a theoretical framework for using HFS among nursing students, and they identified increased self-confidence among the participants after participating in HFS. As a final example of studies using deliberate practice in simulation, Pukenas et al. (2014) found improved intraoperative handoff communication and retention of skills at one year among anaesthesiology residents after participating in simulation-based education with deliberate practice.

4.2 Experiential learning in the context of simulation

Experiential learning theory was developed by David Kolb in 1971, and he defined learning as 'a process whereby knowledge is developed through a combination of a grasping and transforming experience' (Kolb, 1984, p. 41). He believes that learning relies on reflective observations as an individual progress from being involved to thinking about the experience and assimilating it into abstract concepts for future actions. He describes an experiential learning cycle as containing four related parts of concrete experience, reflective observation, abstract conceptualisation and active experimentation (Kolb, 1984). According to Kolb (1984), the experience is used as the major source of learning, but both thinking and doing are required and must be related in the learner's mind.

Schön (1983) is also concerned with the importance of reflection. Schön describes two types of reflection—reflection-in-action and reflection-on-action. Reflection-in-action is the self-monitoring that occurs while an individual is engaged in an experience, with the artistry that the practitioner displays as knowledge from past experiences integrated into an unfamiliar situation. Schön

(1983) states that this response's level is influenced by the structure of the institution, the profession's body of knowledge and the practitioners' competence. Reflection-on-action is the conscious review of an interaction once it is completed. The goal of reflection-on-action is to critique an event to discover new understandings with the intent to apply new knowledge to future practice (Schön, 1983). Moon (2013) identifies characteristics of reflective practice as involving cognitive processes, involving a strong critical element, reviewing and reconstructing ideas with the aim to improve practice, aiming for self-development and having emotional involvement (Husebø, O'Regan & Nestel, 2015).

Numerous research studies examining the effects of using HFS in undergraduate nursing education report that Kolb's experiential learning theory (1984) guided the studies (Williams & Spurlock, 2019; Strickland & March, 2015; Kameg, Englert, Howard & Perozzi, 2013). Kameg, Englert, Howard and Perozzi (2013) sought to determine whether simulation enhanced students' theoretical knowledge and retention of knowledge related to the content of three simulation scenarios. The theory was used to explain how students' engagement in a simulated experience could result in knowledge acquisition. The simulation scenarios and the debriefing questions were developed to support problem-solving, decision-making and reflection, which are associated with enhanced learning in Kolb's theory (1984). The study did not reveal improved student knowledge following the HFS experiences. However, students responded positively to the simulation experiences, indicating agreement that the HFS experience helped them to better understand nursing concepts (Kameg, Englert, Howard & Perozzi, 2013).

4.3 Situated learning in the context of simulation

Lave and Wenger (1991) focus on the relative aspects of learning. The most important element of their theory on situated learning is the concept of community of practice. They think that students in higher education are all participants in different communities of practice and that knowledge is related primarily to the community, not the individual. They do not see learning as 'a one-person act' but a process that takes place in a participatory framework. Participating in a team is central in simulation settings. Patient simulation scenarios combine human, technical and social elements and interactions. To

participate in a simulation intervention in a meaningful way, one needs to know, understand and apply its rules (Dieckmann, 2009). Simulations can provide an opportunity to learn while participating in a community of practice. According to Lave and Wenger (1991), the members of the practice community get access to it by participating in actions in the social community. They describe the term *legitimate peripheral participation* as an analytical tool to understand how the learning process occurs in a practice community. It is not an educational form or a pedagogical strategy but a way to understand learning. Newcomers, who are on the periphery of the practice community, learn from their more experienced colleagues ('old-timers'). As newcomers increasingly master the tasks, legitimacy increases, and they move from the periphery to become full-fledged members of the practice community. Lave and Wenger (1991) use the terms *peripheral participation, partial participation* and *full participation* to show the diversity and variations in the learning process.

Lave and Wenger (1991) focus on the relationship between learning and the social situations in which it occurs. Activities, tasks, functions and understandings do not exist in isolation and are part of the broader system of relationships in which they have meaning. This can easily be linked to the simulation context, in which the individual learner is not gaining a discrete body of abstract knowledge that he or she then will transport and reapply in later contexts. Instead, he or she acquires the skills to perform by actually engaging in the specific context. The generality of any form of knowledge always lies, according to Lave and Wenger (1991), in the power to renegotiate the meaning of the past and future in constructing the meaning of present circumstances.

According to Lave and Wenger (1991), identity, knowing and social membership are all related. Developing identity as a nurse is an important aspect of nursing education and is tied strongly to a conception of motivation. Participating in a social practice such as a simulation setting can be a valuable contribution in developing an identity as a nurse. Dieckmann (2009) argues that identity constructions occur in practice rather than through teaching. If the person is both a member of a community and an agent of activity, Lave and Wenger (1991) argue that the concept of the person closely links meaning and action in the real world. Rather than asking what kind of cognitive processes and conceptual structures are involved, Lave and Wenger (1991) ask what kind of social engagements provide the proper context for learning to take place. The common element here is the premise that meaning, understanding and learning

are all defined relative to actional contexts, not to self-contained structures. This means, among other things, that they are mediated by the differences of perspective among the co-participants. In a simulated setting, several participants learn by sharing their perspectives on the same situation.

Theories on situated learning have been highlighted in simulation (Liebrecth & Montenery, 2016; Wyrostok, Hoffart, Kelly & Ryba, 2014). Wyrostok, Hoffart, Kelly and Ryba (2014) used situated cognition as a learning framework for international end-of-life simulation. They found that the students' rating of the learning outcomes indicated that they had gained a great deal of insight into the specific skills, behaviours and attributes required. Liebrecht and Montenery (2016) suggests that confidence and competence related to the skills of therapeutic communication, interpersonal interaction, empathy, active listening, teamwork, delegation and professionalism may improve among nursing students after participating in simulation.

4.4 Patient-focused simulation

Deliberate practice, experiential learning and situated learning were developed in real settings, and this must be taken into account when using it in HFS (Bearman, Nestel & McNaughton, 2018). All these learning theories are important contributors to HFS and can help faculty when planning and organising HFS. However, a combination of them is seen as beneficial in this PhD project.

Drawing on these three theories, Nestel and Kneebone (2010) developed the concept of patient-focused simulation (PFS) for learning procedural skills. The aim of PFS is to create a safe environment where students, especially novices, can practice clinical procedural skills in a way that reflects reality (Nestel & Kneebone, 2010). Nestel and Kneebone (2010) had noticed that teaching basic procedural skills on a task trainer was effective, but the experience was out of context and not situated. They argued that safe training approaches need to include ways in which learners can integrate complex sets of skills as they will be required in situations with real patients in clinical practice. Elements of deliberate practice include motivating individuals, encouraging goal setting, multiple repetitions in different context and feedback. From situated learning, PFS located the procedural skill in a clinical context with a standardised patient. From experiential learning, reflection-on-action was adopted, most commonly as

facilitated dialogue between the learner, standardised patient and observers after the simulation (Bearman, Nestel & McNaughton, 2018).

4.5 Knowledge

INACSL's (2016) standards define *knowledge* as '*the awareness, understanding and expertise an individual acquires through experience or education'* (p. 43). The nursing profession comprises different kinds of knowledge. Carper (1978) identified the following four fundamental patterns of knowing in nursing: *empirical*, *aesthetic*, *ethical* and *personal*. Empirical knowledge is specific, measurable, observable, tested and scientific (Stayt, 2012). Carper (1978) described the aesthetic pattern of knowing as an expressive form of knowledge which bridges the gap between recognition and perception. Furthermore, Carper (1978) suggested that personal knowledge involves the inner experience of being self-aware and is essential for the therapeutic use of self in nursing. Ethical knowledge represents that which the individual values highly due to their belief that it is good or right to do. It involves having to make decisions for which there are no prescriptive answers (Stayt, 2012).

Eraut (2004) has defined personal knowledge as '*what individual persons bring to situations that enables them to think, interact and perform'* (p. 202). He argues that the ability to learn from experience is a better predictor of future performance than a final assessment. A simulation exercise is a good example of how to learn from experience. A key challenge for professionals and professional programmes is to develop meaningful relationships between theoretical knowledge and practical problem-solving (Grimen, 2008), and the use of simulation can enhance the transition from theory to practice.

Professional knowledge comprises 'knowing that' (i.e. knowing that something is the case) and 'knowing how' (i.e. knowing how to do something) (Ryle, 1949). Polanyi's (1967) distinction between *tacit knowledge* and *explicit knowledge* is another example of a somewhat related dichotomy. Both these patterns of knowledge are included in the measurements in Study 2 and Study 3 in this PhD project, such as questions about what normal vital sign values are and what usually happens with these values with acute major blood loss ('knowing that') and questions about nursing procedures ('knowing how').

4.6 Self-confidence

Prior to the attainment of self-confidence, various earlier acquisitions of knowledge must be achieved. Several researchers have identified knowledge as one antecedent of self-confidence (see Table 3). *Self-confidence* can be defined as *'a person's belief that he or she can succeed'* (Perry, 2011, p. 219). Self-confidence is a self-perceived measure of one's belief in one's own abilities, dependent upon contextual background and setting, and is highly contextual and task-specific (Kumar & Jagacinski, 2006; Moreno, Castillo & Masere, 2007; Savitsky et al., 1998; Wise, 2007). The extant nursing literature uses self-confidence predominantly in the context of clinical practice with reference to skill acquisition, clinical decision-making, professional socialisation, collaboration and autonomy (Lindsey & Kleiner, 2005; Messmer, Jones & Taylor, 2004; Oermann & Moffitt-Wolf, 1997; Ronsten, Andersson & Gustafsson, 2005).

Self-confidence can be related to self-efficacy theory. According to Bandura (1997), *self-efficacy* is *'a belief in one's personal capability to perform given actions'*. Those with high self-efficacy in a specific task are more likely to make more of an effort and sustain effort longer than those with low self-efficacy (Schunk, 1990). Self-efficacy is an important prerequisite for learning (Bandura, 1997) and an attribute of self-confidence (Perry, 2011). According to Bandura's (1986) self-efficacy theory, self-efficacy is enhanced by the following four main factors: successful performances (competence), vicarious experience, verbal persuasion (including praise and encouragement) and emotional state. When one masters a new technical skill, one generally feels successful, and this creates a sense of efficacy. Vicarious reinforcement is the process of being educated while observing others in certain situations. Witnessing others become successful through observations also raises observer's beliefs that they also possess the capabilities to master comparable activities required to succeed (Bandura, 1994). Positive verbal persuasion received from others allows for boosts in individual self-efficacy and will help individuals to try harder and promote the development of skills with an accompanied sense of self-efficacy. Finally, emotional state or reactions related to how these feelings and associated learning are perceived are also important. According to Bandura (1994), self-efficacy provides the basis for human motivation, wellbeing and personal accomplishments (Bandura, 1994). It includes an individual's ability within the contextual condition to change or adapt through psychological, emotional or physiological changes.

According to Perry (2011), the concept of self-confidence has attributes and antecedents, moderating factors, influential factors of self-efficacy and consequences. Self-confidence informs self-efficacy, which influences learning, which further influences self-confidence, learning and affective domains. Moreover, self-confidence has attributes/antecedents which further influence self-confidence (consequence), whether positively or negatively (increased versus decreased). The PhD student has created an overview of reported attributes, antecedents and outcomes from possessing self-confidence identified in the literature (see Table 3).

Table 3. Attributes, antecedents and outcomes of possessing self-confidence.

Attributes of self-confidence (positive and negative):
-Emotional intelligence/emotional competence, resilience (Abraham, 2004)
-Confidence, attitude, cognitive ability (Al-Nasir & Robertson, 2001)
-Trust (Abraham, 2004)
-Intuition (Koriat, 2008)
-Narcissism (Campbell, Goodie & Foster, 2004)
-Depression (Stone, Dodrill & Johnson, 2001)
-Doubt, uncertainty (De Cremer & Van Hiel, 2008)
Antecedents of self-confidence:
-Knowledge (Nokelainen, Tirri & Merenti-Valimaki, 2007; Vidal & Moller, 2007)
-Support (Lindsey & Kleiner, 2005; Schunk & Pajares, 2005)
-Experience (Hutchinson & Mercier, 2004)
-Gearing-up/preparation (Schunk & Pajares, 2005)
-Success (Chesser-Smyth, 2005; Clark, Owen & Tholcken, 2004)
Outcomes of possessing self-confidence:
- Better clinical performance (Savitsky et al., 1998; Schunk & Pajares, 2005)
- Taking on challenges (Chesser-Smyth, 2005)
- Developing full potential (Kumar & Jagacinski, 2006)
- Successful practice (Kumar & Jagacinski, 2006; Messmer, Jones & Taylor, 2004)
- Action (Moreno, Castillo & Masere, 2007)
- Change (Bowman, 1999)
- Risk taking (Berman, 2006; Chesser-Smyth, 2005)
- Power (Davidhizar, 1993)
- Motivating/reassuring others (Vidal & Moller, 2007)
- Autonomy (Bowman, 1999; Lindsey & Kleiner, 2005)

Self-confidence is crucial in undergraduate nursing education and nursing practice (White, 2009), and several research studies include assessments of self-confidence or self-efficacy in healthcare simulation (Labrague et al., 2019; Curl et al., 2016; Meurling et al., 2013; Creutzfeldt et al., 2010). Creutzfeldt et al. (2010) found increased self-efficacy levels among medical students after repeated team training of cardiopulmonary resuscitation in a virtual world. Levels of self-efficacy were measured four times in the study, before and after training, with a six-month interval between two simulation sessions. After six months, the self-efficacy scores showed a decrease. However, after the second simulation session, the scores increased again. The authors interpret this as an indication that virtual simulation can be used effectively to rebuild confidence (Creutzfeldt et al., 2010). Increased levels of self-efficacy were also found in a study among nurses and physicians in regard to the ability to understand and manage an emergent clinical situation after participating in simulation-based team training (Meurling et al., 2013). Several qualitative studies have also found that simulation-based training promotes self-confidence among undergraduate nursing students (Hustad, Johannessen, Fossum & Hovland, 2019; Zieber & Sedgewick, 2018).

Nursing students' lack of self-confidence may interfere with their ability to acquire new knowledge and hinder their ability to tackle challenging situations (Lundberg, 2008). Anxiety level plays a pivotal role in the amount of self-confidence that one possesses and becoming self-aware can stave off anxiety. A person self-regulates when he or she recognises a need to ask for help as part of adequately preparing and confirming internal control of situations (Savitsky et al., 1998). Low self-confidence has been linked to higher levels of anxiety and increased burnout (Yu, Chae & Chang, 2016), and self-confidence is therefore an important topic to examine. The concept of self-confidence is important for nursing faculty members and students to understand so that antecedents can be fostered in simulation sessions and clinical placement. The promotion of knowledge, experience, preparation, support systems and successes precede the acquisition of self-confidence (see Table 3). Fostering attributes of self-confidence—such as belief in positive achievements, persistence and self-awareness—among nursing students will benefit the students and the nursing programme (Perry, 2011).

5.0 DESIGN, METHODS AND RESULTS

5.1 The PhD project's study design and philosophical underpinnings

Most of the data to address the study's overall aim in this PhD project are quantitative, analysed with statistics and represent the positivist paradigm. Positivists maintain a deterministic philosophy in which causes determine effects and outcomes. This is also reductionist in the sense that the intent is to reduce ideas into small, discrete sets for testing, such as variables that comprise hypotheses and research questions (Creswell, 2014).

To provide valuable insight into why an intervention fails or has unexpected results, or why a successful intervention works and how it can be optimised, individual interviews were embedded within Study 2 and Study 3 as process evaluations (Craig et al., 2008). Data from individual interviews are qualitative, and much qualitative work has its origins in phenomenology. Phenomenologists believe that individuals seek to understand the world in which they live and work; therefore, their research's goal is to rely on participants' views of the situation being studied as much as possible (Creswell, 2014).

In this PhD project, the use of human patient simulators raises important ontological questions about what characterises a patient or human being. According to Edmund Husserl (1859-1938), the founder of phenomenology in the modern sense of the term, *consciousness* is a defining characteristic of a human being (Husserl, 1970). The simulator is only an object, with no body language or consciousness, so it merely reacts through the simulator operator who controls it through a computer in the control room. This also raises epistemological questions concerning the validity of knowledge gained in a simulated environment, which lacks some contextual factors in relation to the clinical practice environment in the real world. The practical value of knowledge and the fact that knowledge only has power in specific circumstances or cultures, as Lave and Wenger (1991) highlight, can also be linked to INACLS's (2016) definition of *fidelity*, which approaches it from a holistic perspective to include conceptual, physical and psychological factors in addition to group culture and dynamics (see section 3.1).

The Kirkpatrick model is a commonly used ranking model that evaluates training programmes and the transfer of learning outcomes (INACSL, 2016, p. 13). It comprises the following four measurement levels: 1) students' *reactions*, 2) the amount of *learning* (knowledge, skills and attitudes) that students realise,

3) the degree to which students' *behaviour* in other settings reflects what they have learned and 4) the extent to which *results* are improved (e.g. productivity, revenue and employee retention) (Kirkpatrick & Kirkpatrick, 2006). All studies in this PhD project employed a pre- and post-test design and operated at Level 2 for measuring, in accordance with the Kirkpatrick framework. The qualitative process evaluations embedded within Study 2 and Study 3 represent findings at Level 1 under the Kirkpatrick measuring framework. An overview of the research designs and methods used in this PhD project is provided in Table 4 and will be explained further.

Table 4. Overview of research designs and methods used in this PhD project.

Study	Design	Samples	Data Collection	Data Analysis
1	A Systematic Review and Meta-Analysis	14 Intervention Studies	Literature Search	Meta-Analysis
2	A Feasibility Study	107 undergraduate nursing students	Questionnaire	Statistics
		8 undergraduate nursing students	Individually Interviews	Qualitative Thematic Analysis
3	A Randomized Controlled Trial	158 undergraduate nursing students	Questionnaire	Statistics
		6 faculty members	Individually Interviews	Qualitative Thematic Analysis
		5 undergraduate nursing students		

5.2 Study 1

Study 1's design, data collection, data analysis and results will be presented in the following sections.

5.2.1 Design

A systematic review and meta-analysis were conducted in Study 1. The best evidence on decisions may come from systematic reviews. Reviewing extant literature in this way means that the researcher uses a specific and reproducible method to identify, select and appraise studies with a previously agreed-upon

quality level relevant to a particular question. The studies' results then are analysed and summarised (Booth, Sutton & Papaioannou, 2016). A key element in most systematic reviews is the statistical synthesis of the data, or the meta-analysis. *Meta-analysis* is a statistical technique used to summarise results from several individual studies into an estimate (Bland, 2015). It involves the aggregation of a weighted average of results from individual studies to calculate an overall effect size for an intervention (Denyer, Tranfield & Van Aken, 2008).

5.2.2 Data collection

To focus the research questions, factors of concepts—including population, intervention and outcome framework—were used (Booth, Sutton & Papaioannou, 2016). Appropriate keywords in various combinations were identified in close collaboration with a university librarian. We searched Medline, CINAHL, the Cochrane Library, ERIC, Embase, PsycINFO and SveMed+ (see Table 5 for an example and all the final searches in Appendix 1). In the smaller Nordic database SveMed+, we broadened the search and used only the keywords in concepts one and two. The same keywords were used for all the other searches. The final database searches were conducted on 24 November 2016, with an update on 20 February 2018. In total, 4,048 citations were identified.

Table 5. Literature search conducted in Study 1 in 'CINAHL Plus with Full Text (EBSCOhost)'.

#	**Query**	**Results**
S1	nurs* N3 (student* OR educat* OR graduat* OR undergraduat* OR baccalaur*)	116938
S2	Simulat*	38683
S3	Learning N3 ("game-based" OR "computer-based" OR "computer assisted" OR interactive OR virtual*)	1093
S4	"Computer assisted instruction"	6404
S5	Virtual* N3 (patient* or realit*)	4155
S6	Mannequin*	389
S7	Manikin*	769
S8	S2 OR S3 OR S4 OR S5 OR S6 OR S7	48414
S9	Judgment	12574
S10	Decision N3 making	93352
S11	Problem N3 solving	12924
S12	((emergenc* or critical*) N3 (patient* or ill* or care or nurs*))	107491
S13	Clinical N3 (competence* OR assessment* OR incident* OR risk OR measure*)	153717
S14	Awareness*	37116
S15	Deteriorat*	11974
S16	S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15	400985
S17	**S1 AND S8 AND S16**	**1557**

Two independent researchers reviewed the titles, abstracts and full-text screenings of the identified studies. Any point of disagreement was discussed until these researchers arrived at an agreement. The inclusion criteria were as follows: 1) the intervention studies had to include high-fidelity simulations and the use of a human-patient simulator, 2) they had to be written in English, 3) the simulation sessions had to be aimed to improve participants' ability to recognise and respond to deteriorating adult patients, 4) the sample had to comprise undergraduate nursing students, 5) the research had to have a pre- and post-test design, and 6) the research had to operate at Level 2 under the Kirkpatrick measuring framework (Kirkpatrick & Kirkpatrick, 2006). Exclusion criteria were as follows: 1) comparative studies in which high-fidelity simulation was tested against other simulations or clinical practice with 'real' patients, and 2) studies in which the intervention is a course over a longer period in which high-fidelity simulation is included in the course.

To add depth to the review, reference lists from the included studies were also examined. Four articles were included from these reference lists along with

one recommendation from a colleague after the literature search. Grey literature was searched using Google Scholar (http://scholar.google.com) and OpenGrey (http://www.opengrey.eu). *Grey literature* is defined as '*a field in library and information science that deals with the production, distribution, and access to multiple document types produced on all levels of government, academics, business, and organization in electronic and print formats not controlled by commercial publishing i.e. where publishing is not the primary activity of the producing body'* (GreyNet, 2020). Examples of grey literature include, for example, conference abstracts, presentations, unpublished trial data, government publications and dissertations/theses (GreyNet, 2020). No intervention studies that met the inclusion criteria were identified from the grey literature searches.

The included studies' quality was appraised critically, and the knowledge was summarised. Critical Appraisal Skills Programme (CASP) checklists for randomised controlled trials (RCTs) and cohort studies were used (Critical Appraisal Skills Programme, 2018). The checklist that the Joanna Briggs Institute developed was used for quasi-experimental studies (Joanna Briggs Institute, 2018). The critical appraisal process was conducted by two independent researchers, and the records on the screening questions are documented in Appendix 2. Based on these checklists' content, the included studies were ranked by their quality level (low, medium and high). The search process is presented in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow diagram (Figure 2).

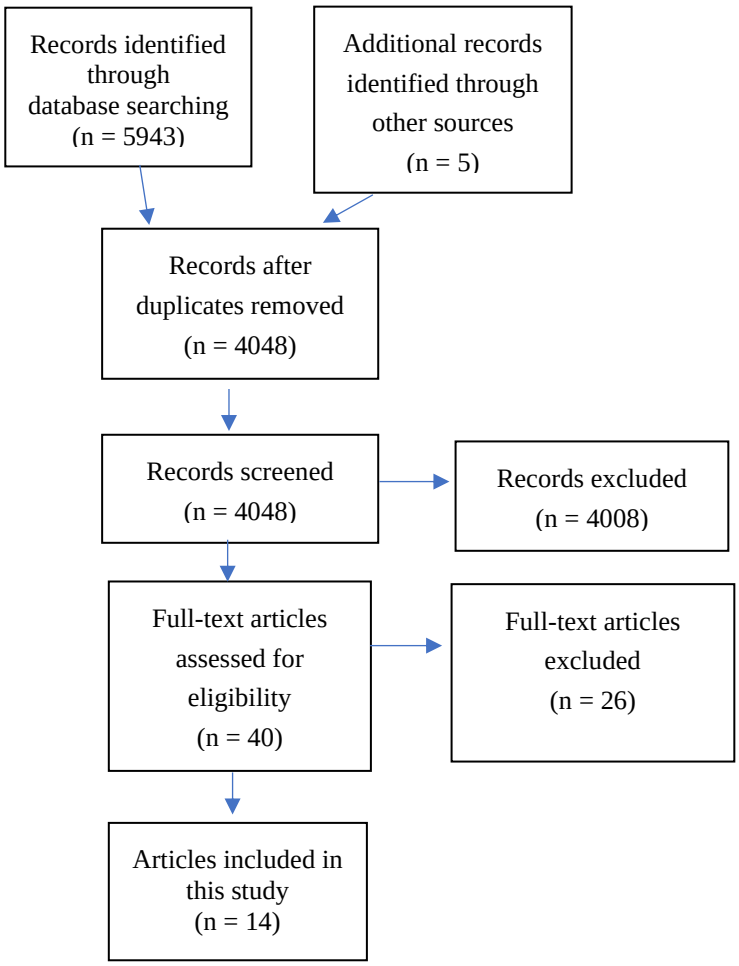


Figure 2. The Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) flow diagram, developed from www.prisma-statement.org.

5.2.3 Data analysis

Characteristics of the included studies were presented under the following sub-headings: *authors*, *publication year*, *countries*, *design*, *quality*, *participants*, *the HFS intervention, instruments* and *outcomes*. The meta-analysis software package in the statistical program R was used to perform the meta-analysis (R Project for Statistical Computing, 2017). The effects of HFS were assessed using the standardised mean difference at post-test as the outcome. Inclusion criteria for the meta-analysis were studies that reported similar outcomes (knowledge, skill performance and self-confidence) both pre- and post-intervention and that had a control group. A pooled analysis was conducted using a random-effects model and meta-analysis framework with inverse variance weighting (Booth,

Sutton & Papaioannou, 2016). The random-effects models assume that each individual study has a different population (Borenstein et al., 2009). To assess statistical heterogeneity and the study results' inconsistency, the proportion of variance was calculated. The heterogeneity includes all differences and can be defined as I^2 (Bland, 2015). Standard mean difference and 95% confidence intervals were calculated. All measures of relative effects were pooled, and no restriction was set for heterogeneity.

5.2.4 Results from Study 1

The results from Study 1 describe the findings from 12 studies presented in 14 journal articles (see Table 6) and will be presented in the following sections: *The participants, the HFS interventions, Instruments and outcomes* and *Meta-analysis*. Two studies were ranked as high quality and 12 studies as medium quality. The two studies ranked as high quality both used an RCT design. Three studies also using RCT design were ranked as medium quality because all the participants came from the same nursing school, and the sample sizes were small (31–34 participants).

Table 6. Included journal articles in Study 1 (n=14).

Authors, year and country	Design	Quality
1. Zieber & Sedgewick (2018), Canada	Mixed methods	Medium
2. Kim & Kim (2015), Korean	Quasi-experimental	Medium
3. Merriman, Stayt & Ricketts (2014), United Kingdom	Randomized controlled trial	Medium
4. Kelly, Forber, Conlon, Roche & Stasa (2014), Australia	Quasi-experimental	Medium
5. Lindsey & Jenkins (2013), USA	Randomized controlled trial	High
6. Thidemann & Söderhamn (2012), Norway	Quasi-experimental	Medium
7. Wood & Toronto (2012), USA	Quasi-experimental	Medium
8. Shinnick & Woo (2012), USA	Quasi-experimental	Medium
9. Shinnick, Woo & Evangelista (2012), USA	Randomized controlled trial	High
10. Liaw, Scherpbier, Rethans & Piyanee (2011a), USA	Randomized controlled trial	Medium
11. Liaw, Rethans, Scherpbier & Piyanee (2011b), USA	Randomized controlled trial	Medium
12. Burns, O'Donnell & Artman (2010), USA	Quasi-experimental	Medium
13. Ackermann (2009), USA	Quasi-experimental	Medium
14. Alinier, Hunt & Gordon (2003), United Kingdom	Cohort	Medium

The participants

The participants in the included studies were all undergraduate nursing students. The sample size varied from 24 to 162 participants, with three articles having over 100 participants (Shinnick & Woo, 2012; Shinnick, Woo & Evangelista, 2012; Burns, O'Donnell & Artman, 2010). In each study, all participants—except those from two articles—were recruited from one nursing school. In two articles, the participants came from three different nursing schools (Shinnick & Woo, 2012; Shinnick, Woo & Evangelista, 2012). Eleven included articles reported demographic information such as gender and age (Zieber & Sedgewick, 2014; Kim & Kim, 2015; Merriman, Stayt & Ricketts, 2014; Kelly et al., 2014; Wood & Toronto, 2012; Shinnick & Woo, 2012; Shinnick, Woo & Evangelista, 2012; Liaw et al., 2011a; Liaw et al., 2011b; Burns, O'Donnell & Artman, 2010; Alinier, Hunt & Gordon, 2003). The participants predominantly were female (79%-97%), with a mean age ranging from 19 to 33 years. Several of the included studies were conducted at a single site with a small sample. More than

half of the included studies lacked randomisation of participants or lacked control groups.

The HFS interventions

The setups in all the HFS interventions comprised several deteriorating conditions with a human patient simulator. Information reported on each patient included 'cardiopulmonary arrest', 'shortness of breath', 'acute decompensated heart failure', 'gastrointestinal bleed due to oesophageal rupture', 'fracture with extreme leg pain', 'patient experienced rapid clinical deteriorating (code blue)', 'intoxicated trauma patient' and 'postoperative patient experiencing a myocardial infarction'. All the interventions took place in simulation laboratories at the nursing schools where the participants attended. Four of the included studies reported that they offered the participants repeated exposure to the same clinical scenario (Kelly et al., 2014; Liaw et al., 2011a; Liaw et al., 2011b; Alinier, Hunt & Gordon, 2004). Briefings, clear objectives, student support, feedback and debriefings were identified as being important HFS features for implementing effective learning.

Instruments and outcomes

This systematic review revealed that many different instruments were used to measure knowledge, skill performance and self-confidence in the included studies. All the instruments to measure knowledge were multiple-choice questionnaires specially designed for the unique study. The research teams also designed or modified most of the instruments to measure skill performance and self-confidence from the original versions to fit the simulation scenarios for the specific study. Instruments that were not made especially for the study, and had been used previously in other studies to measure skill performance, were the *Nurse Competence Scale* (Watson et al., 2002), the *Health Sciences Reasoning Test* (Falcione & Falcione, 1996) and the *California Critical Thinking Disposition Inventory* (Falcone, Falcone & Sanchez, 1994). The *Nursing Anxiety and Self-confidence with Clinical Decision Making Tool* (White, 2014) was the only instrument to measure self-confidence that was used previously in other studies.

The pre- and post-tests' time of administration in the studies varied. The pre-tests' time ranged from three months before the intervention to immediately before and, for the post-tests, from immediately after the intervention to three

months after the intervention. A total of 12 studies measured skill performance, 10 studies measured self-confidence and nine studies measured knowledge both pre- and post-intervention. All studies reported that knowledge and skill performance increased after the HFS intervention. The increase was documented either from pre-test to post-test scores or from improved results for the intervention group compared with the control group at post-test. Increased self-confidence from pre-test to post-test was shown in four studies (see Table 7).

Table 7. Outcomes and results from the included studies in Study 1 (n=14).

Outcome	Results
Knowledge (9 studies)	Increased in all studies
Skill performance (12 studies)	Increased in all studies
Self-confidence (10 studies)	Increased in four studies

Meta-analysis

Six studies were included in the meta-analysis (Kim & Kim, 2015; Merriman, Stayt & Ricketts, 2014; Lindsey & Jenkins, 2013; Wood & Toronto, 2013; Liaw et al., 2011b; Ackermann, 2009). The pooled between-group effect size in the four studies that measured pre- and post-simulation skill performance was 1.07 (95% confidence interval: 0.44 to 1.69) in favour of HFS (Merriman, Stayt & Ricketts, 2014; Lindsey & Jenkins, 2013; Wood & Toronto, 2013; Liaw et al., 2011b). The differences between pre- and post-test knowledge results for the HFS intervention and control groups showed an increase in outcomes in all included studies in favour of HFS. The pooled between-group effect size was 0.92 (95% confidence interval: 0.27 to 1.57) (Lindsey & Jenkins, 2013; Liaw et al., 2011b; Ackermann, 2009). The differences between the pre- and post-test self-confidence results for the HFS intervention and control groups showed improvement in self-confidence after the HFS in one study (Merriman, Stayt & Ricketts, 2014), whereas two studies did not (Kim & Kim, 2015; Liaw et al., 2011b). The pooled between-group effect size was -0.08 (95% confidence interval: -0.39 to 0.23).

Further research based on Study 1

The findings from this systematic review and meta-analysis indicate a need for more studies comprising high-quality research designs and improved

measurement practices to produce generalisable evidence concerning the efficacy of HFS interventions. As the meta-analysis shows that self-confidence increased after HFS only in one study, whereas in two studies it did not, more research on self-confidence and HFS is needed. As an identified need exists for more research to examine self-confidence as a co-variable in simulations (see Table 1), and knowledge has been identified as one antecedent of self-confidence (see Table 3), both *knowledge* and *self-confidence* were chosen to be the outcome measures in Study 2 and Study 3 in this PhD project.

All the instruments measuring knowledge used in the included studies in this systematic review comprised multiple-choice questionnaires developed for the unique study. Therefore, the questionnaire used in this PhD project was also developed especially for the study. The scale used to rate self-confidence in the questionnaire was found in one of the included studies in this systematic review (Kim & Kim, 2015).

5.3 Study 2

Study 2's design, sample, setting, data collection, data analysis and results will be presented in the following sections.

5.3.1 Design

Study 2 was a feasibility study with a pre- and post-test design. A *feasibility study* is '*pre-study research that is done to gather pieces of information needed to formulate the plan for the main study'* (Giangregorio & Thabane, 2015, p. 128). Feasibility studies are used to estimate important parameters for a future planned study, e.g., sample size, number of eligible participants, designing a suitable outcome measure, follow-up rates, response rates to questionnaires, compliance rates and time needed to collect and analyse data (National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC), 2018). Feasibility studies typically are described as having flexible designs and ask whether something can be done, should be done and if so, how it should be done (Eldridge et al., 2016).

5.3.2 Sample

Data were collected from two samples. First, a self-selected convenience sample of 124 third-year undergraduate nursing students from one university in southern Norway were invited to participate. The inclusion criterion was that the students enrolled must be in the same undergraduate nursing course, which included an HFS intervention. A total of 108 students signed up, and one student failed to complete the post-test. Since evaluation of change required paired data from participant assessments before and after the HFS intervention, the assessments from 107 participants were analysed. Eight nursing students also participated in individual interviews as process evaluations embedded within the feasibility study. A year later (August 2018), a convenience sample of 28 third-year nursing students from one campus at the same university was invited to participate to test a revised version of the questionnaire. A total of 21 students volunteered and answered the questionnaires. Participant demographics are shown in Table 8.

Table 8. Participant demographics in Study 2.

Participant demographics in Study 2 (n=128):	***Aug. 2017 (n=107:)***	***Aug. 2018 (n=21):***
Gender (n, %)		
Female	99 (83)	16 (76)
Male	8 (7)	5 (24)
Age (years)		
Median (range)	23 (20–56)	23 (20-41)
Previous experience with use of a patient simulator (n)		
Yes	1 (1)	21 (100)
No	106 (99)	
Study place (n)		
A	38 (32)	
B	51 (43)	21 (100)
C	18 (15)	
Process evaluation (n=8):	***Aug. 2017:***	
Gender (n)		
Female	8	
Age (years)		
Median (range)	22.5 (21–39)	
Previous experience with use of a patient simulator (n)		
Yes	1	
No	7	
Study place (n)		
A	4	
B	4	

5.3.3 The high-fidelity simulation intervention

The specific intervention was chosen in this study because it was a compulsory part of the nursing students' educational programme. Several faculty members developed the simulation scenario for the participants' specific education level, which aligns with national curriculum regulations (Ministry of Education & Research, 2019b). It had been used in the undergraduate nursing programme for several years at the specific university, and the PhD student was not involved in the development phase of the HFS intervention.

The HFS intervention in Study 2 took place in one simulation laboratory at one university in southern Norway and included the use of a patient simulator (SimMan 3G). The students were divided into 11 simulation groups of between six and 14 participants each; six faculty members participated as well. A repeated scenario was offered to the participants' in six of the simulation groups based on the faculty members' previous experiences with organising the intervention. In each simulation scenario, two faculty members were actively involved, with one as a facilitator and the other as a simulator operator. All the faculty members had previous experience organising HFS in undergraduate nursing education. The research team was not involved in selecting the six faculty members that organised the intervention. The characteristics of the simulation groups are displayed in Table 9.

Table 9. Characteristics of the simulation groups in Study 2.

Group number	Group size	Repeated scenario	Observers location during the scenario
1	13	Yes	Via audio and video on a screen in another room
2	12	Yes	Via audio and video on a screen in another room
3	13	Yes	Via audio and video on a screen in another room
4	14	Yes	Via audio and video on a screen in another room
5	13	Yes	Via audio and video on a screen in another room
6	12	Yes	Via audio and video on a screen in another room
7	6	No	Directly in the simulation room
8	12	No	Directly in the simulation room
9	12	No	Directly in the simulation room
10	10	No	Directly in the simulation room
11	7	No	Directly in the simulation room

The observation of vital signs and management of patients' physiological deterioration are generic nursing competencies (Ministry of Education &

Research, 2019b). All the participants received information about the patient case and learning objectives approximately one week prior to the intervention. They also received suggestions on relevant reading material to prepare. The HFS intervention was divided into the following three phases, as recommended by INACSL (2016, p. 8): *prebriefing*, *simulation scenario* and *debriefing*.

Prebriefing phase

The prebriefing phase lasted approximately 50 minutes and included the following:

1. Review of the patient case

The patient case was read aloud to everyone in the simulation group. It was about a 75-year-old female patient with a history of heart failure. She had been hospitalised because she received a complete right-side prosthesis of the hip. She had been bleeding during the surgery and had now been transferred to the orthopaedic ward.

2. Review of the learning objectives

The learning objectives were read aloud to everybody, and they were *'to assess, recognise and respond to changes in a patient's condition'* and *'to communicate and work appropriately in a team'.*

Information about the learning objectives included the presentation of two learning tools that the participants were encouraged to use during the intervention:

2a. The airway, breathing, circulation, disability, exposure (ABCDE) approach (Smith & Bowden, 2017). This approach enabled the students to identify and respond to life-threatening conditions in order of priority. The patients' vital signs should be measured as part of the ABCDE assessment. On completion of the ABCDE assessment, a calculation of the NEWS or other appropriate equivalent score should be done. In this study, an EWS named Early Identification of Life-Threatening Conditions (TILT) developed by Sørlandet sykehus based on MEWS was used (Pedersen, 2014).

2b. A modified version of the Identify, Situation, Background, Assessment and Recommendation (ISBAR) communication structure (Moi et al., 2019). ISBAR was created to standardise the effective transfer of information in the U.S. armed

forces and was adopted by the public health service in the 2000s (Narayan, 2013).

3. Agreeing on mutual respect and confidentiality

This included the establishment of ground rules and expectations for the participants and faculty members. The faculty members acknowledged that mistakes may happen and will be reflected upon during the debriefing phase. Agreeing to confidentiality about what is happening in the HFS intervention was also elaborated.

4. Selection of an active or observer role

The participants were asked to participate voluntarily in the available roles, which were two registered nurses, one family member and observers. The observers were given particular observation tasks for the scenario performed. The different areas of focus for the observers were the nurses' assessments and handlings, the collaboration within the team and the communication between the nurses and the other participants in the scenario. The simulator operator acted as the patient's voice and as the physician on the phone. In some scenarios, a student acted as the physician on the phone to ensure that more students were engaged in active roles. In these scenarios, the student sat next to and was guided by the simulator operator during the scenario.

5. Orientation regarding the simulator and the environment in the simulation room

Before starting the simulation scenario, the participants were provided with an orientation to the simulation environment. They were exposed to the patient simulator and its functions, for example, they could feel the simulator's pulse rate. The participants also got the opportunity to try some of the equipment that could be used during the scenario and ask questions if needed.

Simulation scenario

The simulation scenario lasted approximately 15 minutes, and the setup was a deteriorating patient scenario. The scenario started with the patient complaining that she was not feeling well, the stated reason being that the patient had experienced acute major blood loss after surgery, classified as a class II haemorrhage by the American College of Surgeons Committee on Trauma (2013,

p. 69). The patient's clinical vital signs in the simulation scenario included *tachycardia* (heart rate above 100), *tachypnea* (20–30), *decreased urinary output* and *anxiety and fright*. Most patients with a class II haemorrhage are stabilised initially with crystalloid solutions (American College of Surgeons Committee on Trauma, 2013).

The patient was placed in a bed in a hospital-ward setting, and the simulation room included a heart monitor, simulated oxygen, equipment for measuring vital signs and an intravenous pump with intravenous fluids infusing, which could be regulated. Supplies needed to care for the patient (e.g. medications and bandages) and a phone were also available in the room. The facilitator was present in the simulation room during the scenario and offered practical assistance with the simulator or the equipment if needed. The students were dressed in health service uniforms and were given information such as the patient's medical history and medication records. In each simulation group, three students performed actions in the simulation room (two as nurses and one as a family member) while the rest of the group followed the performance via audio and video on a screen in another room or directly in the simulation room (see Table 9). The observers' different positions during the scenario were based on the facilitator's previous experiences with organising HFS. During the simulation scenarios, the participants made actual phone calls to faculty members or students acting as physicians. If students acted as physicians, the simulator operator told them what to answer. The physician answered that the nurse could administer oxygen, speed up the intravenous administration of fluid and raise the foot end of the bed. All the scenarios ended when the physicians entered the simulation room.

Debriefing phase

The faculty members and students re-examined what happened in the scenario immediately after it ended. The debriefing phase lasted approximately 45 minutes and followed the three phases (descriptive, analytic and application) described by Steinwachs (1992) and presented in section 3.3.3.

After the debriefing phase, the same scenario was repeated with the students reversing their roles as observers and role players in six out of the 11 simulation groups. This was followed by a shorter debriefing phase (approximately 20 minutes). The repeated scenario allowed more students to

have hands-on practice for each scenario and enabled them to apply what they had learnt from the debriefing session.

5.3.4 Data collection

A self-report pre- and post-test questionnaire was developed and validated.

Development of the questionnaire

Based on previous research and findings in Study 1 (see section 5.2.4), a self-reported questionnaire with knowledge and self-confidence as the measurement outcomes was developed. Data were also collected on gender, age, campus and previous experience with HFS. The research team developed the items for the simulation scenario used in Study 2, and they were linked to the learning objective *'to assess, recognise and respond to changes in a patient's condition'.* The 20 knowledge items comprised multiple-choice questions with three response alternatives. The items referred to three dimensions: *normal values in vital signs*; *how these vital sign values usually change after major acute blood loss;* and *nursing procedures*. Perceived self-confidence was assessed using 18 items paired to the knowledge items. There were two fewer self-confidence items than knowledge items because four knowledge items contained aspects of the same area and resulted in only two self-confidence items (see Appendix 3; knowledge items 11 and 13 resulted in self-confidence item 12, and knowledge items 18 and 20 resulted in self-confidence item 18). Examples of questions used in the questionnaire are shown in Table 10, and all content from the questionnaire is attached (Appendix 3).

Table 10. Examples of questions used in the questionnaire in Study 2.

<table>
<tr><th>Outcome</th><th>Question</th><th colspan="5">Response answers</th></tr>
<tr><td>Knowledge</td><td>What happens usually with the respiratory rate at major blood loss?</td><td colspan="5">A. Decreasing
B. No change
C. Increasing</td></tr>
<tr><td>Levels of self-confidence</td><td>How confident are you that you can detect clinical changes in respiratory rate at major blood loss?</td><td>Not at all confident</td><td>Somewhat confident</td><td>Average confident</td><td>Largely confident</td><td>Very confident</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

The self-confidence items were rated on a five-point scale using the following categories: *not at all, somewhat confident, average confident, largely confident,* and *very confident.* The self-confidence items were adapted, with permission, from the critical-care Self-Confidence Scale (Hicks, Coke & Li, 2009) used in previous studies (Omer, 2016; Zavotsky et al., 2016) and in an edited version in one of the included studies in Study 1 (Kim & Kim, 2015). The measurement level corresponds to Level 2 of the Kirkpatrick framework (Kirkpatrick & Kirkpatrick, 2006) (see section 5.1). The development of the questionnaire was based on the American Heart Association's (AHA) examination for Basic Life Support after approval from the AHA (2016). This was chosen because it was used in a similar published study included in Study 1 in this PhD project (Ackermann, 2009). A Nordic database of up-to-date evidence-based procedures for use in healthcare practice (VAR Healthcare, 2017) and two Norwegian textbooks that were required reading for the students participating in the intervention (Kristoffersen et al., 2016; Stubberud et al., 2016) also were used.

Questionnaire validity

Validity is an overall quality concept on item scales and refers to the extent to which a questionnaire measures what it is intended to measure (Polit & Beck, 2017). In the validation of the questionnaire, the item scales' content validity refers to the elements of the deteriorating patients' simulation scenario. In the judgement-quantification stage of instrument development, content experts were involved (Grant & Davis, 1997). The *Standards for Educational and Psychological Testing* (American Educational Research Association, American Psychological Association and National Council on Measurement in Education, 2014) emphasise the necessity of content experts' relevant training, experiences and qualifications. The PhD student chose two intensive care nurses and two administrators involved in the course's planning, to test the instrument. They were chosen because they were experts in the topic being assessed, and they were not involved in the intervention and could not affect the students' learning in the simulation session because they knew the questionnaire's content.

Eight individual feedback interviews were used to determine face validity and comprehensiveness. The PhD student asked all the simulation groups (n=11) whether one self-selected member of the group would participate voluntarily in an individual interview immediately after they had responded to the post-test questionnaire. The interviews were audio-recorded and varied from five to 21 minutes each (mean: 11 minutes). They referred to these open-ended questions: *How would you describe your experience of completing the questionnaire? What were the positive/negative aspects of the questionnaire? Is there anything you would like to add to the questionnaire?* (Appendix 4). The findings from the feedback interviews, an examination of the distribution of the item-response knowledge alternatives and statistical tests used to analyse the data resulted in a revised questionnaire (Appendix 5). To validate the revised questionnaire, 21 third-year nursing students responded to it pre-intervention and 19 post-intervention in August 2018. The participants attended the same nursing course and HFS intervention as the other participants in Study 2, and the same faculty members were involved.

Administration of the questionnaires

The PhD student informed all participants about the study and administered all the questionnaires, which took about 10 minutes each to complete, and the pre- and post-test questionnaires contained the same items. The participants

completed the questionnaires at the universities where they attended. The timing concerning when the pre-test questionnaire was completed varied from eight days to immediately before the intervention. The post-test questionnaire was administered to participants immediately after the intervention. Some of the participants attended an HFS intervention about cardiopulmonary resuscitation between responding to the two questionnaires (n = 57 of 107), see Table 11. This HFS intervention was one of three compulsory HFS interventions that the students attended during this period in their nursing programme, and it lasted for approximately two hours.

Table 11. Administration of the questionnaires in Study 2.

Group number	**Time before intervention responded to pre-test questionnaire**	**Time after intervention responded to post-test questionnaire**	**Attended an HFS intervention about cardiopulmonary resuscitation between responding to the questionnaires**
1	One day	Immediately after	No
2	One day	Immediately after	No
3	Two days	Immediately after	Yes
4	Two days	Immediately after	Yes
5	Five days	Immediately after	Yes
6	Immediately before	Immediately after	No
7	Immediately before	Immediately after	No
8	Seven days	Immediately after	No
9	Seven days	Immediately after	No
10	Eight days	Immediately after	Yes
11	Eight days	Immediately after	Yes

5.3.5 Data analysis

The data collection comprised both quantitative and qualitative data.

The statistical analysis

The quantitative data were analyzed using the SPSS (V24) software program and a free software program (Avdic & Svensson, 2010). If a participant had chosen two response options of an item of knowledge, and one of which was the correct one, then that one was consistently recorded. When two of the five item-categories of self-confidence were marked, or the assessment was placed between two adjacent categories, the lower level was consistently recorded. For each knowledge item, the proportion of participants who had changed their

responses from incorrect to correct after the intervention was compared with the proportion of participants who had changed from the correct to an incorrect response. The difference between these paired proportions of increased and of decreased numbers of correct responses was calculated and expressed as percentage units. The differences between the paired proportions of higher levels and of lower levels of self-confidence were also calculated. The distribution of the item response alternatives of knowledge was also examined in order to validate the content of the questionnaire.

The variable self-confidence was assessed on ordered categorical item scales. These values are rank ordered, meaning that each response category has more of the attribute being measured than the previous category, but the differences between the categories are unknown. Non-parametric rank-based statistical methods that take account of the non-metric properties of ordered categorical data were used to obtain reliable results (Hand, 1996; Svenson, 2001; Svensson, 2012).

The responsiveness of each self-confidence item was evaluated using the Svensson method for paired ordinal data that identifies and measure systematic change in responses separately from individual variation (Svensson, 1998; Svensson et al., 2015). In a test-retest design, the data sets consist of pair of assessments made before and after the intervention. Therefore, the frequency distribution of all pairs is shown by a square table, see Figure 3. Pairs from students who assessed a higher level of self-confidence after the intervention than before, like (*average*, *very*) appear in the upper left region (denoted A), and pairs with lower level of self-confidence after the intervention than before (*very*, *average*) is found in the lower right region (denoted B). Pairs of unchanged level of self-confidence, such as (*largely*, *largely*) appear in the diagonal (denoted C).

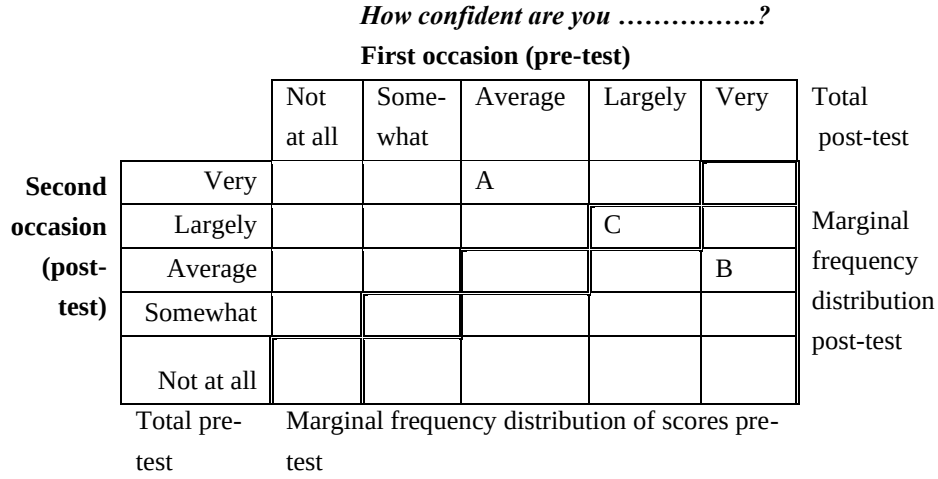


Figure 3. The components of a 5 x 5 square contingency table for frequency distributions of pairs of assessments of perceived self-confidence on an item scale with five ordered categories. The regions for pairs with increased, unchanged and decreased levels of self-confidence are indicated by the positions of the pairs A (average, very), B (very, average), and C (largely, largely).

The proportion of participants with unchanged self-confidence levels (percentage agreement) was calculated. Besides the frequency distribution of the pairs in the 5 x 5 table, the frequency distributions of self-confidence before and after intervention are shown as marginal frequencies. Different marginal distributions indicate presence of a systematic group change and is measured by the relative position. The relative position expresses the extent to which the marginal distribution on the retest occasion is shifted towards higher levels of self-confidence than the marginals from first set, rather than the opposite. Possible relative positions values range from −1 to 1, a positive relative position value indicate that the group of students has systematically assessed higher rather than lower categories of self-confidence on the retest occasion compared with the first occasion. Additional individual variability was calculated by the measure relative rank variance, ranging from 0 to 1. Non-zero relative rank variance indicates presence of individual variations, that cannot be explained by a systematic group change in assessments, for example heterogeneity among participants, incomplete understanding of the scenario, or misinterpretation of a question. The percentage agreement, relative position, relative rank variance and the 95% confidence intervals of relative position and relative rank variance were calculated using a free software program (Avdic & Svensson, 2010). Good responsiveness, which mean high sensitivity to changes, is indicated by 95%

confidence intervals of relative position that does not cover the zero value, and negligible unexplained individual variations, relative rank variance.

Qualitative analysis

All the qualitative data were analyzed and inspired by Braun and Clarke's thematic analysis (2006). The authors suggest a six-step thematic analysis be performed to identify codes, themes and subthemes (Braun & Clarke, 2006, p. 87). The six steps were as follows:

1. *Familiarising oneself with the data.* In this phase, all the data were transcribed into written form by the PhD student. The data were read and re-read, and initial ideas were written down in notes. The PhD student was searching for meanings and patterns.
2. *Generating initial codes.* In this phase, the PhD student collated and organised the data into meaningful groups.
3. *Searching for themes.* Next, the codes were collated into potential themes.
4. *Reviewing themes.* This phase involved two levels of reviewing and refining the themes. Level one involved reviewing at the level of the coded data, and at level two the validity of individual themes in relation to the whole dataset were considered.
5. *Defining and naming themes.* This phase included an ongoing analysis to refine the specifics of each theme. Making sub-themes was useful for describing and defining the theme.
6. *Producing the report.* This phase was the final opportunity for analysis where the final analyses of the selected extracts were done.

The PhD student was involved in all the six steps, and three members of the research team reviewed the themes together. An example of the qualitative thematic analysis process is displayed in Table 12.

Table 12. One example of qualitative thematic analysis from Study 2.

Example of text coded	**Sub-theme**	**Theme**
Item number 16 of knowledge is not relevant for the content in the intervention	Some of the content in the items of knowledge is not relevant	Experiences related to the content

5.3.6 Results from Study 2

Evaluation of the validity and responsiveness of the knowledge and self-confidence items included: 1) *content experts*; 2) *follow-up interviews*; 3) *calculation of the differences between proportion of participants* with increased and decreased correct knowledge responses, and higher and lower levels of self-confidence responses; 4) *measures of change in assessments of self-confidence* (relative position, relative rank variance and percentage agreement); and 5) *distribution of the knowledge items' response alternatives*. The findings resulted in several adjustments to the questionnaire. An overview of the changes made to the questionnaire is provided in Table 13 and will be explained further.

Table 13. An overview of the changes made to the questionnaire after the feasibility study for future use.

Change in knowledge items:
- Clarification of content (item 6, 8, 11, 12, 15 and 17)
- Removal of items that were not relevant to the intervention's content (item 16, 18, 19 and 20)
- Development of four new relevant items
Change in self-confidence items:
- Changes to the order and content so that all items are paired with similar knowledge-item numbers
Change in administration of the questionnaire:
- Administer the questionnaire to all participants immediately before and after the intervention to better control for confounding variables

Content experts and follow-up interviews

The content experts provided useful feedback for improvements, such as reformulation of items and explanations of abbreviations, and they agreed on what the correct answers were. The analysis of the follow-up interviews resulted in three themes concerning participants' experiences while responding to the

questionnaire: *item content*; *item style;* and *administration* of the questionnaire for future use. Experiences with *item content* resulted in clarification of content, removal of items from the questionnaire that were not relevant to the intervention's content and development of new relevant items. Experiences with *administration* resulted in a change to how the questionnaire was administered. It was recommended that the questionnaire be administered to participants immediately before and after the intervention to better control for confounding variables. More information about the three themes is presented in Table 14.

Table 14. Qualitative findings in the validity process in Study 2.

Themes	
1	**Item content.** All participants found that most items addressed relevant aspects of their experiences during the intervention but made several suggestions for improvement. The intervention's difficulty level was found to be acceptable, and the number of items was deemed appropriate.
2	**Item style.** Participants felt that it was good to offer three response alternatives for the knowledge items, and they understood that they should choose one alternative. For the self-confidence items, seven participants found the five response alternatives to be appropriate. One participant thought that one out of three response alternatives would have been an easier choice selection.
3	**Administration.** Participants reported that it was good that the same questionnaire was used before and after the intervention. They also felt that the pre-intervention questionnaire helped prepare them and increased attention, motivation and learning throughout the intervention. They reported increased awareness of what they knew and could manage, as well as what they needed to learn more about. One participant argued that other relevant work she had done after the pre-intervention questionnaire, in addition to the intervention, influenced her answers on the post-test questionnaire.

Calculation of differences between the proportion of participants

Tables showing the frequency distribution of the pairs of assessments of each of the 20 knowledge and 18 self-confidence items were made. For examples, see Table 15 (knowledge item number 9) and Table 16 (self-confidence item number 11).

Table 15. Frequency distribution of pairs of knowledge responses for item number 9 in Study 2. The changed responses are highlighted.

	Right answer after intervention	*Wrong answer after intervention*	Total
Right answer before intervention	72	**5**	77
Wrong answer before intervention	**25**	4	29
Total	97	9	106*

*One missing response

Table 16. Frequency distribution of pairs of self-confidence responses for item number 11 in Study 2. The diagonal of unchanged responses is highlighted.

		First occasion (pre-test)					
		Not at all	*Somewhat*	*Average*	*Largely*	*Very*	Total
	Very		4	7	4	**2**	17
Second occasion (post-test)	*Largely*	2	11	29	**10**	2	54
	Average	2	18	**10**	4		34
	Somewhat			1			1
	Not at all						
	Total	4	33	47	18	4	106*

*One missing response

The difference between the proportion of participants with increased and decreased correct knowledge responses on each item were then calculated and ranged from −25.5 (item 15) to 24.8 (item 20) percentage units. The difference between the proportion of participants with higher and lower levels of self-confidence on each item were also calculated and ranged from 16.5 (item number 3) to 66.0 (item number 11) percentage units. More participants changed to the correct alternative than to an incorrect alternative for knowledge items number 2, 4, 5, 8, 9, 13, 14, 16, 19 and 20. Responses to knowledge items number 3, 6, 7, 11, 12, 15 and 17 showed the opposite pattern and indicated a negative difference in paired proportions. These negative differences in paired proportions may be explained by a lack of understanding of the questions or response options in

relation to the simulation session and resulted in some clarification of content for future use.

Measures of change in assessments of self-confidence

For each of the 18 self-confidence items, the relative position measure of systematic group changes was also calculated and ranged from 0.14 to 0.58. These values are strong indicators of responsiveness, since none of the 95% confidence intervals covered the zero value. The relative rank variance value ranged from 0.01 to 0.25. The proportion of participants with *unchanged* self-confidence levels after the HFS intervention (percentage agreement) ranged from 21% (item number 11) to 71% (item number 1 and 3), see Table 17.

Table 17. Measures of change in assessments of self-confidence after the high-fidelity simulation intervention in Study 2.

Self-confidence items	Relative position (RP) (95% Cl)	Relative rank variance (RV) (95% Cl)	Percentage agreement (PA)
1 (n=106)	0.15 (0.08 to 0.22)	0.01 (0.00 to 0.01)	71 %
2 (n=106)	0.24 (0.15 to 0.38)	0.06 (0.01 to 0.11)	59 %
3 (n=106)	0.14 (0.05 to 0.23)	0.04 (0.00 to 0.07)	71 %
4 (n=106)	0.34 (0.24 to 0.49)	0.08 (0.03 to 0.14)	45 %
5 (n=106)	0.25 (0.15 to 0.34)	0.05 (0.00 to 0.09)	50 %
6 (n=105)	0.16 (0.08 to 0.25)	0.03 (0.00 to 0.05)	62 %
7 (n=105)	0.15 (0.04 to 0.26)	0.12 (0.03 to 0.20)	49 %
8 (n=106)	0.15 (0.06 to 0.24)	0.09 (0.06 to 0.12)	62 %
9 (n=106)	0.56 (0.46 to 0.66)	0.25 (0.12 to 0.38)	30 %
10 (n=103)	0.52 (0.42 to 0.62)	0.22 (0.10 to 0.34)	33 %
11 (n=106)	0.58 (0.41 to 0.74)	0.18 (0.08 to 0.28)	21 %
12 (n=105)	0.32 (0.21 to 0.42)	0.19 (0.08 to 0.30)	40 %
13 (n=106)	0.27 (0.17 to 0.37)	0.07 (0.02 to 0.12)	51 %
14 (n=105)	0.41 (0.31 to 0.51)	0.21 (0.16 to 0.27)	40 %
15 (n=104)	0.45 (0.35 to 0.54)	0.05 (0.00 to 0.11)	34 %
16 (n=103)	0.38 (0.28 to 0.48)	0.12 (0.06 to 0.17)	34 %
17 (n=106)	0.22 (0.12 to 0.32)	0.08 (0.03 to 0.13)	57 %
18 (n=106)	0.20 (0.10 to 0.30)	0.06 (0.01 to 0.11)	56 %

Distribution of the knowledge items response alternatives

The distribution of the knowledge items response alternatives was examined (see Table 18). The correct answers are highlighted. Incorrect alternatives that were rarely chosen (item number 8 and 11) or chosen more often than the correct one (item number 6) have been reformulated or the item have been removed (item number 16).

Table 18. Distribution of the item response alternatives of knowledge in Study 2. Changes and results from testing the revised questionnaire are written in parentheses.

Variable	**N (total)**	**Response alternatives**	**Distribution of the answers (n) PRE-TEST**	**Distribution of the answers (n) POST-TEST**
1.What is usually considered as a normal blood pressure in healthy adults?	Pre: 107 *(21)* Post: 107 *(19)*	A: 100/60 **B: 120/80** C: 140/80	 **104** ***(21)*** 3	2 **104** ***(19)*** 1
2.What happens usually with the blood pressure at acute major blood loss?	Pre: 107 *(21)* Post: 106 *(19)*	**A: Decreasing** B: No change C: Increasing	**88** ***(18)*** 19 *(3)*	**101** ***(19)*** 1 4
3.Which of these causes may give to low blood pressure?	Pre: 104 *(21)* Post: 107 *(18)*	A: The patient is sitting with dangling legs **B: The cuff is too big** C: The cuff is below the heart level	3 *(1)* **77** ***(10)*** 24 *(10)*	14 *(1)* **72** ***(10)*** 21 *(7)*
4.What is usually considered as normal resting pulse in healthy adults?	Pre: 107 *(21)* Post: 107 *(19)*	**A: 60-100** B: 40-80 C: 80-120	**72** ***(13)*** 1 *(8)* 34	**81** ***(13)*** *(6)* 26
5.What happens usually with the pulse rate at acute major blood loss?	Pre: 107 *(21)* Post: 107 *(19)*	A: Decreasing B: No change **C: Increasing**	26 *(4)* 1 **80** ***(17)***	11 *(4)* 4 **92** ***(15)***
6.What is included in the assessment of pulse quality?	Pre: 107 *(21)* Post: 106 *(19)*	A: Frequency and depth *(A: Frequency)* **B: Fullness, voltage and elasticity** ***(B: Fullness)*** C: Rhythm and frequency *(C: Rhythm)*	20 *(4)* **8** ***(14)*** 79 *(3)*	29 *(2)* **7** ***(14)*** 70 *(3)*
7.Where is the most common place to measure the pulse in adults?	Pre: 105 *(21)* Post: 107 *(18)*	**A: Arteria radialis** B: Arteria brachialis C: Arteria femoralis	**89** ***(21)*** 14 2	**89** ***(17)*** 15 *(1)* 3
8.What is usually considered as normal respiratory rate at rest in healthy adults?	Pre: 106 *(21)* Post: 107 *(19)*	A: 6-10 **B: 10-15** ***(B: 9-15)*** C: 14-22 *(C: 16-22)*	4 **87** ***(21)*** 15	5 *(1)* **93** ***(18)*** 9
9.What happens usually with the respiratory rate at acute major blood loss?	Pre: 106 *(20)* Post: 107 *(19)*	A: Decreasing B: No change **C: Increasing**	26 *(5)* 3 *(1)* **77** ***(14)***	9 **98** ***(19)***

10.What are the recommendations for counting irregular respiratory rate?	Pre: 107 *(21)* Post: 106 *(19)*	A: Count for 30 seconds and multiply by 2 **B: Count for 60 seconds** C: Count for 15 seconds and multiply by 4	8 **99** ***(21)***	6 *(1)* **98** ***(18)*** 2
11.What is usually considered as normal body temperature in healthy adults (Celcius degree)?	Pre: 107 *(21)* Post: 106 *(19)*	A: 35.4-37.5 *(A: 35.4-37.0)* B: 36.4-38.5 *(B: 36.4-38.0)* **C: 36.4-37.5**	8 *(3)* 1 **98** ***(18)***	5 *(4)* 6 **95** ***(15)***
12.What happens usually with the body temperature at acute major blood loss? *(12.What happens usually with the body temperature a while after acute major blood loss?)*	Pre: 106 *(21)* Post: 106 *(19)*	A: Increasing B: No change **C: Decreasing**	6 *(3)* 1 *(1)* **99** ***(17)***	22 *(2)* 5 *(1)* **79** ***(16)***
13.Which method of measuring body temperature usually offers the most accurate measurement results?	Pre: 107 *(21)* Post: 107 *(19)*	**A: Rectal** B: Oral C: Tympanic	**103** ***(21)*** 2 2	**104** ***(19)*** 1 2
14.What is usually considered as normal oxygen saturation in the blood in healthy adults?	Pre: 107 *(21)* Post: 107 *(19)*	A: 85-100% B: 90-100% **C: 95-100%**	3 *(1)* 11 *(1)* **93** ***(19)***	2 *(2)* 6 *(1)* **99** ***(16)***
15.At what time can a nurse administer oxygen to a hospitalized patient? *(15.What happens usually with the oxygen saturation in the blood at acute major blood loss?)*	Pre: 106 *(21)* Post: 107 *(19)*	A: When it is discovered that the patient has too low oxygen in the blood *(A: Increasing)* **B: When it is instructed by a physician** ***(B: Decreasing)*** C: When the patient asks for it *(C: No change)*	19 *(1)* **87** ***(3)*** *(17)*	47 **60** ***(12)*** *(7)*
16.What are the clinical signs of partial wound rupture? *(16.At what time can a nurse administer oxygen to a hospitalized patient in a ward setting?)*	Pre: 96 *(21)* Post: 102 *(19)*	**A: Sudden pain and sore from the wound without signs of infection** *(A: When it is discovered that the patient has too low oxygen in the blood)* B: Dull pain and sieving of serous fluid from the wound ***(B: When it is instructed by a physician)*** C: The wound is open, there is swelling locally and tenderness in palpation *(C: When the patient asks for it)*	**21** *(5)* 26 ***(16)*** 49	**26** *(5)* 26 ***(14)*** 50
17.What is the purpose of having bandage on a surgical wound? *(17.What is usually considered as normal*	Pre: 106 *(21)* Post: 106 *(19)*	A: Provides moisture to the wound *(A: 0-1 litre)* **B: Protects against microbes and absorb secretion** ***(B: 1-2 litre)***	1 **85** ***(17)*** 20 *(4)*	 **83** ***(14)*** 23 *(5)*

production of urine a day in healthy adults?)		C: Provides compression to prevent bleeding *(C: 2-3 litre)*		
18.If the patient loses consciousness and performing CPR is needed, what is the correct treatment? *(18.What happens usually with the production of urine at acute major blood loss?)*	Pre: 106 *(21)* Post: 107 *(19)*	A: 15 compressions to 2 breaths *(A: No change)* **B: 30 compressions to 2 breaths** *(B: Increasing)* C: 30 compressions to 1 breath ***(C: Decreasing)***	*(2)* **105** 1 ***(19)***	**107** *(2)* ***(17)***
19.What is important to do before performing CPR? *(19.What is the purpose of having compression bandage on a surgical wound?)*	Pre: 106 *(21)* Post: 107 *(19)*	**A: Check the patient's consciousness, establish free airways and check the patient's respiratory rate** *(A: Provides moisture to the wound)* B: Check the patient's consciousness, respiratory rate, pulse and if the patient is to be revived (documented by a physician) ***(B: Reduces bleeding)*** C: Check the patient's consciousness and possible risk of infections by mount-to-mount breathing *(C: Protects against microbes)*	**75** 31 ***(20)*** *(1)*	**77** 30 ***(18)*** *(1)*
20.When should rescuers switch positions during CPR? *(20.What is ABC a shortening for in the 'ABCDE'-approach?)*	Pre: 106 *(21)* Post: 106 *(19)*	A: The rescuers should change positions after every 5-minutes *(A: Airway, Breathing, Consciousness)* **B: The rescuers should change positions after every 2-minutes** *(B: Assess Blood Circulation)* C: The rescuers should change positions after every 7-minutes ***(C: Airway, Breathing, Circulation)***	63 *(1)* **40** 3 ***(20)***	38 *(1)* **65** 3 ***(20)***

The correct answers are highlighted.

The revised questionnaire resulted in 20 knowledge items paired with 20 self-confidence items. All changes and the distribution of the item response alternatives when testing the revised questionnaire (August 2018) are written in parentheses in Table 18. No other changes in the knowledge or self-confidence items were made after the testing before using the questionnaire in Study 3. However, two questions for demographic data about experience with critical ill patients and grades at nursing exam in the first year were added at the questionnaire for all participants (Appendix 6).

5.4 Study 3

Study 3's design, sample, setting, data collection, data analysis and results will be presented in the following sections.

5.4.1 Design

The design for Study 3 was an RCT with a pre- and post-test design. The use of manipulation, control and randomisation characterises a true RCT (Polit & Beck, 2017). Because of the problem of multiple testing, a primary outcome variable to investigate the specific hypothesis should be defined (Bland, 2015). In this study, knowledge was determined to be the primary outcome, with self-confidence levels the secondary outcome. As recommended by Craig et al. (2008), a process evaluation was embedded within the trial, including interviewing students and faculty members. Process evaluation is an essential part of designing and evaluating complex interventions (Moore et al., 2015; Craig et al., 2008).

5.4.2 Sample

Based on published intervention studies about the effect of HFS included in Study 1 (Lindsey & Jenkins, 2013; Kim & Kim, 2015), the intervention group's estimated expected learning effect, in relation to the control group, was chosen to be 20 percentage units in Study 3. According to Altman (1991, pp. 455–459), we can calculate the appropriate sample size, as shown in Table 19.

Table 19. Estimation of the sample size in Study 3.

Standardized difference = $(p_1\text{-}p_2)/\sqrt{p_m\,(1-p_m)}$
p1 = 0.50
p2 = 0.30
pm = 0.4
p1 – p2 = 0.2
1 – pm = 0.6
0.2/0.49 = 0.41
Standardized difference: 0.41

p1 = outcome intervention group, p2 = outcome control group, pm = mean of P1 and P2

Assuming a difference in expected learning effects between the proportion of students in the intervention and the control groups being 20 percentage units,

and the proportion participants with positive outcome being 50% and 30% respectively, gives a standardized difference of 0.41. This indicates that a total sample of 160 participants will detect the assumed difference in learning effects with a power of 80% on the significance level of 5% (Altman, 1991). The estimation of sample size was done in collaboration with a statistician.

A self-selected convenience sample (n=177) of second-year undergraduate nursing students from three campuses at two universities in Norway was invited to participate in Study 3 during the November-December 2018 period. All the students were enrolled in one undergraduate nursing course that included the HFS intervention in the programme. The lab coordinators at the two universities scheduled students in groups of 8 to 15 each, which were selected randomly to serve as intervention (n=8) or control (n=7) groups. The statistician performed a stratified block randomisation to ensure balance, i.e., that similar numbers of student groups were allocated to the intervention and control groups on each campus (Altman, 1991).

Altogether, 166 students completed the pre-test questionnaire, and 158 completed the post-test questionnaire. As change evaluation required paired data from participant assessments before and after the HFS intervention, the assessments from 158 participants were analysed. Five nursing students and six faculty members participated in individual interviews. The six faculty members interviewed had all previous experience with organising simulations for nursing students in undergraduate nursing education. The experience varied from 1.5 to 15 years: 1 year, 4 years, 6 years, 14 years and 15 years. All except one had attended a course that focussed on how to be a facilitator in simulations. Two faculty members acted as both facilitators and operators because they were involved in more than one scenario during the data collection period. Participant demographics are shown in Table 20.

Table 20. Participant demographics in Study 3.

Participant demographics in study 3 (n=158):	***Control (n=69):***	***Intervention (n=89):***
Gender (n, %)		
Female	61 (88)	78 (88)
Male	8 (12)	11 (12)
Age (years)		
Median (range)	21 (19–47)	22 (20–48)
Previous experience with critically ill patients (n, %)		
Yes	41 (60)	62 (70)
No	27 (40)	26 (30)
Study place (n, %)		
A	31 (44)	41 (46)
B	20 (29)	30 (34)
C	18 (26)	18 (20)
Process evaluation (n=11):	***Nursing students (n=5)***	***Faculty members (n=6)***
Gender (n)		
Female	3	5
Male	2	1
Age (years)		
Median (range)	29 (22-43)	46 (39-64)
Study place (n)		
A	2	2
B	2	2
C	1	2
Roles in the scenarios		
Nurse	2	
Physician	1	
Observer	2	
Facilitator		3
Operator		1
Both facilitator and operator		2
Previous experience with organizing simulations in undergraduate nursing education		
Yes		6
No		
Had attended a course that focussed on how to be a facilitator in simulations		
Yes		5
No		1

5.4.3 The high-fidelity simulation intervention

The HFS intervention in Study 3 took place in two simulation laboratories at two universities, one in southern Norway with two campuses, the same as in Study 2, and one in eastern Norway. The HFS intervention was mostly the same as in Study 2. However, the HFS intervention had been a compulsory part of the nursing students' education programme for several years at both universities, and some changes were made to adapt equally to the two different universities' educational programmes. In an attempt to standardise the organisation of the HFS intervention, a written guide on how to organise it was created by the PhD student. The guide's content was summarised based on the PhD student's experiences with conducting Study 1 and Study 2, with the following changes:

1. Changes to the patient case

The patient case was about a 75-year-old female patient who was hospitalised with cancer coli. She had gone through surgery (hemicolectomy), and she was now transferred to the surgical ward.

2. Minor changes regarding the patient's vital signs values during the scenario controlled by the simulator operator

These adjustments were made after an anaesthesiologist, with many years of experience facilitating simulation sessions for health professionals in hospitals, checked the HFS intervention for quality before the assessments in Study 3. The changes were made to increase the fidelity of the scenario.

3. Repeated scenario was not offered to any of the participants to ensure equality

4. Changes to the debriefing phase

The debriefing phase followed the structured debriefing script, called PEARLS, by Eppich and Cheng (2015), as presented in section 3.3.3 and Appendix 7. This change was based on a recommendation from INACLS's Standards of Best Practice in Simulation (2016) and the PhD student's experiences after attending a facilitator course in November 2017.

5. Because of the different universities' locations, a total of 38 participants in Study 3 used NEWS instead of TILT as an EWS system after conducting the ABCDE assessments in the scenario.

Except for these changes, the HFS intervention was organised as described in Study 2. The written guide was provided to all participating faculty members a month before the intervention (Appendix 7).

Altogether, eight simulation groups were involved, comprising between eight and 15 participants each. Each simulation experience lasted up to two-and-a-half hours. Seven faculty members helped organise the intervention. The research team was not involved in selecting the faculty members that organised the intervention. The characteristics of the simulation groups are displayed in Table 21.

Table 21. Characteristics of the simulation groups in Study 3.

Group number	Group size	Observers location during the scenario
1	10	Via audio and video on a screen in another room
2	12	Via audio and video on a screen in another room
3	12	Directly in the simulation room
4	12	Directly in the simulation room
5	8	Directly in the simulation room
6	14	Via audio and video on a screen in another room
7	15	Via audio and video on a screen in another room
8	13	Via audio and video on a screen in another room

5.4.4 Data collection

A revised version of the self-report pre- and post-test questionnaire, developed and validated in Study 2, was used to collect data in Study 3 (Appendix 6). The PhD student informed the participants about the study and administered the questionnaire to the participants in all the intervention groups (n=8) and in four of the control groups. Because data collection occurred at the same time in some groups, two other faculty members informed and administered the questionnaires to the remaining control groups. All the participants in the *intervention* groups responded to the questionnaire immediately before and after the HFS intervention. The participants in the *control* groups responded to the questionnaire immediately before and after meetings. In five of the seven *control* groups, the participants attended a classroom meeting to receive practical information about their upcoming clinical practice periods. In the remaining *control* groups, the participants attended a reflection meeting about clinical practice. The questionnaire's content was not presented or discussed in any of the *control* groups during the time between responding to the questionnaires. The

HFS intervention and the meeting were the same length (up to two-and-a-half hours).

As a process evaluation embedded within the trial, the PhD student asked the students and faculty members to share their experiences while participating in the intervention in individual interviews after the intervention. All the intervention groups (n=8) were asked whether one self-selected member of each group voluntarily would participate after having responded to the questionnaire the second time. All the faculty members involved in organising all phases of the intervention (n=6) were asked before the intervention to participate voluntarily. An interview guide comprising the following five open-ended questions was used: *What role did you have when participating in the HFS-intervention, how will you describe your experience of the HFS-intervention, what was positive with the HFS-intervention, what was negative with the HFS-intervention,* and *do you have something to add about the HFS-intervention*? (Appendix 8)

The students were also asked to share their experiences while responding to the questionnaire by answering the following open-ended questions: *How would you describe your experience filling out the questionnaire? What were positive/negative aspects of the questionnaire? Do you have anything to add about the questionnaire?* (Appendix 9)

The PhD student audio-recorded and conducted all the interviews at the university where the intervention took place. The interviews with the students lasted 10 to 13 minutes each (mean: 11 minutes) and were conducted immediately after the intervention. Interviews with the faculty members lasted 17 to 48 minutes each (mean: 33 minutes) and were conducted within one week after the intervention. The data collection flow in Study 3 is shown in Figure 4.

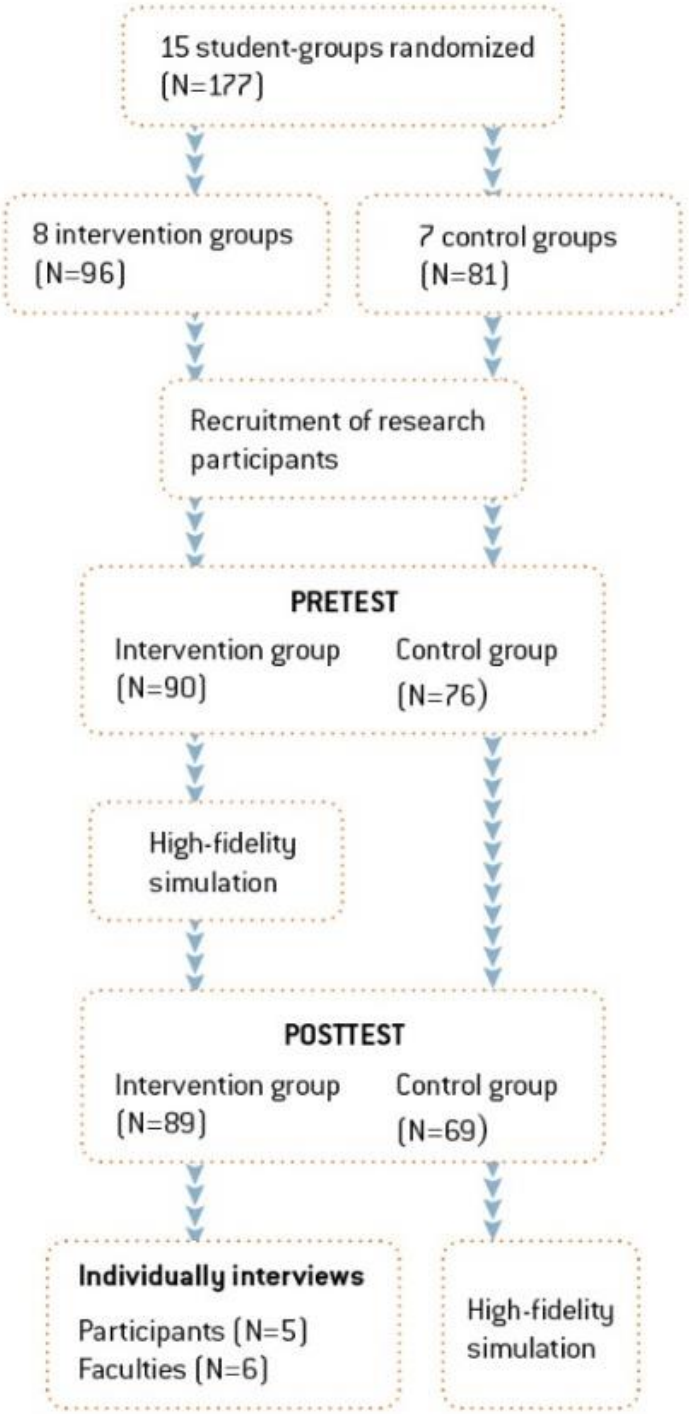


Figure 4. Flow of the data collection in Study 3.

5.4.5 Data analysis

The quantitative data in Study 3 were analyzed using a free software program (Avdic & Svensson, 2010) and the SPSS (V24) software program. If a participant had chosen two response options of an item of knowledge, and one of which was correct, then that one was consistently recorded. When two of the five item-categories of self-confidence were marked, or the mark was placed between two adjacent categories, the lower level was consistently recorded to avoid overestimation of intervention effect. The main outcome was the change in the number of correct responses of knowledge after the intervention when compared with corresponding outcome in a control group. The two sets of changes in the number of correct responses of knowledge were compared by the Wilcoxon-Mann-Whitney rank-sum test adjusted for tied observations (Siegel & Castellan, 1988). The proportion students in the intervention and control groups with decreased, unchanged, and increased numbers of correct responses of knowledge regarding each of three dimensions in the questionnaire was also calculated. The three dimensions were chosen to be:

1) **Normal values**

Item number 1: What is usually considered a normal blood pressure for healthy adults?

Item number 4: What is usually considered a normal resting pulse for healthy adults?

Item number 8: What is considered a normal respiratory rate at rest for healthy adults?

Item number 11: What is usually considered a normal body temperature in healthy adults (degrees Celsius)?

Item number 14: What is usually considered normal blood oxygen saturation for healthy adults?

Item number 17: What is usually considered as normal urine production a day in healthy adults?

2) **Clinical changes**

Item number 2: What usually happens to the blood pressure after acute major blood loss?

Item number 5: What usually happens to the pulse rate after acute major blood loss?

Item number 9: What usually happens to the respiratory rate after acute major blood

loss?

Item number 12: What usually happens to the body temperature a while after acute major blood loss?

Item number 15: What usually happens with the oxygen saturation in the blood at acute major blood loss?

Item number 18: What usually happens with the production of urine at acute major blood loss?

3) Nursing procedures

Item number 3: Which of these causes may lead to low blood pressure?

Item number 6: What is included in the assessment of pulse quality?

Item number 7: At which location is the pulse most commonly measured in adults?

Item number 10: What are the recommendations for counting an irregular respiratory rate?

Item number 13: Which method of measuring body temperature usually offers the most accurate measurement results?

Item number 16: At what point can a nurse administer oxygen to a hospitalized patient?

Item number 19: What is the purpose of having compression bandage on a surgical wound?

Item number 20: What is ABC a shortening for in the 'ABCDE' approach?

As the three dimensions of items covered different aspects of the same concept, a single global score of each dimension was defined. There are various approaches to aggregate multi-item ordered categorical assessments to a global dimensional score (Svensson, 2001; Allvin et al., 2009; Svensson, 2010). Because the responses of knowledge are recorded as correct or incorrect answers, the use of the sum of correct answers within each dimension defines the global dimensional score of knowledge. The proportion students with all items correctly answered on both occasions was described separately from students with incomplete number of unchanged items.

The global score of perceived self-confidence of each of the same three dimensions as for knowledge were also calculated and was defined by the median score. The dimensions consist of an even number of items, six and eight. When the two central item responses differ, the median cannot be defined as the average of these categories because of the non-numerical properties. For an ordered set of six item responses '*somewhat, somewhat, average, largely,*

largely, and *very*', both '*average*' and '*largely*' will serve as a median. The category that reflects the lower level of self-confidence has been chosen to be used as a global score to avoid overestimation of intervention effect. In cases of an intermediate possible category between the two central categories, for example, between '*average* and *very*' or '*somewhat* and *large*' the intermediate category '*largely*' and '*average*', respectively, was chosen.

All the qualitative data were analyzed and inspired by Braun and Clarke's thematic analysis (2006) as presented in 6 steps in Study 2 (see section 5.3.5). Two examples of the qualitative thematic analysis process are displayed in Table 22.

Table 22. Two examples of qualitative thematic analysis from Study 3.

Examples of text coded	**Sub-theme**	**Theme**
Faculty member: It is often in the debriefing session that I need to help those who have been in active roles to see what really happened in the scenario.	Different perspective on the situation/scenario	Promoting reflection
Student: It made me more secure that before being in an active role in the scenario, I had the opportunity to feel the simulator's pulse rate.	Orientation regarded the simulator and the environment	A safe environment

5.4.6 Results from Study 3

The results from Study 3 were describing and estimating the change in undergraduate nursing students' knowledge and perceived self-confidence after the HFS-intervention. The results from the process evaluations also identified barriers and enablers that may impact successful implementation of an HFS intervention.

Intervention' effects on knowledge

The number of correct responses to the 20 knowledge items by the participants in the intervention group ranged from 11 to 20 (Md: 17; Q_1: 16, Q_3: 18), and from 12 to 20 in the control group (Md: 17; Q_1: 16, Q_3: 18) at study start, see Table 23.

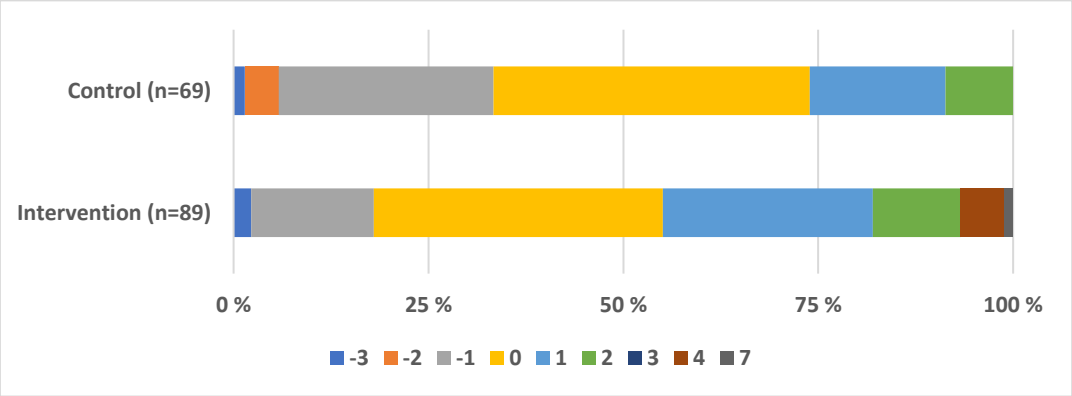
Table 23. Number of correct knowledge responses (0-20) in Study 3.

	N	Mean	SD	Median	Quartiles (Q_1; Q_3)	Range (min, max)
Intervention group baseline	89	16.9	2.1	17	(16; 18)	(11, 20)
Intervention group post-test	89	17.5	1.6	18	(16; 19)	(13, 20)
Control group baseline	69	17.2	1.7	17	(16; 18)	(12, 20)
Control group post-test	69	17.2	1.8	17	(16; 19)	(11, 20)

The distribution of changes in the number of correct responses in the intervention group ranged from -3 to 7 and was significantly higher than the changes in the control group that ranged from -3 to 2 (p=0.004), see Table 24.

Table 24. Changes in the number of correct responses of knowledge among the participants in Study 3.

Difference post-pre	-3	-2	-1	0	1	2	3	4	>4	Total
Intervention group	2	0	14	33	24	10	0	5	1	89
Control group	1	3	19	28	12	6	0	0	0	69
Total	3	3	33	61	36	16	0	5	1	158



The proportions of students in the intervention and control groups that have increased the number of correct responses on the post-test questionnaires were 45% and 26%, respectively. The 95% confidence interval of this difference of 19 percentage units, ranges from 4 to 34 percentage units. This means that in a representative population one can expect an intervention effect of about 3 to 34 percentage units more students to increase the number of correct answers of knowledge than without. Corresponding comparisons of the proportion students in the intervention and control groups with increased number of correct responses post-test were made on the three groups of items referring to the knowledge of 'normal values', 'clinical changes' and to 'nursing procedures' see Tables 25-27. The participants with all items correct both pre- and post-test were not included in the sample size when comparing the intervention and control groups.

Table 25. The numbers (proportions) of students with decreased, unchanged, increased numbers of correct responses referring to the dimension '*normal values*' items of knowledge post-test, and the number of students with correct responses to all six items both pre- and post-test in Study 3.

	Decreased	**The same number of correct items pre- and post-test**	**Increased**	**All items correct pre- and post-test**
Intervention group (n=89)	17 (19%)	29 (33%)	22 (25%)	21 (24%)
Control group (n=69)	9 (13%)	29 (42%)	3 (4%)	28 (40%)
Intervention effect on knowledge *Difference in proportion students with increased number of correct responses post-test, intervention vs control (participants with all items correct pre- and post-test not included):*				
22/68 = 0.324 vs 3/41 = 0.073. Δp: 25 percentage units. 95% confidence interval (Δp): 11 to 39 percentage units. p=0.005.				

Table 26. The numbers (proportions) of students with decreased, unchanged, increased numbers of correct responses referring to the dimension '*clinical changes*' items of knowledge post-test, and the number of students with correct responses to all six items both pre- and post-test in Study 3.

	Decreased	**The same number of correct items pre- and post-test**	**Increased**	**All items correct pre- and post-test**
Intervention group (n=89)	9 (10%)	22 (25%)	22 (25%)	36 (40%)
Control group (n=69)	17 (25%)	21 (30%)	10 (14%)	21 (30%)
Intervention effect on knowledge *Difference in proportion students with increased number of correct responses post-test, intervention vs control (participants with all items correct pre- and post-test not included):*				
22/53 = 0.415 vs 10/48 = 0.208. Δp: 21 percentage units. 95% confidence interval (Δp): 3 to 38 percentage units. p=0.04.				

Table 27. The numbers (proportions) of students with decreased, unchanged, increased numbers of correct responses referring to the dimension '*nursing procedures*' items of knowledge post-test, and the number of students with correct responses to all eight items both pre- and post-test in Study 3.

	Decreased	**The same number of correct items pre- and post-test**	**Increased**	**All items correct pre- and post-test**
Intervention group (n=89)	14 (16%)	33 (37%)	25 (28%)	17 (19%)
Control group (n=69)	5 (7%)	39 (57%)	10 (14%)	15 (22%)
Intervention effect on knowledge *Difference in proportion students with increased number of correct responses post-test, intervention vs control (participants with all items correct pre- and post-test not included):*				
25/72 = 0.347 vs 10/54 = 0.185. Δp: 16 percentage units 95 % confidence interval (Δp): 1 to 31 percentage units. p=0.07.				

The wide, but non-zero, confidence intervals indicate statistical evidences of intervention effect on knowledge, especially regarding items of 'normal values', from 11 to 39 percentage units (p=0.005), and of 'clinical changes', from 3 to 38 percentage units (p=0.04).

Intervention' effects on self-confidence

The global levels of perceived self-confidence regarding 'normal values' ranged from *average* to *very confident*, and from *somewhat* to *very confident* regarding 'clinical changes' and 'nursing procedures' assessed by the two groups of students' pre-tests. A majority, 55 %, of the students in the intervention group assessed higher levels of self-confidence referring to 'clinical changes' after intervention, see Table 29. Corresponding proportion students in the control group that scored higher levels of self-confidence post-test was 10%. The 95% confidence interval of this difference of 45 percentage units, ranges from 32 to 58 percentage units, which is strong evidence of significant intervention effect on perceived self-confidence referring to clinical changes (p<0.0001). No significant intervention effect was identified regarding the dimensions 'normal values' (p=0.76) and 'nursing procedures' (p=0.11), see Table 28 and 30.

Table 28. The number (proportion) students with lower, unchanged, higher levels of perceived self-confidence regarding the dimension '*normal values*' on the follow-up occasion according to paired data from pre- and post-assessments in Study 3.

	Lower	**Unchanged**	**Higher**
Intervention group (n=89)	4 (4%)	64 (72%)	21 (24%)
Control group (n=69)	4 (6%)	51 (74%)	14 (20%)
Intervention effect on perceived level of self-confidence			
Difference in proportion students with higher self-confidence post-test, intervention vs control groups:			
24% vs 20%, Δp: 4 percentage units.			
95% confidence interval (Δp):			
-10 to 16 percentage units.			
p=0.76.			

Table 29. The number (proportion) students with lower, unchanged, higher levels of perceived self-confidence regarding the dimension '*clinical changes*' on the follow-up occasion according to paired data from pre- and post-assessments in Study 3.

	Lower	**Unchanged**	**Higher**
Intervention group (n=89)	1 (1%)	39 (44%)	49 (55%)
Control group (n=69)	9 (13%)	53 (77%)	7 (10%)
Intervention effect on perceived level of self-confidence			
Difference in proportion students with higher self-confidence post-test, intervention vs control groups:			
55% vs 10%, Δp: 45 percentage units.			
95% confidence interval (Δp):			
32 to 58 percentage units.			
p<0.0001.			

Table 30. The number (proportion) students with lower, unchanged, higher levels of perceived self-confidence regarding the dimension '*nursing procedures*' on the follow-up occasion according to paired data from pre- and post-assessments in Study 3.

	Lower	**Unchanged**	**Higher**
Intervention group (n=89)	5 (6%)	59 (66%)	25 (28%)
Control group (n=69)	8 (12%)	50 (72%)	11 (16%)
Intervention effect on perceived level of self-confidence			
Difference in proportion students with higher self-confidence post-test, intervention vs control groups:			
28% vs 16%, Δp:12 percentage units.			
95% confidence interval (Δp):			
-0.6 to 25 percentage units.			
p=0.11.			

Process evaluation

The process evaluation to identify the barriers and enablers that may impact successful implementation of the HFS intervention elicited three themes from the students and three from the faculty members (see Table 31).

Table 31. Barriers and enablers identified in Study 3 that may impact successful implementation of the high-fidelity simulation intervention identified.

Themes from the students:	**Themes from the faculty members:**
1. A safe environment	1. Creating a safe environment
2. Fidelity	2. Promoting reflection
3. Learning in different roles	3. Student-centered learning

The students described the simulation experience with words such as '*exciting', 'frightening', 'interesting', 'fun'* and *'I learned a lot'*. The analysis of their experiences resulted in three themes:

1) A safe environment

Feeling secure seems to be essential for learning, and the students emphasised the importance of aspects that made them feel safer and more secure before, during and after the intervention. Getting information about the patient's case and the learning objectives one week before the intervention and reviewing it in a group at the start of the intervention helped reduce their stress and feel more secure. The orientation and exposure regarding the simulator and its functions also made them feel more secure.

During the scenario, the observed students reported that the observers made them feel less secure and reduced learning outcomes. However, one student said, 'After a little while, I forgot the observers and got in my own "zone" because I had to focus on the patient'. They also strongly noted that smaller groups would have made it easier to feel safe and share experiences more honestly, especially when things did not go so well in the scenarios. Support and positive feedback from group members were important in feeling secure. One student noted, 'If it is known by the students that the focus is mostly directed to negative aspects done during the scenario, I think the majority of the students would be more scared and not (dare) to attend simulation in the future'. This quote demonstrates that the students viewed security as an important prerequisite for learning. Knowing that they could not harm the patient in the scenario also made the students feel more secure.

2) Fidelity

It seems that contextual factors impact every aspect of the simulation experience, and the students reported that fidelity is important, noting that their opportunities for learning outcomes increased when the simulated environment felt realistic. By using the patient simulator and realistic medical equipment and furnishings, they said it felt as if they were in situations with real patients in real clinical settings. Talking about the simulator as if it were a real patient and not a simulator also made the context more realistic. However, the presence of many observers in the simulation room and a minor technical error with the patient simulator were described as barriers that made the scenario seem less realistic.

3) Learning in different roles

The learning outcomes in simulation should not only be linked to hands-on experience, as reported by the students discussing their learning in different roles. They felt that they had learned a lot, but the observers would have preferred to have taken an active role as well. Both observers elaborated on the importance of their role in providing another perspective on the situation and learning through reflection. Both observers were sitting in a separate room and watched the scenario on a screen. They highly valued the opportunity to reflect with the other observers during the scenario without interrupting the students in active roles. They particularly noted that being an observer allowed them to learn from other students' approaches and mistakes and gave them ideas about how to change their actions. Therefore, they missed the feeling of reflection-in-action and suggested repeated scenarios in each simulation group to increase learning outcomes. The students who were acting as nurses reported that they had a sense of mastering something and learned many things about themselves. Practising working together as a team also was important to them. Both were thankful for observers' feedback on their performance, but they found it challenging to be the centre of attention. They would like to have more simulation exercises during their nursing education, both before and during their clinical placement and as preparation for theoretical exams. They stressed that the simulation environment supported linking theory and practice.

The students described aspects of *item style* and *item content* regarding their experiences while responding to the questionnaire. They found that most items addressed relevant aspects of their experiences during the intervention, and they understood most of the content, including how to fill out the questionnaire.

The analysis of the experiences organising the intervention resulted in three themes and suggestions for future simulation exercises from faculty members:

1) Creating a safe environment

Feeling secure was reported to be a key factor in the learning process, and the faculty members elaborated on the importance of creating a safe environment for the students. Several factors that can foster this before, during and after the intervention were highlighted. Giving the students an opportunity to read through the patient's case and learning objectives and suggest relevant theories for preparation a week before the simulation experience were deemed important in participants' reports. Starting the intervention with a review of the patient's case and learning objectives was described as being important to reducing stress and making the students feel more secure and ready for action. This phase of the intervention (the prebriefing phase) also included repetition of relevant knowledge, theoretical principles and an agreement on terms of mutual respect and confidentiality. The importance of telling the students that the simulation is an exercise and not an exam, and the usefulness of learning by making mistakes in a patient-safe environment before meeting real patients in clinical practice were stressed. They also encouraged the students to be engaged and active during the simulation sessions. Meeting the students at the right level was reported as being important. To ensure that they are on the right level, half the faculty members felt that the students should be mostly active during the prebriefing phase, but that they should not be overloaded with too much information.

At the end of the prebriefing phase, the roles were distributed, and most of the faculty members reported that it could be challenging to get students to volunteer to be nurses in the scenario. Students often described acting in the role of a nurse as 'frightening', and they rarely volunteered for it immediately. Knowing the students before the intervention was an advantage because it seemed easier for the students to participate voluntarily, and the faculty members knew whom they could challenge to participate in active roles. Some students contacted the faculty members before the intervention about being exempted from participating in active roles for various personal reasons. However, one student volunteered for the physician role after she received more information about the simulation from a faculty member. The faculty members reported that it was important to talk with all the students about their roles and provide a good

orientation and exposure to the patient simulator and its functions. The importance of giving everyone in the simulation group some level of responsibility also was emphasised, and the observers were assigned tasks to focus on during the scenario.

During the scenario, the facilitators reported that they were present in the simulation room and offered help if needed, e.g., practical assistance with the simulator or equipment. Some also offered cues to participants during the scenario, but they were careful to avoid interfering with the students' independent problem solving. They elaborated on the need for technical expertise to manage the simulator, and that technical errors during the scenario could make the students feel insecure. However, two of the faculty members experienced a technical error that occurred during the scenario and made the students' work more independent, as they paid more attention to clinical observations and were not as dependent on technical measuring instruments.

The faculty members perceived that the students were uncomfortable being observed during the scenario, but these feelings dissipated when they began concentrating on what to do. After the scenario, the faculty members emphasised the importance of directing most of the focus to what the students did well to make them feel more secure. The faculty members noted that starting the debriefing session by asking about the students' emotional situation could shift the focus away from learning outcomes, so they did not dwell on the emotional side of participating and instead focussed more on learning objectives.

2) Promoting reflection

Another theme is the high value that all faculty members placed on debriefing. The faculty members highlighted the importance of learning from reflecting on the situation within the groups after the scenario. They mostly noted that students who were in active roles reported that they made many mistakes; therefore, the need for sharing different perspectives on the situation in the group was appreciated highly and viewed as helpful to the learning process. The importance of inviting someone to summarise their descriptions of key events during the patient case early in the debriefing session to ensure that everybody in the group was on the same page also was reported. The faculty members emphasised that the debriefing session should be tailored to learning objectives.

3) Student-centred learning

The faculty members reported that simulation activities should meet the students' needs. Not knowing how the students would respond and not being prepared for new aspects of a situation were reported as being characteristics of organising simulation exercises. Working with simulations was described as unpredictable because different students possessed varying personalities and skills. The faculty members who acted as operators during the scenarios pointed out that sometimes they had to give the patient in the scenario more symptoms than they had planned and more than what was realistic (such as higher blood pressure or reduced awareness) to get students to respond. The debriefing sessions also were described as unpredictable because they were based on what the students were highlighting. To reduce the unpredictability, the faculty members appreciated being two professionals who shared the organization of the simulation. Having another professional for support during the whole simulation intervention was described as important. They could communicate during the scenario if necessary, as well as help each other and make appointments before the scenario started.

The faculty members emphasised the importance of allowing more students to participate actively during the scenarios. To manage this, they suggested repeating the scenarios in each simulation group or splitting the scenarios into sections with breaks in which they changed roles along the way. They thought that more students in active roles would increase their sense of achievement, making them feel more secure and making it easier for them to get to know each other better in the group. Most of the faculty members wanted more simulation exercises during the undergraduate nursing education programme, both before and during the students' clinical practice periods. The value of simulation exercises during the clinical practice periods that were tailored to the students' own practical experiences was highlighted to improve their learning outcomes.

5.5 Ethical approvals and considerations

The studies in this PhD project were conducted in accordance with the guidance of the Norwegian National Research Ethics Committees and the principles of the Declaration of Helsinki (The Norwegian National Research Ethics Committees, 2014). Institutional approval was received to perform data collection, and the

PhD project was approved by the Norwegian Centre for Research Data, project No. 52110 (Appendix 10). A comprehensive study protocol for Study 3 is registered and accessible on *clinicaltrials.gov*, ID: NCT 04063319, Protocol ID: 52110. Due to the studies' aims, the PhD project did not require ethical approval. Participation in the HFS intervention was a compulsory part of nursing education. However, responding to the questionnaire and participating in an interview were voluntary and did not affect students' course grades. All participation required oral and written information distribution and signed informed consent (Appendices 11-16). The principles of anonymity, voluntariness and the right to withdraw from the study without reporting a reason were emphasised in both written and oral consent information. As the simulation settings were a part of the participants ordinary program, it could represent a change that the students might perceive responding to the questionnaires also to be mandatory and included in the program. Therefore, the principle of voluntariness was emphasised strongly in the written consent information and repeated in the oral consent information when the questionnaires were distributed. Nursing students are not deemed a vulnerable group, as they are adults who possess autonomy and consent competence; however, a teacher-student relationship is characterised by disequilibrium regarding power balance. Thus, the members of the research team were not in a teacher-student relationship with the invited students during the study period. The research team was aware that participating in the intervention could trigger negative feelings; therefore, in the written consent information, students were offered the opportunity to consult one of the researchers if they had any questions or concerns after participating in the intervention (although no one did so). The participants in the control groups in Study 3 received no instructional intervention between responses to the questionnaires. To ensure an equal learning opportunity for all students, the participants in the control groups attended the HFS intervention within a week after they responded to the questionnaire the second time.

6.0 SUMMARY OF THE OVERALL RESULTS

To address this PhD project's overall aim, a summary of the identified intervention effects from the three studies will be presented in this chapter.

6.1 Interventions' effects on knowledge

All the HFS interventions included in the meta-analysis reported an increase in knowledge in the intervention groups compared with the control groups (the pooled between-group effect size: 0.92, 95% confidence interval: 0.27 to 1.57). Most of the knowledge items in Study 2 did not cover the zero value when calculating the difference between the proportion of participants with increased and decreased correct responses to each item. Therefore, they identified an increase in knowledge after the intervention (ranging from 0.9 to 24.8 percentage units). In Study 3, the Wilcoxon-Mann-Whitney rank-sum test, adjusted for tied observations, showed a statistically significant increase in the number of total correct responses to knowledge in the intervention group compared with the control group ($p=0.004$). The distribution of changes in the total number of correct responses in the intervention group ranged from -3 to 7, compared with -3 to 2 in the control group. Regarding the three groups of items referring to the knowledge of 'normal values', 'clinical changes' and 'nursing procedures', the results showed statistical evidence of intervention effects on items referring to 'normal values' ($p=0.005$), and 'clinical changes' ($p=0.04$). However, no significant intervention effect was identified regarding the 'nursing procedures' dimension ($p=0.07$).

6.2 Interventions' effects on self-confidence

Three HFS interventions measuring self-confidence levels pre- and postintervention were included in the meta-analysis, with only one showing an increase in favour of HFS (the pooled between-group effect size: -0.08, 95% confidence interval: -0.39 to 0.23). When calculating the difference between the proportion of participants with higher and lower self-confidence levels on each item in Study 2, the results showed that no values covered the zero value (ranging from 16.5 to 66.0 percentage units), i.e., all self-confidence items were sensitive to changes toward higher levels after the intervention. The same applied

to the relative position values of systematic group changes on the self-confidence items (ranging from 0.14 to 0.58). In Study 3, global levels of perceived self-confidence identified a statistically significant increase in intervention effects on items referring to ‘clinical changes’ ($p<0.0001$). However, regarding the dimensions ‘normal values’ ($p=0.76$) and ‘nursing procedures’ ($p=0.11$), no significant intervention effect was found.

7.0 DISCUSSION OF RESULTS AND METHODOLOGICAL CONSIDERATIONS

The overall aim of this PhD project was to evaluate the efficacy of using HFS in undergraduate nursing education. The findings showed that use of HFS may elicit positive effects on students' knowledge and self-confidence levels in managing acute patient deteriorating events. Several other studies have found similar positive effects (Labrague et al., 2019; Zieber & Sedgewick, 2018; Orique & Phillips, 2017; Hart et al., 2014; Kelly et al. 2014).

Interactions with the patient during the HFS interventions in this PhD project present learning limitations. Some features of the human body are not well represented, such as skin texture, skin colour, facial expression, muscle tonus and movements. Often, such features are basic for displaying how patients' conditions develop and are prerequisites for training on recognition and response to deteriorating patients (Escher et al., 2017). Nursing is also an interpersonal process and involves interactions and relationships between the nurse and the unique patient (Carper, 2011). This raises important ontological and epistemological questions regarding the value of the measurements in this PhD project. It is argued in this PhD project that a combination of learning theories from deliberate practice, experiential learning and situated learning are beneficial in order to maximise the nursing students' learning outcomes (see Chapter 4). For example, using only behaviourist learning theories does not take into account the complex nature of the diversity of individual learning styles and the non-linear nature of learning (Stayt, 2012).

The results from this PhD project will be discussed according to the following sections: *theoretical framework, the prebriefing phase, the scenario phase* and *the debriefing phase.* At the end, *methodological considerations* will be discussed.

7.1 Theoretical framework

Within the HFS context of measuring the patient's vital signs as included in this PhD project, the empirical pattern of knowing, as described by Carper (1978; see section 4.5), may include anatomical and physiological explanations, normal values and the procedural and psychomotor elements of performing the

measurements. It is the 'knowing that' and the 'knowing how' (Ryle, 1949; Polyani, 1967) which are the knowledge patterns included in the measurements in Study 2 and Study 3 in this PhD project (see section 4.5). An empirical pattern of knowing assumes an objective ontology wherein knowledge exists in the external world, free from social, cultural or historical influences. This aligns with behaviourist learning theory (see section 4.0), where the assumed role of the teacher is knowledge transmission, and the learners are passive recipients responding to stimuli (Stayt, 2012). During the acquisition of a new behaviour or skill, repeated practice is deemed essential (McGaghie, 2011; Ericsson, 2008; Feingold et al., 2004).

Deliberate practice highlights the necessity of repetitive practice to achieve outcomes (see Chapter 4). Four of the included studies in Study 1 in this PhD project reported that they offered the participants repeated exposure to the same clinical scenario (Kelly et al., 2014; Liaw et al., 2011a; Liaw et al., 2011b; Alinier, Hunt & Gordon, 2004). In Study 2, repeated scenario was offered to the participants' in six of the 11 simulation groups. Both students and faculty members in the process evaluation embedded within Study 3 suggested that repeated exposure to clinical scenarios increased learning outcomes (see section 5.4.6). The students particularly noted that being an observer allowed them to learn from other students' approaches and that they missed acting during re-training. Most of the faculty members reported that it could be challenging to get students to volunteer in an active role because the students often described it as *'frightening'*. They thought that more students in active roles within each simulation group would make it easier to volunteer. Both the students and the faculty members also reported that the students in active roles were uncomfortable being observed during the scenario.

Nielsen and Harder (2013) found that being observed led to discomfort. DeCarlo et al. (2008) indicated that being filmed was a barrier to nurses' participation in simulations, while Kelly, Hager and Gallagher (2014) found that filming ranked low in terms of what 'mattered' most in simulation activities. Trokan-Mathison (2013) indicated that being watched in simulations was less stressful than being observed in clinical practice. If more students were able to be in active roles and experience being observed in each simulation group in Study 3 in this PhD project, it may not have felt so uncomfortable to be observed. It would also have made it easier for the students to get to know each other better in the simulation group (see section 5.4.6). Repeated exposure to clinical scenarios

through simulation has been confirmed as being especially effective in several studies (Wighus & Bjørk, 2018; Hart et al. 2014; Abe et al., 2013; Auerbach et al., 2011, Johannesson et al., 2010). However, Bambini, Washburn and Perkins (2009) found that participants' previous experience with simulation did not affect outcomes for novice nursing students.

The value of repetitive practice was not only identified within the same simulation intervention, but the participants in the process evaluation in Study 3 also wanted more repetitive simulation exercises in the undergraduate nursing education programmes. They suggested that HFS interventions were included during nursing education both before and during the students' clinical practice periods. In addition, they highlighted that the HFS interventions were tailored to the students' own practical experiences to improve their learning outcomes. The number of rehearsals required to achieve autonomy in, for example, measuring the patients' vital signs, may be impossible to achieve in the unpredictable environment of clinical practice. Therefore, the simulated environment where multiple rehearsals are available, may theoretically enable students to gain autonomous skills more rapidly than if left to learning through clinical practice (Stayt, 2012).

Educationalists across a range of disciplines deem the behaviourist pedagogy as necessary for skill acquisition and maintain that it may be the most conducive to psychomotor skills acquisition (Kneebone et al., 2007). However, behaviourist theories of learning have attracted criticism (Stayt, 2012; Parker & Myrick, 2009). Behaviourist learning theories view learning as a linear process; if one does *a*, *b* and then *c*, one will achieve *d*. Learning in the HFS interventions in this PhD project is, however, far from linear, and individual learner needs are diverse and complex. Specifically, behaviourism has been criticised for only satisfying lower cognitive functions and neglecting higher level functions such as problem-solving and critical thinking (Stayt, 2012). Most significantly, behaviourism is charged with encouraging a passive student role, potentially limiting the opportunities for students to develop critical thinking skills (Stayt, 2012). Managing a deteriorating patient, such as in this PhD project, is a complex scenario that requires problem-solving and critical-thinking skills. 'Knowing how' entails far more than possessing technical skills; it is also the ability to understand what should be done in a specific situation and why (Heggen, Smeby & Vågan, 2015). Therefore, as noted before, learning theories such as

experiential learning and situated learning are also seen as beneficial in this PhD project to maximise the nursing students' learning outcomes (see Chapter 4).

With regards to measuring a patients' vital signs such as blood pressure, aesthetic knowledge, as described by Carper (1978), (see section 4.5), permits the nursing student to perceive the patient as more than the sum of their empirical parts. It involves the holistic appreciation of patients and allows the interpretation of the process within the psychosocial and cultural context of individual patients (Stayt, 2012). This aligns with experiential learning and situated learning theories (see Chapter 4). Knowledge is not passed from teacher to learner but is created individually by learners by processing experiences and interactions with their environment in relation to previously acquired knowledge and comprehension (Stayt, 2012). This process encourages concrete experience, reflective observation, abstract conceptualisation and active experimentation, as described in Kolb's (1984) experiential learning cycle (see section 4.2).

Furthermore, Kolb's (1984) belief that learning relies on reflective observations was supported by this PhD project's participants' emphasis on the importance of learning in different roles (see section 5.4.6). To use HFS in nursing education programmes effectively, it is crucial to understand students' perceptions of their assigned roles and the effects that these perceptions may have on students' learning (Harder, Ross & Paul, 2013). Through collaborations, students can understand and express different perspectives by performing different roles during a simulated scenario (Onda, 2012). Reflection occurs explicitly before and afterward but also implicitly during the scenario (Dieckmann, 2009). Several students in this PhD project were observers, but they all participated in the prebriefing and debriefing phases and were given particular observation tasks for the scenario performed. While it may appear ideal to train each participant in an active role, this may not always be possible due to resource limitations. Some of the observers reported that they missed the feeling of reflection-on-action, as described by Schön (1983) (see section 4.2). Reflection-on-action during the debriefing phase was described as important for increasing the learning outcomes of all the participants and faculty members in this PhD project. Articulation and group discussion, especially during the reflection-on-action phase, contribute to tacit knowledge becoming explicit. This collaboration within groups enables social, and eventually individual, understanding of cognitive processes (Onda, 2012).

Reflection also appears essential to the development of a personal and ethical pattern of knowing, as described by Carper (see section 4.5). These patterns of knowledge are independent of any specific clinical skill and permeate all nursing practice (Stayt, 2012). Carper (1978) highlights that personal knowledge involves the inner experience of being self-aware, and it is evidenced that becoming self-aware can stave off anxiety and increase self-confidence (see section 4.6). Therefore, personal knowledge is connected to measures of self-confidence.

In this PhD project, all participants were undergraduate nursing students in the same year of their education and, thus, may all be described as newcomers in managing the situation in the simulation scenarios. According to Lave and Wenger's (1991) theory on situated learning, learning occurs while participating in a context of practice (see section 4.3). Newcomers on the periphery of the practice community learn from their more experienced colleagues ('old-timers'). However, the faculty members were involved in all phases in the HFS interventions, and they can be described as the 'old-timers'. It also may be possible that some participants had more experience with deteriorating patients or seemed more secure compared with other participants and, therefore, could be described as more experienced by some participants or faculty members. The terms *peripheral participation, partial participation* and *full participation* are used to show the diversity in the learning process in the community of practice (Lave & Wenger, 1991) and can describe characteristics of the different roles used in the scenario.

In Study 3 in this PhD project, 66 participants reported that they were in observer roles, and 23 said they were participating actively in the scenario in the simulation room. The results showed no statistically significant difference in self-confidence levels between the groups. Regarding intervention effects on knowledge, no statistically significant differences were identified regarding the *'clinical changes'* and *'nursing procedures'* dimensions between the groups. However, a statistically significant difference was found regarding the *'normal values'* dimension between the groups in favour of the observer role. This may be explained by the results from the process evaluation revealing that students found participation in the scenario to be stressful and limited their learning outcomes (see section 5.4.6). Bong et al. (2017) found that participants in active roles experienced higher stress, both objective stress responses, such as heart rate and cortisol levels, and subjective stress responses, than those in observer roles

(Bong et al., 2017). Nevertheless, it is important to note that the two groups' samples in Study 3 were small.

Limited studies have demonstrated the benefit of simulation observation (Bullard et al., 2018; Bong et al., 2017; O`Regan et al., 2016). In a systematic review of observer roles that optimise learning in healthcare simulations, O`Regan et al. (2016) reported that learning and satisfaction in observer roles are associated closely with observer tools, learner engagement, role clarity and contributions to the debriefing. Learners who valued observer roles described them as affording an overarching view to examine details from a distance, then eliciting meaningful feedback during debriefing (O`Regan et al., 2016).

Furthermore, learners who did not value observer roles described them as passive or boring compared with hands-on engagement during the simulation encounter. In the nine studies from the sample in the systematic review, O'Regan et al. (2016) identified four studies that showed no difference in outcomes between the hands-on learners and observers (Hober & Bonnel, 2014; Thidemann & Söderhamn, 2012; Bell et al., 2014; Kaplan, Abraham & Gary, 2012), two studies that reported superior outcomes in the hands-on groups (Stiefel et al., 2013; Harder, Ross & Paul, 2013) and one study that reported better outcomes in the observer group (Stegmann et al., 2012). Husebø et al. (2012b) found that observing the training of others during simulated cardiac arrest did not increase subsequent performance among nursing students. Zulkosky (2012) found that viewing a pre-recorded simulation was less effective than participating in a case study and lecture. Kelly et al. (2014) found that students ranked their role assignment in simulation lower than other simulation variables as a contributor to their ability to develop clinical judgement, while van Soeren et al. (2011) found that participants valued being able to play the role of their own profession. Some of the participants in this PhD project acted as a physician on the phone in the scenarios (see section 5.3.3). It could have been challenging for them to transition from their own profession to another. They received detailed role instructions from the faculty members before the scenario; however, this could have affected their ability to fully engage in the simulation scenario. Nevertheless, playing in a role other than their own profession can be a beneficial experience. Van Soeren et al. (2011) found that it was positive because it allowed the participants to empathise with the particular challenges related to another profession.

7.2 The prebriefing phase

Both students and faculty members in this PhD project elaborated on the need for a safe environment and briefing before the scenario to improve simulation outcomes (see section 5.4.6). All the participants in Study 2 and Study 3 received information about the patient case, learning objectives and suggestions for relevant reading material for preparation prior to the intervention (see section 5.3.3). Specific prior knowledge can be helpful in enhancing learning during HFS (Paige & Daley, 2009). If students are informed prior to the lab day about the simulation scenario, they may refer to books, relevant articles, class notes or any other materials they have at their disposal in anticipation of what may transpire during the simulated exercise. This is also an opportunity to reflect on what specific types of actions may be expected of them (Onda, 2012). It is evident that students who participated in briefing activities that comprised learning engagement and orientation tasks perceived higher overall simulation efficacy (Chamberlain, 2017). The term '*gearing-up'*, as a means of preparation for situations, has been used in the extant literature as an antecedent of self-confidence (Schunk & Pajares, 2005). A Delphi study about quality indicators for simulation demonstrated that participants should be oriented to the simulation environment before the scenario (Arthur, Levett-Jones, & Kable, 2013).

However, the simulator offers a variety of options, and it is important that participants not get overloaded with too much information during orientation. If it feels unattainable, the simulation will not be an effective learning experience, and the participants can become more insecure. Beischel (2013) found that participants who were more *'ready to learn'* were less anxious, while those who spent more than one hour preparing for simulation activities were more anxious. Cuerva et al. (2018) found that the debriefing results were better after a short briefing session and an abrupt start to the scenario in HFS training on childbirth rather than a long briefing session that includes direct instruction in the scenario.

The simulation groups in Study 2 and Study 3 in this PhD project consisted of between six and 15 participants in each group (see Table 9 and Table 21). The results from the process evaluation showed that the participants strongly desired smaller simulation groups (see section 5.4.6). They reported that smaller groups would have made it easier to feel safe and share experiences more honestly, especially when things did not go so well in the scenarios. Group size is a factor that is largely within the facilitator's control (Jeffries, 2016). Curl et al. (2016) recommend that the group size during the active part of the HFS should

be limited to five students. Partin, Payne and Slemmons (2011) found that students' express dissatisfaction when a group comprises more than six students. Rezmer et al. (2011) reported that a group size of up to four participants elicits no effect, suggesting that the best practice may be having four to six participants per group.

7.3 The scenario phase

An anaesthesiologist with many years of experience facilitating simulation sessions for health professions in hospitals checked the quality of the simulation scenario used in Study 3 before the assessments (see section 5.4.3). Murray et al. (2008) propose that if the scenario needs to mimic clinical practice, practitioners' input is also essential. This may have some basis through nurse academics spending limited time in clinical practice, raising concerns about the validity, reliability, authenticity and transferability of simulated learning in the absence of currently practising clinical nurse involvement (Hogg, Pirie & Ker, 2006).

Developing a written guide for organising all intervention phases in Study 3 in this PhD project (Appendix 7) may have decreased differences in the intervention's content. Ensuring that the plans for integrating process and outcome data are agreed upon from the outset is a key recommendation for evaluation (Moore et al., 2015). The same scenario and patient simulator were used with all participants, with minor changes in the scenario for Study 3 (see section 5.4.3). However, the facilitation of the intervention varied as it involved up to eight different faculty members. Variations within each faculty member's facilitation were also identified. The results from the process evaluation showed that working with simulations is unpredictable because different students possessed varying personalities and skills. Sometimes the facilitators had to give the patient in the scenario more symptoms than the information in the written guide to get the students to respond (see section 5.4.6). Different facilitators may have caused small differences in the intervention's content although all participating faculty members agreed on the intervention's feasibility in this PhD project.

To bridge the gap between the appearance of a real patient and the simulator, several faculty members in this PhD project mentioned that they offered cues to participants during the scenario (see section 5.4.6). *Cues* may include observations, statements from patients and others, laboratory and

assessment data, patient responses or lack thereof and intuition (Groom et al., 2014). Paige and Morin (2013) concluded that two types of cues exist—*conceptual cues*, which help the participant achieve the simulation's instructional objectives, and *reality cues*, which help the participant navigate or clarify any gaps in the simulation's fidelity. This PhD project's facilitators reported both cue varieties. Binder et al. (2014) found that both verbal and equipment-generated feedback were effective. Garrett, MacPhee and Jackson (2010) indicated that participants valued timely cues, such as patient status changes, but it is important for the facilitator to be aware of feedback frequency. The participant should be allowed to make a decision, take action and reflect on that action before feedback is provided (Jeffries, 2012). If facilitators provide lots of feedback during the simulation, the participant may become dependent on the facilitator for the *'next step'*. Students have identified that they prefer feedback after the simulation because this enhanced flow and concentration (Wighus & Bjørk, 2018). Assistance should come in the form of cues that offer sufficient information to allow participants to continue with the simulation but do not interfere with their independent problem-solving (Jeffries, 2012).

The students in this PhD project reported that fidelity, or the feeling of realism, during the simulation experience was important to increasing their learning outcomes. They highlighted that use of the human patient simulator and realistic medical equipment and furnishings made them feel like they were in situations with real patients in real clinical settings (see section 5.4.6). Simulation activities should have real-world relevance and provide students with the opportunity to define the tasks and subtasks required to complete the activity. Authentic tasks are coherent, meaningful and purposeful activities that represent a culture's ordinary practices (Onda, 2012). From a situated perspective of learning, the level of fidelity is to be seen as a result of the participants' interactions with each other and the material environment (Rystvedt, Dahlgren & Kelly, 2019; Lave & Wenger, 1991). In comparison, other researchers have pointed out how simple techniques can increase the level of fidelity (Nestel et al., 2018). For example, Andreatta et al. (2014) found that an inexpensive fruit model provided adequate fidelity for teaching highly technical operative skills. Several studies found similar learning outcomes with various fidelity levels (Beebe, 2012; Lane & Rollnick, 2007). However, Grady et al. (2008) found higher performance and more positive participant attitudes associated with high vs low fidelity. Butler, Veltre and Brady (2009) noted that learners perceived that HFS

impacted their problem-solving abilities more than low-fidelity simulations. In contrast, Yang, Thompson and Bland (2012) noted that increased realism in simulation activities was associated with reduced confidence and judgement accuracy among participants. Close alignment between the clinical task and simulation task is often more important than structural fidelity for achieving training goals. In many circumstances, it might be more beneficial to stray from realism to increase learning (Dieckmann, 2009).

To *'assess, recognise and respond to changes in a patient's condition'* was the learning objective that was the focus for the measurements in Study 2 and Study 3 in this PhD project (see section 5.3.3). The identified intervention effects on perceived knowledge and self-confidence, referring to *'clinical changes'* compared with the control group, were both significant ($p = 0.04$ and $p < 0.0001$) in Study 3. In validating the questionnaire, the evaluation of the paired proportion of students' responses for knowledge items numbers 2, 4, 5 and 9—referring to *'clinical changes'*—showed that more students changed answers to correct, rather than to incorrect, responses. In addition, the self-confidence items referring to *'clinical changes'* in Study 2 also showed higher levels post-intervention. These findings support the idea that defining clear objectives may be important in eliciting positive intervention effects. In a recent cross-sectional study on elements in scenario-based simulations associated with nursing students' self-confidence and satisfaction, Olaussen, Heggdal and Tvedt (2019) found that clear objectives were associated with self-confidence. In addition, Smith and Roehrs (2009) found that clear objectives geared towards an appropriately challenging goal were correlated with increased satisfaction and confidence. Dieckmann (2009) pointed out that the training situation's relevance for reaching learning goals should outweigh striving to maximise simulation fidelity as such. To be an effective training setting, he argues that the simulation environment does not necessarily need to be identical to a clinical work environment. It should provide learning experiences that meet the learning goals, often involving events that are rare in a clinical work environment. The realism needs to be provided in the right form and amount to support for the learning objective and should not be considered a goal in itself (Dieckmann, 2009).

Many observers in the simulation groups and a minor technical error with the patient simulator were identified as factors that made the scenario less realistic for the participants during this PhD project (see section 5.4.6). Deckers (2011) indicated that within a given experience, consistency in fidelity improved

learning and that interruptions within the experience should be avoided. The different positions of the observers during the scenario in this PhD project may have created different learning conditions for the observing students (Nyström, Dahlberg, Hult & Dahlgren, 2019). Some observers were sitting directly in the simulation room, and some were sitting in a separate room around a table where they could watch the simulation scenario on a screen (see Table 9 and Table 21). The opportunity to communicate with each other without interrupting the participants in active roles during the scenario was highly valued by the participants in the process evaluation (see 5.4.6). The sight of several observers in the simulation room could also affect the participants' performance in the scenario more compared with not be able to see them. However, the observers sitting in another room had no instructor who could guide and assist their observations along the way. Some of the aspects in the scenario could also be missed when they did not observe it directly in the simulation room. Nyström, Dahlberg, Hult and Dahlgren (2016) explored two ways of observation in simulation. At one site, the observers were sitting in the operator room. At the other site, the observers were sitting in separate room watching the scenario on a screen. The study findings emphasise the importance of a better understanding of how to use the observation room as a learning environment.

The participants in this PhD project described participating in the HFS with words such as '*exciting', 'frightening', 'interesting', 'fun'* and *'I learned a lot'* (see section 5.4.6). Participants' motivation, enthusiasm and personal feelings about the simulation, as well as their willingness to suspend disbelief, affect their ability to immerse themselves firmly in simulation activities (van Soeren et al., 2011; Leighton & Sholl, 2009). Learners may support simulation activities' fidelity by wearing attire that exudes professionalism (Hope, Garside, & Prescott, 2011) as well as participating appropriately as simulated patients and family members (Nicholson, 2012). Students have reported high satisfaction with HFS (Crafford et al., 2019; Sarman & Pardi, 2019; Thidemann & Söderhamn, 2012) and greater satisfaction with HFS than traditional didactic approach (Stayt et al., 2015). Student satisfaction may contribute to a student's intrinsic motivation to learn and the attainment of better learning outcomes. The concept of self-confidence has a dynamic nature and is highly individualised (see section 4.6). It is affected by many factors, such as the student's perspective, role and experiences related to the context or setting (Perry, 2011). It is also affected by the student's self-efficacy. Those with high self-efficacy in a specific task are

more likely to make more of an effort than those with low self-efficacy (Schunk, 1990). Sarman and Pardi (2019) found evidence on the relationship between satisfaction and confidence in their study investigating undergraduate nursing students' satisfaction and self-confidence. Alfes (2011) reported a similar finding but with a strong positive correlation. This led Alfes (2011) to propose that when students have a higher level of self-confidence, their level of satisfaction with learning will also be higher. On the other hand, for those with lower levels of self-confidence, their level of satisfaction in learning will also be lower.

7.4 The debriefing phase

In this PhD project, the debriefing session in Study 3 followed the structured framework PEARLS (Eppich & Cheng, 2015), as recommended by INACSL (2016; see section 3.3.3). Research has identified that how educators facilitate debriefings varies greatly (Tannenbaum & Cerasoli, 2013), and structured and scripted debriefings in simulation-based education may counter the variability in debriefing style and structure (Cheng et al., 2013). Cheng et al. (2013) found that novice instructors who used a debriefing script were more effective at increasing learners' knowledge acquisition and team leader behavioural skills than educators who did not use a script. The facilitators in Study 3 received written and oral information from the PhD student about the PEARLS framework one month before organising the intervention. However, the PhD student had no experience with using PEARLS, and it could have strengthened the study results if someone with experience had prepared the facilitators before organising the intervention. Nevertheless, the PhD student had theoretical knowledge about PEARLS and was a resource that the facilitators could discuss the use of it with.

By using PEARLS in this PhD project, the reactions phase sets the tone and context for the rest of the debriefing (Cheng et al., 2016). Cheng et al. (2016) highlight that by allocating insufficient time for learners to share initial reactions to the simulated event, educators risk having unresolved negative emotions among learners that may decrease the learning outcomes. The authors have observed that educators often missed or ignored the participants' emotions, such as anger, frustration and anxiety, in debriefings (Cheng et al., 2016). Husebø et al. (2013) found that facilitators asked mostly evaluative and few emotional questions in debriefings, whereas nursing students answered with mostly evaluative and analytic responses and few emotional responses. In the process

evaluation in Study 3, the faculty members noted that starting the debriefing session by asking about the students' emotional situation could shift the focus away from the learning outcomes (see section 5.4.6). Therefore, they did not dwell on the emotional side of participating and instead focused more on learning objectives in the debriefing session. They emphasised that the debriefing session should be tailored to the learning objectives. Another theoretical framework to guide debriefing that includes the dimension of emotion, is Gibbs's reflective cycle (1988). It is a reinterpretation of the experiential learning cycle by Kolb (1984) and comprises the following six stages: description, feelings, evaluation, analysis, conclusion and action plan (Husebø, O'Regan & Nestel, 2015). As with Eppich and Cheng (2015), Gibbs (1988) emphasises that if descriptions and feelings are not dealt with adequately, learners may return to these at a later stage in the debriefing phase when they should be considering implications and actions. However, focusing on the participants' feelings with the simulation experience as stage number two in the debriefing, by using Gibbs's reflective cycle (1988), could have been a better way to structure the debriefing in this PhD project.

Bullard et al. (2018) agreed that observations, when paired with debriefing, may reap educational benefits similar to being in an active role in the scenario. They identified the debriefing phase as necessary for maximal learning in both roles. Deickmann et al. (2009) suggested allowing participants to do most of the talking during debriefing to boost their efficacy. A comparison of debriefing methods and learning outcomes showed that nursing students who received facilitated debriefing after simulations registered higher scores on the next simulation compared with students in the groups that only received feedback or self-debriefing (Gantt et al., 2018). Hayden et al. (2014) qualified their landmark finding that up to 50% of the time spent in clinical practice may be replaced with simulations but stressed that the simulations must be of 'high-quality' and accompanied by 'theory-based debriefing' (p. 538). Cheng et al. (2014) found a short debriefing session to be slightly more favourable than a longer one. One meta-theme within the debriefing theme concerns the use of video as a supplement to debriefing (Jeffries, 2016). Video in the debriefing phases was not used in this PhD project. Cheng et al. (2014) found negligible differences between video-enhanced and non-video-enhanced debriefings. Results from a systematic review by Levett-Jones and Lapkin (2014) about the

efficacy of debriefing affirmed that it was important but that no significant differences were discerned with or without the use of video.

The faculty members in this PhD project reported they mostly noted that students who were in active roles reported in the debriefing session that they had made many mistakes during the scenario (section 5.4.6). They frequently identified mistakes they had made that other team members may not have noticed. Both students and faculty members emphasised the importance of receiving positive feedback to feel secure. Eppich and Cheng (2016) have observed that facilitators in debriefings often engage learners in self-assessment that quickly turns into an extensive listing of performance gaps, with no discussion of positive behaviours. Receiving negative feedback may lead to stress and anxiety (Wighus & Bjørk, 2018).

However, debriefing in simulations provides unique opportunities to talk about things that did not go so well in the scenario (Dieckmann, 2009). Talking about mistakes in a safe environment can make participants more confident that they will not repeat the same mistakes. However, the mastery of a skill through repeated scenarios relies on immediate instructor feedback on the learner's actions, otherwise the learner is at risk of consistently repeating mistakes. Research indicates that feedback and expert modelling from facilitators and peers improved participants' motivation, learning and performance (Wighus & Bjørk, 2018; Abe et al., 2013). Vast amounts of the extant literature cited *support* as an important antecedent to self-confidence (see Table 3). Feedback provides positive and negative reinforcement that behaviourist theory deems essential for behaviour change (Stayt, 2012). In the scenario in this PhD project, the facilitator was present in the simulation room and offered practical assistance with the simulator or equipment if needed (see section 5.3.3), however the feedback was given in the debriefing phase.

Debriefing with good judgement means being tolerant but not colluding with participants by saying something was okay when it really was not. *Success* can be both an antecedent to and a consequence of self-confidence (see Table 3). One can have knowledge about a procedure, gain a support system, practise a skill and be appropriately geared up for situations, but if successes do not occur, self-confidence will be stalled. Several authors note that the more clinical successes a student experiences, the more self-confidence is reinforced (Chesser-Smyth, 2005; Clark, Owen & Tholcken, 2004). Success definitely supports confidence building (Bandura, 1986; Moreno et al., 2007; Savitsky et al., 1998),

and nursing students have highlighted the value of skill competence as a source of confidence in simulations (Zieber & Sedgewick, 2018). Zieber and Sedgewick (2018) found that skills were related directly to feelings of competence and confidence.

7.5 Methodological considerations

This PhD project has strengths and limitations regarding the included studies' validity and reliability that may have influenced the results. Validity and reliability must be addressed when considering research quality. Methodological issues according to the three studies are discussed in the following sections.

7.5.1 Study 1

In Study 1, articles that were not written in English were excluded, and only simulation interventions that were defined as HFS were included. This means that some relevant simulation interventions may have been excluded because the authors did not define the simulation intervention as HFS. Only published, peer-reviewed articles with pre- and post-test designs were reviewed. This can be both a strength and a limitation. It is a strength in that it secured a certain quality standard and data to compare before and after participating in HFS. The inclusion of grey literature along with the peer-reviewed articles may have provided a more balanced view of the evidence (Mahood, Van Eerd & Irvin, 2013). No intervention studies were identified and included from the grey literature searches performed (see section 5.2.2). However, there are numerous sources to locate grey literature in, and to locate grey literature requires considerable time and effort (Mahood, Van Eerd & Irvin, 2013). Using pre- and post-test designs in the included studies secured more accurate data on the effects of HFS compared to studies using only post-test designs.

Another strength regarding Study 1 is that two independent researchers handled all phases in the reviewing process, and any point of disagreement was discussed until an agreement was reached. Close collaboration with a university librarian when conducting the database searches was also deemed important as appropriate keywords needed to be used in various combinations. The outcomes measured in Study 3, *knowledge* and *levels of self-confidence*, were not included in the searches because the measurement outcomes were not determined at this

phase of the PhD project. However, it could have been a strength to include them as keywords in the searches. Many nurse educators use the terms *'self-confidence'* and *'self-efficacy'* interchangeably (Labrague, 2019; Martins et al., 2017; Lundberg, 2008). This was also done in Study 1, and it would have strengthened the study if both terms had been presented. Validated quality appraisal checklists that the Joanna Briggs Institute (2018) and Critical Appraisal Skills Programme (2018) developed were used, and these checklists were designed to be used as educational pedagogic tools. Collaboration with a statistician when conducting the meta-analysis ensured a quality standard for the statistical process.

7.5.2 Instrument validation

The concept of validity is an important aspect of questionnaire quality (Polit & Beck, 2017). In Study 2, validity was established by an expert panel that reviewed the relevance, appropriateness and fitness of the items for the intervention. The eight follow-up interviews also enabled an examination of construct validity in terms of the knowledge domains assessed and the item-response options. The responsiveness of the questionnaire was confirmed by means of statistical methods that consider the non-metric properties of ordered categorical data (Svensson, 1998; Svensson et al., 2015).

Although the use of multiple-choice questions (MCQs) is a common approach in knowledge assessment, it has been debated whether they really fit the purpose (Levett-Jones et al., 2011). In addition, few academics in undergraduate nursing programmes have adequate experience and training in developing quality MCQs (Tarrant et al., 2006). The results from the interviews conducted within Study 2 and Study 3 stated that the participants found most items in the questionnaire addressed relevant aspects of their experiences in the intervention, the level of difficulty was acceptable and the number of items was appropriate. These findings indicate that the increase in knowledge and levels of self-confidence identified in this project may be an effect from the intervention. However, correct answers on MCQs do not necessarily correspond with students' actions in real situations of patient deterioration.

The content in the questionnaire was based on the American Heart Association's (AHA) examination for Basic Life Support, VAR Healthcare and two textbooks that were required reading for the students participating in the

HFS intervention (see section 5.3.4). It would have been a strength if the content had also been based on the EWSs used in the HFS intervention (TILT and NEWS, see sections 5.3.3 and 5.4.3); however, these two EWSs represent different scoring values. The scoring values in TILT and NEWS also differ from those in one of the textbooks the students were required to read before participating in the HFS intervention (Kristoffersen et al., 2016).

In Study 2 and Study 3, the assessment of the questionnaire's validity was carried out before and immediately after the intervention. Kirkpatrick and Kirkpatrick's (2006) framework for evaluating training programmes' efficacy emphasises the importance of how much students' behaviour in other settings reflects what they have learned (see section 3.4). Asking the participants to respond to the questionnaire again, for example, three to six months after the intervention, would have strengthened the studies. Assessing sensitivity to capturing change over time is important regarding the potential of HFS to have sustained knowledge of and confidence in nursing students' practice over time. This was not done in this PhD project because of the limited study time frame.

7.5.3 Risk of bias in Study 2 and Study 3

A bias is a systematic error that impacts the validity and reliability of a study's findings. Different biases can lead to the underestimation or overestimation of true intervention effects (Higgins & Green, 2011). Recognising the importance of a standardised approach to describing potential bias, the Cochrane collaboration developed a tool to assess bias risk in RCTs (Higgins & Green, 2011), dividing bias into the following five forms: *selection*, *performance*, *attrition*, *detection* and *reporting*. This division of bias is used to address the validity and reliability in Study 2 and Study 3.

Selection bias

Selection bias refers to systematic differences between baseline characteristics of the groups that are compared (Higgins & Green, 2011). A stratified block randomisation performed by a statistician, using a random number table developed by Altman (1991, p. 540), contributed to making the different groups more equal in Study 3. The student groups randomly were selected to serve as intervention (n=8) or control (n=7) groups. It would have strengthened the randomisation process if each participant randomly was selected to serve as an

intervention or control and had not been scheduled in groups before the randomisation. The research team planned to perform a randomisation process before the students were scheduled in groups, but it was viewed as too challenging for the faculty members responsible for the nursing courses to handle, as this would lead to a new organisation of student groups. It also would have strengthened the study had the intervention and control groups existed in the same numbers in the study. However, the samples in both Study 2 and Study 3 comprised large numbers of undergraduate nursing students, and large sample sizes are viewed as a strength.

Performance bias

Performance bias refers to systematic differences between groups concerning the care that is provided, or exposure to factors other than intervention interest (Higgins & Green, 2011). About half of the participants in Study 2 engaged in relevant activities during the time between completing the two questionnaires, which may have increased intervention effects. They attended an HFS intervention about cardiopulmonary resuscitation (n = 57 of 107, see Table 11). One strategy to reduce co-intervention is to exclude those who planned to receive another form of intervention during the study period (Feeley & Cossette, 2015). Another strategy is to reduce the time between completion of the two questionnaires. Contamination of study content may have occurred with students discussing simulation and the questionnaires during the period from pre-test to post-test. As a result of Study 2, the assessments in Study 3 were completed immediately before and immediately after the intervention or meetings for both the intervention and control groups to control for confounding variables. Student participants and the faculty members involved ideally should not be aware of whether they are in an intervention or control group. Blinding may reduce the risk that knowledge of the intervention received, rather than the intervention itself, affects outcomes (Higgins & Green, 2011). However, blinding is not always possible, as in the case of Study 3 in this PhD project, in which the participants in the control group received no instructional intervention. Nevertheless, none of the student participants or faculty members involved knew the questionnaires' content beforehand or were involved in assessing the outcomes.

Attribution bias

Attrition bias refers to systematic differences between groups in withdrawals from a study (Higgins & Green, 2011). Recruiting and retaining trial participants can be extremely difficult. Reducing follow-up losses was a strength, in that the HFS interventions in Study 2 and Study 3 were a compulsory part of the undergraduate nursing programmes. However, participation in the studies was voluntary. It is also a strength that all the assessments were done within eight days in Study 2 and within three hours a day for all the participants in Study 3. In Study 2, only one participant failed to complete the post-test questionnaire. In Study 3, one participant did not respond to the post-test questionnaire in the intervention group, compared with seven in the control group. This resulted in a difference of 20 participants in the intervention and control groups (89/69). A CONSORT flow diagram is used in Study 3 so the reader can judge the process (see Paper 3).

Detection bias

Detection bias refers to systematic differences between groups in how outcomes are determined (Higgins & Green, 2011). The measured outcomes in Study 2 and Study 3 were determined based on the results from Study 1 in this PhD project. The analyses were done by the research team that was not involved in organising the HFS interventions.

All the measurements in Study 2 and Study 3 were self-assessments. Baxter and Norman (2011) suggest that methods of self-assessment are not reliable indicators of an individual's ability to self-assess their performance in a clinical setting. Research studies have found a negative correlation between self-assessment and performance because participants who were weaker believed their abilities to be greater than they actually were, whereas, participants who were strong and able to engage in tasks typically viewed themselves as slightly less capable than their actual performance. One specific example is a study by Hodges et al. (2001) in which 24 first-year family medicine residents interviewed a standardised patient and gave them 'bad news'. The purpose of the activity was to determine the residents' ability to self-assess their video-taped performance before and after viewing four videos designed to represent a spectrum of performances from incompetence to advanced competence. These authors discovered that those with the least amount of skill were more likely to overestimate their abilities. This is consistent with the study by Kruger and

Dunning (1999), which concluded that *'those who know less also know less about what they know'*. These findings are important to consider in relation to the results on self-confidence in this PhD project.

Reporting bias

Reporting bias refers to systematic differences between reported and unreported findings (Higgins & Green, 2011). A comprehensive study protocol for Study 3 is registered and accessible to the public on *clinicaltrials.gov* (see section 5.5). Both the prespecified primary and secondary outcomes in Study 3 have been reported and the statistical analysis explained. The statistical methods and data analyses summarised in Study 2 and 3 are considered suitable for this PhD project.

A common approach to ordinal data is to use sum scores of scale assessments, often transformed into a standardised score ranging from 0 to 100. However, data from scale assessments comprise categories that represent an ordered structure without any information regarding distance and standardised magnitude. Thus, calculations of sum scores or differences in scale assessments are not appropriate analytical operations, and conclusions drawn from mathematical calculations on ordinal data may not be valid (Svensson, 2001). You may want to ask yourself: If a continuous scale ranging from '*not at all confident*' to '*very confident*' really exists, how can we determine whether the differences between '*somewhat confident*' and '*average confident*' and between '*largely confident*' and '*very confident*' are the same? It is highly likely that each point on the scale represents an interpretive difference in feeling, attitude and experiential value concerning the issue under study. In other words, one answer may not mean the same as another answer, even though they represent the same item on the questionnaire (Plowright, 2010). Another strength with the statistical analysis used is that the data show each participant's individual assessments, e.g., the distribution of responses on each item as presented in Table 15 and Table 16. It can be argued that this may provide a more accurate description of paired data than, for example, if one merges data into average pre-test and post-test values.

7.5.4 Trustworthiness of qualitative data from the process evaluation

For the qualitative data from the process evaluation, issues of trustworthiness must be addressed. Trustworthiness values—such as credibility, dependability

and transferability (Lincoln & Guba; 1985; Graneheim & Lundman, 2004)—in qualitative analyses are safeguarded by the chosen procedure for a qualitative design. Criteria for credibility, understood as maintaining the PhD project's focus, were met by choosing participants relevant for the research questions; both students and faculty members were representative participants in the simulation scenarios. Dependability was met by using the same interview guide for all participants, and no major changes were made to the data collection and analysis process. By describing the participants, context and research-process transferability thoroughly, it should be possible to achieve the same standards with similar studies. Thus, it is argued that the qualitative part of the study meets the criteria for trustworthiness.

The PhD student asked the participants to take part voluntarily in the interviews, which could have made it more difficult for them not to participate. It also could have given the participants a better opportunity to provide voluntary consent if someone else had asked them to participate. In Study 2, eight female students voluntary were interviewed to share their experiences regarding the questionnaire. To achieve a better gender balance, the PhD student could have asked the male students more directly to participate in an interview. However, the principle of voluntariness among the participants dominated the recruiting process, and there was a large majority of women in the sample. The PhD student also conducted all the interviews. Because they knew that the PhD student had developed the questionnaire, this could have made it more difficult for the participants to share their experiences about the questionnaire honestly, especially suggestions for improvements. The same goes for responses on the experiences of participating in the HFS intervention. Because the participants knew that the PhD student was evaluating the intervention and was a colleague of the faculty that organised the intervention, it could have been more difficult to answer honestly. However, the PhD student was aware of this and encouraged all participants to share all their experiences—both negative and positive aspects. The PhD student had no previous experience in organising simulation exercises in nursing education, which can be viewed as a strength in this setting. It can also be viewed as a strength that the data from all the interviews comprised both positive and negative aspects.

Questions about the outcomes in Study 3 were not included in the interviews. It would have strengthened the process evaluations if data in that regard had also been included. However, the aim of the process evaluation

embedded within the trial was to identify enablers and barriers that impact successful implementation of the HFS intervention, and not the outcomes of it. Qualitative process evaluations may use a range of qualitative data collection methods, including individual interviews, focus group discussions, observations and participant diaries (Atkins et al., 2015). Each method has its advantages and disadvantages, and the research team in this PhD project agreed that conducting individual interviews was an appropriate data collection method embedded within the trials.

8.0 CONCLUSIONS

The results from this PhD project support the contention that knowledge and self-confidence levels in undergraduate nursing students who receive a tailored educational programme, including HFS, will increase compared with nursing students who do not attend HFS, concerning the topic of recognition of and response to acute patient deterioration.

The conducted systematic review stated that the briefings, clear objectives, feedback, student support and debriefings were deemed important HFS features for implementing effective learning. The systematic review revealed that many different instruments were used to measure knowledge, self-confidence and skill performance in the included studies, several of which the research team designed to fit the simulation scenarios for that specific study. Findings support that a need exists for more studies with improved measurement practices and high-quality research designs to produce generalizable evidence concerning the efficacy of HFS.

The meta-analysis in this PhD project showed that all included studies in the systematic review reported that knowledge and skill performance increased after HFS, whereas increased self-confidence was shown in one out of three studies.

The validity of the questionnaire used to measure the efficacy of HFS in Study 3 was determined by expert reviews, individual interviews and estimates of changes in knowledge and perceived self-confidence. The questionnaire's responsiveness was confirmed by means of statistical methods that consider ordered categorical data's non-metric properties.

In this PhD project, undergraduate nursing students' knowledge and levels of self-confidence scores were compared before and after an educational intervention with HFS. The results showed significantly greater improvement in total correct responses to the knowledge items in the intervention group compared with the control group. Regarding the groups of items referring to knowledge of 'clinical changes' and 'nursing procedures', the results showed statistically significant evidence of intervention effects. Global levels of perceived self-confidence identified a statistically significant increase in intervention effect on items referring to 'clinical changes'.

Undergraduate nursing students who participated in this PhD project identified the need for a safe environment, learning in different roles and fidelity as important enablers that impact successful implementation of the HFS intervention.

From the faculty members' perspective on this PhD project, creating a safe environment and promoting reflection and student-centred learning were reported to be important enablers that impact successful implementation of the HFS intervention.

8.1 Implications for practice and further research

The results from this PhD project may have implications for education, clinical practice and future research. In today's healthcare environment, nurses must be prepared to recognise and respond appropriately to acute patient deterioration events (Norwegian Directorate of Health, 2020). The graduate nurse needs to be work-ready, be self-motivated, be able to face challenges and show persistence in the clinical practice. The delayed detection of patient deterioration and its mismanagement are significant problems which can be improved with targeted education, such as HFS (Buykx et al., 2011).

In the national health and hospital plan for 2020–2023 in Norway, the value of simulation is highlighted (Ministry of Health and Care Services in Norway, 2019). The increased use of simulation in healthcare is recommended to improve practice. Increased collaboration across institutions on organising simulation experiences is also elaborated in the health and hospital plan (Ministry of Health and Care Services in Norway, 2019). The increased use of simulation is also a priority in undergraduate nursing education as a result of the new national curriculum law that will regulate nursing education from autumn 2020 (Ministry of Education and Research, 2019b). It is therefore important to establish the role of simulation in developing knowledge and self-confidence not only to ensure students achieve academic learning outcomes but also to transfer their attributes to the clinical environment, where patient outcome and safety are paramount. Poor patient outcomes and death may result from delayed assessment and management of the deteriorating adult patient (Norwegian Directorate of Health, 2020).

The findings in this PhD project identified that a structured and comprehensive approach to acute patient deterioration events in HFS had

positive effects on nursing students' knowledge and self-confidence levels. To the best of the PhD student's knowledge, no other studies have used the statistical methods that consider the non-metric properties of ordered categorical data to measure the effects of HFS, as done in this PhD project. The statistical analysis conducted provides an accurate description of paired data from each participant on each item of the questionnaire used. As outcomes of possessing self-confidence have been reported as better clinical performance, power and autonomy (see Table 3), this PhD project's findings may contribute to better clinical performance resulting in reduced mortality among patients. The positive findings can also support the use of simulation in other topics in undergraduate nursing education to increase the students' learning outcomes.

As written in section 3.4, a need exists for more rigorous study designs with larger sample sizes and more randomisation in nursing simulation research to examine the effects of HFS (see Table 1). Husebø, Silvennoinen, Rosqvist and Masiello (2018) conducted an integrative review on the status of Nordic research on simulation-based learning in healthcare. They found that most Nordic research on simulation-based learning employs a qualitative or a descriptive design and identified a need for well-designed RCTs or robust evidence that supports simulation as an effective educational method. A recently published study by Williams and Spurlock (2019) suggests that future studies should include multi-site studies. This PhD project may help to fill these gaps. As HFS is an increasingly used and resource-intensive pedagogical approach in undergraduate nursing education (Kim, Park & Shin, 2016), it is important to examine the students' learning outcomes. This PhD project's evidence may support the use of HFS as a beneficial option, thereby justifying the additional costs. Continued evaluation and investment into the resources required to provide effective clinical simulation is worthwhile (Stayt et al., 2015).

The Ministry of Health and Care Services in Norway (2019) also emphasises the importance of sharing knowledge on organising simulation sessions across institutions. Planned studies across nursing training programmes that utilise identical clinical simulation procedures and the same evaluation tools could provide strong experimental evidence of simulations' effect on clinical knowledge (Cant & Cooper, 2017). When comparing test scores and evaluating simulation outcomes, it is important for the simulation and testing environments to be as consistent as possible across all participants (Jeffries, 2014). Scenarios then should be delivered in a uniform fashion from participant to participant,

group to group and, if multi-centre, from institution to institution. Allowing too much variation in case delivery would change the intervention of interest or add unnecessary confounders (Cheng et al., 2014).

However, to determine whether an intervention is efficacious, reliable and competent intervention providers are essential. Faculty members need to be aware of barriers and enablers that may impact the successful implementation of HFS interventions. Many researchers have highlighted the importance of debriefing as a key part of faculty development programmes (Bullard et al., 2018; Hayden et al., 2014; Issenberg et al., 2005). Nevertheless, a faculty member should be skilled in all aspects of simulation, from instructional design all the way through to impact evaluation. Still, the extant research that describes the other key components needed to support a valid and impactful development programme remains limited (Olaussen, Heggdal & Tvedt, 2019; Edgar, Moneypenny & May, 2018). This PhD project may contribute to these needs as the findings may, for example, be used in facilitator training and to standardise simulation teaching in undergraduate nursing education. The PhD student will collaborate with colleagues in a group on how to integrate the use of simulation more systematically and gradually during the three years of the undergraduate nursing education. Nurse educators need to consider the complexity of a scenario against the defined learning objectives. For example, if the goal of a simulation session is to help students to practice and retain how to measure blood pressure (for example in their first year), it is important to avoid scenarios that introduce extraneous interpersonal information or complicating medical illnesses for the 'simulated' patient, thereby allowing nursing students to focus solely on the blood pressure measurement. Depending on the learning objectives of the simulation session, the PhD student will consider whether behaviourism, cognitivism, constructivism or social learning theories can provide a basis for the use of simulation. As noted above, a combination of deliberate practice, experiential learning theory and situated learning was argued as beneficial in this PhD project. However, the PhD student has learned that it is important not to make the simulation session too complex for the students and will be more focused on this in further work and research on the topic of simulation in undergraduate nursing education.

This PhD project's positive findings indicate neither if the increased knowledge and self-confidence are transferred to the clinical setting nor if they have an impact on patient safety and outcomes. Several studies recommend

completing future longitudinal studies that would follow students into their new graduate years (see Table 1) as doing so would provide insight regarding how university simulation experiences impact performance in similar situations in clinical practice. Williams and Spurlock (2019) recommend futures studies to include a second post-test assessment after some interval to determine whether the knowledge is retained over a more extended period. This topic would be interesting to examine in future studies.

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Appendices

Papers 1–3

1. The Final Literature Searches Study 1.
2. The Quality Appraisal Process Study 1.
3. Questionnaire developed and used for data collection Study 2.
4. Interview guide Study 2.
5. Revised questionnaire used for data collection before Study 3 (Test).
6. Revised questionnaire used for data collection Study 3.
7. Guide developed to the faculty members about
   the high-fidelity simulation intervention in Study 3.
8. Interview guide (faculty members) Study 3.
9. Interview guide (students) Study 3.
10. Approvals from the Norwegian Centre for Research Data.
11. Information about Study 2 (questionnaire) and
    informed consent form to participants.
12. Information about Study 2 (interview) and
    informed consent form to participants.
13. Information about Study 3 (questionnaire, intervention groups) and
    informed consent form to participants.
14. Information about Study 3 (questionnaire, control groups) and
    informed consent form to participants.
15. Information about Study 3 (interview, students) and
    informed consent form to participants.
16. Information about Study 3 (interview, faculty members) and
    informed consent form to participants.

Paper 1

Nursing Students Managing Deteriorating Patients: A Systematic Review and Meta-Analysis

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Review Article

Nursing Students Managing Deteriorating Patients: A Systematic Review and Meta-Analysis

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KEYWORDS
simulation;
manikin;
nursing education;
judgment;
problem solving;
deteriorating patient

Abstract

Background: The objective was to summarize knowledge and systematically collect and quantify meta-analytical results regarding the effects of high-fidelity simulation in nursing education to improve students' ability to recognize and respond to deteriorating patients.

Methods: In total, 4048 citations were screened, 40 articles were selected for full-text screening, and 14 articles were included. Six articles were subsequently included in the meta-analysis.

Results: Knowledge and performance increased after simulation. Four studies reported an increase in self-confidence.

Conclusion: Findings support that studies with high-quality research designs and improved measurement practices are required to produce generalizable evidence concerning the effectiveness of simulation.

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Nurses must contend with rapid changes in technology and ways of managing complex illness in today's dynamic health care environment (Eyikara & Baykara, 2018). This requires the application of an innovative approach to nursing education. High-fidelity simulation (HFS) is used to improve nursing students' skills in the recognition and early detection of physiological deterioration (Cooper et al., 2010; Fisher & King, 2013). In HFS, students have opportunities to learn and practice clinical skills in a simulated clinical environment using clinical scenarios and high-fidelity patient manikins, which have been replicated as closely as possible to the real-life situation. Instructors can control the manikin's responses, and the manikin can respond to interventions provided by the student (Aqel & Ahmad, 2014). The simulated environment provides a safe environment that gives students a hands-on opportunity to care for a patient without fear of harming that

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patient. Students also learn from observing other students and from feedback during debriefing sessions. Simulation is considered an active learning strategy that is learner centered, with the educator acting as a learning facilitator (Jeffries, 2016).

Key Points

- Use of high-fidelity simulation (HFS) in nursing education may improve students' skills in the recognition and early detection of physiological deterioration.
- Objectives, briefing, student support, feedback, and debriefing are important features for effective learning in HFS.
- Studies with high-quality research designs are needed to produce generalizable evidence concerning the effectiveness of HFS.

Facility-based patient safety initiatives have decreased the number of available student nurse placements (Lee, Kelley, Alfes, Bennington, & Dolansky, 2017; Shin, Jin-Hwa, & Jung-Hee, 2015), which in turn limits the students' hands-on experiences and restricts opportunities to engage in clinical decision-making. Current literature has highlighted the fact that a gap exists between the expectations that colleges have for recently graduated nurses and those held by leaders in the practice (Burgess, Buc, & Brennan, 2018; Huston et al., 2018). Therefore, the increased use of simulated learning in nursing education might be a strategy to address this gap (Huston et al., 2018).

During an undergraduate program in nursing, it is vital that students learn how to accurately observe, recognize, and respond to the management of patients' physiological deterioration (Cooper et al., 2010). The theoretical background for this review was the Nursing Education Simulation Framework, which was developed to guide the design, implementation, and evaluation of simulations used in nursing education (Jeffries, 2016). According to Jeffries (2016), simulation design should incorporate five features: objectives, fidelity, problem solving, student support, and debriefing. Although the body of knowledge surrounding HFS in undergraduate nursing education is growing, there is still a need for high-quality research that can establish a cause-and-effect relationship between HFS and learning. Recent research revealed significant differences in assessment methods leading to a wide variety of measurement outcomes (Doolen et al., 2016). Summarizing the existing knowledge regarding the effects of HFS in this study gathers more information that provides more insight into these limitations. This study serves as an important preparation for planning a future randomized controlled trial (RCT) study. The development of a complex intervention inevitably requires the preparation of a systematic review of the existing evidence to inform all steps of the development and evaluation processes (Köpke, Noyes, Chandler, & Meyer, 2015). The objective of this particular systematic review was to summarize knowledge as well as to systematically collect and quantify meta-analytical results regarding the effects of HFS used in nursing education to improve students' ability to recognize and respond to deteriorating patients. Regarding this particular work, the specific research questions were as follows:

1) What are the features of HFS interventions that lead to effective learning?
2) Which instruments are used to measure the outcomes in the intervention studies?
3) What are the effects of HFS interventions on students' knowledge, performance, and self-confidence?

Methods

Search Strategies

To begin, factors including population, intervention, comparison, and outcome framework were used to focus the research questions (Booth, Sutton, & Papaioannou, 2016). Appropriate keywords in various combinations were identified in close collaboration with a university librarian (Table 1). We searched CINAHL, Medline, Embase, PsycINFO, ERIC, the Cochrane Library, and SveMed+. The same keywords were used for all searches with the exception of SveMed+. Because SveMed+ is a smaller Nordic database, we broadened the search and used only the keywords in concepts one and two. The final database searches were conducted on November 24 (2016), with an update on February 20 (2018). In total, 4048 matches were identified after duplicates were removed.

Eligibility Criteria

Kirkpatrick's framework for evaluating the effectiveness of training programs (1998) may be used as a guide for assessing simulations (Schumann, Anderson, Scott, & Lawton, 2001). It consists of four levels of measuring: (a) the reactions of the students, (b) the amount of learning achieved by the students, (c) the degree to which the behavior of students in other settings reflect what they have learned, and (d) the extent to which results are improved (Schumann et al., 2001). One inclusion criterion in this study was that the studies had a pretest and posttest design and that they were at level two of measuring in accordance with Kirkpatrick's framework.

In this study, HFS and manikin have been chosen to be used synonymously because the inclusion criterion describes HFS as including the use of a manikin. HFS is defined as "simulation experiences that are extremely realistic and provide a high level of interactivity and realism for the learner (INACSL, 2013) and can apply to any mode or method of simulation, for example, human,

Table 1 The Keywords Used in the Literature Search

Population (Concept 1)	Intervention (Concept 2)	Outcome (Concept 3)
- Nursing - Student - Education - Graduate - Undergraduate - Baccalaureate	- Simulation - Game-based/computer-based/ computer-assisted/interactive/virtual learning - Virtual patient/reality - Mannequin - Manikin	- Judgment - Decision-making - Problem solving - Emergency/critically patient/ill/care/nurse - Clinical competence/assessment/incident/risk/ measure - Awareness - Deteriorating

manikin, task trainer, or virtual reality'' (Lopreiato et al., 2016, p. 14). Close alignment between the clinical task and simulation task is often more important than structural fidelity for achieving the training goals. A simulator that is considered low fidelity in one circumstance might be considered high fidelity in another (Hamstra, Brydges, Hatala, Zendejas & Cook, 2014).

Comparative studies in which HFS was tested against other simulations or clinical practice with ''real'' patients were excluded because the decision was made to examine the effect of HFS only as it compared to traditional lecture methods or traditional clinical training not defined as simulation by the authors. Studies in which the intervention was a course over a longer period, in which HFS was included in the course, were also excluded. In these studies, the participants were also taking part in clinical practice; therefore, the effect cannot specifically identify the HFS or a combination of experiences in the clinical setting and simulation. The inclusion and exclusion criteria are displayed in Table 2.

Study Selection

Titles, abstracts, and full-text screening of identified studies were reviewed by two independent researchers. Any point of disagreement was discussed until these researchers arrived at an agreement. The screening process was completed in Covidence, which is the recommended software for conducting systematic reviews (Covidence, 2018). To add depth to the review, reference lists from the included studies were also reviewed. Four articles were included from these reference lists along with one recommendation from a colleague after the literature search. Gray literature was searched using Google Scholar, OpenGrey, and ProQuest. Gray literature is defined as ''information produced on all levels of government, academics, business, and industry in electronic and print formats not controlled by commercial publishing, that is, where publishing is not the primary activity of the producing body'' (GreyNet, 2008). A total of 14 studies were included and reviewed in full text. The quality of these studies was critically appraised, and the information was summarized. The search process is presented in the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) flow diagram (Figure 1).

Critical Appraisal

Critical Appraisal Skills Programme checklists for RCTs and cohort studies were used (CASP, 2018). The checklist developed by the Joanna Briggs Institute was used for quasi-experimental studies (The Joanna Briggs Institute, 2018). Based on the content of these checklists, the included studies were ranked by their quality level (low, medium, and high).

Analyses

The effects of HFS were assessed using standardized mean difference after HFS as the outcome. Studies that reported

Table 2 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
- Intervention studies that included high-fidelity simulation, use human patient simulators (SimMan 2G or SimMan 3G), and written in English - The simulation sessions aimed to improve the ability of participants to recognize and respond to deteriorating adult patients - The sample: undergraduate nursing students - Pretest and posttest design - At level two of measuring according to Kirkpatrick's framework (Kirkpatrick, 1998)	- Comparative studies in which high-fidelity simulation was tested against other simulations or clinical practice with "real" patients - Studies in which the intervention is a course over a longer period for which high-fidelity simulation is included in the course

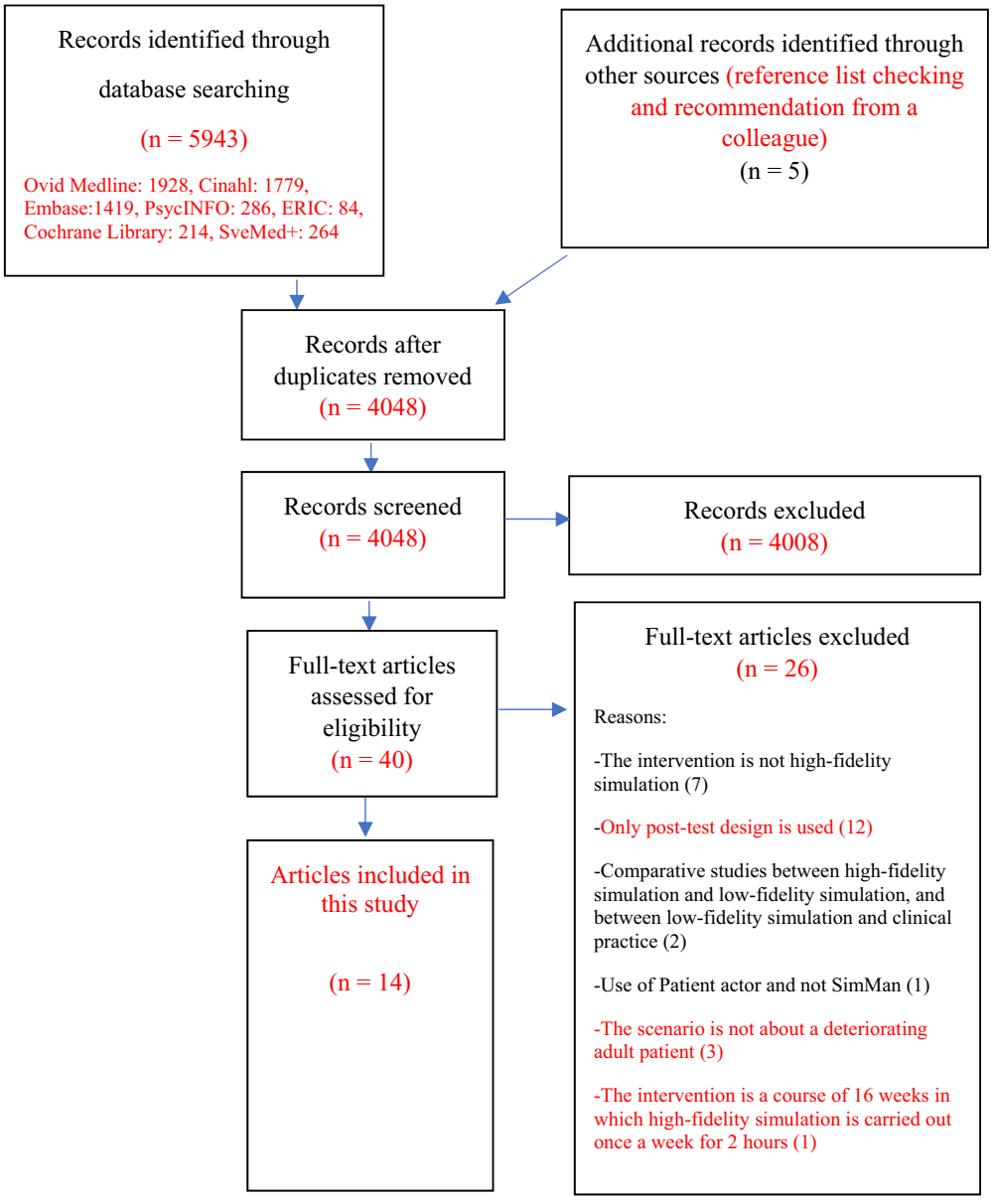

Figure 1 PRISMA flow diagram, developed from www.prisma-statement.org.

similar outcomes, knowledge, skill performance, and self-confidence were included in the meta-analysis. Meta-analysis is a statistical technique for summarizing the results of several single studies into an estimate (Bland, 2015). A pooled analysis was conducted using a random-effects model and meta-analysis framework with inverse-variance weighting (Booth et al., 2016). The random-effect models assume that each individual study has a different population (Borenstein, Hedges, Higgins, & Rothstein, 2009). The meta-analysis software package in the statistical program R was used to perform the meta-analysis (The R Project for Statistical Computing, 2017). To assess statistical heterogeneity and inconsistency of study results, the proportion of variance was calculated. The heterogeneity includes all differences and can be defined as I^2 (Bland, 2015). Standard mean difference and 95% confidence intervals were calculated. All measures of relative effects were pooled, and no restriction was set for heterogeneity.

Results and Discussion

The results describe findings from 12 studies presented in 14 journal articles. Two articles (Shinnick & Woo, 2012; Shinnick, Woo, & Evangelista, 2012) presented results from one study. Articles by Liaw, Rethans, Scherpbier, and Piyanee (2011a) and Liaw, Scherpbier, Rethans, and Piyanee (2011b) also focused on an individual study. The

Table 3 Characteristics of Included Studies (N = 14)

The Article Number	Authors, Year and Countries	Purpose	Design	Participants	Intervention	Measures	Results	Quality
1	Zieber and Sedgewick (2018), Canada	Examine the effect of a significantly advanced knowledge and skill intervention on competence, confidence, and knowledge retention	A mixed quantitative and qualitative design	N = 24	The intervention consisted of a three-hour knowledge presentation, followed by a three-hour practical advanced cardiac skills session using high-fidelity clinical simulation	1. Nursing anxiety and self-confidence with clinical decision-making tool 2. Nursing Student Competence Scale 3. Knowledge test	There was a statistically significant increase from pretest to posttest for all measures (self-confidence, competence, and knowledge)	Medium
2	Kim and Kim (2015), Korean	Examine the effects of adding a one-time simulation experience to the didactic curriculum on nursing students' related knowledge acquisition, clinical reasoning skills, and self-confidence compared with the traditional curriculum	Quasi-experimental crossover design	N = 94	Intervention group (A) attended a two-hour simulation session with a high-fidelity SimMan Control group (B) then crossed over and received two hours of simulation	1.Self-reported self-confidence questionnaire 2.Knowledge test 3.Clinical reasoning skills test (nursing process model-based rubrics)	Group A scored significantly higher for clinical reasoning skills and related knowledge than Group B No differences in self-confidence were found	Medium
3	Merriman, Stayt and Ricketts (2014) (Acc. March 2014), United Kingdom	Determine whether clinical simulation is more effective than traditional classroom teaching in teaching the assessment skills required to recognize an acutely unwell, deteriorating patient	Phase II, single randomized, controlled trial with single-blinded assessments	N = 34	The clinical high-fidelity simulation session comprised a two-hour simulation	1. The Objective Structured Clinical Examination (OSCE) checklist 2. General perceived self-efficacy 3. Self-reported competency 4. Student evaluation of teaching questionnaire	Intervention group performed a systematic ABCDE assessment more effectively than the control group No correlation between general perceived self-efficacy, self-reported competence scale, and OSCE performance in either group	Medium
4	Kelly, Forber, Conlon, Roche and Stasa (2014) (Acc. Aug. 2013), Australia	Determine the impact of a deteriorating patient simulation on increasing senior undergraduate nursing students' ability to recognize and respond appropriately	Descriptive pretest and posttest design	N = 57	All students participated in the simulation scenario	Survey items: 1. Skill ability 2. Confidence in approaching others	Overall presimulation mean score (23.7) increased significantly to the postsimulation mean score (27.4)	Medium
5	Lindsey and Jenkins (2013) (Acc. Jan.-Mar. 2013), USA	Examine the impact of a novel educational intervention on nursing student's clinical judgment regarding the	Pretest and posttest two-group randomized experimental design	N = 79	All participants received a Code Blue scenario and the rapid response education intervention	Eleven-item multiple-choice survey	Both the groups showed improved scores after test. Students who received the rapid response education intervention	High

(*continued on next page*)

Table 3 (*continued*)

The Article Number	Authors, Year and Countries	Purpose	Design	Participants	Intervention	Measures	Results	Quality
		management of patients experiencing rapid clinical deterioration					had significantly higher posttest scores.	
6	Thidemann and Söderhamn (2012) (Acc. Dec. 2012), Norway	Evaluate high-fidelity simulation scenario experiences among nursing students in small simulation groups with different roles	Quasi-experimental design	N = 57 (2009) N = 87 (2010) Eighty-seven students completed the evaluation; 85 took the test.	One medical simulation scenario and one surgical simulation scenario were designed by the responsible teacher	1. Knowledge test 2. Student satisfaction 3. Self-confidence in learning	Knowledge about the specific patient focus increased after the high-fidelity simulation activity. Satisfaction and self-confidence in learning was overall highly rated	Medium
7	Wood and Toronto (2012) (Acc. Apr. 2012), USA	Assess the influence of human patient simulator (HPS) practice on critical thinking dispositions in a sample of undergraduate nursing students	Quasi-experimental design	N = 85	Students in the experimental group (42) practiced critical assessment competency skills for two hours with a HPS manikin and also practiced traditionally (out-of-class practice with peer partners)	1. The California Critical Thinking Disposition Inventory 2. The critical assessment competency examination	Experimental group students performed significantly better after test than before test For control group students, there were no significant differences from pretest to posttest	Medium
8	Shinnick and Woo (2012) (Acc. Apr. 2012), USA	Determine if critical thinking (CT) improved in prelicensure nursing students after human patient simulator (HPS) experience Determine the predictors of higher CT scores	One-group, quasi-experimental, pretest—posttest design	N = 154	Three simulation scenarios of clinical cases of acute decompensated heart failure	1. Knowledge test 2. Health Science Reasoning Test 3. Self-efficacy 4. Learning style	Statistically significant gains in knowledge after the HPS, but no statistically significant gains in CT Predictors of higher CT scores included older age, higher baseline knowledge, and low self-efficacy in "management of a patient's fluid status"	Medium
9	Shinnick, Woo and Evangelista (2012) (Acc. Jan-Feb. 2012), USA	Identify whether human patient simulator (HPS) would be an independent predictor of heart failure (HF) knowledge gains among prelicensure nursing students	Two-group, repeated-measures, experimental design Randomized controlled trial	N = 162	Three simulation scenarios of clinical cases of acute decompensated HF were created; cases were identical in design with exception of patient history and gender	1. Knowledge test 2. The Health Science Reasoning Test 3. Self-efficacy 4. Learning style	Prelicensure nursing students participating in HPS had higher knowledge scores on an HF clinical knowledge test	High
10	Liaw, Scherpbier, Rethans and Piyanee (2011b) (Acc. Oct. 2011), USA	Determine whether self-reported confidence and knowledge tests were indicators of	Prospective, randomized controlled trial with a pretest—posttest design	N = 31	After baseline evaluation of all participants in a simulated environment, the	1. Rescuing a Patient in Deteriorating Situation tool to measure skills performance	Intervention group had superior clinical performance and knowledge in assessing	Medium

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Table 3 (*continued*)

The Article Number	Authors, Year and Countries	Purpose	Design	Participants	Intervention	Measures	Results	Quality
		clinical performance in a simulation-based assessment on care of a deteriorating patient			intervention group went through four simulation scenarios in a six-hour education session	2. Multiple-choice knowledge questionnaire 3. Confidence scale	and responding to patient deterioration than the control group The increased self-confidence after simulation training in the intervention group was not statistically significant when compared with the control group	
11	Liaw, Rethans, Scherpbier and Piyanee (2011a) (Acc. Apr. 2011), USA	Evaluate the learning outcomes of a simulation program for developing nursing student's competency in assessing, managing, and reporting patients with physiological deterioration	Prospective, randomized controlled trial with a pretest and posttest design.	N = 31	After baseline evaluation of all participants in a simulated environment, the intervention group went through four simulation scenarios in a six-hour education session	1.Rescuing a Patient in Deteriorating Situation tool to measure skills performance 2. Survey to evaluate learning experiences	Posttest mean score of the intervention group in reporting deterioration was significantly higher than the baseline and posttest mean scores of the control group	Medium
12	Burns, O'Donnell and Artman (2010), USA	Test the efficacy of high-fidelity simulation in addition to traditional lecture content to improve the knowledge and attitudes of nursing students in relation to the nursing process	Pretest and posttest design	N = 125 Eighty-four participants completed both pretest and posttest measurement of knowledge; 114 participants completed the pretest and posttest attitudinal survey	All students participated in a three-hour simulation experience	1. Knowledge test 2. 14-item attitude instrument (survey)	69 students gained knowledge when compared between before to after test Students demonstrated improvement on six of the 14 survey items, as measured by a paired samples t-test	Medium
13	Ackermann (2009), USA	Compare the effects of two teaching methods on the initial acquisition and three-month retention of cardiopulmonary resuscitation (CPR) knowledge and skills for nursing students	Quasi-experimental design	N = 65 Forty-nine students returned three months later to participate in the retention phase	The two teaching methods were: 1. Standard CPR review 2. Standard CPR review and HFS	1. Knowledge test 2. Skills checklist	Using high-fidelity simulation assisted students to acquire and retain a higher level of CPR knowledge and skills	Medium
14	Alinier, Hunt and Gordon (2003), United Kingdom	Determine the impact of simulation training on nursing students'	Cohort study	N = 67	Experimental group was exposed to simulation training, whereas the	1. OSCE checklist 2.Questionnaire covering demographic	Experimental group had a greater improvement in performance than the	Medium

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Table 3 (*continued*)

The Article Number	Authors, Year and Countries	Purpose	Design	Participants	Intervention	Measures	Results	Quality
		competence and confidence			other students followed their usual nursing courses An Objective Structured Clinical Examination (OSCE) comprising 15 stations was designed	details, experience in health care, level of confidence, and how stressful students found working in a technological environment	control group No significant difference in the level of confidence between the experimental and control groups	

Note. HFS = high-fidelity simulation.

study by Zieber and Sedgewick (2018) used both a quantitative and qualitative approach; however, only the quantitative results will be presented in this study. The articles will be referred to by an assigned number, as presented in Table 3.

Research Designs

The designs used for the included studies were eight quasi-experimental designs, five RCTs, and one cohort study. The sample size varied from 24 to 162 participants, with three studies (8, 9, and 12) having over 100 participants. Information about the participants is shown in Table 4.

Six studies (3, 4, 5, 6, 7, and 12) included a conceptual or theoretical framework, that is, the Nursing Education Simulation Framework (Jeffries, 2005), experiential learning theory (Kolb, 1984), and Tanner's clinical judgment model (Tanner, 2006).

Although it is generally agreed that simulation ''works,'' the supporting evidence varies in scope and quality (Jeffries, 2016). Two studies were ranked as of high quality and the remaining studies as medium. Although the studies that were ranked as high quality were both RCTs, three of the studies using RCT design were ranked as medium quality because (a) the sample sizes were small (31-34 participants) and (b) all the participants came from the same nursing school (studies 3, 10, and 11). There is a need for high-quality research designs (Yuan, Williams, & Fang, 2011b; Yuan, Williams, Fang, & Ye, 2011a), as this study also indicates. Sample size is a major issue in conducting and evaluating quantitative research (Polit & Beck, 2016), and the small sample size in many of the included studies is a weakness. Researchers can estimate how large their samples should be to adequately test their research hypotheses through power analysis, and quantitative research often strives for the largest possible sample so as to be representative (Polit & Beck, 2016). However, large samples are no assurance of accuracy; for example, concerning nonprobability sampling, even a large sample can harbor extensive bias (Polit & Beck, 2016). The samples in all included studies were reliable because they comprised undergraduate nursing students. Tantamount to sample size are the issues of confounding variables located within simulations, such as case-to-case, site-to-site, educator-to-educator, and technology-to-technology. These simulation-specific confounding variables serve as threats to the internal validity of simulation studies (Cheng et al., 2014a).

Quasi-experimental designs, as used in eight studies, lack randomization or a control group (Polit & Beck, 2016). Randomly assigned groups are expected to be generally comparable with respect to an infinite number of biological, psychological, and social traits at the study outset. Group differences on outcomes observed after random assignment can therefore be inferred as being caused by the

Table 4 Information About the Participants' in the Included Studies

Information	Studies
From a self-selected convenience sample	All studies
Enrolled in the same nursing course	Studies 2, 4, 7, 8, 9, 10, and 11
All first-year nursing students	Studies 12 and 13
All second-year nursing students	Studies 3, 6, and 14
All third- or fourth-year students	Study 1
From the same nursing school	Studies 1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 13, and 14
From three different nursing schools	Studies 8 and 9
Randomly assigned to a control or an experimental group	Studies 3, 5, 7, 9, 10, 11, 13, and 14
Nonrandomly assigned to a control or an experimental group	Study 2
All participants attended an high-fidelity simulation intervention (no control group)	Studies 1, 4, 6, 8, and 12

intervention (Polit & Beck, 2016). Another weakness of these studies was the lack of a conceptual or theoretical framework in half of them. Kaakinen and Arwood (2009) have discovered that theory is a missing component in most simulation research. Rourke, Schmidt, and Garga (2010) agree that most simulation literature does not adequately address the theoretical foundation.

Features of HFS Interventions

All interventions started with a short briefing about the simulation sessions. Seven studies used one or two different simulation scenarios, one study did not report any information about use of scenarios, and the remaining studies used more than two different scenarios (7, 8, 9, 10, 11, and 12). Participants attended more than one scenario through direct participation in addition to being observers through a remote classroom audiovisual feed. After the simulation experience, participants in all studies participated in a debriefing session. Studies 6, 10, and 11 used the three phases (descriptive, analytic, and application) described by Steinwachs (1992) to facilitate the debriefing sessions, and study 12 used "the ADPIE-C debriefing log from the SimLab" to guide the debriefing session. The other studies did not report which methods of debriefing were used. In studies 6 and 14, the simulations were videotaped for use in the debriefing sessions. Although videotapes of the simulations were also reported in four other studies (7, 10, 11, and 12), no data were included to indicate how this was used. A summary of the features of the HFS interventions is shown in Table 5.

A review by Issenberg, McGaghie, Petrusa, Gordon, and Scalese (2005) entitled "Best Evidence Medical Education" describes features and uses of HFS that lead to effective learning: feedback, repetitive practice, curriculum integration, range of difficulty level, multiple learning strategies, captured clinical variation, controlled environment, individualized learning, defined outcomes or benchmarks, and simulator validity. Cook et al. (2013) have confirmed the features of effective simulation described by Issenberg et al. (2005) and contributed additional features, including distributed practice, interactivity, mastery learning, longer time in simulation, and group instruction.

Objectives are considered essential when using simulation (Groom, Henderson, & Sittner, 2014). The simulation objectives must reflect the intended outcome of the experience, specify expected participant behaviors, and include sufficient detail to allow learners to participate in the simulation effectively (Jeffries, 2012). It is evident that students who participated in prebriefing activities of learning engagement and orientation tasks perceived overall higher simulation effectiveness (Chamberlain, 2017). However, the simulator has a variety of options, and it is important that participants are not overloaded with too much information during orientation. If the level is unattainable, the simulation will not be an effective learning experience for participants. Some researchers also believe that providing an introduction of the manikin features decreases the subsequent fidelity in the simulation session. For example, Cuerva et al. (2018) have found that the debriefing results were better after a short briefing session and an abrupt start to the scenario in HFS training on childbirth.

Facilitators have an important role in how participants experience and learn from HFS. Facilitators need to be self-aware and help reduce obstacles that may hinder participants' ability to learn. It is important that a climate of mutual respect is fostered in which participants feel comfortable asking questions that enhance learning (Jeffries, 2012). In half of the included studies, the scenarios were facilitated by the same two or more faculty who provided guidance during the activity when necessary. Research indicates feedback and expert modeling from facilitators, and peers improved participants' learning and performance (Abe, Kawahara, Yamashina, & Tsuboi, 2013). Cues may include observations, statements from patients and others, laboratory and assessment data, patient response or lack of response, and intuition (Groom et al., 2014). However, it is important that the facilitator is aware of the frequency of feedback. The participant should be

Table 5 Features of High-Fidelity Simulation Interventions

Learning objectives	Were given to all participants, except for participants in studies 8 and 9, as the study matter (heart failure) would have been revealed.
Patient data	All the simulation sessions contained elements of the deteriorating patient, in most cases the situation culminated in the patient going into cardiopulmonary arrest
Format	The simulation experience composed of the following: - Review of the learning objectives and the patient case - Receiving an orientation regarding the simulator and environment - Selecting an active or observer role - Working through the simulation with guidance from the academic (if required) - Participating in a facilitated debriefing session
Roles	Registered nurse Family member Physician Observer Academic as the patients' voice/doctor on the phone
Simulation running time	12-60 minutes
Debriefing time	10-60 minutes
Simulation group	3-11 students in each group

allowed to make a decision, take action, and reflect on that action before feedback is given (Jeffries, 2012). If facilitators provide a lot of feedback during the simulation, the participant may become dependent on the facilitator for the ''next steps.'' Assistance should be in the form of cues that offer sufficient information to allow the participant to continue with the simulation but do not interfere with their independent problem solving ability (Jeffries, 2012). Repeated exposure to clinical scenarios through simulation is also particularly effective (Abe et al., 2013). Five of the studies in this review offered participants repeated exposure to clinical scenarios. Alinier, Hunt, and Gordon (2003) have noted that this maximizes participants' exposure to the simulated environment because they benefit from observing their peers, recording notes, and taking part in the debriefing for several scenarios.

Table 6 Outcomes and Instruments Used in the Included Studies

Outcome	Instrument
Knowledge	Specifically designed for the unique study: Multiple-choice questionnaires
Skill performance	Specifically designed for the unique study: - Objective Structured Clinical Examination checklists - Rescuing a Patient in Deteriorating Situation tool - A rubric - Surveys - Checklist for cardiopulmonary resuscitation skills - The critical assessment competency examination Have been used previously in other studies: - Nursing Student Competence Scale (Watson, Calman, Norman, Redfern, & Murrells, 2002) - The California Critical Thinking Disposition Inventory (Facione, Facione, & Sanchez, 1994) - The Health Sciences Reasoning Test (Facione & Facione, 1996)
Self-confidence	Self-reported questionnaires, edited version of: - The Self-Efficacy for Nursing Skills Evaluation Tool (Ravert, 2004) - The scale originally developed by Hicks, Coke, and Li (2009) - Two validated tools developed by Bartlett, Westcott, and Hand (1998) and Schwarzer and Born (1997) - Confidence scale developed by Grundy (1993) - A 13-item instrument developed and tested by the National League for Nursing and Laerdal Medical multi-site project group (Jeffries & Rizzolo, 2006) Have been used previously in other studies: - Nursing Anxiety and Self-confidence with Clinical Decision-Making tool (White, 2014)

Table 7 Outcomes, Measurements, and Results in the Included Studies

Outcome	Measurement	Results
Knowledge	Before and after intervention: studies 1, 5, 6, 8, 9, 10, 12, and 13 After intervention: study 2	Increased in all studies after high-fidelity simulation interventions. The increase was documented either from pretest to posttest scores or improved results for the intervention group compared with the control group at posttest
Skill performance	Before and after intervention: studies 1, 3, 4, 5, 7, 8, 9, 10, 11, and 14 After intervention: studies 2 and 13	Increased in all studies after high-fidelity simulation interventions. The increase was documented either from pretest to posttest scores or improved results for the intervention group compared with the control group at posttest
Self-confidence	Before and after intervention: studies 1, 2, 3, 4, 8, 9, 10, and 12 After intervention: studies 6 and 14	Increased in study 1, 3, 4, and 12 after high-fidelity simulation interventions

Debriefing is accepted as best practice in simulation (Cheng et al., 2014a). This reflective thinking session provides opportunity for participants to assess their actions, decisions, communications, and ability to deal with the unexpected in the simulation (Jeffries, 2012). Cheng et al. (2014b) have found a short debriefing session to be slightly favorable to a longer debriefing session. Results from a systematic review by Levett-Jones and Lapkin (2014) have confirmed that debriefing is important; however, there are no significant differences with or without the use of video. One specific gap in the literature is a lack of consensus regarding the use of video in debriefing sessions (Jeffries, 2016).

Instruments and Outcomes

All 14 studies reported knowledge, skill performance, and/or self-confidence as outcome measures. The time for administering the pretest in the studies varied from three months before the intervention to immediately before it. Six studies administered the posttest immediately after the intervention (studies 1, 4, 5, 6, 7, and 14), and in the remaining studies, the time for administering the posttest varied from one week to three months after the intervention. In two of the included studies (1 and 14), the participants returned after the intervention for measuring three-month retention scores. According to Kirkpatrick's third level of measurements, the learner's behavior must be measured in other settings than in the simulation setting (Kirkpatrick, 1998); therefore, all measurements in this study were taken at Kirkpatrick's level two. All included studies reported that knowledge and skill performance increased after HFS, whereas increased levels of self-confidence were shown in four studies. Outcomes and instruments used in the included studies are shown in Table 6, whereas Table 7 displays the results of the measurements.

Students' satisfaction with the intervention was evaluated in four studies (3, 6, 11, and 12), and the results indicated that they were very satisfied. Eleven studies also reported demographic information (1, 2, 3, 4, 7, 8, 9, 10, 11, 12, and 14). Participants were predominately female (79%-97%), with a mean age range of 19.4-32.6 years. Study 14 reported participants' average age to be 31.3 years. Study four did not collect data about participants' age, as it reported that 55% had less than two years of nursing

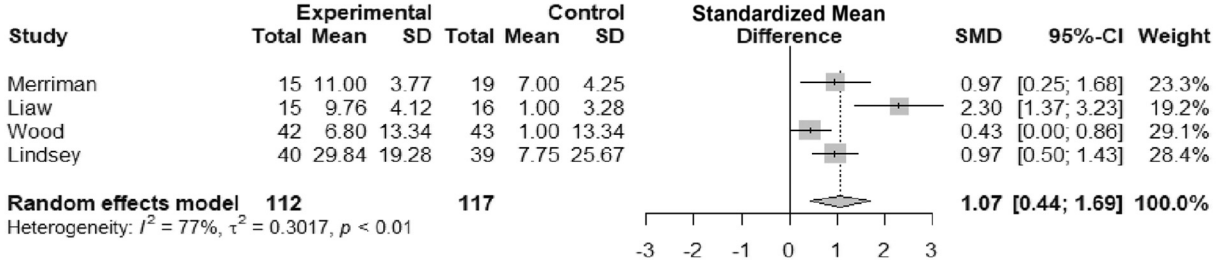

Figure 2 Forest plots demonstrating pooled effects of the difference between pretest and posttest skill performance results for intervention (high-fidelity simulation) and control groups. *Note*. SMD, standardized mean difference; CI, confidence interval; SD, standard deviation.

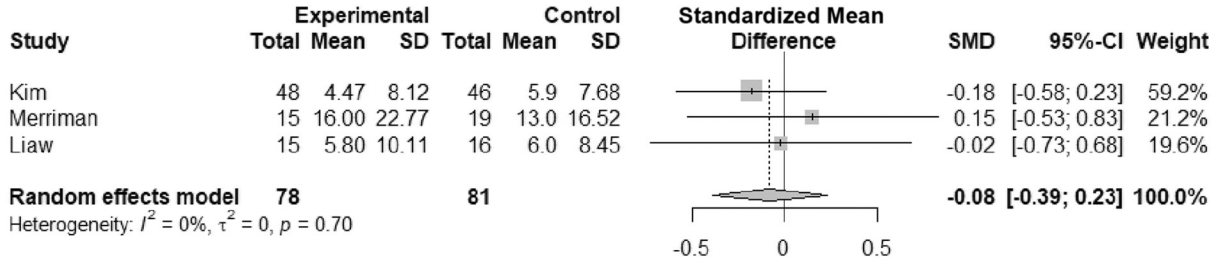

Figure 3 Forest plots demonstrating pooled effects of the difference between pretest and posttest self-confidence results for intervention (high-fidelity simulation) and control groups. *Note*. SMD, standardized mean difference; CI, confidence interval; SD, standard deviation.

experience. Study 12 reported that all students were aged 18 to 22 years, except for one student.

Meta-analysis

Six of the 14 studies report both pretest and posttest results for the intervention and control groups and have been included in the meta-analysis (Kim & Kim, 2015; Merriman, Stayt, & Ricketts, 2014; Lindsey & Jenkins, 2013; Wood & Toronto, 2012; Liaw et al., 2011b; Ackermann, 2009). Lindsey and Jenkins (2013) have used a survey to measure both knowledge and skill performance, and data from that study have been chosen to be shown in Figure 2 (skill performance). Kim and Kim (2015) use two scenarios and report data from both the scenarios; only data from the first scenario have been chosen to be shown in Figure 3 (self-confidence).

The pooled between-group effect size in the studies that measured presimulation and postsimulation skill performance was 1.07 (95% confidence interval: 0.44-1.67) in favor of HFS (Figure 2). Figure 4 shows differences between pretest and posttest knowledge results for the HFS intervention and control groups. The results showed an increase in outcomes in all included studies. Figure 3 shows differences between pretest and posttest self-confidence results for HFS intervention and control groups. One study shows improvement in self-confidence after the HFS, whereas two studies do not.

Research has identified multiple participant-related variables that influence skill performance, including age, gender, readiness to learn, personal goals, preparedness, tolerance for ambiguity, self-confidence, learning style, cognitive load, and level of anxiety (Fenske, Harris, Aebersold, & Hartman, 2013). Participants' motivation, enthusiasm, and personal feelings about simulation may affect their ability to fully immerse themselves in simulation activities (van Soeren et al., 2011). However, there are also some participant-associated factors that influence the simulation experience which are largely within the facilitator's control. These factors include role assignment, orientation, and group size (Jeffries, 2016). Partin, Payne, and Slemmons (2011) have found that students express dissatisfaction when there are more than six students in a group. Rezmer, Begaz, Treat, and Tews (2011) have reported that a group size of up to four participants has no effect, which suggests that best practice may be having four to six participants in a group. There is also evidence that higher fidelity increases participants' outcomes (Dancz, Sun, Moon, Chen, & Ozel, 2014; Yang, Thompson, & Bland, 2012), and the results from the included studies have indicated that students have been very satisfied with the HFS interventions. However, a comparison study between a paper-and-pencil case study and HFS has revealed that the paper-and-pencil case study group was more satisfied than the HFS group (Tosterud, Hedelin, & Hall-Lord, 2013).

Two studies used researcher-designed OSCE checklists. Many OSCE tools focus on the achievement of technical tasks and do not necessarily assess human factor skills, which are equally critical for effective clinical performance (Stayt, Merriman, Ricketts, Morton, & Simpson, 2015). Recognizing and responding to a deteriorating patient requires additional complex and nontechnical skills such as empathy, compassion, teamwork, situational awareness, and clinical decision-making; these skills are inherent to patient safety measures (World Health Organization, 2009). Nursing simulation-based education may consider traditional technical skill acquisition; however,

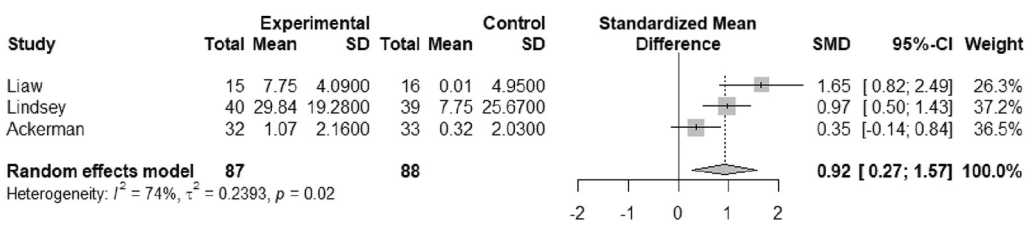

Figure 4 Forest plots demonstrating pooled effects of the difference between pretest and posttest knowledge results for intervention (high-fidelity simulation) and control groups. *Note*. SMD, standardized mean difference; CI, confidence interval; SD, standard deviation.

nontechnical, human factor skills must also be considered (Stayt et al., 2015). Many researchers have argued there is a need for improved measurement practices to produce generalizable evidence about the effectiveness of simulation (Kim & Kim, 2015; Yuan et al., 2011a; Yuan et al., 2011b). Only two of the included studies (Zieber & Sedgewick, 2018; Ackermann, 2009) have measured students' retention scores three months after the original HFS. Several of the included studies recommended completing future longitudinal studies that would follow students into their new graduate year (Merriman et al., 2014; Kelly, Forber, Conlon, Roche, & Stasa, 2014; Wood & Toronto, 2012), as doing so would provide insight into how university simulation experiences impact on performance in similar situations in clinical practice.

Limitations

There were several limitations noted with regard to this study. For example, articles that were not written in English were excluded, the interventions were only HFS, and there were only pretest and posttest designs. The combination of these factors produced only a small sample to analyze. Another limitation was that only published, peer-reviewed articles were reviewed. Relevant PhD dissertations were identified and used to search for relevant peer-reviewed articles.

Conclusion

This study has summarized knowledge in addition to systematically collecting and quantifying meta-analytical results regarding the effects of HFS used in nursing education to improve student's ability to recognize and respond to deteriorating patients. This work has stated that providing briefing, clear objectives, student support, feedback, and debriefing was identified as being an important HFS feature for implementing effective learning. It has also revealed that many different instruments were used to measure knowledge, skill performance, and self-confidence in the included studies, several of which having been designed by the research team to fit the simulation scenarios for that specific study. All included studies in this review reported that knowledge and skill performance increased after HFS, whereas increased self-confidence was shown only in four studies. Several of the included studies were conducted at a single site with a small sample; therefore, generalizability of those results to other settings may be limited. More than half of the included studies lacked participant randomization or a control group. Findings support that there is a need for more studies comprised of high-quality research designs and improved measurement practices to produce generalizable evidence concerning the effectiveness of HFS. Replicating a real-life situation in HFS requires careful accounting for the majority of confounding variables (Cheng et al., 2014a). Thus, in order for researchers to ensure this replication, there is a need for research studies that report specific variables for future replication.

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Paper 2

Validity of a Questionnaire Developed to Measure the Impact of a High-Fidelity Simulation Intervention: A Feasibility Study

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Validity of a questionnaire developed to measure the impact of a high-fidelity simulation intervention: A feasibility study

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Abstract

Aim: To evaluate the validity and responsiveness of a questionnaire developed to measure the impact of a high-fidelity simulation intervention.

Design: A pre- and postintervention design.

Methods: In August 2017, 107 participants completed a questionnaire measuring knowledge and perceived self-confidence pre- and postintervention. Validity of the questionnaire was determined by expert reviews, individual interviews and estimates of the changes in knowledge and perceived self-confidence. The changes were estimated by the differences between paired proportions of participants. The responsiveness of the ordered categorical item scores on self-confidence was evaluated by the measure of systematic group change and individual variations.

Results: The analysis of the interviews resulted in three themes: item content, item style and the administration of the questionnaire. An intervention effect on knowledge assessments was shown by the changes in paired proportions of participants with increased or decreased correct assessments (ranging from −25.5 - 24.8 percentage units). The responsiveness of the self-confidence scale was confirmed by evidence of post-intervention systematic group changes towards higher levels.

Conclusion: This study provides useful experience for a forthcoming randomized controlled study to evaluate the effect of high-fidelity simulation on undergraduate nursing students' knowledge and self-confidence when assessing patient deterioration.

Impact: Cause-and-effect relationship between simulation and learning is required to improve nursing education. A statistically significant rise in students' knowledge and levels of self-confidence after simulation were identified in this study. The study provided important aspects of future research study designs.

KEYWORDS

deteriorating patients, feasibility study, high-fidelity simulation, nursing students' knowledge, nursing students' self-confidence, ordinal data, questionnaire

1 | INTRODUCTION

Feasibility studies permit the use of flexible methodology and are used to identify important aspects of future study design, such as sample size estimation, the measurement process and descriptive and inferential statistical methods (Eldridge et al., 2016; National Institute for Health Research Trials & Studies Coordinating Centre, 2018). Recent studies have measured the effect of high-fidelity simulation (HFS) in undergraduate nursing education (Orique & Phillips, 2017; Zieber & Sedgewick, 2018). Doolen et al. (2016) reported differences in assessment methods leading to a wide variety of measurement outcomes. Eldridge et al. (2016) identified weaknesses in the reporting and conduct of feasibility studies, particularly in relation to studies conducted in preparation for a future planned randomized controlled trial (RCT) assessing the effect of an intervention. Thus; there is a need for a feasibility study providing insights into these limitations highlighted. The present feasibility study serves as an important preparation for a forthcoming RCT regarding the effects of HFS.

1.1 | Background

In HFS, students learn and practice clinical skills in a simulated clinical environment, which replicates as closely as possible a real-life situation, using clinical scenarios and high-fidelity patient manikins (Aqel & Ahmad, 2014). Acquisition of knowledge, clinical skills and cognitive skills are the primary goals of all nursing programmes (Zieber & Sedgewick, 2018). Multiple-choice questions have been used in nursing education to evaluate educational interventions (Considine & Botti, 2005; Curl et al., 2016). Kirkpatrick and Kirkpatrick's framework for evaluating the effectiveness of training programmes (2006) consists of four levels: (a) student reactions; (b) the amount of learning achieved; (c) how much the behaviour of students in other settings reflects what they have learned; and (d) the amount of improvement in results. The evaluations in this study correspond to level two of Kirkpatrick and Kirkpatrick's (2006) framework. Three review studies have empirically assessed the use of feasibility and pilot studies (Arain, Campbell, Cooper, & Lancaster, 2010; Lancaster et al., 2004; Shanyinde et al., 2011). These studies showed that the areas of methodological uncertainty most frequently tested in feasibility studies were recruitment, randomization, retention/drop out, blinding and data collection/outcome assessment. The present feasibility study tested recruitment, drop out and changes in knowledge and perceived self-confidence in undergraduate nursing students who experienced HFS that focused on deteriorating patients.

2 | THE STUDY

2.1 | Aims

The aim of this feasibility study was to evaluate the validity and responsiveness of a questionnaire developed to measure the impact of a high-fidelity simulation intervention.

The specific study aims were to:

1. Develop a questionnaire to measure undergraduate nursing students' acquired knowledge and self-confidence regarding an HFS intervention.
2. Evaluate the validity and the responsiveness of the items of knowledge and self-confidence.

2.2 | Study design and participants

Responsiveness refers to the ability of the items of a questionnaire to detect important changes in perceived self-confidence after intervention (Svensson et al., 2015). Therefore; a pre- and postintervention design was used. Nursing students enrolled in a medical surgical nursing course were eligible for inclusion and a convenience sample (N = 124) of third year undergraduate nursing students from two campuses at one university in southern Norway was invited to participate in August 2017. The participants were from three different classes (A, B, C); the students in class C were living in rural areas and participated in much of the teaching remotely using the Internet. However, all participants were present in the simulation laboratory when the intervention was carried out.

2.3 | Procedure

The intervention took place in a simulation laboratory at the university; the same simulation equipment was used throughout (Laerdal SimMan 3G). The students were divided into 11 groups of between 6-14 members. Each scenario was facilitated by two faculty members, one of whom provided guidance during the activity and remained in the laboratory. The second faculty member provided patient responses through the manikin via wireless microphone and answered a telephone to provide relevant responses. A total of six faculty members participated. Table 1 shows elements of the deteriorating patient simulation scenario.

2.4 | Self-report questionnaire

Data were collected using a self-report questionnaire in August 2017. Knowledge and self-confidence were the main variables, but data were also collected on gender, age, campus and previous experience with HFS. The research team developed the items for the simulation scenario used in the study. The 20 knowledge items comprised multiple-choice questions with three response alternatives. The items referred to vital signs, such as values for normal blood pressure and how these vital sign values usually change after major blood loss. Perceived self-confidence was assessed using 18 items related to the knowledge items. These were rated on a five-point scale using the following categories: not at all, somewhat, average, largely and very confident. The self-confidence items were adapted, with permission, from the critical care Self-Confidence Scale (Hicks et al., 2009) used in previous studies (Zavotsky et al., 2016). The development of the questionnaire was based on the American Heart Association (AHA) examination for Basic Life Support, after approval

TABLE 1 Elements of the deteriorating patient simulation scenario

Learning objectives	At the end of this simulation scenario, participants will have learned to: • Communicate and work appropriately in a team • Assess, recognize, and respond to changes in a patient's condition
Patient information	A 75-year-old female patient with a history of heart failure. She has been hospitalized because she received a complete right-side prosthesis. She has been bleeding during the surgery and has now been transferred to the orthopedic ward.
Format	The simulation experience comprised: • Review of the learning objectives and the patient case • Selection of an active or observer role • Orientation regarding the simulator and environment • Completion of the simulation with guidance from a faculty member (if required) • Participation in a facilitated debriefing session
Roles	Registered nurse x 2 Relative Observers Academic as the patient/doctor on the phone
Simulation running time	15–20 min
Debriefing time	25–35 min

from the AHA. The VAR Healthcare (2018) database, a Nordic database of up-to-date evidence-based procedures for use in healthcare practice and two Norwegian textbooks that were required reading for the students participating in the intervention (Kristoffersen et al., 2016; Stubberud et al., 2016), were also used.

2.5 | Data collection procedures

Most participants completed the pre-test questionnaire at the university when they were informed about the study. The students from class C, who attended the meeting remotely, completed the pre-test questionnaire immediately before participating in the intervention. Therefore, the time at which the pre-test questionnaire was completed varied from 8 days to immediately before the intervention. The post-test questionnaire was completed immediately after the intervention for all the participants. The first author informed and administered all the questionnaires.

2.6 | Expert reviews and individual interviews

Validity is an overall quality concept of item scales and refers to the extent to which a questionnaire measures what it is intended to measure (Polit & Beck, 2017). In this study, the content validity of the item scales refers to the elements of the deteriorating patients' simulation scenario. In the judgment-quantification stage of instrument development, content experts were involved (Grant & Davis, 1997). The *Standards for Educational and Psychological Testing* (American Educational Research Association, American Psychological Association, & National Council on Measurement in Education, 2014), emphasize the necessity of relevant training, experiences and qualifications of content experts. Two intensive care nurses and two administrators involved in the planning of the course, were asked to test the instrument. However, content experts were not directly involved in the intervention. All the simulation groups were asked if one self-selected member of the group would voluntarily participate in an individual interview. The face validity and comprehensiveness were determined by eight individual feedback interviews with students after they had responded to the post-test questionnaire. The interviews were audio recorded and referred to the following open-ended questions: How would you describe your experience of filling the questionnaire? What were positive/negative aspects of the questionnaire? Do you have anything to add to the questionnaire? The interviews were transcribed verbatim by the first author and re-read to obtain familiarity with the data. A six-step thematic analysis based on Braun and Clarke (2006) was performed to identify codes, subthemes and themes. The themes were reviewed by the whole research team. Finally, the revised questionnaire was tested by 21 nursing students pre- and postintervention in August 2018.

2.7 | Ethical considerations

Study participation was voluntary and did not affect students' course grades. The research team members were not in a teacher–student relationship with the students during the study period. Participation required written informed consent. Institutional approval was received before data collection. The study was approved by the Norwegian Centre for Research Data (project number 52110). The study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

2.8 | Statistical methods

The IBM SPSS 24 statistical package was used for data management. The mean and standard deviation (*SD*) were calculated for the number of correct responses of knowledge and median and range were used

to describe demographic data. The variable self-confidence was assessed on ordered categorical item scales. Ordered categorical data represent only an ordering and not numerical values in a mathematical sense, even in case of numerical codes. Therefore, statistical methods for ordinal data differ from traditional methods for quantitative data. The strong assumptions of quantitative, correlated, normally distributed data also invalidate the use of psychometric methods. Nonparametric rank-based statistical methods that take account of the non-metric properties of ordered categorical data were used to obtain reliable results (Hand, 1996; Svenson, 2001; Svensson, 2012).

2.9 | Responsiveness of the self-confidence scale

Each of the items of self-confidence refer to a corresponding question of knowledge. Since the items of knowledge vary in difficulty, the responsiveness to changes in self-confidence after intervention could vary between the items. The responsiveness of each item was evaluated using the Svensson method for paired ordinal data that identifies and measure systematic change in responses separately from individual variation (Svensson, 1998; Svensson et al., 2015). In a test–retest design, the data sets consist of pair of assessments made before and after the intervention. Therefore, the frequency distribution of all pairs is shown by a square table, see Figure 1. Pairs from students who assessed a higher level of self-confidence after the intervention than before, like (*somewhat*, *largely*) appear in the upper left region (denoted A) and pairs with lower level of self-confidence after the intervention than before (*very*, *largely*) is found in the lower right region (denoted B). Pairs of unchanged level of self-confidence, such as (*average*, *average*) appear in the diagonal (denoted C). The proportion of participants with unchanged self-confidence levels (percentage agreement [PA]) was calculated. Besides the frequency distribution of the pairs in the 5 x 5 table, the frequency distributions of self-confidence before and after intervention are shown as marginal frequencies. Different marginal distributions indicate presence of a systematic group change and is measured by the relative position (RP). The RP expresses the extent to which the marginal distribution on the retest occasion is shifted towards higher levels of self-confidence than the marginals from first set, rather than the opposite. Possible RP values range from −1 to 1; in this study, a positive RP value indicate that the group of students has systematically assessed higher rather than lower categories of self-confidence on the retest occasion compared with the first occasion. Additional individual variability was calculated by the measure relative rank variance (RV), ranging from 0 to 1. Non-zero RV indicates presence of individual variations, that cannot be explained by a systematic group change in assessments, for example heterogeneity among participants, incomplete understanding of the scenario, or misinterpretation of a question. The PA, RP and RV and the 95% confidence intervals (95% CI) of RP and RV were calculated using a free software program (Avdic & Svensson, 2010). Good responsiveness, which mean high sensitivity to changes, is indicated by 95% confidence intervals of RP that does not cover the zero value and negligible unexplained individual variations, RV.

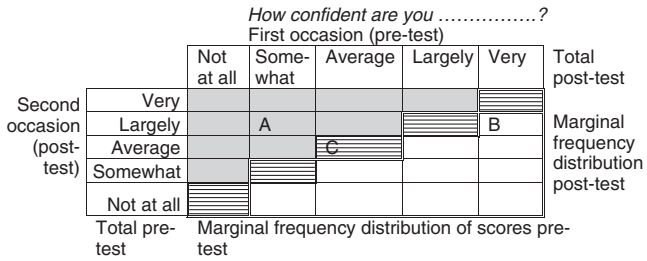

FIGURE 1 The components of a 5 x 5 square contingency table for frequency distributions of pairs of assessments of perceived self-confidence on an item scale with five ordered categories. The regions for pairs with increased, unchanged and decreased levels of self-confidence are indicated by the positions of the pairs A (somewhat, largely), B (very, largely) and C (average, average)

2.10 | Estimation of effects on knowledge and self-confidence

For each knowledge item, the proportion of participants who had changed their responses from incorrect to correct after the intervention was compared with the proportion of participants who had changed from the correct to an incorrect response. The difference between these paired proportions of increased and of decreased numbers of correct responses was calculated and expressed as percentage units (pu). Correspondingly, for each self-confidence item, the difference in the paired proportion of participants with higher and those with lower levels of perceived self-confidence after the HFS intervention was calculated. This analysis of difference in paired proportions provides a summary measure based on dichotomized data and does not take account of the fact that the responses are on scales with five ordered categories. The 95% CI for the difference in paired proportions estimated the expected HFS intervention effects on the students' knowledge and self-confidence (Altman, 1991; Newcombe & Altman, 2000).

3 | RESULTS

3.1 | Study group

A total of 108 of 124 students voluntary completed the questionnaire before the intervention and 107 after the intervention. In addition, one student failed to complete the self-confidence items after the intervention. Evaluation of change required paired data from participant assessments before and after the HFS intervention. There were at most 107 pairs of assessments of knowledge and 106 pairs of self-confidence assessments. Participant demographics are shown in Table 2.

3.2 | Adjustments of the questionnaire based on the feasibility study

The content experts gave useful feedback for improvements of the questionnaire; for example reformulation of items, explanation of

abbreviations and they agreed on what were the correct answers. The analysis of the follow-up interviews resulted in three themes for improvements: item content, item style and administration of the questionnaire. All participants found that most items addressed relevant aspects of their experiences in the intervention but made several suggestions for improvement. The level of difficulty of the questionnaire was found acceptable and the number of items was appropriate. Participants felt that it was good to have three response alternatives for the knowledge items and they understood that they should choose one alternative. For the self-confidence items, seven participants found the five response alternatives appropriate. One participant thought that one out of three response alternatives would have been easier to choose. Participants reported that it was good that the same questionnaire was administered before and after the intervention. They felt that the pre-intervention questionnaire helped them to prepare for the intervention and that it contributed to increased attention, motivation and learning throughout the intervention. They reported becoming more aware of what they knew and could manage and what they needed to learn more about. One participant argued that other relevant work she had done after the pre-intervention questionnaire in addition to the intervention influenced her answers on the post-test questionnaire. These qualitative findings improved the questionnaire for future use; for example clarification of items, removal of items not relevant, development of new relevant items and decision to administer the questionnaire to all participants immediately before and after the intervention to better control confounding variables. The distribution of the item response alternatives of knowledge was also examined. Incorrect alternatives that were rarely chosen or chosen more often than the correct ones have been reformulated.

3.3 | Intervention effect on knowledge

The number of correct responses to the 20 knowledge items ranged from 9–18 (mean 14.8, *SD* 1.9) pre-intervention and from 10–19 (mean 15.4, *SD* 1.7) postintervention. The effect of the intervention on acquired knowledge, expressed as the difference between the proportion of participants with increased or decreased numbers of correct responses to the 20 items, ranged from −25.5 (item 15)–24.8 (item 20) pu (Table 3).

For item 20, 34 students chose the correct alternative and 35 chose an incorrect alternative on both occasions. Thirty-one students changed from an incorrect alternative to the correct alternative and five changed from the correct alternative to an incorrect alternative after the intervention. Therefore, 24.8 pu more participants changed to the correct alternative than to an incorrect alternative. The 95% CI of this difference, 14.1–34.4 pu, indicates strong evidence for a positive intervention effect on knowledge related to item 20. Corresponding evidences hold for the positive changes for the items 2, 4, 5 and 9 (Table 3). Responses to item 15 showed the opposite pattern. Seven students changed from an incorrect to the correct alternative and 34 changed from the correct to an incorrect alternative after the intervention. This indicates a negative difference in paired proportions: 25.5 pu more students changed to an incorrect than to the correct alternative. The 95% CI for this difference, −35.9 – −14.2 pu, indicates a negative intervention effect on students' knowledge related to item 15. Similar result was found for the alternative change for item 12. The difference in paired proportions was 0 for items 1, 10 and 18, for which almost all students had pairs of unchanged correct responses and the number of changes from correct to incorrect was the same as from incorrect to correct.

TABLE 2 Participant demographics (*n* = 107)

	Sample *N* = 107	Individual interviews *N* = 8
Gender (*n*, %)		
Female	99 (83)	8
Male	8(7)	
Age (Median, range)	23, 20–56 years	22.5, 21–39 years
Previous experience with use of a human patient simulator (*n*, %)		
Yes	1 (1)	1
No	106 (99)	7
Class (*n*, %)		
A	38 (32)	4
B	51 (43)	4
C	18 (15)	

3.4 | Responsiveness of the self-confidence scale

The proportion of participants with unchanged self-confidence levels after the HFS intervention (PA) ranged from 21% to 71%. For each of the 18 items, the responsiveness of the self-confidence scale was confirmed by the non-zero positive RP measure of systematic group changes towards higher levels of post-intervention self-confidence. The RP values ranging from 0.14–0.58 are strong indicators of responsiveness, since none of the 95% CI cover the zero value (Table 4). The paired assessments for items 9–11 showed the largest systematic increase in perceived self-confidence; RP values ranged between 0.52–0.58.

Figure 2 shows the frequency distribution of the pairs of assessments of self-confidence for item 11. As evident from the two sets of marginal distributions, most assessments are shifted towards higher levels of self-confidence after the intervention. The categories *largely* and *very confident* were chosen by 71 participants postintervention compared with 22 pre-intervention. The RP value of 0.58 means that it is 58 percentage units more likely with a change to higher than to lower categories of self-confidence after the intervention. The 95% CI from 0.41-0.74 confirms the strong statistical evidence of a systematic increase in self-confidence regarding this item. The RV value of 0.18 indicates some heterogeneity. The paired scores of the items 1 and 3 have 71% unchanged self-confidence. The main explanation of the remaining 29% pairs of assessments of item 3 (Figure 3) is the RP measure, 0.14, indicating a systematic group change in favour

TABLE 3 Difference between paired proportions (Δp) percentage units (pu) of students with increased and decreased numbers of correct responses on knowledge items after the high-fidelity simulation intervention

Items	*N*	Δp (95% CI) pu
1. What is usually considered a normal blood pressure for healthy adults?	107	0.0 (−4.5 to 4.5)
2. What usually happens to the blood pressure after major blood loss?	106	12.3 (3.9–21.0)
3. Which of these causes may lead to low blood pressure?	104	−4.8 (−13.9 to 4.4)
4. What is usually considered a normal resting pulse for healthy adults?	107	10.3 (1.9–18.6)
5. What usually happens to the pulse rate after acute major blood loss?	107	11.2 (1.8–20.6)
6. What is included in the assessment of pulse quality?	105	−1.0 (−7.1 to 5.0)
7. At which location is the pulse most commonly measured in adults?	105	−1.0 (−10.9 to 9.0)
8. What is considered a normal respiratory rate at rest for healthy adults?	106	4.7 (−2.3 to 12.0)
9. What usually happens to the respiratory rate after major blood loss?	106	18.9 (9.0–28.6)
10. What are the recommendations for counting an irregular respiratory rate?	106	0.0 (−4.5 to 4.5)
11. What is usually considered a normal body temperature in healthy adults (degrees Celsius)?	106	−2.8 (−9.4 to 3.4)
12. What usually happens to the body temperature after major blood loss?	105	−19.0 (−29.0 to −8.9)
13. Which method of measuring body temperature usually offers the most accurate measurement results?	107	0.9 (−4.4 to 6.5)
14. What is usually considered normal blood oxygen saturation for healthy adults?	107	5.6 (−1.1 to 12.9)
15. At what point can a nurse administer oxygen to a hospitalized patient?	106	−25.5 (−35.9 to −14.2)
16. What are the clinical signs of partial wound rupture?	96	8.3 (−2.6 to 19.0)
17. What is the purpose of putting a bandage on a surgical wound?	106	−5.7 (−14.5 to 3.2)
18. If the patient loses consciousness and it is necessary to perform CPR, what is the correct treatment?	106	0.0 (0.0–0.0)
19. What is it important to do before performing CPR?	106	0.9 (−7.3 to 9.2)
20. When should rescuers switch positions during CPR?	105	24.8 (14.1–34.4)

Note: Abbreviations: Δp, difference between paired proportions; CI, confidence interval; pu, percentage units.

of higher levels of self-confidence after intervention, even though all participants were quite confident regarding the topic of the item pre-intervention. The RV (0.04) and the 95% CI (0.00; 0.07) indicate negligible additional individual variation.

3.5 | Estimation of change in perceived self-confidence

The impact of the HFS intervention on the perceived self-confidence is also evident by the difference in paired proportions of change in self-confidence between the two occasions. The frequency distribution of the pairs of assessments of the item 11, Figure 2, shows that 77 of the 106 participants assessed higher and 7 lower levels of self-confidence post-test. This means that 66.0 pu more students assessed higher rather than lower levels of self-confidence levels after the HFS intervention. According to these dichotomized data, there is strong evidence that most students from a representative population will assess higher rather than lower self-confidence regarding this item topic after the intervention, since the 95% CI for the difference in proportions ranges from 60.2–77.4 pu in favour of change to higher levels of self-confidence. Corresponding difference in paired proportions refers to item 3 with 71% unchanged pairs (Figure 3) and 16.5 pu more students assessed higher rather than lower levels of self-confidence after the intervention. The evidence of general conclusions is confirmed by the 95% CI from 6.7–26.3 pu.

4 | DISCUSSION

The concept of validity is an important aspect of questionnaire quality (Polit & Beck, 2017). In this study, validity was established by an expert panel who reviewed the relevance, appropriateness and fitness of the items for the intervention. The follow-up interviews also enabled examination of the construct validity, in terms of the knowledge domains assessed and the item response options. Qualitative process evaluations may help to understand reasons for trial failure or success and provide knowledge on the feasibility, transferability and sustainability of trial interventions (Atkins, Odendaal, Leon, Lutge, & Lewin, 2015). Sandelowski (1996) has also elaborated on the role of qualitative methods in experimental trials to explain individual variations, verify outcomes and clarify discrepancies between the actual intervention and how participants experience it (Creswell et al., 2006). The importance of assessing the fidelity of instruments and interventions have been elaborated and identified as rationales for using both quantitative and qualitative research (Collins et al., 2006).

TABLE 4 The measures of change in assessments of self-confidence after the high-fidelity simulation intervention (PA, RP, RV), and the difference between paired proportions (Δp) percentage units (pu) of change in perceived self-confidence after the high-fidelity simulation intervention

Items	*N*	PA	RP (95% CI)	RV (95% CI)	Δp (95% CI) pu
1. How confident are you that you can perform the correct blood pressure measurement on an adult?	106	71%	0.15 (0.08–0.22)	0.01 (0.00–0.01)	19.8 (10.2–29.4)
2. How confident are you that you can recognize the value of a normal blood pressure in a healthy adult?	106	59%	0.24 (0.15–0.38)	0.06 (0.01–0.11)	27.4 (16.4–38.3)
3. How confident are you that you can perform the correct heart rate measurement on an adult?	106	71%	0.14 (0.05–0.23)	0.04 (0.00–0.07)	16.5 (6.7–26.3)
4. How confident are you that you can recognize the value of what is considered a normal resting pulse in a healthy adult?	106	45%	0.34 (0.24–0.49)	0.08 (0.03–0.14)	39.6 (27.7–51.5)
5. How confident are you that you can correctly assess the pulse quality of a healthy adult?	106	50%	0.25 (0.15–0.34)	0.05 (0.0–0.09)	33.0 (21.1–44.9)
6. How confident are you that you can perform the correct measurement of respiratory rate on an adult at rest?	105	62%	0.16 (0.08–0.25)	0.03 (0.00–0.05)	21.0 (10.0–31.9)
7. How confident are you that you can recognize the value of a normal respiratory rate of a healthy adult?	105	49%	0.15 (0.04–0.26)	0.12 (0.03–0.20)	19.0 (5.8–32.2)
8. How confident are you that you can recognize the value of a normal body temperature of a healthy adult?	106	62%	0.15 (0.06–0.24)	0.09 (0.06–0.12)	17.5 (6.2–28.7)
9. How confident are you that you can detect clinical changes in blood pressure after major blood loss?	106	30%	0.56 (0.46–0.66)	0.25 (0.12–0.38)	60.4 (49.4–71.4)
10. How confident are you that you can detect clinical changes in pulse rate after major blood loss?	103	33%	0.52 (0.42–0.62)	0.22 (0.10–0.34)	57.7 (46.5–68.9)
11. How confident are you that you can detect clinical changes in respiratory rate after major blood loss?	106	21%	0.58 (0.41–0.74)	0.18 (0.08–0.28)	66.0 (60.2–77.4)
12. How confident are you that you can detect clinical changes in body temperature after major blood loss?	105	40%	0.32 (0.21–0.42)	0.19 (0.08–0.30)	39.0 (28.3–51.8)
13. How confident are you that you can recognize the value of normal blood oxygen saturation of a healthy adult?	106	51%	0.27 (0.17–0.37)	0.07 (0.02–0.12)	32.0 (20.2–43.9)
14. How confident are you that you know at what point a nurse can administer oxygen therapy to a hospitalized patient?	105	40%	0.41 (0.31–0.51)	0.21 (0.16–0.27)	48.6 (37.0–60.1)
15. How confident are you that you can recognize the clinical signs of partial wound rupture?	104	34%	0.45 (0.35–0.54)	0.05 (0.00–0.11)	60.6(50.1–71.0)
16. How confident are you that you know the purpose of putting a bandage on a surgical wound?	103	34%	0.38 (0.28–0.48)	0.12 (0.06–0.17)	48.5 (36.0–61.1)
17. How confident are you that you can assess the need for starting CPR?	106	57%	0.22 (0.12–0.32)	0.08 (0.03–0.13)	22.6 (10.9–34.5)
18. How confident are you that you can perform correct CPR on an adult?	106	56%	0.20 (0.10–0.30)	0.06 (0.01–0.11)	23.6 (11.7–35.4)

Note: Abbreviations: PA, percentage agreement; RP, relative position; RV, relative rank variance; CI, confidence interval; Δp, difference between paired proportions; pu, percentage units.

Both the correct alternative and the incorrect alternative (the so-called distractors) in a questionnaire should be similar in grammatical form, style and length (Masters et al., 2001). The proportion of participants with correct responses for items of varying difficulty is an indicator of knowledge level and also the quality of the response alternatives (Considine & Botti, 2005). Distractors that were rarely chosen or chosen more often than the correct option have been reformulated in this study. In this study, assessment of the validity of the questionnaire was carried out before and immediately after the intervention. Kirkpatrick & Kirkpatrick's framework for evaluating the effectiveness of training programmes (2006) emphasizes the importance of how much the behaviour of students in other settings reflects what they have learned (level 3). Asking the participants to respond to the questionnaire again after,

Item 11: How confident are you that you can detect clinical changes in respiratory rate after major blood loss? (n = 106) – PA 21%

		First occasion (pre-test)					
		Not at all	Somewhat	Average	Largely	Very	Total
Second occasion (post-test)	Very		4	7	4	2	17
	Largely	2	11	29	10	2	54
	Average	2	18	10	4		34
	Somewhat			1			1
	Not at all						
	Total	4	33	47	18	4	106

FIGURE 2 Frequency distribution of pairs of self-confidence responses for item 11. The diagonal of unchanged responses are marked. PA, percentage agreement

for example 3–6 months following the intervention would have strengthened the study. Assessing sensitivity to capturing change over time is important with regard to the potential of HFS to have sustained knowledge and confidence on nursing students' practice over time.

The evaluation of the paired proportion of students' responses for knowledge items 2, 4, 5, 9 and 20 showed that significantly more students changed to correct than to incorrect responses. These items are very important for achieving the learning objectives for the intervention. In contrast, more students changed to incorrect than to correct responses for items 12 and 15. This may reflect a lack of understanding of the questions or response options in relation to the simulation session. The responses for the other items showed negligible changes.

4.1 | Limitations

This study did not evaluate the effects of the intervention on possible relationships between knowledge and self-confidence; this topic would be interesting to examine in future studies. There are many advantages to running a feasibility study prior a randomized controlled trial; for example single-arm studies are easier to conduct and it is possible to undertake a more detailed qualitative study if all participants receive the intervention (Taylor et al., 2015). Possible contamination and co-intervention should be examined in a feasibility study, because they can threaten the validity of the findings. Replicating a real-life situation in HFS requires careful accounting for most of the confounding variables (Cheng et al., 2014). Some participants engaged in relevant activities in the time between completing the two questionnaires, which may have increased the scores. One strategy to reduce co-intervention is to exclude those who planned to receive another form of intervention during the study period (Feeley & Cosette, 2015). Another strategy is to reduce the time between completion of the two questionnaires, although this might increase the chance of improved scores owing to memory of the questionnaire content. The same scenario, equipment and environment were used in our study for all participants; however, the facilitation of the intervention varied as it involved up to six faculty members. This may have caused small differences in the content of the intervention, although all the faculty members agreed about the feasibility of the intervention. Curl et al. (2016) recommend that the group size during the active part of the HFS should be limited to five students. Repeated exposure to the scenario may solve the problem of having a large number of participants in the group. In this study, participants in half of the simulation groups received repeated exposure. Repeated exposure to clinical scenarios through simulation is described as particularly effective (Abe, Kawahara, Yamashina, & Tsuboi, 2013).

5 | CONCLUSION

The content validity, the face validity and the comprehensiveness of the questionnaire were determined by expert panel review and individual interviews. The responsiveness of the questionnaire was confirmed by means of statistical methods that consider the non-metric properties of ordered categorical data. The measures of individual variations were small. The non-zero positive RP values showed that all self-confidence item responses were sensitive to changes towards higher levels after the intervention. Hence, the main explanation of the change is the systematic group change, which indicated the responsiveness of the five-point perceived self-confidence scale. We also used appropriate classical statistical methods to evaluate the effects of the intervention on

Item 3: How confident are you that you can perform the correct heart rate measurement on an adult? (n = 106) – PA 71%

		First occasion (pre-test)					
		Not at all	Somewhat	Average	Largely	Very	Total
Second occasion (post-test)	Very			2	16	30	48
	Largely			6	38	7	51
	Average			7			
	Somewhat						
	Not at all						
	Total			15	54	37	106

FIGURE 3 Frequency distribution of pairs of self-confidence responses for item 3. The diagonal of unchanged responses are marked. PA, percentage agreement

the students' acquired knowledge and on the dichotomized data for changes in self-confidence. The methodological and statistical approaches used and the evaluation of the findings, provide useful information for the forthcoming design of a randomized controlled study.

CONFLICT OF INTEREST

No conflict or interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; involved in drafting the manuscript or revising it critically for important intellectual content; given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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Paper 3

Recognition of and Response to Deteriorating Patients: A Multi-Center Randomized Controlled Trial and a Process Evaluation

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RECOGNITION OF AND RESPONSE TO DETERIORATING PATIENTS: A MULTI-CENTER RANDOMIZED CONTROLLED TRIAL AND A PROCESS EVALUATION

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Recognition of and Response to Deteriorating Patients: A Multi-Center Randomized Controlled Trial and a Process Evaluation

Abstract

The overall aim of this study was to examine the effects of a high-fidelity simulation intervention developed to identify how recognizing and responding to patient deterioration improves the knowledge and self-confidence of undergraduate nursing students. Participants in eight intervention groups attended a high-fidelity simulation intervention and participants in seven control groups received no instructional intervention. Pre- and posttest assessments of 158 participants' knowledge and levels of self-confidence, and process evaluation with six faculty members and five students were conducted. The two sets of changes in the number of correct responses to knowledge-based questions were compared and differences in paired proportion were evaluated for both groups. Transcribed interviews were analyzed with qualitative thematic analysis. A significantly larger proportion of students in the intervention than in the control group increased the number of correct responses of knowledge and levels of self-confidence postintervention. As enablers for successful implementation of the intervention, a need for a safe environment, fidelity and learning in different roles were identified by students, and creating a safe environment, promoting reflection and student-centered learning were reported by the faculty members. This study showed an evident intervention effect on knowledge and self-confidence in participants who attended a high-fidelity simulation intervention.

Keywords

Randomized controlled trial
High-fidelity simulation
Nursing students' knowledge
Nursing students' self-confidence

INTRODUCTION

Researchers have conducted a variety of studies measuring the effectiveness of high-fidelity simulation (HFS) in undergraduate nursing education (Zieber & Sedgewick, 2018; Orique & Phillips, 2017). However, significant differences in assessment methods leading to a wide variety of measurement outcomes is revealed (Doolen et al., 2016; Mariani & Doolen, 2016). Further, findings in a recently published systematic review identified that high-quality research designs and improved measurement practices are required to produce generalizable evidence concerning the effectiveness of HFS (Author et al., 2018). Therefore; there is a need for high quality research that can establish a cause-and-effect relationship between HFS and learning outcomes. Mariani & Doolen (2016) also identified a need for further research about simulation designs; why some things work, and why it is important to include certain elements in the design of a simulation.

Simulations offer a safe nonthreatening environment without causing harm to patients and offers all students equal experiences. Increased attention on patient safety has decreased the number of available student nurse placements (Lee et al., 2017; Shin, Jin-Hwa, & Jung-Hee, 2015), and current literature has highlighted the fact that a gap exists between the expected learning outcomes for newly graduated nurses and the expectations held by leaders in the practice (Burgess et al, 2018; Huston et al, 2018). Kirkpatrick's framework for evaluating the effectiveness of training programs (2006) may be used as a guide for assessing simulations. It consists of four levels of evaluation (1) the reactions of the students, (2) the amount of learning achieved by the students, (3) the degree to which the behavior of students in other settings reflect what they have learned, and (4) the extent to which results are improved (Kirkpatrick & Kirkpatrick, 2006). All measurements in this randomized controlled trial (RCT) were taken at Kirkpatrick's level one and two.

THE STUDY

Aims

The overall aim of this study was to examine the effects of an HFS intervention developed to identify how recognizing and responding to patient deterioration improves the knowledge and self-confidence of undergraduate nursing students. The specific aims were:

1) To describe and estimate the change in undergraduate nursing students' knowledge and perceived self-confidence after an HFS intervention.

2) To identify the barriers and enablers that may impact a successful implementation of the HFS intervention.

The primary hypothesis was that the knowledge of nursing students who receive a tailored educational program, including HFS, will increase compared with nursing students who do not attend HFS in the topic recognition and response to acute patient deterioration.

Design

A randomized experimental pre- and post-test research design was employed. The main outcomes refer to change in knowledge and change in perceived self-confidence after the intervention.

Participants

Assuming a difference in the expected learning effect between the proportion of students in the intervention and the control groups being 20 percentage units, and the proportion participants with positive outcome being 50% (intervention group) and 30% (control group), gives a standardized difference of 0.41. This indicates that a total sample of 160 participants will detect the assumed difference in learning effects with a power of 80% on the significance level of 5% (Altman, 1991). A convenience sample (n=177) of second-year undergraduate nursing students and seven faculty members from three campuses at two universities in southern (two) and eastern (one) Norway (campus A, B, C) were invited by the first author to participate in the study in November-December 2018. The lab coordinators scheduled groups of 15 students to be randomized. A statistician performed a stratified block randomization to ensure balance, which means similar numbers of student groups being allocated to the intervention and control groups within each campus (Altman, 1991).

Data Collection

The HFS-intervention took place in two simulation laboratories at two universities and the human patient-simulator Laerdal SimMan 3G was used in all the scenarios. The group size varied from 9 to 14 students. Each scenario was facilitated by two faculty members. One faculty member provided guidance during the activity when necessary and remained within the laboratory. In two scenarios, the facilitator (i.e., the faculty member) also answered a telephone to role-play a physician providing relevant responses. In the remaining six scenarios, one student had the role as a physician. A second faculty member provided patient

responses through the manikin using a wireless microphone. Seven faculty members were involved. The debriefing was structured upon the four phases; reaction, description, analysis, and application, as described by Eppich & Cheng (2015). A written guide for how to implement all phases in the intervention was given to all the facilitators involved one month before the interventions were conducted. Elements of the deteriorating patient simulation scenario are detailed in Table 1.

(Insert Table 1 about here)

The questionnaire used in this study has been validated in a recently published feasibility study (Author et al., 2019), and it consists of three parts. Part one elicits demographic data containing questions about gender, age, campus, grade and previous experience with HFS and deteriorating patients. Parts two and three contain items about knowledge and self-confidence. Measuring the variables of knowledge and perceived self-confidence referring to the same concepts of learning is a multi-conceptual problem. Hence, these variables are considered to be multi-dimensional, covering items of the three dimensions: normal values of vital signs and urine production, clinical changes in vital signs and urine production at acute major blood loss, and nursing procedures. The 20 items of the main variable, knowledge, were operationally defined to the dimensions accordingly: normal values (1,4,8,11,14,17), clinical changes (2,5,9,12,15,18), and nursing procedures (3,6,7,10,13,16,19,20) (see Table 2). They were multiple choice-questions (MCQs) with three response alternatives and were developed by the research team to fit the simulation scenario for this study. The 20 items of perceived self-confidence were assessed on ordered categorical scales with the categories *not at all, somewhat, average, largely,* and *very self-confident.* These items refer to corresponding concepts and dimensions of knowledge. As the groups of items covered different aspects of the same concept, a single global score of each dimension was defined. There are various approaches to aggregate multi-item ordered categorical assessments to a global dimensional score (Svensson, 2001a; Allvin et al., 2009; Svensson, 2010). Because the responses of knowledge are recorded as correct or incorrect answers, the use of the sum of correct answers within each dimension defines the global dimensional score of knowledge. In this study, the global score of perceived self-confidence of each dimension was defined by the median score. In case of an odd number of items, the median score is well-defined by the ordered item category that comes halfway in the range of assessments. In this study, the dimensions consist of an even number of items, six and eight. When the two central item responses differ, the

median cannot be defined as the average of these categories because of the non-numerical properties. According to the definition of the median of ordered categorical data, any of the two central categories, and any other between the ordered set of item responses, will serve as a median (Kruskal, 1958). For example, for an ordered set of six item responses "*somewhat, average, average, largely, largely,* and *very*", both "*average*" and "*largely*" will serve as a median. Then the category that reflects the lower level of self-confidence will be used as a global score to avoid overestimation of intervention effect. In cases of an intermediate possible category between the two central categories, for example, between "*somewhat* and *largely*" or "*average* and *very",* the intermediate category "*average*" and "*largely*", respectively, is chosen.
(Insert Table 2 about here)

The questionnaire took about 10 minutes to complete. All the participants in the *intervention* groups responded to the questionnaire immediately before and after the HFS intervention. The intervention lasted for about 2 hours. The time between the two occasions for responding to the questionnaire was the same for the participants in the *control* groups. However, they received no instructional intervention before responding to the questionnaire the second time. In five of the seven *control* groups the participants had a classroom meeting with practical information about their upcoming clinical practice period. In the remaining *control* groups, the participants had a reflection meeting about clinical practice. The content of the questionnaire was not presented or discussed in any of the *control* groups during the time between their first and second respond to the questionnaire. To ensure an equal learning opportunity for all students, the participants in the *control* groups attended the HFS intervention after they had responded to the questionnaire the second time (the same day or within the following 8 days). The first author informed about the study and administered all the questionnaires in the *intervention* groups and in half of the *control* groups. Because of practical considerations, two other faculty members administered the questionnaire in the remaining *control* groups.
All the *intervention* groups were asked if one self-selected member of the group would voluntarily participate in individual interviews as a part of the evaluation process after having responded to the questionnaire the second time. Faculty members involved in all phases in the intervention were also asked to share their experiences regarding the feasibility of the HFS intervention. An interview guide consisting of five open-ended questions was used: *What role did you have when participating in the HFS intervention? How would you describe your*

experience with the HFS intervention? What were positive points of the HFS intervention? What were negative points of the HFS intervention, and *Do you have something to add about the HFS intervention?* The students were also asked to share their experiences on responding to the questionnaire: *How would you describe your experience of completing the questionnaire? What were positive/negative aspects of the questionnaire*, and *Do you have anything to add to the questionnaire?* All the interviews were audio recorded and lasted from 10 to 48 minutes (mean: 23 minutes). They were conducted by the first author at the university where the intervention took place. For the students, all interviews were conducted immediately after the intervention. For the faculty members, all interviews were conducted within one week after the intervention. The flow of the data collection is displayed in Figure 1.

(Insert Fig. 1 about here)

Ethical Considerations

Participation in the intervention was part of the students' nursing education and was compulsory. However, responding to the questionnaire and participating in an interview was voluntary and did not influence students' course grades. The members of the research team were not in a teacher-student relationship with the invited students during the study-period. Participation required oral and written information and signed informed consent. Institutional approval was received to recruit participants and perform data collection. Because of the study aims, ethical approval was not required. The study was approved by the Norwegian Centre for Research Data, project number 52110. A comprehensive study protocol is registered and accessible on clinicaltrials.gov, ID: NCT 04063319, Protocol ID: 52110. None of the faculty members involved in delivering the HFS intervention knew the content of the questionnaire, thus; they could not affect the results in that way.

Data Analysis

Data were entered into the SPSS (V25) software program. If a participant had chosen two response options of an item of knowledge, and one of which was correct, then that one was consistently recorded. When two of the five item-categories of self-confidence were marked, or the mark was placed between two adjacent categories, the lower level was consistently recorded.

The data were described by proportions (%), frequencies, or median (Md) and quartiles (Q_1, Q_3), when appropriate. The main outcome of this study was the change in the number of correct responses of knowledge after the intervention when compared with the corresponding outcome in a control group. The two sets of changes in the number of correct responses of knowledge were compared by the Wilcoxon-Mann-Whitney rank-sum test, adjusted for tied observations (Siegel & Castellan, 1988).

The proportion of students in the intervention and in the control groups with decreased, unchanged, and increased numbers of correct responses of knowledge regarding each of the three dimensions of knowledge were calculated. The proportion of students with all items correctly answered on both occasions was described separately from students with incomplete number of unchanged items. The proportion of students with an increased number of correct responses of knowledge in the intervention and control groups were compared. The 95% confidence interval for the differences in proportions, and corresponding statistical test with continuity correction for comparing proportions in two independent groups were calculated. The same statistical methods were used for describing the proportion of students with decreased, unchanged and increased global levels of perceived self-confidence regarding each of the three dimensions, and for comparing the two groups of students with increased levels of self-confidence post-test (Altman, 1991).

The interviews were transcribed verbatim by the first author, and the transcribed text was further read in order to be familiarized with the data. A thematic analysis in six steps based on Braun & Clarke (2006) was performed to identify codes, subthemes and themes. The six steps that we followed are, 1) Familiarization with the data, 2) Generating the initial codes, 3) Searching for themes, 4) Reviewing the themes, 5) Defining and naming the themes and 6) Producing the report. The themes were reviewed by three members of the research team. Two examples of the thematic analysis are displayed in Table 3.

(Insert Table 3 about here)

RESULTS

Baseline characteristics of the participants are displayed in Table 4. A total of 158 of 177 students voluntarily completed the questionnaire. All the participants had experience with simulation in nursing education. In addition, five students also participated in interviews.

They were three females and two males, and the age ranged from 22 to 43 years old (Md: 29). They were from all the three study campuses (campus A=2, campus B=2, and campus C=1). Two interviewees had role-played nurses in the scenario, one had role-played a physician and two were observers. Six faculty members who organized the intervention were also interviewed. They were five females and one male, and the age ranged from 39 to 64 years (Md: 46). All of them had previous experience with organizing simulations for nursing students in undergraduate nursing education. The years of experiences varied from 1.5 to 15 years. All of them except for one had attended a course that focused on how to be a facilitator in simulations. The faculty members were from all the three study campuses (campus A=2, campus B=2, and campus C=2). Three faculty members were facilitators in the scenarios, one was an operator and the remaining two acted both as facilitators and operators because they were involved in more than one scenario during the data collection period.

(Insert Table 4 about here)

The number of correct responses to the 20 knowledge items by the students in the intervention group ranged from 11 to 20 (Md: 17; Q_1: 16, Q_3: 18.5), and from 12 to 20 in the control group (Md: 17; Q_1: 16, Q_3: 18) at study start. The distribution of changes in the number of correct responses in the intervention group ranged from -3 to 7 and was significantly higher than the changes in the control group that ranged from -3 to 2 (p=0.004). The proportions of students in the intervention and control groups that increased the number of correct responses on the follow-up assessment were 45% and 26%, respectively. The 95% confidence interval of this difference of 19 percentage units ranges from 4 to 34 percentage units. This means that in a representative population, one can expect an intervention effect of about 3 to 34 percentage units more of students to increase the number of correct answers of knowledge than without. Corresponding comparisons of the proportion of students in the intervention and control groups with an increased number of correct responses posttest were made on the three groups of items referring to the knowledge of normal values, clinical changes and to nursing procedure (see Table 5). The wide but non-zero confidence intervals indicate statistical evidence of an intervention effect on knowledge, especially regarding items of normal values, from 11 to 39 percentage units (p=0.005), and of clinical changes, from 3 to 38 percentage units (p=0.04).

(Insert Table 5 about here)

The global levels of perceived self-confidence regarding normal values ranged from *average* to *very confident*, and from *somewhat* to *very confident* regarding clinical changes and nursing procedures assessed by the two groups of students' pretests. A majority (55%) of the students in the intervention group had higher levels of self-confidence referring to clinical changes after intervention (see Table 6). The corresponding proportion students in the control group that scored higher levels of self-confidence posttest was 10%. The 95% confidence interval of this difference of 45 percentage units, ranges from 32 to 58 percentage units, which is strong evidence of a significant intervention effect on perceived self-confidence referring to clinical changes ($p<0.0001$).

(Insert Table 6 about here)

The students described the simulation experience as "*frightening, exciting, interesting, fun* and *I learned a lot*". The analysis of their experiences of the intervention resulted in three themes:

1. A need for a safe environment

Feeling secure seems to be essential for learning and the students indicated several factors that made they feel safe before, during and after the intervention. To get information about the patient's case one week before and a review in a group at the start of the intervention helped them reduce stress. Orientation and exposure regarding the simulator also made them feel more secure. During the scenario, the observed students reported that the observers made them less secure. However, one student reported: "*After a little while I forgot the observers and got in my own "zone" because I had to focus on the patient*". Smaller simulation groups were strongly wanted to share experiences honestly, especially upon things that did not go so well in the scenario. One student that acted as a nurse reported that she was thankful that the feedback was mostly positive, and that the support helped her to feel secure. Knowing that they could not harm the patient in the scenario also made the students more secure.

2. Fidelity

The contextual factors impacted every aspect of the simulation experience. Fidelity was important as the students reported that it increased their opportunities for learning outcomes that the simulated environment felt realistic. By using the patient-simulator and realistic medical equipment and furnishings, students reported that it felt as if they were in situations with real patients in real clinical settings. Always talking about the simulator as a patient and not a doll also made the context more realistic. A minor technical error with the patient-

simulator for a few seconds and the presence of many observers made the scenario less realistic.

3. Learning in different roles

The learning outcomes in simulations should not only be linked to hands-on experience, as evidenced by the students discussing their learning in different roles. Both observers emphasized the importance of the observer's role in giving another view to the situation and learning through reflection. However, they missed the feeling of reflection-in-action and suggested a repeated scenario in each simulation group to increase the learning outcomes. The students that were acting as nurses, reported that they learned a lot about themselves and got a sense of mastering something. Both said that it was challenging to be the center of attention, but they were thankful for the feedback from the observers on their performance. They thought that the simulation environment supported the linking of theory and practice.

Aspects of the *item content* and *item style* where described by the students regarding their experience of responding to the questionnaire. They understood most of the content and found that most items addressed relevant aspects of their experiences in the intervention. All students understood easily how to fill in the questionnaire.

The analysis of the experience of organizing the intervention from the faculty members resulted in three themes:

1. Creating a safe environment

Feeling secure, especially at the beginning, was reported as a key factor in the process of learning. Several factors to create a safe environment before, during and after the intervention were reported, such as giving the students information a week before the intervention and starting the intervention together with a review of the patient's case, learning objectives, repetition of relevant theoretical knowledge, and agreeing on terms of mutual respect and confidentiality. Talking with all the students about their roles and providing a good orientation to the patient simulator were also described as important. During the scenario, the facilitators reported that they were present in the simulation room and offered practical assistance or cues if needed. They emphasized the need for technical expertise to manage the patient simulator, and that technical errors during the scenario could make the students insecure. The faculty members had the perception that the students found it uncomfortable to be observed during the scenario, but the feeling reduced when they began concentrating on what to do. After the scenario, the faculty members emphasized the importance of having

most of the focus on the positive aspects on what the students did well to make them more secure.

2. Promoting reflection

Another theme is the high value placed on debriefing. The faculty members highlighted the importance of learning from reflection through analysis and discussion in the group after the scenario. They mostly noted that students who were in active roles reported the situation as being chaotic and of making many mistakes. Therefore, the need for sharing different perspectives of the situation in the group was highly appreciated. The faculty members emphasized that the debriefing session should be tailored to the learning objectives. To increase the learning outcomes, the faculty members emphasized the importance of more students being allowed to participate in active roles during the scenarios. To manage this, they suggested repeated scenarios in each simulation group or splitting the scenarios with breaks where they changed roles along the way.

3. Student-centered learning

The faculty members reported that simulation activities should be student-centered and meet the students' needs. Not knowing how the students will respond and not being prepared for new aspects of a situation made the organizing of the intervention unpredictable. The faculty members that acted as operators in the scenarios pointed out that sometimes they had to give the patient more symptoms than they had planned for and more than what was realistic (such as higher blood pressure or reduced awareness) to get the students to respond. To reduce the unpredictability, the faculty members appreciated that there were two professionals who shared the organization of the simulation. They made appointments before the scenario started and could communicate during the scenario if necessary.

DISCUSSION

The importance of assessing the fidelity of interventions has been identified as a rationale for combining quantitative and qualitative approaches (Collins et al., 2006). Process evaluations may help us understand the feasibility, transferability and sustainability of trial interventions and reasons for trial success or failure (Atkins et al, 2015). Sandelowski (1996) has also elaborated on the role of qualitative methods in experimental trials to explain individual variations, verify outcomes, and clarify discrepancies between the actual intervention and how participants experience it (Creswell et al., 2006). The findings in this study may be of interest to educators because increasing importance is being placed on enhancing students' knowledge

acquisition. Several similar studies have also found an increase in knowledge and self-confidence after attending HFS (Haukedal et al., 2018; Zieber & Sedgewick, 2018). Objectives are considered essential when using simulation and Smith & Roehrs (2009) found that clear objectives geared at an appropriately challenging goal were correlated with increased satisfaction and confidence. To "assess, recognize and respond to *changes* in a patient's condition" was one learning objective in the HFS intervention, and the intervention effects identified on perceived knowledge and self-confidence referring to *clinical changes* in this study were both significant ($p=0.04$ and $p<0.0001$). However, there are many factors that could have influenced the assessments in this study. The same scenario and patient simulator were used in our study for all participants; however, the facilitation of the intervention varied as it involved up to seven faculty members. This may have caused small differences in the content of the intervention, although all the faculty members agreed about the feasibility of the intervention. Developing a written guide for implementing all phases in the intervention may have decreased differences in the content of the intervention. Ensuring that the plans for integration of process and outcome data are agreed to from the outset is a key recommendation for evaluation (Moore et al., 2015). Group size is another factor that is largely within the facilitator's control (Jeffries, 2016). Curl et al. (2016) recommend that the group size during the active part of the HFS should be limited to five students. The process evaluation identified that large numbers of participants in the simulation group decreased the learning outcomes and both students and faculty members suggested repeated exposure to the scenario. Repeated exposure to clinical scenarios is described as particularly effective (Abe et al., 2013).

Contamination and co-intervention can pose threats to the validity of an evaluation study's findings (Feeley & Cossette, 2015). All the assessments in this study were completed immediately before and after the intervention or a meeting, within three hours, to control for contamination and co-interventions. It was a strength of this study that, to reduce follow-up loss, the intervention was a compulsory part of an undergraduate nursing program, while the participating in the study being voluntary. Murray et al. (2008) propose that if the scenario needs to mimic clinical practice, a practitioner's input is also essential. An anesthesiologist with many years of experience facilitating simulation sessions for health professions in hospitals quality checked the simulation scenario used in this study before the assessments. The statistical methods used are appropriate for comparison of changes in ordered categorical data between the intervention and control groups as well as for evaluation of group changes (Svensson, 2011b). The use of median as a global score of multi-item scales provides

interpretable dimensional ordered categories of self-confidence. A very common approach to global scoring is to use sum scores, often transformed to a standardized score ranging from 0 to 100, seemingly quantitative and continuous. However, data from scale assessments consist of categories that represent an ordered structure without any information regarding distance and standardized magnitude. Hence, calculations of sum scores or differences in scale assessments are not appropriate analytical operations. The fact that data from assessments on ordered categorical scales do not have the same mathematical properties as laboratory data has been considered in the choice of statistical methods to ensure reliable results (Svensson, 2001b).

Trustworthiness values, such as credibility, dependability and transferability (Lincoln & Guba; 1985; Graneheim & Lundman, 2004) in qualitative analyses are safeguarded by the chosen procedure for a qualitative design. Criteria for credibility, understood as keeping the focus of the project, was met by choosing participants relevant for the research questions; both students and faculty members were representative of participants in the simulation scenarios. Dependability was met by using the same interview guide for all participants and no major changes were done during the data collection and analysis process. By thoroughly describing the participants, context and research process transferability, it should be possible to achieve the same standard as for similar studies. Thus, we argue that the qualitative part of the study meets the criteria for trustworthiness.

Limitations

Although the use of MCQs is a common approach in knowledge assessment, there are discussions about whether they are really appropriate (Levett-Jones et al., 2011). In addition, few academics in undergraduate nursing programs have adequate experience and training in developing quality MCQs (Tarrant et al., 2006). The process evaluation stated that the participants found that most items in the questionnaire addressed relevant aspects of their experiences in the intervention. In validation of the questionnaire, the participants also reported that the level of difficulty was acceptable, and the number of items was appropriate (Author et al., 2019). These findings indicate that the increase in knowledge and levels of self-confidence shown in this study may be an effect of the intervention. However, correct answers on MCQs do not necessarily correspond with how students will perform in real situations of patient deterioration. Knowledge and levels of self-confidence were only measured immediately after the intervention in this study, thus yielding no information on long-term knowledge retention. This topic would be interesting to examine in future studies.

CONCLUSIONS

Students' knowledge and self-confidence scores were compared before and after an educational intervention with HFS in this study. The results showed significantly greater improvement of scores in the intervention group than in the control group. A need for a safe environment, fidelity and learning in different roles were identified by students as important enablers that had an impact on a successful implementation of the HFS intervention. From the faculty members' point of view, creating a safe environment, promoting reflection and student-centered learning were reported as enablers.

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Figure 1

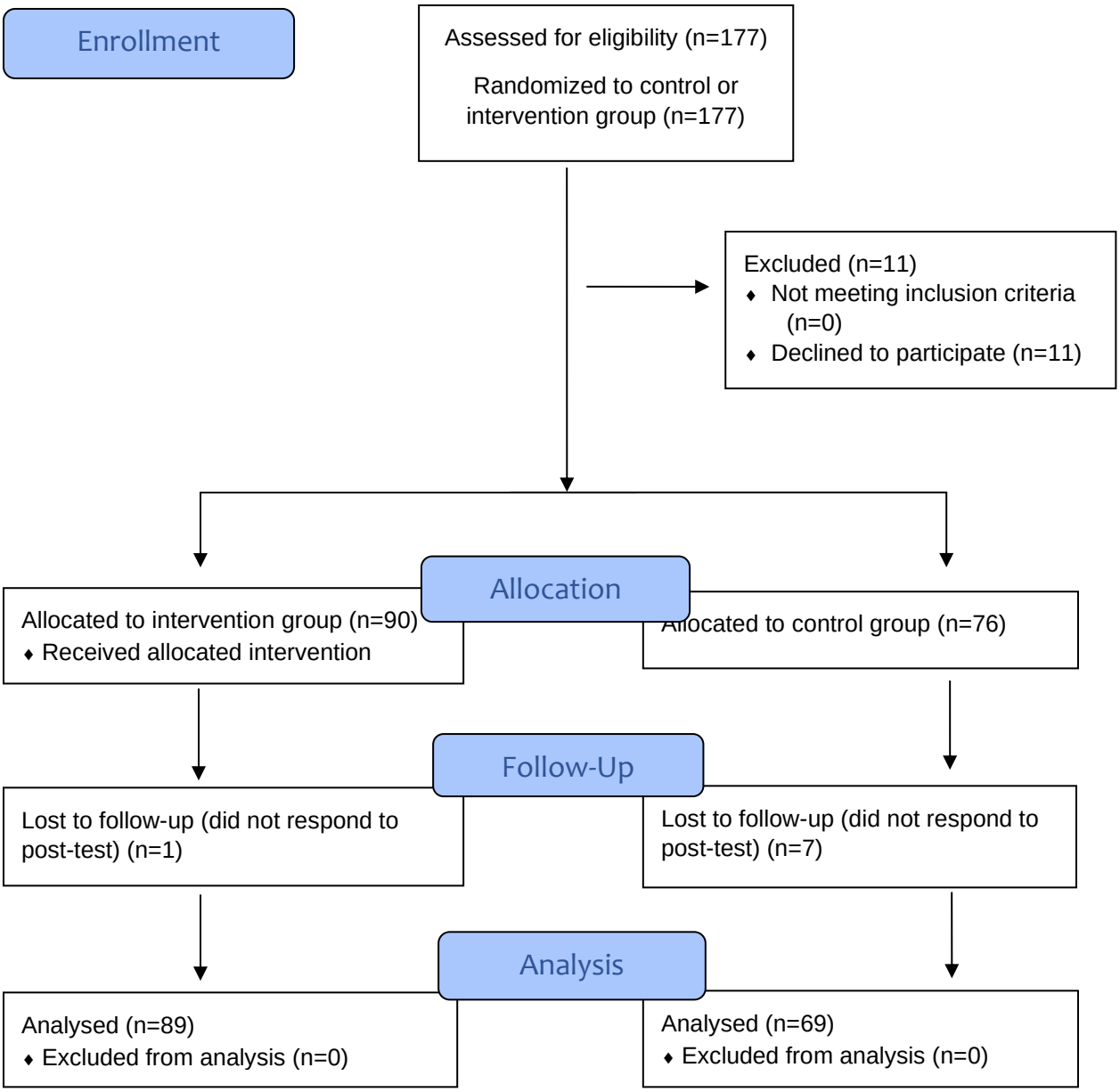

Figure 1. Flow of the data collection, developed from http://www.consort-statement.org/consort-statement/flow-diagram

Table 1

Table 1. Elements of the deteriorating patient simulation scenario.

Learning objectives	At the end of this simulation scenario, participants have learned to: -Communicate and work appropriately within a team -Assess, recognize and respond to changes in a patient's condition
Patient information	A 75-year-old, female patient hospitalized with cancer coli. She has gone through surgery (hemicolectomy) and has been transferred to the surgical ward.
Format	The simulation experience was composed of: -Review of the learning objectives and the patient's case. Selecting an active participant or observer role (30 min) -Receiving orientation regarding the simulator and environment (20 min) -Working through the simulation with guidance from a faculty member if required (15 min) -Participating in a facilitated debriefing session (45 min)
Roles	Registered nurse x 2 Relative Physician Observers Student or academic as the patients' voice/physician on the phone Facilitator Operator

Table 2

Table 2. Knowledge and self-confidence items in the questionnaire covering three dimensions.

Normal Values (knowledge items number 1,4,8,11,14,17)
1.What is usually considered a normal blood pressure for healthy adults?
4.What is usually considered a normal resting pulse for healthy adults?
8.What is considered a normal respiratory rate at rest for healthy adults?
11. What is usually considered a normal body temperature in healthy adults (degrees Celsius)?
14. What is usually considered normal blood oxygen saturation for healthy adults?
17. What is usually considered as normal urine production a day in healthy adults?
Clinical Changes (knowledge items number 2,5,9,12,15,18)
2.What usually happens to the blood pressure after acute major blood loss?
5.What usually happens to the pulse rate after acute major blood loss?
9.What usually happens to the respiratory rate after acute major blood loss?
12. What usually happens to the body temperature a while after acute major blood loss?
15. What usually happens with the oxygen saturation in the blood at acute major blood loss?
18. What usually happens with the production of urine at acute major blood loss?
Nursing Procedures (knowledge items number 3,6,7,10,13,16,19,20)
3.Which of these causes may lead to low blood pressure?
6.What is included in the assessment of pulse quality?
7.At which location is the pulse most commonly measured in adults?
10. What are the recommendations for counting an irregular respiratory rate?
13. Which method of measuring body temperature usually offers the most accurate measurement results?
16. At what point can a nurse administer oxygen to a hospitalized patient?
19. What is the purpose of having compression bandage on a surgical wound?
20. What is ABC a shortening for in the “ABCDE” approach?
Normal Values (self-confidence items number 1,4,8,11,14,17)
1.How confident are you that you are able to recognize the value of a normal blood pressure in a healthy adult?
2.How confident are you that you are able to recognize the value of what is considered as a normal resting pulse in a healthy adult?
8.How confident are you that you are able to recognize the value of the normal respiratory rate of a healthy adult?
11. How confident are you that you are able to recognize the value at the normal body temperature of a healthy adult?

14. How confident are you that you are able to recognize the value of a normal oxygen saturation in the blood of a healthy adult?

17. How confident are you that you are able to recognize the value of normal production of urine per day in healthy adults?

Clinical Changes (self-confidence items number 2,5,9,12,15,18)

2.How confident are you that you are able to detect clinical changes in blood pressure at acute major blood loss?

5.How confident are you that you are able to detect clinical changes in pulse rate at acute major blood loss?

9.How confident are you that you are able to detect clinical changes in respiratory rate at acute major blood loss?

12. How confident are you that you are able to detect clinical changes in body temperature a while after acute major blood loss?

15. How confident are you that you are able to detect clinical changes in oxygen saturation in the blood at acute major blood loss?

18. How confident are you that you are able to detect clinical changes in the production of urine at acute major blood loss?

Nursing Procedures (self-confidence items number 3,6,7,10,13,16,19,20)

3.How confident are you that you are able to perform the correct blood pressure measurement on an adult?

6.How confident are you that you are able to correctly assess the pulse quality of a healthy adult?

7.How confident are you that you are able to perform the correct heart rate measurement in an adult?

10. How confident are you that you are able to perform the correct measurement of respiratory rate in an adult at rest?

13. How confident are you that you are able to perform the measurement of body temperature that gives the most correct result?

16. How confident are you that you know when a nurse can administer oxygen therapy to a hospitalized patient?

19. How confident are you that you know the purpose of having a compression bandage on a surgical wound?

20. How confident are you that you can recognize what ABC is a shortening for in the “ABCDE” approach?

Table 3

Table 3. Qualitative thematic analysis.

Code	Subtheme	Theme
Student: «The simulation experience is useful because the context is really realistic. There is a patient who is controlled by a person you can't see. We can do nursing actions such as feeling the patient's pulse and the patient can communicate. And it looks like a room in a real hospital".	Experiences about the simulation context	Fidelity
Faculty member: "I know that some of the nursing students have limited previous experience with high-fidelity simulation, and I understand that there are a lot of new impressions for them. It takes some time to feel safe and comfortable, so I think my most important role is to make them safe before the scenario."	Preparing for the scenario	Creating a safe environment

Table 4

Table 4. Participant demographics (n=69/89, n=11).

	Control n=69	**Intervention n=89**
Gender N (%)		
Female	61 (88)	78 (88)
Male	8 (12)	11 (12)
Age Years		
Md (Q_1, Q_3), Range	21 (20, 23.5), 19–47	22 (20, 25), 20–48
Previous experience with critically ill patients N (%)		
Yes	41 (60)	62 (70)
No	27 (40)	26 (30)
Study place N (%)		
A	31 (44)	41 (46)
B	20 (29)	30 (34)
C	18 (26)	18 (20)

Process evaluation – individual interviews

	Nursing students n=5	**Faculty members n=6**
Gender (n)		
Female	3	5
Male	2	1
Age (Median, Range)	29, 22–43 years	46, 39–64 years
Study place (n)		
A	2	2
B	2	2
C	1	2
Roles in the scenarios		
Nurse	2	
Physician	1	
Observer	2	
Facilitator		3
Operator		1
Both facilitator and operator		2

Table 5

Table 5. The numbers (proportions) of students with decreased, unchanged, increased numbers of correct responses referring to the three subgroups items of knowledge posttest, and the number of students with correct responses to all six/eight questions both pre- and posttest, respectively.

	Decreased	**The same number of correct items pre- and posttest**	**Increased**	**All items correct pre- and posttest**	**Intervention effect on knowledge** Difference in proportion students with increased number of correct responses posttest, intervention vs control (participants with all items correct pre- and posttest not included)
	Normal values (Items 1,4,8,11,14,17)				
Intervention Group (n=89)	17 (19%)	29 (33%)	22 (25%)	21 (24%)	22/68=0.324 vs 3/41=0.073, Δp:25 pu 95% CI (Δp): 11 to 39 pu p=0.005
Control Group (n=69)	9 (13%)	29 (42%)	3 (4%)	28 (41%)	
	Clinical changes (Items 2,5,9,12,15,18)				
Intervention Group (n=89)	9 (10%)	22 (25%)	22 (25%)	36 (40%)	22/53=0.415 vs 10/48=0.208 Δp:21 pu 95% CI (Δp): 3 to 38 pu p=0.04
Control Group (n=69)	17 (25%)	21 (30%)	10 (15%)	21 (30%)	
	Nursing procedures (Items 3,6,7,10,13,16,19,20)				
Intervention Group (n=89)	14 (16%)	33 (37%)	25 (28%)	17 (19%)	25/72=0.347 vs 10/54=0.185 Δp:16 pu 9 % CI (Δp): 1 to 31 pu p=0.07
Control Group (n=69)	5 (7%)	39 (57%)	10 (14%)	15 (22%)	

Δp=difference between paired proportions, CI=confidence interval, pu=percentage units

Table 6

Table 6. The number (proportion) students with lower, unchanged and higher levels of perceived self-confidence on the follow-up occasion according to paired data from pre- and post-assessments.

	Lower	**Unchanged**	**Higher**	**Intervention effect on perceived level of self-confidence** Difference in proportion students with higher self-confidence posttest, intervention vs control groups
Normal Values (Items 1,4,8,11,14,17)				
Intervention group (n=89)	4 (4%)	64 (72%)	21 (24%)	24% vs 20%, Δp:4 pu 95% CI (Δp): -10 to 16 pu p=0.76
Control group (n=69)	4 (6%)	51 (74%)	14 (20%)	
Clinical Changes (Items 2,5,9,12,15,18)				
Intervention group (n = 89)	1 (1%)	39 (44%)	49 (55%)	55% vs 10%, Δp:45 pu 95% CI (Δp): 32 to 58 pu p<0.0001
Control group (n = 69)	9 (13%)	53 (77%)	7 (10%)	
Nursing Procedures (Items 3,6,7,10,13,16,19,20)				
Intervention group (n=89)	5 (6%)	59 (66%)	25 (28%)	28% vs 16% Δp:12 pu 95% CI (Δp): -0.6 to 25 pu p=0.11
Control group (n=69)	8 (12%)	50 (72%)	11 (16%)	

Δp=difference between paired proportions, CI=confidence interval, pu=percentage units

Appendix 1

The Final Database Searches Study 1

The Final Literature Searches in Study 1 (24.11.16)

1) **Database: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present> Search Strategy:**

1 (nurs* adj4 (student* or educat* or graduat* or undergraduat* or baccalaur*)).ti,ab,hw,kf. (105035)
2 simulat*.ti,ab,hw,kf. (533411)
3 (Learning adj4 ("game-based" or "computer-based" or "computer assisted" or interactive or virtual*)).ti,ab,hw,kf. (2384)
4 computer assisted instruction.ti,ab,hw,kf. (11359)
5 (virtual* adj4 (patient* or realit*)).ti,ab,kf,hw. (10313)
6 mannequin*.ti,ab,hw,kf. (1320)
7 manikin*.ti,ab,hw,kf. (5112)
8 2 or 3 or 4 or 5 or 6 or 7 (552716)
9 judgment.ti,ab,hw,kf. (35171)
10 (decision adj4 making).ti,ab,kf,hw. (171416)
11 (problem adj4 solving).ti,ab,kf,hw. (37803)
12 ((emergenc* or critical*) adj4 (patient* or ill* or care or nurs*)).ti,ab,kf,hw. (166068)
13 (clinical adj4 (competence* or assessment* or incident* or risk or measure*)).ti,ab,hw,kf. (198756)
14 awareness*.ti,ab,hw,kf. (122733)
15 deteriorat*.ti,ab,hw,kf. (106207)
16 9 or 10 or 11 or 12 or 13 or 14 or 15 (793098)
17 1 and 8 and 16 (1591)

2) CINAHL Plus with Full Text (EBSCOhost) Advanced search, Search modes - Boolean/Phrase

#	Query	Results
S1	nurs* N3 (student* OR educat* OR graduat* OR undergraduat* OR baccalaur*)	116938
S2	Simulat*	38683
S3	Learning N3 ("game-based" OR "computer-based" OR "computer assisted" OR interactive OR virtual*)	1093
S4	“Computer assisted instruction”	6404
S5	Virtual* N3 (patient* or realit*)	4155
S6	Mannequin*	389
S7	Manikin*	769
S8	S2 OR S3 OR S4 OR S5 OR S6 OR S7	48414
S9	Judgment	12574
S10	decision N3 making	93352
S11	Problem N3 solving	12924
S12	((emergenc* or critical*) N3 (patient* or ill* or care or nurs*))	107491
S13	Clinical N3 (competence* OR assessment* OR incident* OR risk OR measure*)	153717
S14	Awareness*	37116
S15	Deteriorat*	11974
S16	S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15	400985
S17	**S1 AND S8 AND S16**	**1557**

3) Database: Embase <1974 to 2016 Week 47> Search Strategy:

1 (nurs* adj4 (student* or educat* or graduat* or undergraduat* or baccalaur*)).ti,ab,hw,kw. (104075)
2 simulat*.ti,ab,hw,kw. (463083)
3 (Learning adj4 ("game-based" or "computer-based" or "computer assisted" or interactive or virtual*)).ti,ab,hw,kw. (2980)
4 computer assisted instruction*.ti,ab,hw,kw. (836)
5 (virtual* adj4 (patient* or realit*)).ti,ab,hw,kw. (18751)
6 mannequin*.ti,ab,hw,kw. (1960)
7 manikin*.ti,ab,hw,kw. (3363)
8 2 or 3 or 4 or 5 or 6 or 7 (481447)
9 judgment.ti,ab,hw,kw. (25556)
10 (decision adj4 making).ti,ab,hw,kw. (339312)
11 (problem adj4 solving).ti,ab,hw,kw. (40673)
12 ((emergenc* or critical*) adj4 (patient* or ill* or care or nurs*)).ti,ab,hw,kw. (220301)
13 (clinical adj4 (competence* or assessment* or incident* or risk or measure*)).ti,ab,hw,kw. (301515)
14 awareness*.ti,ab,hw,kw. (163613)
15 deteriorat*.ti,ab,hw,kw. (149800)
16 9 or 10 or 11 or 12 or 13 or 14 or 15 (1159981)
17 1 and 8 and 16 (1154)

4) Database: PsycINFO <1806 to November Week 3 2016> Search Strategy:

1 (nurs* adj4 (student* or educat* or graduat* or undergraduat* or baccalaur*)).ti,ab,hw,id. (15295)
2 simulat*.ti,ab,hw,id. (61001)
3 (Learning adj4 ("game-based" or "computer-based" or "computer assisted" or interactive or virtual*)).ti,ab,hw,id. (5382)
4 computer assisted instruction.ti,ab,hw,id. (15143)
5 (virtual* adj4 (patient* or realit*)).ti,ab,hw,id. (7649)
6 mannequin*.ti,ab,hw,id. (148)
7 manikin*.ti,ab,hw,id. (316)
8 2 or 3 or 4 or 5 or 6 or 7 (84226)
9 judgment.ti,ab,hw,id. (50896)
10 (decision adj4 making).ti,ab,hw,id. (95968)
11 (problem adj4 solving).ti,ab,hw,id. (46776)
12 ((emergenc* or critical*) adj4 (patient* or ill* or care or nurs*)).ti,ab,hw,id. (11395)
13 (clinical adj4 (competence* or assessment* or incident* or risk or measure*)).ti,ab,hw,id. (26168)
14 awareness*.ti,ab,hw,id. (81192)
15 deteriorat*.ti,ab,hw,id. (17682)
16 9 or 10 or 11 or 12 or 13 or 14 or 15 (310592)
17 1 and 8 and 16 (233)

5) ERIC:

#	Query	Results
S1	nurs* N3 (student* OR educat* OR graduat* OR undergraduat* OR baccalaur*)	6969
S2	Simulat*	24443
S3	Learning N3 ("game-based" OR "computer-based" OR "computer assisted" OR interactive OR virtual*)	8270
S4	“Computer assisted instruction”	28888
S5	Virtual* N3 (patient* or realit*)	961
S6	Mannequin*	50
S7	Manikin*	28
S8	S2 OR S3 OR S4 OR S5 OR S6 OR S7	54965
S9	Judgment	15138
S10	decision N3 making	51443
S11	Problem N3 solving	47471
S12	((emergenc* or critical*) N3 (patient* or ill* or care or nurs*))	1307
S13	Clinical N3 (competence* OR assessment* OR incident* OR risk OR measure*)	1423
S14	Awareness*	56383
S15	Deteriorat*	1842
S16	S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15	163466
S17	**S1 AND S8 AND S16**	**81**

6) Cochrane Library:

#	Query	Results
S1	nurs* near/3 (student* OR educat* OR graduat* OR undergraduat* OR baccalaur*):ti,ab,kw	2253
S2	Simulat*:ti,ab,kw	9928
S3	Learning near/3 ("game-based" OR "computer-based" OR "computer assisted" OR interactive OR virtual*):ti,ab,kw	246
S4	“Computer assisted instruction”:ti,ab,kw	1096
S5	Virtual* near/3 (patient* or realit*):ti,ab,kw	1258
S6	Mannequin*:ti,ab,kw	203
S7	Manikin*:ti,ab,kw	928
S8	#2 OR #3 OR #4 OR #5 OR #6 OR #7	12157
S9	Judgment:ti,ab,kw	1602
S10	decision near/3 making:ti,ab,kw	6796
S11	Problem near/3 solving:ti,ab,kw	2833
S12	((emergenc* or critical*) near/3 (patient* or ill* or care or nurs*)):ti,ab,kw	10038
S13	Clinical near/3 (competence* OR assessment* OR incident* OR risk OR measure*):ti,ab,kw	22278
S14	Awareness*:ti,ab,kw	4582
S15	Deteriorat*:ti,ab,kw	7553
S16	#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15	52915
S17	**#1 AND #8 AND #16**	**179**

7) Sökhistorik från SveMed+

Nr	Sökstring	Antal träffar
1	exp:"Students, Nursing"	525
2	exp:"Education"	12637
3	student* OR educat* OR nurs* OR graduat* OR undergraduat* OR baccalaur*	17241
4	#1 OR #2 OR #3	20241
5	exp:"Simulation Training"	53
6	exp:"Patient Simulation"	60
7	simulat*	196
8	virtual OR virtually OR virtuals	32
9	exp:"Manikins"	40
10	mannequin*	2
11	exp:"Computer-Assisted Instruction"	71
12	game-based OR computer-based OR computer assisted OR interactive learning	568
13	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12	781
14	**#4 AND #13**	**264**

Appendix 2

The Quality Appraisal Process Study 1

The Quality Appraisal Process in Study 1

Critical Appraisal Skills Programme (CASP) Checklists for Randomised Controlled Trials (RCT) and Cohort Studies

RCT Criteria Y=Yes U=Unclear N=No	***Did the trial address a clearly focused issue?***	***Was the assignment of patients to treatments randomized?***	***Were all of the patients who entered the trial properly accounted for at its conclusion?***	***Were patients, health workers and study personnel "blind" to treatment?***	***Were the groups similar at the start of the trial?***	***Aside from the experimental intervention, were the groups treated equally?***	***Can the results be applied to the local population, or in your context?***	***Were all clinically important outcomes considered?***	***Are the benefits worth the harms and costs?***			***Total yes/ applicable items***
Merriman et al. (2014)	Y	Y	Y	Y	Y	Y	Y	Y	Y			9/9
Lindsey & Jenkins (2013)	Y	Y	Y	Y	U	Y	Y	N	Y			7/9
Shinnick et al. (2012)	Y	Y	Y	N	Y	Y	Y	Y	Y			8/9
Liaw et al. (2011a)	Y	Y	Y	Y	Y	Y	Y	N	Y			8/9
Liaw et al. (2011b)	Y	Y	Y	Y	Y	Y	Y	Y	Y			9/9
Cohort Study Criteria Y=Yes U=Unclear N=No	***Did the study address a clearly focused issue?***	***Was the cohort recruited in an acceptable way?***	***Was the exposure accurately measured to minimize bias?***	***Was the outcome accurately measured to minimize bias?***	***Have the authors identified all important confounding factors?***	***Have the authors taken account of the confounding factors in the design and/or analysis?***	***Was the follow up of subjects complete enough?***	***Was the follow up of subjects long enough?***	***Do you believe the results?***	***Can the results be applied to the local population?***	***Do the results of this study fit with other available evidence?***	***Total yes/ applicable items***
Alinier et al. (2003)	Y	Y	Y	Y	U	U	N	U	Y	Y	Y	7/11

The Joanna Briggs Institute (JBI) Checklist for Quasi-Experimental Studies

Criteria **Y = Yes** **U = Unclear** **N = No** **NA = Not applicable**	***Is it clear in the study what is the "cause" and what is the "effect"?***	***Were the participants included in any comparisons similar?***	***Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?***	***Was there a control group?***	***Were there multiple measurements of the outcome both pre and post the intervention/ exposure?***	***Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?***	***Were the outcomes of participants included in any comparisons measured in the same way?***	***Were outcomes measured in a reliable way?***	***Was appropriate statistical analysis used?***	***Total yes/ applicable items***
Kim & Kim (2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	9/9
Kelly et al. (2013)	Y	NA	NA	N	Y	N	NA	Y	Y	4/6
Thidemann & Söderhamn (2012)	Y	NA	NA	N	Y	Y	NA	Y	Y	5/6
Wood & Toronto (2012)	Y	Y	Y	Y	Y	Y	Y	Y	U	8/9
Shinnick & Woo (2012)	Y	NA	NA	N	Y	Y	NA	Y	Y	5/6
Burns et al. (2010)	Y	NA	NA	N	Y	Y	NA	Y	Y	5/6
Ackermann (2009)	Y	Y	Y	Y	Y	Y	Y	Y	U	8/9
Zieber & Sedgewick (2018)	Y	NA	NA	N	Y	Y	NA	Y	Y	5/6

Appendix 3

Questionnaire developed and used for data collection Study 2

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Bakgrunnsopplysninger

Sett ring rundt eller fyll inn riktig svar.

1. Kjønn
   A. Kvinne
   B. Mann

2. Jeg er _____ år gammel

3. Har du vært med på simulering før simuleringsukene du deltar på nå?
   A. Ja
   B. Nei

   Hvis ja, hvilken type simulering har du vært med på?

   _____

   _____

4. Har du vært med på smågruppesimulering i løpet av disse to simuleringsukene (besvares kun etter du har vært med på simulering)?
   A. Ja
   B. Nei

5. Hvor studerer du?
   A. NN
   B. NN
   C. NN

Tusen takk for at du fyller ut denne undersøkelsen i forbindelse med deltakelse på simulering

Kunnskapstest – Sykepleie ved postoperativ blødning

Sett ring rundt det alternativet du mener er riktig svar på spørsmålet.

1. Hva regnes oftest som normalt blodtrykk hos friske voksne?
   A. 100/60
   B. 120/80
   C. 140/80

2. Hva skjer vanligvis med blodtrykket ved større blodtap?
   A. Det synker
   B. Ingen forandring
   C. Det stiger

3. Hvilke av disse årsakene kan gi for lav blodtrykksverdi?
   A. Pasienten sitter med dinglende bein
   B. Mansjetten er for stor
   C. Mansjetten ligger under hjertenivå

4. Hva regnes oftest som normal hvilepuls hos friske voksne?
   A. 60 – 100
   B. 40 – 80
   C. 80 – 120

5. Hva skjer vanligvis med pulsfrekvensen ved akutt større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

6. Hva inngår i vurdering av pulskvalitet?
   A. Frekvens og dybde
   B. Fyldighet, spenning og elastisitet
   C. Rytme og frekvens

7. Hvor er det mest vanlig å måle pulsen hos en voksen person?
   A. Arteria radialis
   B. Arteria brachialis
   C. Arteria femoralis

8. Hva regnes som normal respirasjonsfrekvens i hvile hos friske voksne?
   A. 6 – 10
   B. 10 – 15
   C. 14 – 22

9. Hva skjer vanligvis med respirasjonsfrekvensen ved større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

10. Hva er anbefalingene for telling av uregelmessig respirasjon?
   A. Tell i 30 sekunder og gang med 2
   B. Tell i 60 sekunder
   C. Tell i 15 sekunder og gang med 4

11. Hva regnes vanligvis som normal kroppstemperatur hos friske voksne?
   A. 35,4 – 37,5
   B. 36,4 – 38,5
   C. 36,4 – 37,5

12. Hva skjer vanligvis med kroppstemperaturen ved større blodtap?
   A. Den stiger
   B. Ingen forandring
   C. Den synker

13. Hvilken metode for å måle kroppstemperatur gir vanligvis mest korrekt måleresultat?
   A. Rektal
   B. Oral
   C. Tympanisk

14. Hva regnes vanligvis som normalt oksygeninnhold i blodet til en frisk voksen person?
   A. 85 - 100 %
   B. 90 - 100 %
   C. 95 – 100 %

15. Når kan sykepleier administrere oksygentilførsel til en pasient innlagt på sykehus?
    A. Når det oppdages at pasienten har for lav oksygenmetning i blodet
    B. Når det er forordnet av lege
    C. Når pasienten ber om å få det

16. Hva er de kliniske tegnene ved partiell (delvis) sårruptur?
    A. Plutselige smerter og siving fra såret uten infeksjonstegn
    B. Murrende smerte og siving av serøs væske fra såret
    C. Såret er åpent, det er hevelse lokalt, og ømhet ved palpasjon

17. Hva er hensikten med bandasje på et operasjonssår?
    A. Bandasje gir fuktighet til såret
    B. Beskytte mot mikrober og absorbere sekresjon
    C. Bandasje gir kompresjon slik at blødning forhindres

18. Dersom pasienten mister bevisstheten og livreddende førstehjelp må iverksettes, hva er riktig behandling?
    A. 15 kompresjoner og 2 innblåsinger
    B. 30 kompresjoner og 2 innblåsinger
    C. 30 kompresjoner og 1 innblåsing

19. Hva er viktig før hjerte- lungeredning settes i gang?
    A. Sjekke pasientens bevissthet, etablere frie luftveier og sjekke pasientens åndedrett
    B. Sjekke pasientens bevissthet, åndedrett, puls og om pasienten skal gjenopplives (dokumentert i journalen av lege)
    C. Sjekke pasientens bevissthet og evt. smittefare ved munn-til-munn metode

20. Når hjerte- lungeredning utøves, når er det hensiktsmessig å bytte roller på den som utfører kompresjoner og den som gjør innblåsinger?
    A. Bytte roller hvert 5. min
    B. Bytte roller hvert 2. min
    C. Bytte roller hvert 7. min

Spørsmål om hvordan du opplever din sikkerhet i situasjonen

	Ikke i det hele tatt	I liten grad	Middels	I stor grad	I meget stor grad
1.Hvor sikker er du på at du kan utføre riktig blodtrykksmåling på en voksen person?					
2.Hvor sikker er du på at du kan gjenkjenne verdien av et normalt blodtrykk hos en voksen frisk person?					
3.Hvor sikker er du på at du kan utføre riktig pulsmåling hos en voksen person?					
4.Hvor sikker er du på at du kan gjenkjenne verdien av det som regnes som normal hvilepuls hos en voksen frisk person?					
5.Hvor sikker er du på at du kan vurdere pulskvaliteten riktig hos en voksen frisk person?					
6. Hvor sikker er du på at du kan utføre riktig måling av respirasjonsfrekvens hos en voksen person i hvile?					
7.Hvor sikker er du på at du kan gjenkjenne verdien på normal respirasjonsfrekvens hos en voksen frisk person?					
8. Hvor sikker er du på at du kan gjenkjenne verdien på normal kroppstemperatur hos en voksen frisk person?					
9. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i blodtrykksverdien ved større blodtap?					
10. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i pulsfrekvensen ved større blodtap?					
11. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i respirasjonsfrekvensen ved større blodtap?					
12. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i kroppstemperatur ved større blodtap?					
13. Hvor sikker er du på at du kan gjenkjenne verdien av et normalt oksygeninnhold i blodet til en voksen frisk pasient?					
14. Hvor sikker er du på at du vet når en sykepleier kan administrere oksygen til en pasient innlagt på sykehus?					
15. Hvor sikker er du på at du kan gjenkjenne kliniske tegn ved partiell sårruptur?					
16. Hvor sikker er du på at du vet hensikten med å ha bandasje på et operasjonssår?					
17. Hvor sikker er du på at du kan vurdere behov for å utføre hjerte- og lungeredning?					
18. Hvor sikker er du på at du kan utføre riktig hjerte- og lungeredning på en voksen person?					

Takk for hjelpen!

Appendix 4

Interview guide Study 2

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Intervjuguide sykepleierstudenter studie 2

Navn, etternavn og kontaktinformasjon innhentes og kodes med respondent 1 og oppover.

Spørsmål før intervjuet starter:

1. Alder?
2. Tidligere erfaring med simulering?

Hensikten med dette intervjuet er at du forteller oss mest mulig om dine erfaringer med bruken av spørreskjemaene du fylte ut i forbindelse med simuleringen om vitale tegn:

Spørreskjema 1 (Kunnskapstest)

1. Hvordan opplevde du å fylle ut dette skjemaet?
2. Hva var positivt med dette skjemaet?
3. Hva var negativt eller kunne vært formulert på en annen måte i skjemaet?
4. Er det noen spørsmål du ønsker å legge til/eventuelle andre kommentarer til bruken av dette skjemaet?

Spørreskjema 2 (Spørsmål om hvordan du opplever din sikkerhet i situasjonen)

5. Hvordan opplevde du å fylle ut dette skjemaet?
6. Hva var positivt med dette skjemaet?
7. Hva var negativt eller kunne vært formulert på en annen måte i skjemaet?
8. Er det noen spørsmål du ønsker å legge til/eventuelle andre kommentarer til bruken av dette skjemaet?

Appendix 5

Revised questionnaire used for data collection before Study 3 (Test)

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Bakgrunnsopplysninger

Sett ring rundt eller fyll inn riktig svar.

1. Kjønn
   A. Kvinne
   B. Mann

2. Jeg er _____ år gammel

3. Har du vært med på simulering før?
   A. Ja
   B. Nei

   Hvis ja, hvilken type simulering har du vært med på?

   _____

   _____

4. Hvor studerer du?
   A. NN
   B. NN
   C. NN

5. Hvilken rolle hadde du i simuleringen (besvares kun etter simuleringen)?
   A. Aktiv rolle inne på simuleringsrommet
   B. Rolle som observatør

Tusen takk for at du fyller ut denne undersøkelsen i forbindelse med deltakelse på simulering

Kunnskapstest – Sykepleie ved postoperativ blødning

Sett ring rundt det alternativet du mener er riktig svar på spørsmålet.

1. Hva regnes oftest som normalt blodtrykk hos friske voksne?
   A. 100/60
   B. 120/80
   C. 140/80

2. Hva skjer vanligvis med blodtrykket ved akutt større blodtap?
   A. Det synker
   B. Ingen forandring
   C. Det stiger

3. Hvilken av disse årsakene kan gi for lav blodtrykksverdi?
   A. Pasienten sitter med dinglende bein
   B. Mansjetten er for stor
   C. Mansjetten ligger under hjertenivå

4. Hva regnes oftest som normal hvilepuls hos friske voksne?
   A. 60 – 100
   B. 40 – 80
   C. 80 – 120

5. Hva skjer vanligvis med pulsfrekvensen ved akutt større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

6. Hva inngår i vurdering av pulskvalitet?
   A. Frekvens
   B. Fyldighet
   C. Rytme

7. Hvor er det mest vanlig å måle pulsen hos en voksen person?
   A. Arteria radialis
   B. Arteria brachialis
   C. Arteria femoralis

8. Hva regnes oftest som normal respirasjonsfrekvens i hvile hos friske voksne?
   A. 6 – 10
   B. 9 – 15
   C. 16 – 22

9. Hva skjer vanligvis med respirasjonsfrekvensen ved akutt større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

10. Hva er anbefalingene for telling av uregelmessig respirasjon?
   A. Tell i 30 sekunder og gang med 2
   B. Tell i 60 sekunder
   C. Tell i 15 sekunder og gang med 4

11. Hva regnes vanligvis som normal kroppstemperatur hos friske voksne?
   A. 35,9 – 37,0
   B. 36,4 – 38,0
   C. 36,4 – 37,5

12. Hva skjer vanligvis med kroppstemperaturen en stund etter akutt større blodtap?
   A. Den stiger
   B. Ingen forandring
   C. Den synker

13. Hvilken metode for å måle kroppstemperatur gir vanligvis mest korrekt måleresultat?
   A. Rektal
   B. Oral
   C. Tympanisk

14. Hva regnes vanligvis som normalt oksygeninnhold i blodet til en frisk voksen person?
   A. 85 - 100 %
   B. 90 - 100 %
   C. 95 – 100 %

15. Hva skjer vanligvis med oksygeninnholdet i blodet ved akutt større blodtap?
    A. Det stiger
    B. Det synker
    C. Ingen forandring

16. Når kan sykepleier administrere oksygentilførsel til en pasient innlagt på sengepost på sykehus?
    A. Når det oppdages at pasienten har for lavt oksygeninnhold i blodet
    B. Når det er forordnet av lege
    C. Når pasienten ber om å få det

17. Hva regnes oftest som normal døgnproduksjon av diurese hos friske voksne?
    A. 0-1 liter
    B. 1-2 liter
    C. 2-3 liter

18. Hva skjer vanligvis med produksjonen av diurese ved akutt større blodtap?
    A. Ingen forandring
    B. Den stiger
    C. Den synker

19. Hva er hensikten med en kompresjonsbandasje på et operasjonssår?
    A. Gi fuktighet til såret
    B. Redusere blødning
    C. Beskytte mot mikrober

20. Hva står de tre bokstavene ABC for i primærundersøkelsen «ABCDE»?
    A. Frie luftveier, ventilasjon og bevissthet (Airway, Breathing, Consciousness)
    B. Vurdere blodsirkulasjonen (Assess Blood Circulation)
    C. Frie luftveier, ventilasjon og sirkulasjon (Airway, Breathing, Circulation)

Spørsmål om hvordan du opplever din sikkerhet i ulike situasjoner

	Ikke i det hele tatt	I liten grad	Middels	I stor grad	I meget stor grad
1.Hvor sikker er du på at du kan gjenkjenne verdien av et normalt blodtrykk hos en voksen frisk person?					
2. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i blodtrykksverdien ved større blodtap?					
3. Hvor sikker er du på at du kan utføre riktig blodtrykksmåling på en voksen person?					
4.Hvor sikker er du på at du kan gjenkjenne verdien av det som regnes som normal hvilepuls hos en voksen frisk person?					
5. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i pulsfrekvensen ved større blodtap?					
6. Hvor sikker er du på at du kan vurdere pulskvaliteten riktig hos en voksen frisk person?					
7. Hvor sikker er du på at du kan utføre riktig pulsmåling hos en voksen person?					
8. Hvor sikker er du på at du kan gjenkjenne verdien på normal respirasjonsfrekvens hos en voksen frisk person?					
9. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i respirasjonsfrekvensen ved større blodtap?					
10. Hvor sikker er du på at du kan utføre riktig måling av respirasjonsfrekvens hos en voksen person i hvile?					
11. Hvor sikker er du på at du kan gjenkjenne verdien på normal kroppstemperatur hos en voksen frisk person?					
12. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i kroppstemperatur en stund etter større blodtap?					
13. Hvor sikker er du på at du kan utføre måling av kroppstemperatur som gir mest korrekt resultat?					
14. Hvor sikker er du på at du kan gjenkjenne verdien av et normalt oksygeninnhold i blodet til en voksen frisk person?					
15. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i oksygeninnholdet i blodet ved større blodtap?					
16. Hvor sikker er du på at du vet når sykepleier kan administrere oksygentilførsel til en pasient innlagt på sengepost på sykehus?					
17. Hvor sikker er du på at du kan gjenkjenne verdien av normal døgnproduksjon av diurese hos en voksen frisk person?					
18. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i produksjonen av diurese ved akutt større blodtap?					
19. Hvor sikker er du på at du vet hensikten med å ha en kompresjonsbandasje på et operasjonssår?					
20. Hvor sikker er du på at du vet hva de tre bokstavene ABC står for i primærundersøkelsen «ABCDE»?					

Takk for hjelpen!

Appendix 6

Revised questionnaire used for data collection Study 3

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

NTNU

Bakgrunnsopplysninger

Sett ring rundt eller fyll inn riktig svar.

1. Kjønn
   A. Kvinne
   B. Mann

2. Jeg er _____ år gammel

3. Har du vært med på simulering før?
   A. Ja
   B. Nei

   Hvis ja, hvilken type simulering har du vært med på?
   _____

4. Hvor studerer du?
   A. NN
   B. NN
   C. NN

5. Har du vært i situasjoner i praksis eller jobb der du har opplevd akutt forverrelse i helsetilstanden til en pasient?
   A. Ja
   B. Nei

6. Hvilken karakter fikk du på eksamen i grunnleggende sykepleie/klinisk sykepleie i 1.studieår på bachelorutdanningen i sykepleie?
   A. A
   B. B
   C. C
   D. D
   E. E
   F. F

7. Hvilken rolle hadde du i simuleringen?*
   A. Aktiv rolle inne på simuleringsrommet
   B. Rolle som observatør

*Dette spørsmålet ble bare stilt til deltakere i intervensjonsgruppene etter intervensjonen.

Kunnskapstest – Sykepleie ved postoperativ blødning

Sett ring rundt det alternativet du mener er riktig svar på spørsmålet.

1. Hva regnes oftest som normalt blodtrykk hos friske voksne?
   A. 100/60
   B. 120/80
   C. 140/80

2. Hva skjer vanligvis med blodtrykket ved akutt større blodtap?
   A. Det synker
   B. Ingen forandring
   C. Det stiger

3. Hvilken av disse årsakene kan gi for lav blodtrykksverdi?
   A. Pasienten sitter med dinglende bein
   B. Mansjetten er for stor
   C. Mansjetten ligger under hjertenivå

4. Hva regnes oftest som normal hvilepuls hos friske voksne?
   A. 60 – 100
   B. 40 – 80
   C. 80 – 120

5. Hva skjer vanligvis med pulsfrekvensen ved akutt større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

6. Hva inngår i vurdering av pulskvalitet?
   A. Frekvens
   B. Fyldighet
   C. Rytme

7. Hvor er det mest vanlig å måle pulsen hos en voksen person?
   A. Arteria radialis
   B. Arteria brachialis
   C. Arteria femoralis

8. Hva regnes oftest som normal respirasjonsfrekvens i hvile hos friske voksne?
   A. 6 – 10
   B. 9 – 15
   C. 16 – 22

9. Hva skjer vanligvis med respirasjonsfrekvensen ved akutt større blodtap?
   A. Den synker
   B. Ingen forandring
   C. Den stiger

10. Hva er anbefalingene for telling av uregelmessig respirasjon?
   A. Tell i 30 sekunder og gang med 2
   B. Tell i 60 sekunder
   C. Tell i 15 sekunder og gang med 4

11. Hva regnes vanligvis som normal kroppstemperatur hos friske voksne?
   A. 35,9 – 37,0
   B. 36,4 – 38,0
   C. 36,4 – 37,5

12. Hva skjer vanligvis med kroppstemperaturen en stund etter akutt større blodtap?
   A. Den stiger
   B. Ingen forandring
   C. Den synker

13. Hvilken metode for å måle kroppstemperatur gir vanligvis mest korrekt måleresultat?
   A. Rektal
   B. Oral
   C. Tympanisk

14. Hva regnes vanligvis som normalt oksygeninnhold i blodet til en frisk voksen person?
   A. 85 - 100 %
   B. 90 - 100 %
   C. 95 – 100 %

15. Hva skjer vanligvis med oksygeninnholdet i blodet ved akutt større blodtap?
    A. Det stiger
    B. Det synker
    C. Ingen forandring

16. Når kan sykepleier administrere oksygentilførsel til en pasient innlagt på sengepost på sykehus?
    A. Når det oppdages at pasienten har for lavt oksygeninnhold i blodet
    B. Når det er forordnet av lege
    C. Når pasienten ber om å få det

17. Hva regnes oftest som normal døgnproduksjon av diurese hos friske voksne?
    A. 0-1 liter
    B. 1-2 liter
    C. 2-3 liter

18. Hva skjer vanligvis med produksjonen av diurese ved akutt større blodtap?
    A. Ingen forandring
    B. Den stiger
    C. Den synker

19. Hva er hensikten med en kompresjonsbandasje på et operasjonssår?
    A. Gi fuktighet til såret
    B. Redusere blødning
    C. Beskytte mot mikrober

20. Hva står de tre bokstavene ABC for i primærundersøkelsen «ABCDE»?
    A. Frie luftveier, ventilasjon og bevissthet (Airway, Breathing, Consciousness)
    B. Vurdere blodsirkulasjonen (Assess Blood Circulation)
    C. Frie luftveier, ventilasjon og sirkulasjon (Airway, Breathing, Circulation)

Spørsmål om hvordan du opplever din sikkerhet i ulike situasjoner

	Ikke i det hele tatt	I liten grad	Middels	I stor grad	I meget stor grad
1.Hvor sikker er du på at du kan gjenkjenne verdien av et normalt blodtrykk hos en voksen frisk person?					
2. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i blodtrykksverdien ved større blodtap?					
3. Hvor sikker er du på at du kan utføre riktig blodtrykksmåling på en voksen person?					
4.Hvor sikker er du på at du kan gjenkjenne verdien av det som regnes som normal hvilepuls hos en voksen frisk person?					
5. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i pulsfrekvensen ved større blodtap?					
6. Hvor sikker er du på at du kan vurdere pulskvaliteten riktig hos en voksen frisk person?					
7. Hvor sikker er du på at du kan utføre riktig pulsmåling hos en voksen person?					
8. Hvor sikker er du på at du kan gjenkjenne verdien på normal respirasjonsfrekvens hos en voksen frisk person?					
9. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i respirasjonsfrekvensen ved større blodtap?					
10. Hvor sikker er du på at du kan utføre riktig måling av respirasjonsfrekvens hos en voksen person i hvile?					
11. Hvor sikker er du på at du kan gjenkjenne verdien på normal kroppstemperatur hos en voksen frisk person?					
12. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i kroppstemperatur en stund etter større blodtap?					
13. Hvor sikker er du på at du kan utføre måling av kroppstemperatur som gir mest korrekt resultat?					
14. Hvor sikker er du på at du kan gjenkjenne verdien av et normalt oksygeninnhold i blodet til en voksen frisk person?					
15. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i oksygeninnholdet i blodet ved større blodtap?					
16. Hvor sikker er du på at du vet når sykepleier kan administrere oksygentilførsel til en pasient innlagt på sengepost på sykehus?					
17. Hvor sikker er du på at du kan gjenkjenne verdien av normal døgnproduksjon av diurese hos en voksen frisk person?					
18. Hvor sikker er du på at du kan gjenkjenne kliniske endringer i produksjonen av diurese ved akutt større blodtap?					
19. Hvor sikker er du på at du vet hensikten med å ha en kompresjonsbandasje på et operasjonssår?					
20. Hvor sikker er du på at du vet hva de tre bokstavene ABC står for i primærundersøkelsen «ABCDE»?					

Takk for hjelpen!

Appendix 7

Guide developed to the faculty members about

the high-fidelity simulation intervention in Study 3

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

VEILEDNING FOR LÆRERE SOM SKAL ORGANISERE FULLSKALASIMULERING I STUDIE 3

Hver simuleringsgruppe gjennomfører dette oppsettet:
(klargjøring av utstyr på simuleringsrom ved lærer først – se informasjon i eget skjema over 4 sider lengre bak)

1) **Felles briefing: ca 30 min**
2) **Orientering på simuleringsrom: ca 20 min**
3) **Simulering scenario: 15 min**
4) **Debriefing: ca 45 min**

Til sammen: ca 2 timer.

For de gruppene som deltar i forskningsprosjekt knyttet til simuleringen settes det av 15 min før og 15 min etter til utfylling av spørreskjema.

1) Veiledende mal for innhold i felles briefing (ca 30 min)

- Opplyse om taushetsplikten i simuleringsgruppene (evt skrive under på taushetserklæring).

- Opplyse om læringsmål:

  «Vurderer og oppfatter tegn til akutt forverring i helsetilstand til pasient»
  «Reagerer adekvat på akutt forverring i helsetilstand til pasient»
  «Kommuniserer målrettet i teamarbeid»

- Gå igjennom hva verktøyet **ABCDE** er og brukes til, for eksempel slik:

  A- **Airways** (vurdere luftveiene: frie luftveier?)
  B- **Breathing** (vurdere respirasjonen)
  C- **Circulation** (vurdere sirkulasjonen)
  D- **Disability** (vurdere bevissthet: tiltale, smertestimulering?)
  E- **Exposure/environment** (for eksempel skader på kroppen, utslett, beskytte mot varmetap?)

  (Smith & Bowden, 2017).

- Dele ut oversikt over **ISBAR** til alle og gå kort igjennom:

I **Identifikasjon**	**Oppgi** **Hvem du er** **Hvor du er** **Pasientens navn, alder, evt. kjønn og avdeling**
S **Situasjon**	**Hva er problemet/årsak til kontakt?** • **Jeg ringer fordi… (beskriv)** • **Jeg har målt følgende verdier… (ABCDE)** • **Jeg har observert vesentlige endringer… (ABCDE)** • **Jeg har fått prøvesvar…**
B **Bakgrunn**	**Hvis det haster og/eller du er bekymret – gi beskjed!** **Kort og relevant sykehistorie** • **Innleggelsesdiagnose og -dato** • **Tidligere sykdommer av betydning** • **Aktuelle problemer og behandling/tiltak til nå** • **Allergier**
A **Analyse**	**Analyse (vurdering av situasjon og bakgrunn)** • **Jeg tror problemet/årsaken til pasientens tilstand er… (respiratorisk, sirkulatorisk, nevrologisk…)** • **Jeg kjenner ikke problemet, men tilstanden er forverret…** • **Pasienten er ustabil, vi må gjøre noe…** • **Jeg er bekymret…**
R **Råd**	**Be om konkrete råd og tiltak og tydeliggjør forventninger** • **Jeg foreslår…/Hvilke tiltak anbefaler du?** • **Umiddelbare tiltak** • **Utredning/behandling** • **Hvor ofte skal jeg…** • **Når skal jeg ta kontakt igjen? Når kommer du?** • **Bekreft beskjeder og tiltak med «closed loop»**

Denne oversikten er en tilpasset versjon etter inspirasjon fra ulike ISBAR-modeller nasjonalt og internasjonalt (Moi et al., 2019).

- Gå igjennom scenario, les høyt det som står under Sykehistorie og Aktuelt på studenteksemplaret (side 2 av 4):

  «Pasienten er innlagt etter å ha fått cancer coli, og det har blitt utført en venstresidig hemicolectomi. Pasienten har også kostregulert diabetes type 2. Dere har nettopp kommet på seinvakt og har ansvar for pasienten. Pasienten har ligget på kirurgisk avdeling i 5 timer etter operasjon. Han/hun ringer på og føler seg svimmel og uvel. Pasienten og pasientens sønn/datter er engstelige.»

- Fordele roller: 2 sykepleiere, 1 pårørende (pasientens datter/sønn), 1 lege (evt. fasilitator kan også være lege) og observatører.
  Observatørene får ulike oppgaver:
  1) Observere hvilke kliniske observasjoner og tiltak sykepleierne gjør.
  2) Observere kommunikasjonen mellom sykepleierne og pasient, mellom sykepleierne og pårørende, og mellom sykepleierne seg imellom.

2) Veiledende mal for orientering på simuleringsrommet (ca 20 min)

- Vise alle i simuleringsgruppen hvordan simulator og tilgjengelig utstyr fungerer, for eksempel la studentene få kjenne på pasientens puls. Svare på eventuelle spørsmål studentene har om simulatoren og utstyr på simuleringsrommet.

- Instruere rolleinnehaverne kort (for eksempel at pårørende er engstelig) og svare på eventuelle spørsmål studentene har om rollene.

- Husk å ha medisinkurve ferdig utfylt og liggende inne på simuleringsrommet før scenario starter:

  -Klexane 40 mg sc. x 1 (fast)
  -Paracet 1 g x 4 iv (fast)
  -Ketorax 2.5-5 mg iv ved behov
  -O2-tilførsel opptil 3 liter ved behov
  -1000 ml Ringer Acetat i.v.

3) Simulering (15 min) - Scenario

Se eget vedlegg (4 sider) lengre bak.

4) Veiledende mal for debrifingen (ca 45 min) med utgangspunkt i Eppich & Cheng, 2015, s. 109

Alle i gruppa sitter i en ring eller rundt et bord i klasserommet. Fasilitator starter med å fortelle litt om strukturen på debriefingen, for eksempel slik:

«*Nå har vi ca 45 minutter til å gå igjennom scenarioet sammen. Først er jeg interessert i å høre hvordan dere har det nå når scenarioet er over, deretter vil jeg at noen av dere beskriver hva som skjedde slik at vi sikrer at alle har et likt utgangspunkt for hva vi snakker om.*
Så ser vi videre på hva dere synes dere gjorde bra i scenarioet og hva dere eventuelt ville gjort annerledes og hvorfor. Til slutt oppsummerer vi og tenker på hva vi har lært til vi kommer i lignende situasjoner senere».

1. *Reaksjon*
   Fasilitator spør:
   - Hvordan har dere det nå etter scenarioet?
   - Andre reaksjoner/hvordan har dere andre det?

2. *Beskrivelse*
   Fasilitator spør videre om en av de som hadde rollen som sykepleier i scenarioet kan beskrive hva som skjedde i scenarioet.
   Forslag til videre spørsmål fra fasilitator:
   - Hva skjedde videre?
   - Hva gjorde du for pasienten?
   - Hva gjorde du for pårørende?
   - Er det noen andre som har opplevd situasjonen annerledes enn slik den er beskrevet nå?

3. *Analyse*
   Fasilitator sier: Nå som vi er enige om hva som skjedde, kan vi snakke mer om scenarioet. Jeg synes det er flere ting som dere håndterte bra, og andre ting som var mer utfordrende.
   - Nevn tre ting som du gjorde bra og begrunn hva som var bra med det. Knytt dette til læringsmålene.
   - Er det noen ting dere ville gjort annerledes og hvorfor det?
   - Hvordan kommuniserte dere?
   - Få med pårørendes tilbakemelding på opplevelsen av situasjonen også
   - Få med tilbakemeldinger fra observatørene (definerte oppgaver på forhånd)
   - Få evt. med tilbakemelding fra hvordan pasienten opplevde det (operatør)
   - Er læringsmålene dekket?

   Fasilitator spør om noe er uklart eller om det er andre ting som ønskes tatt opp før oppsummeringen.

4. *Anvendelse*
   Fasilitator sier at han/hun ønsker å avslutte debrifingen med at hver enkelt sier en ting de har lært av scenarioet som de vil ta med seg videre. Det gjør ingenting om noen sier det samme, da er det nok så bra at det kan høres flere ganger!

Referanser

Eppich, W. & Cheng, A. (2015). Promoting Excellence and Reflective Learning in Simulation (PEARLS). *Simulation in Healthcare,* 10, 106-115. doi: 10.1097/SIH.0000000000000072

Moi, E.B., Söderhamn, U., Marthinsen, G.N. & Flateland, S.M. (2019). The ISBAR tool lead to conscious, structured communication by healthcare personnel. *Sykepleien Forskning 14.* doi: 10.4220/Sykepleienf.2019.74699

Smith, D. & Bowden, T. (2017). Using the ABCDE approach to assess the deteriorating patient. *Nursing Standard 32*(14), 51-61. doi: 10.7748/ns.2017.e11030

Målgruppe:	**Bachelor sykepleie høsten 2018**				Side 1 av 4			
Tema:	Postoperativ sykepleie							
Fokus:	Blødning							
Læringsutbytte:	- Vurderer og oppfatter tegn til akutt forverring i helsetilstand til pasient - Reagerer adekvat på akutt forverring i helsetilstand til pasient - Kommuniserer målrettet i teamarbeid							
Tidsramme i min:	Forberedelse:	30	Briefing:	20	Simulering:	15	Debrifing:	45
Forutsetter:	- Veiledet praksis i sykehjem - Aktuelle emner studentene har hatt tidligere i bachelorutdanning i sykepleie							
Litteratur/undervisning:	- Kristoffersen, N.J., Nortvedt, F., Skaug, E.A. & Grimsbø, G.H. (2016). *Grunnleggende sykepleie 2.* Oslo: Gyldendal Norsk Forlag AS: Kap: 11, 12, 13 og 15 - Stubberud, D. G., Grønseth, R. & Almås, A. (2016). *Klinisk sykepleie 1.* Oslo: Gyldendal Norsk Forlag AS: Kap. 8 (s. 263-269) og kap. 9							
Roller for deltakere:	- 2 sykepleiere - Pasientens datter/sønn - Evt .1 lege							
Forberedelse av pasientsimulator og miljø:	Pasienten har operasjonsbandasje på abdomen med spor av blod. Har innlagt perifer venekanyle med pågående Ringer Acetat i langsom takt. Ligger med pasientskjorte. Klam i huden (sprayes på forhånd). Noe hevet hodegjerde.							
Tilgjengelig utstyr:	BT-apparat, stetoskop, temperaturmål, pussbekken, cellestoff, perifer venekanyle, sprøyter, kanyler, O2, brillekateter, maske, pulsoxymeter, ekstra bandasje til forsterkning, permanent urinkateter og kunstig blod. Paracet iv., Ketorax iv. og Ringer Acetat iv.							
Annet: (dokumenter, vedlegg, pasientkurve, lab.ark,….)	Kurve med disse forordningene: - Klexane 40 mg sc. x 1 - Paracet 1 g x 4 iv. - Ketorax 2,5 – 5 mg iv. ved behov - O2 (opptil 3 liter) - 1 liter Ringer Acetat iv.							

Student eksemplar

Læringsutbytte:	Studenten: - Vurderer og oppfatter tegn til akutt forverring i helsetilstand til pasient - Reagerer adekvat på akutt forverring i helsetilstand til pasient - Kommuniserer målrettet i teamarbeid	
Forutsetter:	- Veiledet praksis i sykehjem - Aktuelle emner studentene har hatt tidligere i bachelorutdanning i sykepleie	
Litteratur/undervisning:	- Kristoffersen, N.J., Nortvedt, F., Skaug, E.A. & Grimsbø (2016). *Grunnleggende sykepleie 2.* Oslo: Gyldendal Norsk Forlag AS: Kap: 11, 12, 13 og 15 - Stubberud, D. G., Grønseth, R. & Almås, A. (2016). *Klinisk sykepleie 1.* Oslo: Gyldendal Norsk Forlag AS: Kap. 8 (s. 263-269) og kap. 9	
Roller for deltakere:	- 2 sykepleiere - Pasientens datter/sønn - Evt. 1 lege	
Pasientbeskrivelse:	Navn	Per/Petra Hansen
	Kjønn	Mann/Kvinne
	Alder	75 år
	Vekt	70 kg/63 kg
	Høyde	180 cm/158 cm
	Allergier	Ingen kjente
	Medikamenter	Klexane 40 mg. sc x 1 (fast), 1 g Paracet x 4 iv (ved behov), Ketorax 2,5 – 5 mg iv (ved behov)
	Annet	Kostregulert diabetes type 2. Siste blodsukkerverdi: 6.1
Sykehistorie:	Innlagt etter å ha fått cancer coli. Utført en venstresidig hemicolectomi. Har kostregulert diabetes type 2.	
Aktuelt:	Dere har nettopp kommet på seinvakt og har ansvar for pasienten. Pasienten har ligget på kirurgisk avdeling i 5 timer etter operasjon. Han/hun ringer på og føler seg svimmel og uvel. Pasienten og pasientens datter/sønn er engstelige.	

Fasilitator eksemplar	
Hendelsesforløp:	Innlagt etter å ha fått påvist cancer coli. Utført en venstresidig hemicolectomi laparoskopisk. Dere har nettopp kommet på seinvakt og har ansvar for pasienten. Pasienten har ligget på kirurgisk avdeling i 5 timer etter operasjon. Han/hun ringer på og føler seg svimmel og uvel. Pasienten og pasientens datter/sønn er engstelige. (Postoperativ blødning)
Debrifing: Gjør riktige observasjoner, vurderinger, og iverksetter relevante tiltak og evaluerer disse. Evt. revurdering	A: Frie? Luftveisrisiko? B: Respirasjonsfrekvens (RF), oksygenmetning: vurdere behov for O2 (maske/brillekateter), leieendring? C: Hud, puls (regelmessig), blodtrykk (BT), perifer sirkulasjon, diurese, bandasje, Ringer acetat D: Smerter: lokalisasjon og karakter, pasientopplevelse: engstelig E: Undersøkelse av buken i fire kvadranter, bandasje, temp: 36,9 C: spent i buken/trykkøm?, stor blødning i bandasje?, måle bukomfang
Status og kommentarer:	A: Frie B: Oksygenmetning=93, RF=22-29, puster tungt. Ringer acetat, endret leie (hevet fotende) og O2 (opptil 3 liter) gir RF=18 og oksygenmetning=95, puster mindre tungt C: BT=100/75-90/70, puls=120, lav diurese. Ringer acetat, endret leie (hevet fotende) og O2 (opptil 3 liter) gir etter ca 3-5 min BT=115/75 og puls=95 D: Ringer Acetat, endret leie (hevet fotende) og O2 (opptil 3 liter) gir etter noen minutter mindre svimmelhet E: Palpasjon av buken: spent, øm i nedre venstre kvadrant, økende bukomfang (4 cm) siden forrige måling, litt blod i bandasjene
Team ferdigheter: Kommunikasjon Ledelse Situasjonsovervåkning Gjensidig støtte	- ISBAR - Status av pasient - Samarbeid i team - Arbeidsfordeling

Operatør eksemplar

Observasjoner	Start tilstand	Kommentarer	Respons på tiltak
A	Frie		
B	RF=22-29, oksygenmetning=93	Puster tungt og dypt	Ringer Acetat, endret leie (hevet fotende) og O2 (opptil 3 liter): føler det lettere å puste, oksygenmetning=95-99, RF=18
C	Puls=120, BT=100/75-90/70, konsentrert diurese	Svimmel	Ringer Acetat, endret leie (hevet fotende) og O2 (opptil 3 liter): klam i huden, BT=115/75, puls=95-100, mindre svimmel (effekten tilpasset avhengig av hvor mye som iverksettes)
D	Reagerer adekvat	Engstelig	Beroliges ved god kommunikasjon og informasjon
E	Temp: 36,9 C	Litt blod i bandasjene, spent i buken og øm nedre venstre kvadrant	Tiltak: Palpasjon av buken som er spent og øm i nedre venstre kvadrant. Litt blod i bandasjene, ikke nødvendig å forsterke bandasjene

Pasientopplevelser	Kommentar
1. Trygghet 2. Informasjon 3. Målrettet kommunikasjon 4. Empati	

Appendix 8

Interview guide (faculty members) Study 3

NTNU

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Intervjuguide lærere studie 3

Navn og kontaktinformasjon innhentes og kodes med respondent 1 og oppover.

Spørsmål før intervjuet starter:

1. Alder?
2. Tidligere erfaring med simulering?

Hensikten med dette intervjuet er at du forteller oss mest mulig om dine erfaringer om hvordan du opplevde å organisere simuleringen.

Spørsmål:

1. Hvilken rolle hadde du i gjennomføringen av simuleringen?
2. Hvordan vil du beskrive din opplevelse av gjennomføringen av simuleringen?
3. Hva var positivt med gjennomføringen av simuleringen?
4. Hva var negativt med gjennomføringen av simuleringen?
5. Har du noe å legge til i forhold til gjennomføringen av simuleringen?

Appendix 9

Interview guide (students) Study 3

NTNU

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FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Intervjuguide sykepleierstudenter studie 3

Navn og kontaktinformasjon innhentes og kodes med respondent 1 og oppover.

Spørsmål før intervjuet starter:

1. Alder?
2. Tidligere erfaring med simulering?

Hensikten med dette intervjuet er at du forteller oss mest mulig om hvordan du opplevde å delta på simuleringen, og dine erfaringer med bruken av spørreskjemaene du fylte ut.

Spørsmål:

<u>Opplevelse av deltakelse i simuleringen:</u>

1. Hvilken rolle hadde du når du deltok i simuleringen?
2. Hvordan vil du beskrive din opplevelse av å delta i simuleringen?
3. Hva var positivt med å delta i simuleringen?
4. Hva var negativt med å delta i simuleringen?
5. Har du noe å legge til i forhold til din deltakelse i simuleringen?

Spørreskjema del 1 (Kunnskapstest)

6. Hvordan opplevde du å fylle ut dette skjemaet?
7. Hva var positivt med dette skjemaet?
8. Hva var negativt eller kunne vært formulert på en annen måte i skjemaet?
9. Er det noen spørsmål du ønsker å legge til/eventuelle andre kommentarer til bruken av dette skjemaet?

Spørreskjema del 2 (Spørsmål om hvordan du opplever din sikkerhet i ulike situasjoner)

10. Hvordan opplevde du å fylle ut dette skjemaet?
11. Hva var positivt med dette skjemaet?
12. Hva var negativt eller kunne vært formulert på en annen måte i skjemaet?
13. Er det noen spørsmål du ønsker å legge til/eventuelle andre kommentarer til bruken av dette skjemaet?

Appendix 10

Approvals from the Norwegian Centre for Research Data

Kristine Haddeland
Institutt for helse- og sykepleievitenskap Universitetet i Agder
Postboks 422
4604 KRISTIANSAND S

Vår dato: 14.02.2017 Vår ref: 52110 / 3 / BGH Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 12.01.2017. Meldingen gjelder prosjektet:

52110	*Nursing student's recognition and responses to clinical deterioration events: a multi-center cluster-randomized controlled trial*
Behandlingsansvarlig	*Universitetet i Agder, ved institusjonens øverste leder*
Daglig ansvarlig	*Kristine Haddeland*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/meldeplikt/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 28.09.2023, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Kjersti Haugstvedt

Belinda Gloppen Helle

Kontaktperson: Belinda Gloppen Helle tlf: 55 58 28 74
Vedlegg: Prosjektvurdering

Dokumentet er elektronisk produsert og godkjent ved NSDs rutiner for elektronisk godkjenning.

Personvernombudet for forskning

Prosjektvurdering - Kommentar

Prosjektnr: 52110

INFORMASJON OG SAMTYKKE
Utvalget (sykepleierstudenter) informeres skriftlig og muntlig om prosjektet og samtykker til deltakelse. Informasjonsskrivet er godt utformet, men det bør understrekes at det ikke vil påvirke studentenes vurdering i faget dersom de ikke ønsker å delta.

TREDJEPERSONER
I spørreskjemaet TEAM kan det fremkomme opplysninger om identifiserbare tredjepersoner (team-leder). Om personer som ikke deltar direkte i prosjektet, og som ikke informeres om prosjektet, skal det kun registreres opplysninger som er nødvendig for formålet med prosjektet. Opplysningene skal være av mindre omfang og ikke sensitive, og skal anonymiseres i publikasjon. Så fremt personvernulempen for tredjeperson reduseres på denne måten, kan prosjektleder unntas fra informasjonsplikten overfor tredjeperson, fordi det anses uforholdsmessig vanskelig å informere.

INFORMASJONSSIKKERHET
Personvernombudet legger til grunn at forsker etterfølger Universitetet i Agder sine interne rutiner for datasikkerhet.

PROSJKETSLUTT OG ANONYMISERING
Forventet prosjektslutt er 28.09.2023. Ifølge prosjektmeldingen skal innsamlede opplysninger da anonymiseres. Anonymisering innebærer å bearbeide datamaterialet slik at ingen enkeltpersoner kan gjenkjennes. Det gjøres ved å:
- slette direkte personopplysninger (som navn/koblingsnøkkel)
- slette/omskrive indirekte personopplysninger (identifiserende sammenstilling av bakgrunnsopplysninger som f.eks. bosted/arbeidssted, alder og kjønn)
- slette digitale lyd-, bilde- og videopptak.

Dersom det forekommer endringer i innmeldt prosjektmelding skal det sendes endring til personvernombudet i god tid før endringene trer i kraft.

Kristine Haddeland
Institutt for helse- og sykepleievitenskap
Universitetet i Agder
Postboks 422
4604 KRISTIANSAND S

Vår dato: 07.08.2017 Vår ref: 52110/6/AGH/LR Deres dato: Deres ref:

BEKREFTELSE PÅ ENDRING

Vi viser til endringsmelding mottatt 14.07.2017 med justeringer mottatt 16.07.2017 for prosjektet;

52110 *Nursing students recognition and responses to clinical deterioration events: a multi-center cluster-randomized controlled trial*

Endringen består i at det skal benyttes andre spørreskjemaer i datainnsamlingen.

Siden studentene skal vurdere egen selvsikkerhet/kompetanse, tar personvernombudet høyde for at det kan registreres sensitive personopplysninger relatert til helseforhold.

Personvernombudet finner at behandlingen av personopplysninger i prosjektet vil være regulert av § 7-27 i personopplysningsforskriften, fordi det nå innhentes sensitive personopplysninger. Personvernombudet tilrår videre behandling av personopplysninger i prosjektet.

Personvernombudet bemerker også at når det skal gjøres videoopptak av obligatorisk undervisningsopplegg, må studentene også tilbys å delta i undervisningsopplegget uten å bli filmet. Vi legger til grunn at du tar hensyn til dette.

Personvernombudet forutsetter at prosjektopplegget for øvrig gjennomføres i tråd med det som tidligere er innmeldt, og personvernombudets tilbakemeldinger.

Ta gjerne kontakt dersom noe er uklart.

Vennlig hilsen

Marianne Høgetveit Myhren

Agnete Hessevik

Appendix 11

Information about Study 2 (questionnaire) and

informed consent form to participants

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 2a: Pilottesting av instrumenter til bruk i simulering

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er 3.årsstudent ved bachelorutdanningen i sykepleie ved NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved Universitet i Agder (UiA).

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg å svare på en del spørsmål før og etter at du har deltatt på et undervisningsopplegg med simulering. Spørreskjemaene vil ta ca. 10 minutter å fylle ut. Undervisningsopplegget inngår som en del av din bachelorutdanning, og vil foregå på NN.

Mulige fordeler og ulemper

Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning. Det er ønskelig at forskning på din opplevelse av å delta i et undervisningsopplegg med simulering kan gi økte kunnskaper om hva som får sykepleierstudenter til å bli bedre i å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt i sykehus.

Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å fylle ut spørreskjemaene. Dersom du skulle oppleve ubehag ved å dele erfaringer knyttet til eventuelle vanskelige situasjoner du har opplevd i undervisningsopplegget og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?

Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse

Det er frivillig å delta i studien, og om du deltar eller ikke vil ikke påvirke vurderingen av deg i emnet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte stipendiat Kristine Haddeland, tlf: 38 14 15 24, professor Mariann Fossum, tlf: 37 23 37 56 eller professor Åshild Slettebø, tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse i studie om pilottesting av instrumenter til bruk i simulering

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 12

Information about Study 2 (interview) and

informed consent form to participants

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 2b: Intervju i forhold til pilottesting av instrumenter til bruk i simulering

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er student ved bachelorutdanningen i sykepleie ved NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved UIA.

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg om å delta i et intervju etter at du har vært med på et undervisningsopplegg med simulering. Undervisningsopplegget inngår som en del av din bachelorutdanning, og vil foregå på NN. Intervjuet vil ta utgangspunkt i dine erfaringer med bruk av ulike spørreskjemaer du svarte på knyttet til simuleringen, og foregå på studiestedet ditt når det passer for deg. Når du har samtykket til å delta på intervju, vil forsker kontakte deg for å avtale tid og sted for intervjuet. Intervjuet vil ta ca. 15 min.

Mulige fordeler og ulemper

Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning. Det er ønskelig at forskning på din opplevelse av å delta i et undervisningsopplegg med simulering kan gi økte

kunnskaper om hva som får sykepleierstudenter til å bli bedre i å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt i sykehus.

Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å fylle ut instrumentene som brukes i undervisningsopplegget. Dersom du skulle oppleve ubehag ved å dele erfaringer knyttet til eventuelle vanskelige situasjoner du har opplevd i undervisningsopplegget og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?
Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse
Det er frivillig å delta i studien, og om du deltar eller ikke vil ikke påvirke vurderingen av deg i emnet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte stipendiat Kristine Haddeland, tlf: 38 14 15 24, professor Mariann Fossum, tlf: 37 23 37 56 eller professor Åshild Slettebø, tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse til intervju om bruk av ulike spørreskjemaer

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 13

Information about Study 3 (questionnaire, intervention groups) and informed consent form to participants

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NTNU

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 3a: Gjennomføring av cluster-randomisert kontrollert studie

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er student ved bachelorutdanningen i sykepleie ved NN eller NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved UIA.

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg om å delta i et forskningsprosjekt i forbindelse med et undervisningsopplegg blant annet om vitale tegn. Undervisningsopplegget varer ca 1,5 time. Før og etter vil du bli spurt om å svare på en del spørsmål. Spørreskjemaene vil ta ca. 10 minutter å fylle ut. Undervisningsopplegget inngår som en del av din bachelorutdanning, og vil foregå på NN eller NN.

Mulige fordeler og ulemper

Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning. Det er ønskelig at forskning på din opplevelse av å delta i et undervisningsopplegg om vitale tegn kan gi økte kunnskaper

om hva som får sykepleierstudenter til å bli bedre i å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt i sykehus.
Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å fylle ut spørreskjemaene som brukes i undervisningsopplegget. Dersom du skulle oppleve ubehag ved å dele erfaringer knyttet til eventuelle vanskelige situasjoner du har opplevd i undervisningsopplegget og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?
Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse
Det er frivillig å delta i studien, og om du deltar eller ikke vil ikke påvirke vurderingen av deg i emnet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte stipendiat Kristine Haddeland, tlf: 38 14 15 24, professor Mariann Fossum, tlf: 37 23 37 56 eller professor Åshild Slettebø, tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse i cluster-randomisert studie

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 14

Information about Study 3 (questionnaire, control groups) and

informed consent form to participants

NTNU

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 3b: Gjennomføring av cluster-randomisert kontrollert studie

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er student ved bachelorutdanningen i sykepleie ved NN eller NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved UIA.

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg om å svare på noen spørreskjemaer om vitale tegn. Det vil foregå på NN eller NN.

Mulige fordeler og ulemper

Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning.

Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å fylle ut noen spørreskjemaer. Dersom du skulle oppleve ubehag ved å svare på spørreskjemaene og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?
Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse
Det er frivillig å delta i studien, og om du deltar eller ikke vil ikke påvirke vurderingen av deg i emnet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte stipendiat Kristine Haddeland, tlf: 38 14 15 24, professor Mariann Fossum, tlf: 37 23 37 56 eller professor Åshild Slettebø, tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse i cluster-randomisert kontrollert studie

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 15

Information about Study 3 (interview, students) and

informed consent form to participants

NTNU

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 3c: Intervju i forhold til deltakelse og bruk av instrumenter i simulering

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forvirring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er student ved bachelorutdanningen ved NN eller NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved UiA.

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg om å delta i et intervju etter at du har vært med på et undervisningsopplegg med simulering. Undervisningsopplegget inngår som en del av din bachelorutdanning, og vil foregå på NN eller NN. Intervjuet vil ta utgangspunkt i dine erfaringer med deltakelse og bruk av ulike spørreskjemaer du svarte på knyttet til simuleringen, og foregå på studiestedet ditt når det passer for deg. Når du har samtykket til å delta på intervju, vil forsker kontakte deg for å avtale tid og sted for intervjuet. Intervjuet vil ta ca. 15 min.

Mulige fordeler og ulemper
Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning. Det er ønskelig at forskning på din opplevelse av å delta i et undervisningsopplegg med simulering kan gi økte kunnskaper om hva som får sykepleierstudenter til å bli bedre i å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt i sykehus.

Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å delta på et intervju. Dersom du skulle oppleve ubehag ved å dele erfaringer knyttet til eventuelle vanskelige situasjoner du har opplevd i undervisningsopplegget og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?
Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse
Det er frivillig å delta i studien, og deltakelse/ikke deltakelse vil ikke påvirke vurderingen av deg i emnet. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Kristine Haddeland på tlf: 98 48 04 58 eller professor Mariann Fossum på tlf: 37 23 37 56/91 85 48 45 eller professor Åshild Slettebø, på tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse til intervju om deltakelse og bruk av ulike spørreskjemaer i simulering

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 16

Information about Study 3 (interview, faculty members) and

informed consent form to participants

NTNU

UNIVERSITETET I AGDER
FAKULTET FOR HELSE- OG IDRETTSVITENSKAP

Forespørsel om deltakelse i forskningsprosjekt

"Sykepleierstudenters evne til å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt på sykehus – en cluster-randomisert kontrollert studie"

Studie 3d: Intervju i forhold til gjennomføring av simulering

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som har til hensikt å øke sykepleierstudenters evne til å oppfatte tegn til akutt forvirring i helsetilstanden til pasienter innlagt på sykehus. Du er valgt ut til å delta i studien fordi du er vitenskapelig ansatt ved bachelorutdanningen i sykepleie ved NN eller NN. Studien er et forskningsprosjekt, og forsker er doktorgradsstudent ved Fakultet for helse- og sykepleievitenskap, Institutt for helse- og sykepleievitenskap ved UiA.

Hva innebærer studien?

Deltakelse i denne studien innebærer at forsker gjør en avtale med deg om å delta i et intervju etter at du har vært med på et undervisningsopplegg med simulering. Undervisningsopplegget inngår som en del av bachelorutdanning i sykepleie, og vil foregå på NN eller NN. Intervjuet vil ta utgangspunkt i dine erfaringer med gjennomføringen av simuleringen, og foregå på arbeidsstedet ditt når det passer for deg. Når du har samtykket til å delta på intervju, vil forsker kontakte deg for å avtale tid og sted for intervjuet. Intervjuet vil ta ca. 15 min.

Mulige fordeler og ulemper
Sykepleiere har en viktig rolle i forhold til å observere og gjenkjenne tegn til akutt forverring hos pasienter innlagt i sykehus, og det er viktig at sykepleierstudenter får trening på det i løpet av sin bachelorutdanning. Det er ønskelig at forskning på din opplevelse av å gjennomføre et undervisningsopplegg med simulering kan gi økte kunnskaper om hva som får sykepleierstudenter til å bli bedre i å oppfatte tegn til akutt forverring i helsetilstanden til pasienter innlagt i sykehus.

Deltakelse i studien medfører ikke vesentlig ulempe utover noe ekstra tid til å delta på et intervju. Dersom du skulle oppleve ubehag ved å dele erfaringer knyttet til eventuelle vanskelige situasjoner du har opplevd i undervisningsopplegget og ønsker noen å snakke med etterpå, kan du ta kontakt med stipendiat Kristine Haddeland, tlf: 38 14 15 24 ved UIA.

Hva skjer med informasjonen om deg?
Alle opplysningene om deg vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. De skriftlige dataene fra deg vil merkes med et nummer som viser til en atskilt navneliste og opplysningene vil bli oppbevart atskilt i et låsbart skap og på en passordbeskyttet pc. Det er kun autorisert personell knyttet til prosjektet (forsker og veiledere) som har adgang til opplysningene du har gitt. Når prosjektet er sluttført (12.2023) vil alle personidentifiserbare data bli slettet. Resultatene vil bli publisert slik at identiteten din ikke kommer frem.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser for deg. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke inntil data er gått inn i vitenskapelige analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Kristine Haddeland på tlf: 98 48 04 58 eller professor Mariann Fossum på tlf: 37 23 37 56/91 85 48 45 eller professor Åshild Slettebø, på tlf: 37 23 37 87, alle UiA.

Samtykke til deltakelse til intervju om gjennomføring av simulering

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg kan treffes på følgende telefonnummer ved behov:

Jeg bekrefter å ha gitt informasjon om studien

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