


BMJ Open Online training to improve evidence-based leadership competencies among nurse leaders in Finland and China: study protocols for two randomised feasibility trials

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To cite: Välimäki MA, Kirsi H, Yang M, *et al.* Online training to improve evidence-based leadership competencies among nurse leaders in Finland and China: study protocols for two randomised feasibility trials. *BMJ Open* 2023;**13**:e067306. doi:10.1136/bmjopen-2022-067306

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-067306>).

Received 09 August 2022
Accepted 31 July 2023



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ABSTRACT

Introduction This study protocol describes two randomised feasibility trials that will evaluate the feasibility and preliminary effectiveness of an online training course to improve evidence-based leadership competences among nurse leaders working in hospitals in Finland and China.

Methods and analysis Two randomised, parallel-group studies will be conducted separately: one in Finland (n=140) and one in China (n=160). Nurse leaders who fulfil the eligibility criteria will be randomly allocated (1:1) to participate in either the online evidence-based leadership training or conventional online training (reading material only). The primary outcomes will be acceptance of the online course (logging into the platform) and adherence in the online course (returned course tasks and drop-out rate of the participants). The secondary outcomes will be acceptance of the study regarding recruitment, feasibility of the eligibility criteria and outcome measures and potential effectiveness of the online course on leadership skills, evidence-based knowledge, attitudes, practice, self-efficacy, self-esteem and intention to leave. In addition, the feedback will be asked after the course.

Ethics and dissemination Two separate trials have received ethical clearance from local ethics committees (12/2022 in Finland, E2021167 in China). Permission to conduct the study will be granted by hospital authorities. All participants will provide electronic informed consent before baseline data are collected. The trial results will be published locally, nationally and internationally in professional and peer-reviewed journals, and shared at national and international meetings and conferences.

Trial registration numbers NCT05244512; NCT05244499.

INTRODUCTION

The role of nurse leaders is important in ensuring a high quality of care, patient outcomes and organisational efficiency.^{1 2} Although the use of scientific evidence and embracing an environment of continuous

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Skilful nurse leaders able to use research evidence in decision making are crucial for modern and effective healthcare services.
- ⇒ A systematic, evidence-based leadership training course will be developed for the first time and tested in Finland and China.
- ⇒ Evaluating the feasibility and effectiveness of training programmes is relevant to ensure high quality on-the-job training in health and social care settings.
- ⇒ Differences in language and culture norms of participants might present challenges.
- ⇒ Possible contamination between the experimental and control arms cannot be ruled out since individual-level randomisation will be used in this study.

learning are essential to quality practice, nurse leaders have been slow in adapting evidence in their own work.³ Decisions made by nurse leaders are often based on past experience, intuition^{3 4} and personal views,⁵ leading to an unhealthy work environment, staff dissatisfaction, absenteeism and high turnover.⁶ One of the key competencies that nurse leaders should have is the ability to understand the role of evidence-based knowledge in practice;⁷ this can be an important part of evidence-based culture and approaches in health organisations.^{8 9} Therefore, nurse leaders should be better equipped with evidence-based leadership competencies to perform their daily work.^{10 11}

There is a limited knowledge available on how nurse leaders themselves base their managerial decisions on evidence¹² and how these competencies are most effectively learnt. A report in *The Lancet*¹³ highlights the importance of evidence-based healthcare



knowledge, skills and attitudes, and suggests critical reasoning that can guide the capacity to search, analyse, assess and synthesise information for decision making. Evidence-based decision making refers to how the best available scientific evidence is used and further incorporated in making managerial decisions.¹⁴ Combining small group discussions, case-based teaching, computer laboratory sessions with didactic lectures and e-learning have been proposed as useful evidence for achieving the intended knowledge and skills outcome.^{15 16} Shek *et al*¹⁷ conducted a study in Hong Kong about students' perceptions of online learning methods used to teach leadership in healthcare contexts in generally. The results showed that participants had positive perceptions of both online synchronous lectures and online blended learning to learn leadership issues. However, this study did not focus on specifically on learning evidence-based leadership.

Therefore, we systematically searched PubMed (MEDLINE) for published systematic reviews related to the effectiveness of training interventions to improve evidence-based leadership or decision making among nurse leaders. The search yielded 32 systematic reviews, but none of them focused on the effectiveness of training on evidence-based leadership. We also searched existing systematic reviews using Epistemonikos database and found 12 hits; only one systematic review was related to evidence-based leadership. Geerts *et al*¹⁸ conducted a systematic literature review on evidence-based leadership development for physicians. The authors concluded that, by using development programmes, it is possible to improve physicians' individual-level outcomes, such as knowledge, motivation, skills and behaviour change. These programmes can also substantially improve organisations and benefit the outcomes of patients. Some of the most effective interventions to improve leadership skills include interactive workshops, videotaped simulations, peer and expert feedback, multisource feedback, coaching, action learning and mentoring. Another systematic review¹⁹ found that lack of leadership and non-evidence-based leadership practice in nursing context was associated with lower job satisfaction and poor emotional health, which was closely associated with nurses' intent to leave and actual retention. These issues can further influence staff safety, quality of care and patient outcomes such as mortality.²⁰ Studies have shown that evidence-based leadership among nurse leaders is also critical for the advancement of evidence-based practice (EBP) among staff nurses.²¹ Evidence-based nursing has been found to have a positive impact on the treatment compliance, quality of life and self-efficacy of patients.²² However, none of the previous systematic reviews evaluated the effectiveness of evidence-based leadership. Therefore, robust randomised controlled trial (RCT) study designs are needed to be able to determine the effective type of intervention for increasing nurse leaders' competence in using evidence-based knowledge in their decision making in nursing context globally.

Before undertaking a full RCT to evaluate the effectiveness of interventions related to evidence-based leadership, however, some methodological and practical questions should be addressed, such as what are the most suitable training components of supporting leadership skills,⁹ what are the best learning methods²³ and what might be the most suitable length of an intervention.²⁴ We also need to better understand how participants' engagement could be supported in training courses.²⁵ As rigorous research designs are needed to capture the complexity of interventions in improving leadership abilities,²⁶ we will explore feasibility of the study and outcome measures to estimate the parameters required to design a definite RCT study for evaluating the effectiveness of online training to improve evidence-based leadership competences among nurse leaders. Two randomised feasibility trials will be conducted parallel: one in Finland and one in China. In these two countries, we will test the feasibility of methods and procedures, and search for possible effectiveness factors that could warrant a larger scale RCT study in the future.²⁷ We assume that if the study is replicable in different sites under different healthcare conditions, the credibility of the study might be strengthened in the future.²⁸ The knowledge gained in these two trial studies can also be used to create cross-cultural design strategies for a global audience.

AIM AND OBJECTIVES

The overall aim of these two feasibility trials is to explore feasibility of the study and outcome measures to estimate the parameters required to design a definite RCT study for evaluating the effectiveness of online training to improve evidence-based leadership competences among nurse leaders. The primary objectives are to assess nurse leaders' acceptance of an online course, the feasibility of the RCT study design and the potential effectiveness of the online training courses to improve outcomes related to nurse leaders' leadership skills, EBP, knowledge, attitudes, self-efficacy, self-esteem and intention to leave. In addition, the feedback will be asked after the course.

METHODS AND ANALYSES

Trial design

In this replication study (repetition of the complete design), we will use an individually randomised, two-arm parallel-group controlled feasibility trial design. The study will be run simultaneously in Finland and China from around June 2022 to March 2023. This protocol follows the Consolidated Standards of Reporting Trials (CONSORT 2010) statement extension to randomised pilot and feasibility trials.²⁹ The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)³⁰ checklist was also used to guide the study methodology. In addition, intervention elements in the experimental group are based on the template for intervention

	STUDY PERIOD		
	Enrolment	Allocation	Post-allocation
TIMEPOINT	$-t_1$	0	t_1
ENROLMENT:			
Eligibility screen	X		
Informed consent	X		
Allocation		X	
INTERVENTIONS:			
Experiment group		◆	◆
Active control group		◆	◆
OUTCOME ASSESSMENTS:			
Baseline			
Characteristics of the participants	X		
Feasibility outcomes			
<i>Primary outcomes</i>			
Acceptance in recruitment (or refusal)	X		
Feasibility of the eligibility criteria	X		
Retention in follow-up			X
<i>Secondary outcomes</i>			
Acceptability of the course			X
Adherence on the course			X
Feasibility of the outcome measures	X		X
Feasibility of the outcome domains	X		X
Potential effectiveness			
Leadership skills	X		X
Evidence-based knowledge	X		X
Evidence-based attitude	X		X
Evidence-based practice	X		X
Self-efficacy	X		X
Self-esteem	X		X
Intention to leave	X		X
Final feedback			
Course feedback			X

Figure 1 The modified SPIRIT figure for enrolment, intervention and assessments. SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

description and replication (TiDier) checklist.³¹ The overall schedule is illustrated in [figure 1](#).

The study's methods and procedures will be repeated in different contexts and with different subjects in Finland and China. This will be done to assure that results are reliable, valid and generalisable for different locations, subjects and cultures. Direct replication will be adapted: an experimental procedure will be replicated to as exact a degree as possible in another context in terms of design, equipment, learning material, intervention and statistical analysis. However, language, specific learning technology and time restrictions of the study will be adapted based on the local requirements in the two countries.

Settings and locations

The study will be conducted and reported separately in Finland and China. Nurse leaders will be recruited from two hospital districts (four in total). In Finland, two hospital districts were selected as their hospitals represent typical Finnish public hospital organisations. These hospitals have a total of 140 nurses in managerial positions. The Nordic country of Finland has a population

of 5.5 million citizens³² and about 116 000 registered nurses.³³ The Finnish healthcare system is based on public healthcare services. Municipalities are responsible for organising and financing healthcare services based on their taxation systems. Municipalities can fund services by themselves, in collaboration with other municipalities or by purchasing services from private companies or other healthcare organisations.³⁴ In year 2023, the responsibility for organising public healthcare will be transferred from municipalities to well-being services counties.

Nurse leaders in China will be recruited from two hospitals in one province. These two hospitals have a total of 160 nurses in leadership positions. China is the largest Asian country, with over 4 million registered nurses providing care for 1.4 billion people. The three-tiered healthcare delivery system operates at county: township, village levels in rural areas and at province, city and community levels in urban areas.³⁵ The government-owned health sector is the main healthcare provider. China has three main basic health insurance schemes: rural and urban resident-based health insurance, 70% of which is covered by national

subsidies and employee-based health insurance, which is funded by employer and employee contributions.³⁶

Eligibility criteria for participants

Nurse leaders must have a licence to work as a nurse and an official managerial role at the hospital (eg, Nurse Director, Head Nurse and Charge Nurse). Nurse leaders of any gender will be eligible to participate in the study if they are working at the study sites at the time of the recruitment, either in a full time or part time position. They should also be able to speak, read and write in Finnish/Chinese, willing to join the study based on their own free will and able to give informed consent.

In Finland, nurse leaders are registered nurses or have another type of healthcare degree (eg, radiology nurse), completed as a training programme based on national legislation and decrees. Finnish nurse education is conducted at Universities of Applied Sciences based on the Professional Qualifications Directive of the European Parliament.³⁷ The studies last for 3.5–4.5 years and include a total of 210 ECTS (European Credit Transfer and Accumulation System) credits (1 ECTS credit is 27 hours): 180 ECTS credits include core skills for clinical care and 30 ECTS credits of complementary competence studies that students choose based on their own interests. In total, 90 ECTS credits of the education programme are earned through clinical practice. Nurse students are assessed with national criteria throughout the studies. After earning 180 ECTS credits of general studies, students must pass a national examination to prove their professional competencies in eight areas. The qualification and competence level (European Qualifications Framework, EQF) for registered nurses is categorised at level 6 (out of eight levels) based on The Finnish National Framework for Qualifications³⁸ and the EQF.³⁷ The qualification title of a registered nurse is a Bachelor of Healthcare who can work in different nursing positions in social and healthcare environments (eg, in general healthcare, specialised medical care, social welfare units, the private sector and NGOs) in Finland and other EU countries. However, the qualifications for a nurse leader are not legally defined. Education for nurse leadership is currently provided in academic universities and universities of applied sciences (EQF 7). At academic universities, a Master of Science degree in Healthcare includes a total of 300 ECTS credits and takes about 5 years to complete (including 3 years of bachelor studies and 2 years of master studies). At universities of applied sciences, a master's degree in Healthcare includes 90 ECTS credits, and the planned duration of education is 1.5–2 years (Finnish National Agency for Education, 2023b). Both nurses and nurse leaders are authorised to work in the profession and to use the occupational title granted by the National Supervisory Authority for Welfare and Health (Valvira) published in the public registered database JulkiTerhikki.³⁹

In China, nurses are licensed by the National Health Commission (NHC) after completing college or vocational level nursing education, passing the national

qualification examination and registered on the NHC website. Leadership training for nursing will be offered at the local hospitals. There are five levels of nursing education programmes: (1) vocational programmes (3–4 years after junior high school), diploma programmes (3 years after high school), bachelor's degree programmes (4–5 years after high school), master's degree programmes (3 years) and PhD programmes (4 years).¹ Students in vocational and diploma nursing programmes need to earn 155–175 credits (one credit equals to 16 hours), including at least 8 months in clinical practice,² while students in bachelor's degree nursing programmes need to earn around 194 credits, including at least 10 months in clinical practice. Students who graduate from vocational, diploma and bachelor's degree nursing programmes must take the National Nurse Qualification Examination to gain a certificate to work in clinical settings. By the end of 2021, 80% of the clinical nurses held a diploma-level degree or above. Currently, there is no universal Nursing Leadership course in China for vocational and bachelor's degree students. Only one University in China provides nursing leadership courses for master's degree students. There are different training programmes on nursing leadership for head nurses and nurse directors in hospitals but none of them are based on evidence-based theories.³

Other healthcare professionals (eg, physicians, psychologists and social workers) or nurse leaders off duty during the recruitment period (family leave, long-term sick leave, study leave, or any other reason) will be excluded.

Recruitment

The study will be advertised on the study organisations' websites, bulletin boards, social media and at meetings targeted for nurse leaders at the study organisations. Potential participants in both countries will be identified and screened with the eligibility criteria by the Chief Executive Officer of Nursing according to the human resource data set of each hospital. Eligible participants in both countries (140 in Finland; 160 in China) will receive an invitation to join the study from a hospital contact person by email or WeChat.

In Finland, the email will include an invitation to join the study and a link to study information via Research Electronic Data Capture (REDCap) tools, hosted by the University of Turku. REDCap is a secure, web-based software platform used to conduct research studies.⁴⁰ After becoming familiar with the study information, if interested, participants will give their electronic informed consent (see online supplemental file 1) followed by a baseline survey (background information, baseline data). In China, a link including an invitation letter and study information will be sent through a WeChat group (an instant online chatting platform) created especially for nurse leaders in the two hospitals. The link will be generated by Sojump survey company (www.sojump.com), which has signed a confidential contract with the study team. If the participants are willing to join in the study, they can click the button labelled 'Informed and

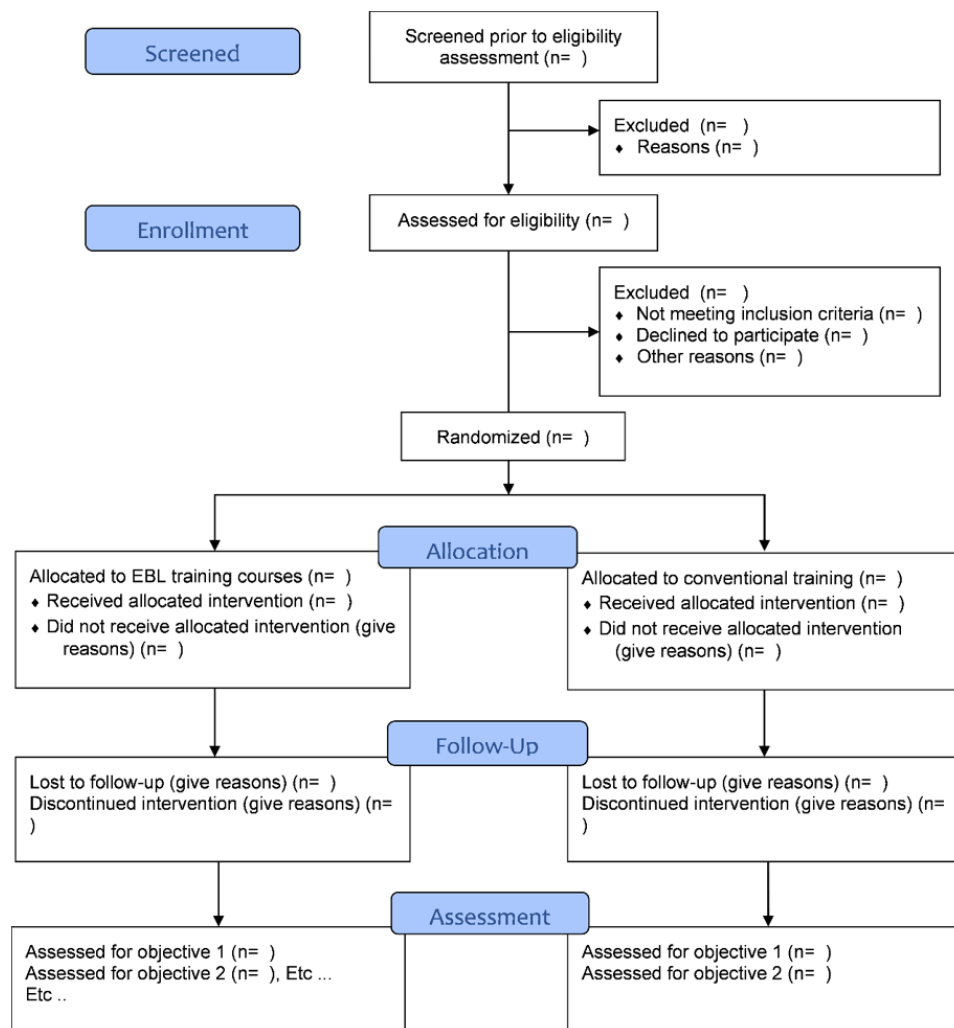


Figure 2 CONSORT diagram reflecting the flow of participants throughout the study. CONSORT, Consolidated Standards of Reporting Trials; EBL, evidence-based leadership.

Agree' (see online supplemental file 1) to access to baseline survey.

The flow of participants for both trials is illustrated in figure 2 using the CONSORT²⁹ flow diagram (figure 2).

Interventions

The aim of the training course is to increase evidence-based leadership competences among nurse leaders in hospital settings. We use the term *leadership* to mean the use of non-coercive influences to coordinate the activities of group members towards the accomplishment of group goals.⁴¹ Participants both in Finland and China will be randomised into two groups: evidence-based leadership training (experimental group) or conventional online training (active control group). Both groups will run parallelly on online learning platforms (Moodle in Finland, Xiaoe-tong in China).

Evidence-based leadership training (experimental group)

Characteristics of the intervention

The online training course **Evidence-based Leadership (EVILEAD)** was developed by the international research team in Finland and China who are experienced in

developing and teaching online courses. The course uses multifaceted learning methods to improve the evidence-based leadership competences of nurse leaders. The course assumes that to lead teams towards their goals and to solve leadership or clinical problems, leaders need the best available evidence combined with good self-awareness, transparency and highly internationalised morals.⁴² The pedagogical approach of the training course is based on Kirkpatrick's (1994) model, which is widely used to produce and assess learning outcomes with a focus on reaction, learning and behaviour.⁴³ The course structure and content were same in both countries.

First, to initiate the learning process, each participant will identify a specific leadership problem to work with during the course; it will act as a reaction for change. Second, learning will be materialised by improving knowledge levels; each participant will familiarise themselves with the learning material on the learning platforms. Participants will also be supported in group discussions and with encouraging feedback offered by tutors with the aim of keeping the participants' attitudes towards evidence-based approach positive. Third, the participants



will gain hands-on skills in how to seek out evidence-based scientific literature. They will also combine information based on organisational information and stakeholder analysis to gain a deeper understanding of the problem to be solved. A reflective learning approach will support the confidence of the nurse leaders in using evidence in their work, while also supporting their self-efficacy and self-esteem. In addition, transparency and ethical sensitivity will be encouraged through small-group discussions.⁴² Fourth, participants will identify solution for their problem based on evidence, implement it into practice and evaluate its impact.

Delivery of the intervention

The training will be delivered online in groups (max. 15 participants). Participants will be able to study at work or at home according to a prestructured schedule. The active study time of the course includes seven modules and a final assessment task to be completed in 7 months including holiday periods, etc. The duration of each module varies from 1 to 6 weeks depending on the learning goal and specific activities required. The structure of the course will follow the steps of the evidence-based approach: (1) each practitioner will identify their own leadership problem in daily practice; (2) organisational data will be collated and analysed to increase the understanding of the key problem; (3) to find a solution to the identified leadership problem, scientific literature will be searched for, identified and critically appraised; (4) the views of stakeholders will be considered along with ethical implications and (5) all sources of information will be implemented into practice, and evaluated in real-world situations.⁴² Each module includes specific learning material and tasks, such as cognitive gains related to a specific topic supported by reading material (power points, scientific articles), peer-group discussions to increase self-awareness and opportunities for peer-supporting, planning and implementing evidence-based solutions into daily practice, and assessment of the impact of changes based on participants' course work. Short assignments (max. 500 words) will help to demonstrate participants' learning.

Trained, native tutors with an academic, evidence-based knowledge and/or healthcare professional background will be responsible for mentoring each module. Each tutor will mentor one group and follow their learning process from beginning to the end of the course. Tutors will also monitor participants' activity, answer any practical questions related to the course via group chat, give feedback on students' assignments and support written peer discussions and self-reflections throughout the course, end them encouraging messages.

Conventional online training (active control group)

The total length and specific topic of the course and each module are identical with those of the experimental group. The participants will access the learning platform for independent reading and respond to self-reflective

tasks. No support from tutors or peer-groups will be offered.

Outcomes

Primary outcomes

Acceptability of the intervention

The degree of execution (success and failure of execution) of the intervention protocol will be determined by calculating the number of logins for each module and all participants.

Adherence in the course

Adherence in the course will be determined by calculating the number of returned course tasks out of all possible tasks.

Adherence in the course tasks

Adherence in the course tasks will be determined by calculating the number of returned course tasks by each participant.

Drop-out rate

The drop-out rate will be determined by the number of participants who have left the study early (no follow-up data).

Secondary outcomes

Acceptability in recruitment

Acceptability in recruitment will be determined by the number of nurse leaders who accept (or refuse) the invitation to participate in the research study.

Feasibility of the eligibility criteria

Feasibility of the eligibility criteria will be determined by the number of nurse leaders who fulfil the eligibility criteria.

Feasibility of the outcome instruments for measuring the potential effectiveness of the online course

Feasibility of the outcome instruments for measuring the potential effectiveness of the online course will be determined by the number of missing variables of each returned instrument.

Leadership skills (Multifactor Leadership Questionnaire, MLQ)

The primary endpoint with respect to effectiveness of the training course will be an improvement in the leadership skills of nurse leaders from baseline to follow-up, measured immediately after the intervention with the Multifactor Leadership Questionnaire.⁴⁴ The MLQ measures how individuals perceive themselves regarding specific leadership behaviours with 45 items: 36 items of leadership styles and 9 items of leadership outcomes. Each item uses a 5-point behavioural scale (0=not at all to 4=frequently if not always). The total score of the MLQ will be calculated by summing the scores of the items, with a score range of 0 to 180. A higher score would indicate that an individual more frequently displays a specific leadership style. The MLQ has been found to have acceptable face validity, content validity, construct validity and internal

consistency with nurses.⁴⁵ The scale has been found to be reliable for these four dimensions (Cronbach's alpha total 0.870, range for dimensions 0.688–0.781).⁴⁶

Evidence-based practice, knowledge and attitudes (Evidence-Based Practice Questionnaire, EBPQ)

The Evidence-based Practice Questionnaire⁴⁷ is a self-administered questionnaire that assesses the implementation of EBP. It includes 24 items (1–7) with three subscales.

- ▶ The 'knowledge/skills' subscale has 14 items, and the range of the sum score varies between 14 and 98, where a higher score indicates greater knowledge in EBP.
- ▶ The 'attitudes' subscale has four items (range of the sum score 4–28). A higher sum score represents more a positive attitude toward EBP.
- ▶ The 'EBP' subscale has six items (range of the sum score 6–42). A higher score is associated with more use of EBP.

The total score of the instrument ranges from 24 to 168 with higher scores indicating positive attitudes towards EBP and its clinical efficacy.⁴⁸ The instrument is widely used, and its Cronbach's alpha coefficient for the entire questionnaire has been found to be good, 0.87.⁴⁷

Self-efficacy (General Self-Efficacy Scale, GSE)

The General Self-Efficacy Scale⁴⁹ is designed to assess optimistic self-beliefs for coping with a variety of difficult demands in life. Self-perception of self-efficacy is assessed with 10 items using a 4-point Likert scale (1=not at all true, 4=exactly true). The item responses are summed up to create a score that ranges from 10 to 40; a higher score indicates better coping abilities. Its psychometric properties have been found to be adequate in a review of studies from 25 countries, in which Cronbach's alpha value for the total sample was 0.86.⁵⁰

Self-esteem (Rosenberg Self-Esteem Scale (RSE))

The Rosenberg Self-Esteem Scale⁵¹ is a self-report instrument for evaluating individual self-esteem. A 10-item unidimensional scale measures global self-worth by measuring both positive and negative feelings about the self. All items are answered using a 4-point Likert scale format ranging from strongly agree to strongly disagree. Five items are reverse scored. The sum score varies from 10 to 40; higher scores indicate higher self-esteem. The instrument has demonstrated a good alpha coefficient of 0.90.⁵²

Nurse leaders' intention to leave

Three items were developed for the study to describe nurse leaders' intention to leave: (1) 'In the last 6 months, how often have you planned to leave your ward?'; (2) 'In the last 6 months, how often have you planned to leave your hospital?' and (3) 'In the last 6 months, how often have you planned to leave your profession?' Five possible answers will be used: 0=never; 1=now and then; 2=quite often; 3=very often; 4=all the time.

Course feedback

After the course, nurse leaders' feedback will be collected with eight items developed for the study: (1) 'This course was appealing to me'; (2) 'I felt happy when I participated in the course'; (3) 'Participation in the course required too much effort from me'; (4) 'It was worth participating in this course'; (5) 'I found this course valuable'; (6) 'I was able to meet the requirements of the course'; (7) 'This course fits well with my personal values' and (8) 'I would recommend the course to others'. Participants will consider the propositions with five possible answers (1=completely disagree; 2=disagree; 3=neither agree nor disagree; 4=agree; 5=completely agree). Possible contamination of the study groups will also be investigated.

Characteristics of the participants

The following information will be collected from the participants: email address, specialty, age, gender, degrees, position, the length of working as a nurse leader and the total length of time working in the healthcare services. The specific background characteristics will be tailored based on respondents' country and its educational and health service system.

Sample size calculation

As this will be a feasibility study, a formal sample size calculation will not be performed for the feasibility outcomes. We will invite 140 nurse leaders in Finland and 160 in China, observe the success of the recruitment with these numbers.

For the future purposes, the study would be powered for the leadership skills. We systematically searched for but have been unable to find any directly relevant published work. Gafni Lachter and Ruland⁵³ evaluated the effects of peer-mentoring to promote professional and leadership skills using the Multifactor Leadership Questionnaire (MLQ, 45 items). Their study showed that improvement in leadership skills was found pre–post assessment, before and after the intervention (MLQ pre-test mean 2.51 (SD 0.32), post-test mean 2.70 (SD 0.26), $F 15.394$, $p < 0.001$). Based on their study, a sample size of 76 was suggested with a 90% power at a 5% significant level (Software PASS V.11). For our possible intervention effect as a full trial, based on the sample size calculation, assuming an effect size of 0.50 for the primary outcome, an alpha level of 0.05 and a test power of 90%, a total sample size of 140 randomised participants might be needed (Software PASS V.11). Some indirect measures from previous studies described above suggest that, if successful in recruitment, our sample of 140 collected separately in both countries might be large enough to show the effectiveness of the intervention. If not successful, the results of our feasibility study can still be used as groundwork of the power calculation for the main study.

Interim analysis and stopping rules

For practical reasons, we will stop the trial early if nurse leaders cannot be recruited or a majority of nurse leaders

drop-out of the study because of COVID-19 or another extraordinary situation. The study does not have the Data monitoring Committee.

Randomisation and masking

Eligible, consented participants will be randomly assigned (1:1) to one of two parallel groups, either the evidence-based leadership training or the active control group. The computer-generated randomisation list will be developed separately for Finnish and Chinese participants by an independent trial statistician at the University of Turku (Department of Mathematics and Statistics), who will have no subsequent involvement in the trial. Random permuted blocks of randomisation will be used to ensure balance between the study groups.

In Finland, after an eligibility screening of the participants conducted by the Training Coordinator, an assignment of the participants will be conducted using REDCap software.⁴⁰ Outside statistician will do allocation of the randomisation using REDCap, and the Training Coordinator will receive the randomisation results from trial statistician. The participants will be registered for the study groups and sign each student to the specific Moodle platform based on the randomisation results. The participants will be encouraged to not share their allocation results. Due to the intervention type, neither the participants nor the researchers can be blinded to the allocation. The randomisation results will be masked to the other staff members in the hospitals until the intervention has been conducted and all data are collected. The statistician who will conduct the data analysis will be blinded to the study groups and have no interaction with the participants.

In China, as soon as the participants have given the electronic informed consent and the baseline data have been collected through the online survey platform, a researcher will ask about the participants' allocation group from the trial coordinator outside the study group. The trial coordinator (not involved in other study procedures) will allocate participants to the study groups based on the randomisation list, and inform the Chinese Training Coordinator about the result. As in Finland, the participants will be encouraged to not share their allocation results. The randomisation results will be sealed from other hospital personnel until the intervention has been conducted and all data are collected. Again, the statistician who will conduct the data analysis in China will be blinded to the study groups and will have no interaction with the participants.

The follow-up data will be collected electronically in both countries after the interventions (about after 7 months).

Type of analysis and missing data

All analyses will be based on the intention-to-treat (ITT) principle. If some outcome data are missing, an evaluation will assess whether they are missing in balanced numbers across the intervention and control groups. Reasons for

missing data will be examined. The same procedures will be used for the secondary outcomes.

Data management and statistical analysis

In Finland, the baseline and follow-up data will be managed with REDCap,⁴⁰ which is a secure web-based platform for conducting research studies (hosted by the University of Turku). The data will be later stored in Seafile along with other study material. Seafile is a secure cloud storage service provided by the university's IT services. The statistician and PI (Principal Investigator) will have access to the data in the study. In China, the data will be saved on the Sojump platform, which is a secure survey platform with a confidential contract with the study team. Later, the data will be exported and stored on an offline computer with password protection. Each data set will be stored and analysed only in its country of origin.

Primary and secondary analyses will be performed on an ITT basis out of all enrolled participants. Regarding secondary outcomes, the population will consist of all participants randomly assigned to the intervention strategies with data on the baseline assessment available.

Feasibility will be evaluated using descriptive statistics. There are three components in the analysis that are important for information required by the full trial to be conducted in the near future: (1) missing data quantity, mechanism and reasons; (2) statistical features of outcome measures and (3) test efficacy of training intervention and power of the test. The missing data analysis will involve descriptive statistics and logistic regression to identify factors associated with missing data, and sensitivity analysis on missing data handling approaches such as imputation or mixed-model analysis. Statistical features of important outcomes shall include examining distribution, mean, SD or proportion of outcomes by trial groups. The preliminary efficacy of the intervention will be examined by comparing secondary outcomes related to the preliminary effectiveness between the two groups, using recommended statistical methods for trial data. The test power of possible group differences in each outcome measure based on the final number of participants will be calculated for later study purposes.

Statistical analyses will be carried out with SPSS IBM V.27, SAS System for Windows, V.9.4 (SAS Institute) or R statistical software (R Core Team, 2016).

Patient and public involvement

An Expert Group of nurse leaders has been established both in Finland and China. The research team have worked with the Expert Group in close partnership to receive feedback on the study. The relevance of the research questions and outcome measures have been discussed with the Expert Group. They have also given feedback on each intervention module and suggestions for how to smoothly carry out the study in clinical settings. The recruitment process and how to conduct the study is based on the ideas of the Expert Group. Regular meetings with the Expert Group will continue to assess any burdens

of the intervention and any problems with the time required to participate in the research. A more detailed dissemination plan will be devised together. Further, the members of the Expert Group will have an important role in sharing the study results at local and national events via seminars and conferences, and through writing professional papers. Patients are not involved in the Expert Group as they are not a primary target group of the study.

Role of the funding source

The funder of the study will not have any role in the study design, data collection, data analysis, data interpretation or in writing the report.

ETHICS AND DISSEMINATION

The trials in Finland and China will be conducted according to globally accepted standards of good clinical trial practices (as defined in the ICH E6 Guideline for Good Clinical Practice).⁵⁴ The general principles of the Declaration of Helsinki⁵⁵ and local ethical regulations will guide practical arrangements of the study. In Finland, the Finnish National Board on Research Integrity will offer more detailed guidance to promote the responsible conduct of research and prevents research misconduct.⁵⁶ The protocol has been approved by Ethics Committees in Finland (12/2022) and China (E2021167). The trial results will be shared locally, nationally and internationally including being published in professional and peer-reviewed journals and presented at national and international meetings and conferences. The anonymised data sets⁵⁷ will be publicly available in OSF (Open Science Framework) as soon as the data have been collected and analysed. Important modifications for the protocol will be communicated to trial registers and ethical boards. In addition, the modifications will be reported in the manuscript for target journals.

The data will be processed in a fair manner and under the rules of the European Union's (EU) General Data Protection Regulation⁵⁸ in Finland and the Personal Information Protection Law of the Mainland approved by the National People's Congress⁵⁹ in China. The data will be collected with participants' informed consent.^{58 59} To secure participants' personal information, access to the local learning platform will not be allowed outside the country. All data analysis will be conducted separately in Finland and China using the same analysis procedures. The participants will have the right to withdraw their participation, to access their personal data, to demand that the data are rectified or deleted, to restrict the processing of personal data and to lodge a complaint if they consider violation of applicable data protection laws to have taken place.^{58 59}

DISCUSSION

This study aims to generate information about feasibility and preliminary evidence of the effectiveness of an online

training course to improve leadership competencies of nurse leaders. The primary aim is to assess the feasibility of conducting the future definitive RCT: whether the future trial can be done and should be done, and what might the possible flaws be in conducting this type of study in the real world.²⁹

We will replicate the same study design in two countries: Finland and China. Replicability—the ability to obtain the same result when an experiment is repeated—is fundamental to science.⁶⁰ Replication involves following the methods and procedures of a study to ensure that the findings and any theoretical conclusions are valid.⁶¹ We will therefore assume that if the study methods are usable in these extremely different countries, the study's procedures and results might be generalised later for larger applications and future research scopes in different settings. On the contrary, if controversial results are identified, future researchers will be better equipped to adapt the study design and procedures for their local context. In addition, catching and verifying mistakes in design, methods or procedures in different settings in early stages of the study could provide a practical contribution to future studies by preventing flaws and mistakes more widely.

One may still argue that it is too time consuming or costly to replicate the study in two contexts at the same time. It has also been argued that behaviour itself is sensitive to context, and that this context is always socially, culturally and historically highly variable. Therefore, we cannot expect the same experiment to have the same effect in different circumstances.⁶² Examples of context-specific indicators include the role of students and remote learning in teaching. For example, in China, the teachers have long led the teaching process and students are rarely active in learning, while in Western countries, students have more significant role in teaching. Remote learning is also widely used in Western healthcare organisations as part of continuing education, but it is still less systematically used as an education method in China; timely, targeted, systematic model of continuing education in China is missing.⁶³ To get better understanding of the feasibility of online courses in different context, we still believe that it is still worth describing different experiences and assessing impacts of nurse leaders learning in healthcare settings, even when our study progress is expected to be slow and costly.

The study designs of the two trials in Finland and China are almost identical. However, some differences in study arrangements vary for practical several reasons. First, these two study settings differ in geographical location and time zones. Second, healthcare services and how nurse leaders are educated, also differ between Europe and Asia. Third, nurses in both countries are non-native speakers of English, and therefore native languages, Finnish and (simplified) Chinese language, will need to be used in the learning platforms. Fourth, participants in both countries will have their own cultural and organisational habits, which may affect how leadership and learner



roles are seen in hospital organisations. Fifth, separate studies are also necessary from the points of the data protection laws, which limit the flow of personal information between Europe and China. This affects student registration processes, access to learning platforms, data sharing and data combination for further analysis. In addition, inherent variation or unrecognised methodological differences may also occur. These factors may present major challenges, curtailing authentic knowledge production and transfer.⁶⁴ However, experiences gained in these studies could be adopted and disseminated in other countries and sectors of the community using multiple languages. If feasible, the online course could be scalable to optimise resources, which are currently scarce in hospital organisations globally. Therefore, describing the study methods in as much detail as possible will allow other researchers to replicate and build their own study based on our research experiences.³¹

There is a general risk in the study is that due to COVID-19, nurse leaders will be too busy to participate in any extra educational activities. They may already be burdened due to extra workloads and challenging situations in hospitals. Nurse leaders may get sick themselves, which may delay their course completion. The length of the course (without holiday breaks) is 6 months, which may be another obstacle for effective recruitment of participants. On the other hand, although the course is scheduled, the specific timing of the course is flexible. Other ongoing problems are a danger for national strike among nurses in Finland, and nurses' turnover, which may affect nurse leaders' willingness to join any training activities. On the other hand, healthcare organisations have taken more online methods into use in staff meetings, training and inpatient care. This extraordinary situation can also serve as a basis for our intervention because nurses are more knowledgeable of using digital tools. In addition, the intervention centres around the evidence-based approach, which might offer usable tool for any healthcare organisations to solve their clinical and practical problems using evidence-based approaches.

Another possible problem could be contamination of the study groups if nurse leaders share their responses to surveys or even course content with participants in the other study group. To avoid this problem, a cluster randomised study design might be more usable, but not use because of the bigger sample size needed. Even though the nurses will know to which group they belong, it may not have an impact on the study, as long as they do not reveal their tasks to those in the other group. If this does happen, it is not probable that nurses would independently start to prepare themselves for the tasks included in the experimental group as they require extra self-reflection and support not available for nurse leaders in the control group. In addition, the structure and content of the online courses are same in both countries. As leadership styles might be different in Western and Asian countries, nurses may find obstacles during the study process due to differences in local cultures in both

countries and treatment systems. For example, Rockstuhl *et al*⁶⁵ highlighted based on their study with 68 587 participants from 23 countries, that although staff members are universally sensitive to how their leaders treat them, members' responses in Asian contexts could be influenced by collective interests and role-based obligations. Therefore, in our study, we attempted to keep ourselves culturally sensitive when appropriate learning methods, content, outcomes and instruments were selected to be used in both countries. In addition, due to cultural, geographical and differences in procedures, training and possible competences between Finland and China may cause challenges in study replication. Although research teams in both countries are working closely together, replicating more recent research, especially projects making controversial claims, may be extremely challenging.

Despite these proposed challenges, the content of the course is timely and aims to offer a solution to nurse leaders' current leadership problems. If well adapted, the model of evidence-based leadership could be integrated into nurse leaders' daily activities, not as a separate part of their work. As the course includes elements of self-reflection and peer-support, and nurse leaders might also find some emotional relief from the stress of their hectic work environment. If successful, the intervention could be sustainable for other target populations in different work environments, healthcare specialities and cultures.

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Acknowledgements We want to thank all hospital organisations that allowed us to test the training programmes, and the University of Turku and the Central South University for the infrastructure of the study.

Contributors The study was conceived and designed by MAV and XL. MV initiated the study protocol and received the grants for the study. KH offered her help in drafting the final study protocol, MY and EL developed the statistical analysis plan and MY planned the sample size calculation. XL contributed to the protocol by commenting on and editing the protocol draft. SH, GL, TL, KH, JV, YT, WC and JC commented on the manuscript drafts. All authors read and approved the final manuscript of the protocol.

Funding The study is funded by the Finnish National Agency for Education, Asia Programme—Education Cooperation (Evidence-based Leadership in Nursing, Asia Cooperation, project code 26/270/2020), and the University of Turku, Finland (internal fund 26003424), obtained by MV. XL is supported by Central South University, China (education ideological reform project for postgraduate course of 'Nursing Leadership and Management', project code 51/2020).

Disclaimer The authors alone are responsible for the views expressed in this article, and they do not necessarily represent the views, decisions or policies of their affiliated study organisations or workplaces.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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