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Conflicts of interest

No conflict of interest has been declared by the authors.

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ABSTRACT

Aim. To describe a study protocol for a study evaluating the effectiveness of a mobile cooperation intervention to improve students' competence level, self-efficacy in clinical performance and satisfaction with the clinical learning environment.

Background. Nursing student–nurse teacher cooperation during the clinical practicum has a vital role in promoting the learning of nursing students. Despite an increasing interest in using mobile technologies to improve the clinical practicum of nursing students, there is limited robust evidence regarding their effectiveness.

Design. A multicentre, parallel group, randomized, controlled, pragmatic, superiority trial. **Methods.** Second-year pre-registration nursing students who are beginning an internal medicine or surgical clinical practicum will be recruited from one university of applied sciences. Eligible nursing students will be randomly allocated to either a control group (engaging in standard cooperation) or an intervention group (engaging in mobile cooperation) for the 5-week the clinical practicum. The complex mobile cooperation intervention comprises of a mobile-application-assisted, nursing student–nurse teacher cooperation and a training in the functions of the mobile application. The primary outcome is competence. The secondary outcomes include self-efficacy in clinical performance and satisfaction with the clinical learning environment. Moreover, a process evaluation will be undertaken. The ethical approval for this study was obtained in December 2014 and the study received funding in 2015.

Discussion. The results of this study will provide robust evidence on mobile cooperation during the clinical practicum, a research topic that has not been consistently studied to date. **Trial registration**. ClinicalTrials.gov: NCT02635295.

Keywords: clinical practicum, competence, cooperation, mobile application, nursing, randomized controlled trial, self-efficacy, student, study protocol

SUMMARY STATEMENT

Why this study or review is needed?

- There is limited robust evidence to support the increasing use of mobile technology in nursing student–nurse teacher cooperation during the clinical practicum.
- There are a lack of mobile applications specifically developed for nursing education to improve the learning of nursing students.
- The complex intervention developed in this study can potentially be used quite extensively at both the national and international level in routine parts of the nursing education.

INTRODUCTION

For nursing students (students), the clinical practicum is the core component of their nursing degree studies (Chan 2002, Price *et al.* 2011, Henderson *et al.* 2012). The clinical practicum, which gives unique learning opportunities to students in direct contact with patients, is an essential part of nursing education and crucial for gaining first-hand experience in practice (Henderson *et al.* 2012, Killam & Heerschap 2013, Flott & Linden 2016). It comprises at least one half (90 ECTS, or 2300 hours) of the minimum duration of professional nursing studies in Europe (European Commission 2005, 2013). It is customary for students to be supervised during the clinical practicum by a mentor (qualified nursing staff) working in clinical practice (European Commission 2013), but also by the nurse teacher (NT), whose cooperation with students is conducted at the educational institutions in question (Price *et al.* 2011). This cooperation increasingly occurs through using information and communication technology (ICT) (Saarikoski *et al.* 2013).

Study findings indicate that nursing student–NT cooperation during the clinical practicum, from students' point of view, is complicated because of limited opportunities to use the existing ICT facilities in the practicum wards (Kenny et al. 2009, Wu & Lai 2009). However, this cooperation is essential for promoting students' learning (Löfmark et al. 2012, Eng & Pai 2015, O'Connor & Andrews 2015), allowing them to integrate theoretical knowledge and practical skills in direct contact with patients (European Commission 2013). Nurse competence (competence) can be defined in different ways (Cowan et al. 2005, Kajander-Unkuri et al. 2016). In this study, competence is viewed as a learning outcome (Watson et al. 2002, Löfmark et al. 2006) and it is defined in a holistic manner (Watson et al. 2002, Cowan et al. 2005, Garside & Nhemachena 2013) as follows: 'the functional adequacy and the capacity to integrate knowledge and skills with attitudes and values into the specific contexts of practice' (Meretoja et al. 2004). In fact, international educational frameworks, such as the Directive 2013/55/EU (European Commission 2013) and the EFN Guideline to implement Article 31 of the Directive 2013/55/EU (EFN 2015) describe competence as a desired learning outcome of the clinical practicum. However, there is limited evidence regarding the competence level of students during their nursing education (Löfmark et al. 2006, Kajander-Unkuri et al. 2014, 2016), with the existing evidence derived from descriptive rather than experimental studies and mostly uncontrolled single-cohort studies.

Based on earlier study findings, learning (Chan 2002, Price *et al.* 2011), similar to the competence (Hakimzadeh *et al.* 2013, Kajander-Unkuri *et al.* 2014) of students, seems to be connected not only to a supportive pedagogical atmosphere, but also with nursing student–NT cooperation (Löfmark *et al.* 2012) and mentor supervision (Saarikoski & Leino-Kilpi 2002) during the clinical practicum. On the other hand, several previous studies have

indicated that self-efficacy influences competence level of students (Lauder *et al.* 2008, Cheraghi *et al.* 2009, Pijl-Zieber *et al.* 2014, Eng & Pai 2015). According to Bandura (1997) self-efficacy is one's beliefs about his or her ability to succeed in specific situations or complete tasks and reach goals. However, students have reported feelings of isolation (Kenny *et al.* 2009, Killam & Heerschap 2013) and a lack of support from the NT (Wu & Lai 2009, Killam & Heerschap 2013) during the clinical practicum, which in turn may decrease the self-efficacy of students (Lauder et al. 2008, Cheraghi *et al.* 2009, Kenny *et al.* 2012, Rowbotham & Schmitz 2013). In fact, researchers (O'Connor & Andrews 2015, Strandell-Laine *et al.* 2015) have suggested using mobile devices as one possible solution for overcoming these challenges, with another group of researchers going so far as to suggest that they may be one of the most important tools for nursing education in general (Martin *et al.* 2011). In addition, there are recommendations to enhance higher education in Europe through use of new technologies (European Commission 2014).

There is limited robust evidence on the effectiveness of mobile technology use during the clinical practicum. Nevertheless, two recent in-depth reviews (O'Connor & Andrews 2015, Strandell-Laine *et al.* 2015) have specifically examined existing knowledge regarding the use of mobile technology during the clinical practicum. Likewise, three recent literature reviews have focused more generally on research on mobile technology use in nursing education (Doyle *et al.* 2014, Guo *et al.* 2015, Raman 2015). The studies found that the use of mobile technology enhances not only flexibility (Doyle *et al.* 2014, Guo *et al.* 2015, Strandell-Laine *et al.* 2015) and the quality of nursing student–NT cooperation (Doyle *et al.* 2014, Strandell-Laine *et al.* 2015), but also students' learning (Doyle *et al.* 2014, Guo *et al.* 2015, Strandell-Laine *et al.* 2015) as well as feelings of support and having a connection with the faculty (Strandell-Laine *et al.* 2015). However, there are still several barriers hindering the

widespread use of mobile technology (O'Connor & Andrews 2015, Strandell-Laine et al.

2015) and strategies are needed for overcoming these challenges (O'Connor & Andrews 2015). In fact, students' overall proficiency in the use of mobile technology was seen as a significant barrier in all of the above-mentioned reviews (Doyle et al. 2014, Guo et al. 2015, O'Connor & Andrews 2015, Raman 2015, Strandell-Laine et al. 2015) and further examination is needed at the baseline in future studies (O'Connor & Andrews 2015). Additionally, sufficient training and technical support before beginning, actually, to use mobile technologies should be ensured in future studies (Strandell-Laine et al. 2015). Moreover, researchers have highlighted the need to not only to develop mobile applications that meet the specific needs of nursing education, but also the need to use the latest mobile devices available on the market in future studies (Guo et al. 2015, O'Connor & Andrews 2015, Strandell-Laine et al. 2015). Even if a certain amount of attention has been paid to the satisfaction of students (Guo et al. 2015, Strandell-Laine et al. 2015) and mobile technology use during the clinical practicum, few activities have yet been developed to promote the use of mobile devices (Raman 2015).

Based on earlier reviews, there is limited evidence regarding the effectiveness of mobile technology on the learning outcomes of students, although its use has increased in nursing education in recent years (Doyle et al. 2014, Guo et al. 2015, O'Connor & Andrews 2015, Raman 2015). However, mobile technology use is still an emerging area in the nursing education field. The reviews discussed above all recommend using high-quality robust study designs to evaluate the effectiveness of the technology-enhanced pedagogical methods used in nursing education (Doyle et al. 2014, Guo et al. 2015, O'Connor & Edwards 2015, Raman 2015, Strandell-Laine et al. 2015). Based on this recommendation, a mobile cooperation intervention with respect to nursing student-NT cooperation was developed by the authors to

facilitate such cooperation by means of the latest mobile technology and to eventually improve students' competence level, self-efficacy in clinical performance and satisfaction with the clinical learning environment.

THE STUDY

Aims

The aim of this study is to evaluate the effectiveness of a mobile cooperation intervention compared with standard nursing student–NT cooperation regarding students' competence level, self-efficacy in clinical performance and satisfaction with the clinical learning environment. In addition, a process evaluation will be conducted.

Hypotheses

The outcomes obtained by the intervention group will be superior to those obtained by the control group: the level of competence, self-efficacy in clinical performance and satisfaction with the clinical learning environment will be statistically significantly ($p \le 0.05$) higher among the intervention group than the control group.

Design

This is a multicentre, parallel group, randomized, controlled, pragmatic, superiority trial. The unit of randomization will be individual students. Eligible students will be randomly allocated to either the control group (engaging in standard cooperation) or the intervention group (engaging in mobile cooperation). In addition, the study includes a process evaluation for a post-hoc explanation. The CONSORT flow diagram of the study is shown in Figure 1.

This study will be conducted in Finland, where bachelor's level nursing degree programmes are carried out in universities of applied sciences (UAS) with a competency-based curricula comprising 210 ECTS (European Credit Transfer and Accumulation System) leading to the qualification of general registered nurse. The study will be conducted in both inpatient and outpatient surgical and internal medicine wards and related specialties and subspecialties at seven hospitals in one hospital district in Finland; it will consist of approximately 1500 yearly clinical practicum periods for nursing students. The study sites are those particular hospitals where the students' clinical practicum procedures have been standardized according to the curriculum and guidelines established by the UAS in question, a medium-sized UAS in Finland (Ministry of Education and Culture 2016). The list of study sites can be obtained from the research approval form for the hospital district (T257/10/5.12.14).

Participants

Inclusion criteria for students are as follows: (1) beginning the clinical practicum in the study hospitals; (2) pre-registration nursing student in the study UAS; (3) at least second-year student, thereby ensuring prior experience with the clinical practicum; (4) beginning a 5week internal medicine or surgical clinical practicum; and (5) informed consent. Exclusion criteria for students are as follows: (1) beginning the clinical practicum somewhere other than in the study hospitals; (2) first year pre-registration nursing student; (3) beginning other than a 5-week internal medicine or surgical clinical practicum; or (4) unwilling to provide consent. All mentors supervising students during the clinical practicum are eligible for the study. Those mentors unwilling to provide informed consent will be excluded from the study. The researcher (the first author) also has the role of NT for the intervention and control group. The stakeholders of the study and their roles are shown in Table 1.

The sample size calculations were based on normality assumptions regarding the primary outcome (Jull & Aye 2015) using the Nurse Competence Scale, NCS (Meretoja *et al.* 2004). The estimated standard deviation was 17.7 for the data collected from students (Kajander-Unkuri *et al.* 2014). The significance level was set at up to 0.05 (two-tailed), with a statistical power of up to 80%. It was determined that a ten-point difference in the NCS sub-scale scores would be clinically significant. Based on these assumptions, the target sample size necessary for achieving the study objectives will be 50 participants per group, which adds up to 100 participants in total. The sample size was estimated using the greatest standard deviation (Lamb & Altman 2015) found from previous publications on the primary outcome (Kajander-Unkuri *et al.* 2014). In addition, a more powerful analysis method can be used for the data analysis than the t-test used for the sample size calculations (estimations for mean changes and standard deviations were not presented in the publications). Therefore, the sample size will be large enough for the study to include a maximum of 10% dropouts.

Recruitment

Students will be enrolled at the pre-orientation lecture of the clinical practicum at the study UAS by the researcher through face-to-face meetings. Students not having an appropriate mobile device (smart phone or tablet PC) will have the opportunity to borrow a mobile device from the UAS to facilitate participant recruitment. The enrolment process for students will be continued until the target sample size is reached. Researchers will recruit mentors during visits to the wards through face-to-face meetings. This might occur as late as the first days of

the clinical practicum as mentors are for the most part assigned to individual students at the beginning of the clinical practicum.

The enrolment process for mentors will continue until all participating students have a mentor willing to participate. After the volunteering mentors sign the informed consent forms, the researcher will provide training in the functions of the mobile application as well as in how the intervention should consistently be implemented and the outcomes assessed. Table 2 summarises the time schedule of enrolment, interventions and assessments from a participant's point of view.

Randomization

Voluntary students meeting the inclusion criteria will be randomly allocated to either the control group or the intervention group via random permuted block randomization and a 1:1 allocation ratio to ensure baseline equivalence between the groups (Jull & Aye 2015, Lamb & Altman 2015). The randomization codes and randomization lists will be programmed using SAS for Windows (version 9.3, SAS Institute Inc., Cary, NC, USA) separately for internal medicine or surgical wards according to the target sample size by an independent statistician not involved in the participant recruitment process and who has not had any prior contact with the students. The allocation will be implemented by the researcher by assigning randomization codes to the students' signed informed consent forms. To ensure allocation concealment (Jull & Aye 2015), the researcher and students will be unaware of the next allocation (Lamb & Altman 2015) and the randomization lists to define the allocation. The researcher later with the computer-generated randomization lists to define the allocation. The researcher will inform students by email two weeks before the intervention whether they are assigned to the control group or the intervention group. The eligible mentors will be allocated based on the student allocations. Blinding will not be possible owning to the pragmatic nature

of the study (Lamb and Altman 2015), which will be implemented in the real clinical learning environment in hospital settings.

Intervention

Control group. Students in the control group will be engaged in standard nursing student–NT cooperation during the 5-week clinical practicum. The content of the standard cooperation consist of supervision in learning objectives, feedback of mid-point and final evaluation as well as support if needed. The control group will not receive any intervention components. Both groups will receive the same standard content in cooperation with the same NT and as well as the same face-to-face pre-orientation and post-orientation lecture concerning the clinical practicum. Nevertheless, the procedures used for the nursing student–NT cooperation and mentors supervision will vary between the groups as described in Table 3.

Intervention group. Students in the intervention group will be engaged in mobile application assisted nursing student –NT cooperation. The mobile cooperation intervention will include: (1) the use of the Study@Campus^{Pro} mobile application (App), developed for this study, in a nursing student–NT cooperation during the 5-week clinical practicum and (2) baseline App functionality training to ensure full understanding and consequently, effective use of the App. Ongoing technical support during the intervention will be provided by the teacher. The App will include the following elements: (1) documentation and an edition of the schedule of the clinical practicum shifts, a learning diary, learning objectives as well as mid-point and final evaluations of the clinical practicum; and (2) a social networking-style component that allows students, the NT and the mentor to communicate with each other by means of individual or group messages. All actions in the App are automatically saved and shared between the student–mentor–NT pair, enabling both synchronous and asynchronous cooperation during

the shifts and outside the clinical practicum. The unique and innovative feature of the App is that it places all procedures in one central, digital environment, which allows for convenient flexible and hands-on use. The web-based App is password protected and works both on iOS and Android devices. The App was developed for this study in collaboration with a Finnish software company, focusing on student and learning management systems. The pilot-testing of the App was conducted during a 5-week clinical practicum in 2014 with the NT (n=1, the researcher) and volunteer pre-registration nursing students (n=6). Based on their feedback, minor changes were made to the App, especially to the screen view.

Outcome measures

Data on the outcome variables and demographic data will be collected via paper-based questionnaires in the study hospitals by the researcher to avoid inter-rater error. In addition, process evaluation data will be collected from students in the intervention group by the researcher at the study UAS (Table 2).

Primary outcome

Competence. The generic Nurse Competence Scale, NCS (Meretoja *et al.* 2004) contains 73 items in seven competence sub-scales: helping role (7 items), teaching–coaching (16 items), diagnostic functions (7 items), managing situations (8 items), therapeutic interventions (10 items), ensuring quality (6 items) and work role (19 items). Originally, the NCS was developed in Finland to measure nurses' competence, but recently it has also been used for students' self-assessments of their competence (Kajander-Unkuri *et al.* 2014) and to compare students' and mentors' assessments (Kajander-Unkuri *et al.* 2016). In the previous study with student sample (Kajander-Unkuri *et al.* 2014) the Cronbach's alpha coefficient ranged from 0.84-0.93. In this study, the main interest sub-scales are the ones with highest factor loadings

with respect to students (Kajander-Unkuri *et al.* 2014): teaching–coaching, therapeutic interventions and work role. Students will provide self-assessments using the NCS at the baseline (T0) and T1. In addition, mentors will use the NCS to assess students at T1 to ensure both an objective and comprehensive assessment of the students (Norman *et al.* 2002)

Secondary outcomes

Self-efficacy in clinical performance and satisfaction with the clinical learning environment. The Self-Efficacy in Clinical Performance instrument, SECP (Cheraghi *et al.* 2009) contains 37 items in four sub-scales: assessment (12 items), diagnosis and planning (9 items), implementation (10 items) and evaluation (6 items). The SECP was developed in Iran based on the internationally used nursing process framework to measure students' self-assessment of their ability to handle their clinical performance. In the previous study with student sample (Cheraghi *et al.* 2009) the Cronbach's-alpha coefficient ranged from 0.90-0.92. In this study, the instrument was double translated from English into Finnish using the back-translation method (Sousa & Rojjanasnirat 2011). In this study, students will assesses themselves via the SECP at the baseline (T0) and T2.

The original Clinical Learning Environment, Supervision and Nurse Teacher scale, CLES+T scale (Saarikoski *et al.* 2008) contains 34 items in five sub-scales: pedagogical atmosphere (9 items), leadership style of the ward manager (4 items), premises of nursing on the ward (4 items), supervisory relationship (8 items) and role of the NT (9 items). The CLES+T scale was developed in Finland to measure students' satisfaction with the clinical learning environment. In the previous studies, the Cronbach's alpha coefficient has ranged from 0.73-0.94 (Saarikoski *et al.* 2008; Johansson *et al.* 2010). In this study, five additional items were developed by the authors (CS-L, MS, HL-K) for the T sub-scale, thereby forming a new 39-

item CLES+T₂ scale, to measure NT's pedagogical cooperation with students. The content validity at the item- and sub-scale level of the five new items was assessed in 2014 via expert panels of teachers (n=2), nursing education researchers (n=2), CLES+T experts (n=2) and second-year pre-registration students (n=2) following the criteria proposed by Lynn (1986). The item-level CVI ranged from 0.88 to 1.0, while the CVI at the sub-scale level was 0.90. In this study, the main interest sub-scales are the ones with highest factor loadings (Saarikoski *et al.* 2008, Johansson *et al.* 2010; Vizcaya-Moreno *et al.* 2015): pedagogical atmosphere on the ward, supervisory relationship and role of the NT. Students will assesses their subjective satisfaction with the clinical learning environment via the CLES+T₂ at T2. In addition, control of the similarity of the learning environments will be determined (Jull & Aye 2015) by the register data collected with the original CLES+T scale in 2014 in the study hospitals at the baseline (T0).

Demographic data

Students' demographic data will be collected at the baseline (T0), including age, gender, education, ongoing nursing studies, clinical practicum, views on the nursing profession, mobile device use and attitudes about on how mobile devices have been used during the nursing education. In addition, mentors' demographic data will be collected at T1, including age, gender, education and work experience as a nurse and mentor as well as their views of the nursing education.

Process evaluation

The process evaluation will be conducted during the study to support the post-hoc interpretation of the results (Craig *et al.* 2013, Moore *et al.* 2015). The level of satisfaction and adherence with the intervention as well as the intervention delivery will be evaluated at

T2 via a process evaluation questionnaire (Peq) developed for this study. The use and functionality of the App will be evaluated through the number of logins and requests for technical support. The ten-item System Usability Scale, SUS (Brooke 1996, 2013), will be used to determine students' perceived usability of the App. The Cronbach's alpha coefficient ranged up to 0.91 in previous study (Bangor *et al.* 2008). In this study, students will assess the usability of the App at T2. In addition, the researcher will keep notes from the training sessions on the mentors and students as well as from events that may have an effect on the intervention implementation. Furthermore, the researcher will collect reasons for dropping out via phone calls or by sending emails to students or mentors asking them the reason they chose not to participate in the study. After the intervention, semi-structured focus group interviews will be conducted by the researcher at the study UAS at T3 and essays at T4 (Table 3.) to obtain information about students' overall level of satisfaction with the intervention.

Data analysis

Analyses will be carried out using an intention-to-treat approach that is all participants randomised in the study will be included in the analysis. The quantitative data for the outcome measures will be analysed and tested using statistical methods, either the statistical IBM SPSS Statistics for Windows software (version 23.0 or later, IBM Corp., Armonk, NY, USA) or SAS for Windows software (version 9.4 or later, SAS Institute Inc., Cary, NC, USA).

Baseline characteristics will be compared between the groups using a two-sample t-test, Wilcoxon rank sum test or Fisher's exact test, depending on the nature of the variable. The primary outcome measure will be analysed using a hierarchical linear mixed model. The

model will determine whether the mean changes in primary and secondary outcome measures (between the baseline and T1 or T2) are statistically significantly different for the intervention group and the control group. In addition, the mean changes can be estimated for both groups using the same model. While this method can include all data available no imputing for missing values will be done. The statistical significance will be set at a two-tailed p-value of 0.05 for all analyses. Qualitative data (results from the open-ended questions, focus group interviews and essays) will be analysed using inductive content analysis independently by two researchers (Grove *et al.* 2013).

Ethical considerations

The principles of research ethics will be followed during all phases of the study (European Science Foundation and ALL European Academies 2011, TENK 2012, World Medical Association WMA 2013). University Research Ethics Committee approval was obtained in December 2014 (Statement 45/2014). Permission for data collection was obtained from the hospital district (T257/10/5.12.14) and from the UAS (2014). When recruiting students and mentors, the researcher will provide verbal and written information about the study. Participants will be informed that if they chose not to participate in the study or wish to withdraw from it at any point, such a decision will not have negative repercussions for them. Participants will be asked to sign informed consent prior to their participation. There will not be a data monitoring committee, because of the short duration and minimal risks of the intervention. Nevertheless, the researcher will be responsible for the protocol amendments. The personal data collected in the study will be stored and protected according to the good research practices regulated by the Finnish Personal Data Act (1999/523). The first author will have access to the final dataset of the study. The details of the data management

procedures can be obtained from the comment request form approved by the University Research Ethics Committee (Statement 45/2014).

Dissemination

The results of the study will be reported in compliance with the CONSORT 2010 Statement (Moher *et al.* 2012) in conjunction with the TIDieR checklist (Hoffmann *et al.* 2014). In addition, the MRC guidance for the process evaluation of complex interventions will be followed when reporting the process evaluation (Moore *et al.* 2015). There are no publication restrictions. The results of the study will be reported regardless of the magnitude or direction of the effect (Gray *et al.* 2016) in the first author's thesis, in appropriate journals, at conferences and on the ClinicalTrials.gov database. Participants will be provided with a summary of the study results in a clear, understandable manner.

Validity and reliability

The robust, pragmatic RCT study design will be used to evaluate the effectiveness of a complex mobile cooperation intervention. Four possible biases will be controlled for in the study (Borglin & Richards 2010). First, the performance bias will be controlled for by strictly following the study protocol as well as by training and supporting mentors and students in intervention procedures, outcome assessments and App use. Second, the allocated randomization process will be used to control for selection bias, whereas allocation concealment and the use of valid and reliable measurement tools for outcome assessments will minimize the detection bias. Third, data analysis will be performed using an intention-to-treat approach to prevent possible attrition bias. (Borglin & Richards 2010.) Fourth, the internal consistency of the CLES+T₂ scale developed for this study will be evaluated during

the study. This study protocol follows the SPIRIT 2013 Statement (Chan *et al.* 2013) in conjunction with the TIDieR checklist (Hoffmann *et al.* 2014).

DISCUSSION

The clinical practicum is a crucial part of nursing education and crucial for gaining first-hand experience in practice (Henderson *et al.* 2012, Killam & Heerschap 2013, Flott & Linden 2016). However, current methods for facilitating nursing student–NT cooperation during the clinical practicum may not result in optimal learning outcomes, such as the competence of students. In addition, there is a lack of robust evidence regarding the effectiveness of technology-enhanced pedagogical methods for improving the learning of students during the clinical practicum (O'Connor & Andrews 2015, Strandell-Laine *et al.* 2015).

The aim of the multicentre, parallel group, randomized, controlled, pragmatic, superiority trial outlined here is to offer robust evidence regarding the effectiveness of nursing student– NT mobile cooperation regarding nursing students' competence level, self-efficacy in clinical performance and satisfaction with the clinical learning environment. The mobile cooperation intervention was developed to facilitate the nursing student–NT cooperation based on an integrative review focusing on the mobile device used during the clinical practicum (Strandell-Laine *et al.* 2015). The Medical Research Council (MRC) guidance for developing and evaluating complex interventions was followed (Craig *et al.* 2013). The mobile cooperation intervention is complex and entails multiple interactive components (Craig *et al.* 2013, Richards 2015): the student, mentor and NT interacting with one another are from two different organisations (hospitals and UAS), the NT interacts with student-mentor pairs from

several dynamic and challenging wards during the intervention and the number of the outcomes assessed by students and mentors.

The results of this study will offer new evidence for addressing developments in the emerging area of nursing education with respect to new technology-enhanced pedagogical methods using the latest mobile technologies to promote the learning of students. The uniqueness of the study has to do with the fact that the developed App places nursing student–NT cooperation procedures together in one central, digital environment, enabling convenient flexible and hands-on use. This study has a robust study design and may offer results that can be generalised and widely applied to routine parts of nursing education both at an international and a national level. The process evaluation, which so far has been scarcely reported in nursing education research, will give important insights into what occurred during the intervention and how that could influence the outcomes of the intervention. The mobile cooperation intervention was conducted during a single spring semester in accordance with each individual student's planned 5-week clinical practicum and it was a part of each student's normal curriculum. At the time of the study protocol manuscript submission the recruitment has closed, the data collection process has been completed and the data is still being analysed.

Limitations

The study will be conducted in real clinical learning environments, thus the confounding factors cannot be controlled for. Because of the random sample of individual students, participant contamination at the ward level is quite possible; however, this potential problem could be controlled for by randomly assigning the wards. The researcher serves in the role of NT for the nursing student–NT cooperation in both groups leading to a risk for researcher

bias. However, the researcher has a multi-dimensional and long experience in different wards as a qualified NT and she will follow the standard clinical practicum procedures of the study UAS with both groups. Moreover, the cost-effectiveness of the mobile cooperation intervention will not be evaluated in this study because of a lack of awareness regarding the appropriate sound variables to be measured when using the new cooperation method. Hence, these issues should be addressed in future studies.

Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/

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Table 1 The	stakeholders	of the	study	and	their roles.
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Stakeholder	Role in the study
Students in the	(1) to take part in the pre- and post-orientation lectures, (2) to give
intervention group	informed consent, (3) to take part in the App functionality
0 1	intervention procedures and assessment training at the baseline, (4) to
	use the App for 5 weeks, (5) to do self-assessment via the NCS and
	SECP at 2 time points, (6) to answer the CLES+ T_2 , SUS and Peg, (7
	to take part in the semi-structured interview, (8) to write an essay.
Mentors in the	(1) to give informed consent, (2) to take part in the App functionality
intervention group,	intervention procedures and assessment training at the baseline, (3) to
intervention	use the App for 5 weeks, (4) to supervise the student using the
providers	standard procedures, (5) to use the NCS to assess students.
Students in the	(1) to take part in the pre- and post-orientation lectures, (2) to give
control group	informed consent, (3) to take part in the intervention procedures and
e onni or Browp	assessment training at the baseline, (4) to do self-assessment via the
	NCS and SECP at 2 time points, (5) to answer the CLES+ T_2 .
Mentors in the	(1) to give informed consent, (2) to take part in the intervention
control group	procedures and assessment training at the baseline, (3) to supervise
eonicol Browp	the student using the standard procedures, (4) use the NCS to assess
	students.
Researcher (first	(1) to recruit students from the study UAS, (2) obtain informed
author)	consent from participants, (3) to implement the allocation, (4) to
,	recruit mentors from the clinical practice, (5) to give the App
	functionality, intervention procedures and assessment training for
	students and mentors at the baseline, (6) to conduct the data
	collection, (7) to amend protocol if needed and list amendments, (8
	to analyse the qualitative data with the co-researcher, (9) to analyse
	the quantitative data.
Teacher (first	(1) to keep pre- and post-orientation lectures, (2) to use the App for 3
author), the main	weeks for mobile cooperation with the intervention group (students
intervention	and mentors), (3) to have standard cooperation with the control group
provider	(students and mentors), (4) to give ongoing technical support fo
ī	students and mentors in the intervention group in the utilization of the
	App.

Table 2 Time schedule of enrolment,	interventions and	assessments.
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	STUDY PERIOD							
	Enrolment	Allocation	ocation Post-allocation		Close-out			
	-T2	-T1	T0	T0	T1	T2	T3	T4
	4 weeks	2 weeks		1-3 days	before the	0-3 days	within 1	within 11
	before the	before the		after T0,	final	before the	week after	weeks after
	intervention	intervention		(mentor	evaluation	end of the	ending the	ending the
				enrolment)		intervention	intervention	intervention
ENROLMENT								
Recruitment	a			d				
Eligibility screen	a			d				
Informed consent	a			d				
Allocation		b		b				
INTERVENTIONS								
App functionality training*			с	d				
Mobile cooperation			♦					
Standard cooperation			•					
ASSESSMENTS								
Baseline characteristics			с		e			
NCS			с		e, f			
SECP			с			g		
CLES+T register data			b					
$CLES+T_2$						g		
Peg*						g		
SUS*						g g		
App logins*			♦			•		
Focus group interviews*							а	
Essays*								f

a = student-researcher face-to-face group meeting at the UAS. Estimated duration: 30 minutes.

b= completed by the researcher.

c= student-researcher face-to-face group meeting in the hospital. Estimated duration: 75 minutes.

d = mentor-researcher face-to-face meeting in the ward. Estimated duration: 30 minutes.

e = completed by the mentor, no face-to-face contact with the researcher. Estimated duration: 20 minutes.

f = completed by the student, no face-to-face contact with the researcher. Estimated duration: 20 minutes.

g = student-researcher face-to-face group meeting in the hospital. Estimated duration: 60 minutes. *= only participants in the intervention group.

epte

Mob	ile cooperation	(Week)	Standard cooperation			
Stud	ent writes individual learning	(1)	Student writes individual learning			
obje	ctives in the App*		objectives on the paper-based			
			evaluation form and sends an email of			
			the objectives to the NT**			
Stud	ent writes the schedule of shifts in	(1–5)	Student writes the schedule of shifts on			
the A	App*		the paper-based form and gives it to the			
			NT at the post-orientation lecture at the			
			UAS***			
Stud	ent writes a voluntary learning	(1-5)	Student writes a voluntary learning diary			
diary	in the App*		on the paper-based notebook and gives it			
			to the NT at the post-orientation lecture at			
			the UAS***			
Com	munication via App if needed*	(1–5)	Communication via email if needed*			
Stud	ent types individual mid-point	(3–4)	Student sends individual mid-point			
eval	uation to the App*		evaluation to the NT by email**			
Men	tor types student's mid-point	(3–4)	Mentor writes student's mid-point			
eval	uation to the App*		evaluation on the paper-based evaluation			
			form and student sends an email of			
			mentor's evaluation to the NT**			
Stud	ent writes individual final	(5)	Student writes individual final evaluation			
eval	uation in the App*		on the paper-based evaluation form and			
			gives it to the NT at the post-orientation			
			lecture at the UAS***			
Men	tor writes student's final	(5)	Mentor writes student's final evaluation			
eval	uation in the App*		on the paper-based evaluation form and			
			student gives it to the NT at the post-			
			orientation lecture at the UAS***			
Men	tor writes student's overall	(5)	Mentor sends an email of student's			
	uation (pass/fail) in the App*		overall evaluation (pass/fail) to the NT**			
	* The immediately nursing student–NT cooperation is possible					

 Table 3 Procedures of the cooperation.

The immediately nursing student–NT cooperation is possible ** The nursing student–NT cooperation is possible after the email has sent

**** The nursing student–NT cooperation is possible after the clinical practicum at the UAS

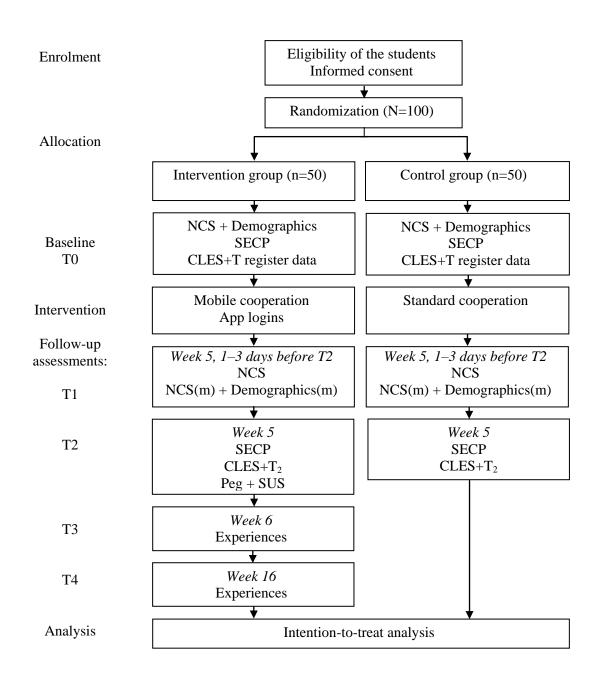


Figure 1 The CONSORT flow diagram of the study. m, data collection from mentors, all other

data from students; CLES+T register data, data collected in the study hospitals.