

Title page

• Short informative title

Randomized controlled trial on the effectiveness of web-based Genomics Nursing Education Intervention for undergraduate nursing students: a study protocol

• Short running title

Web-based Genomic Nursing Education Intervention

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ABSTRACT

Aim: To describe a randomized controlled trial protocol that will evaluate the effectiveness of two web-based genomic nursing education interventions.

Background: Preparing future nurses to be competent in genetic and genomic concepts is fundamental to ensure appropriate clinical application. However, genetics-genomics concepts are still new in the field of nursing. Little is known about what type and kind of web-based nursing education is effective in improving the knowledge of nursing students. To address these knowledge gaps a web-based ‘Genomic Nursing Education Intervention’ will be developed and compared to an existing online education program.

Design: A randomized controlled trial of two-groups with pre-test and repeated post-testing.

Methods: The Genomic Nursing Concept Inventory, a validated tool, will be used to assess the genetics-genomics knowledge of nursing students. Participants will be randomly allocated to either a control or an intervention group. The control group will receive the standard web-based nursing education, while the intervention group will receive a newly developed web-based education intervention. Outcome measures include the students’ knowledge level of nursing genetics-genomics concepts. Participants will be retested at 3 and 6 months.

Discussion: Current evidence shows that ensuring nurses have adequate education in genetic-genomic concepts is challenging. This study will demonstrate which of two web-based nursing education methods is more effective in teaching genetic-genomic concepts. This research project will better prepare the nursing profession in their careers for the emerging advance technologies in genetics-genomics and personalized healthcare.

Ethical Approval: University of Eastern Finland, Committee on Research Ethics issued STATEMENT 21/2018 in October 2018

Trial registration: This study is registered in ClinicalTrials.gov (ID number NCT03963687) <https://clinicaltrials.gov/show/NCT03963687>

Key words: genomics, genetics, education, web-based, protocol, nurses, nursing, midwives

SUMMARY STATEMENT

Why this study or review is needed

- **What problem did the study address?** Current evidence shows major challenges in ensuring that nurses have adequate education in genetics-genomics concepts. Less is known about what approaches to web-based education are effective to improve the knowledge gaps of nursing students in genetics-genomics concepts.
- **What were the main findings?** This study will determine which type of web-based nursing education is effective in improving the genetics-genomics knowledge of nursing students.
- **Where and on whom will the research have impact?** This research project will help better prepare nurses in dealing with advances in genetics-genomics in their careers.

1 INTRODUCTION

Genomics has the potential to make an important impact on the healthcare system and therefore it is essential that society is prepared for this transformation (International Society of Nurses in Genetics, 2020; Ministry of Social Affairs and Health, 2015; World Health Organization, 2020). Genetic information is currently entering various areas of medicine and nurses play a significant role in releasing the great potential of novel genetic tools in a coordinated way (Calzone et al., 2010, 2013; Finnish Institute for Health and Welfare THL, 2019). Precision medicine is an emerging approach to healthcare that considers genetic and genomic information. Successful implementation of precision medicine in the clinical setting requires nurses to integrate genetics-genomics into their everyday practices (Bancroft, 2013; Calzone et al., 2013; Jenkins & Calzone, 2007; Williams, Feero, Leonard, & Coleman, 2017). In today's genomics era, it is important that genetics-genomics concepts become an integral component of nursing education globally, so the next generation of nurses will be prepared to deliver genome-based healthcare.

The World Health Organization (2020) defines *genetics* as the study of heredity and *genomics* as a field of science that studies the interrelationships of all genes, their functions and combined influence on the growth and development of the organism. Genetics-genomics is advancing rapidly and remarkably changing the way of providing care to our clients (Bancroft, 2013; Sanner, Yu, Udtha, & Holtzclaw Williams, 2013). Genomics is increasingly becoming the center of care and is being included in the prevention, screening, diagnostics, prognostics, selection, and monitoring of treatment for all individuals (Beery, Workman, & Eggert, 2018; Williams et al., 2017; World Health Organization, 2020). If used in a systematic, well-organized, ethical, and lawful way, it offers the long-term opportunity of offering novel approaches to the prevention and management of various diseases (World Health Organization, 2020). This further underscores the importance of genomic nursing care in healthcare service delivery. Nursing programs internationally are charged with preparing a nursing workforce ready to embrace the

complexities of genetics-genomics in their practice, so the benefits of genome science are translated in a way that supports safer and higher quality care (Camak, 2016; World Health Organization, 2020).

1.1 Background

In the digitalized era, it is essential to develop an innovative roadmap with new ways to prepare and adapt to the ever-changing healthcare system needs and circumstances of the modern generation of nurses. What is not clear is how we can prepare our nurses for the revolutionary genomics transformation in healthcare in the context of other issues like understaffing, pandemic crises, and budget restraints. This study will take advantage of the flexibility of using online educational platforms to educate nurses in the field of genetics and genomics.

Millennials (people born between 1981 and 1996) make up the biggest generational group that have grown up connected to media technology. Web-based education is an engaging medium for them and is now widely utilized because it is cheaper, flexible, and more convenient for the learner and teacher. For this reason, it is important to conduct research to discover effective approaches for web-based education. This study will compare two online digital platforms and appraise their effectiveness to better understand the best type of online educational material for the next generation of nurses. In an attempt to address the knowledge gap regarding genetics-genomics concepts among undergraduate nursing students, a ‘Web-based Genomic Nursing Education Intervention’ (GNEI) will be developed and compared to an existing online education platform to evaluate its effectiveness. Preparing the next generation of nurses for the emergence of advanced technologies in genetics and genomics will help shape the future of the nursing profession and advance nurses’ careers.

1.1.1 Gaps and Existing Literature

Nurses are expected to be equipped with the necessary concepts and skills to support genomics innovations and its transformation of healthcare. However, there are gaps in the research literature on how to effectively integrate genomics science in nursing education and clinical practice (Bancroft, 2013;

Camak, 2016; Hickey et al., 2018; Munroe & Loerzel, 2016; Ward, 2017; Ward, Haberman, & Barbosa-Leiker, 2014). Current literature shows major challenges in preparing nurses in the field of genetics-genomics including lack of knowledge, confusion, misconceptions, and inadequate training regarding foundational genetics-genomics concepts (Bancroft, 2013; Hickey et al., 2018; Ward, 2017). Even more difficult in incorporating and utilizing the recent advances in genomic healthcare are the disparities and limitations in genetics-genomics content across nursing curricula (Camak, 2016; Munroe & Loerzel, 2016). Current evidence shows that nurses and nursing faculties have limited genetics-genomics knowledge and competency (Dodson & Lewallen, 2011; Munroe & Loerzel, 2016; Seven, Akyüz, Elbüken, Skirton, & Öztürk, 2015; Thompson & Brooks, 2011).

Nursing students and staff nurses seldom use genetics or genomics data for understanding the uniqueness of patients, nor do they apply this information to deliver personalized care (Dodson & Lewallen, 2011; Munroe & Loerzel, 2016). There are existing gaps in incorporating genetic-genomic concepts into nursing curricula and intensive specialized training is needed to substantially increase students' knowledge of genetics-genomics (Camak, 2016; Munroe & Loerzel, 2016; Ward, 2017). A qualitative study done by Ward (2017) to explore sources of difficulty experienced by nursing students in understanding genetics described three particular challenges: the need to (1) acquire a complex vocabulary, (2) integrate concepts across multiple levels of organization, and (3) reconcile pre-instructional misconceptions of genetic concepts.

Factors that may greatly reduce nurses' professional enthusiasm to learn how to integrate genetics-genomics knowledge include nursing workforce shortages, increased workloads, and the already overflowing curriculum (Chair, Waye, Calzone, & Chan, 2019). Therefore, it is sensible to utilize online education platforms to update nurses on genetics-genomics concepts. At present, there are limited freely available online courses specially designed for nurses to update their knowledge on genetics-genomics (Chair, Waye, Calzone, & Chan, 2019). Thus it is appropriate and timely to design a new web-based

education program and compare it to an existing online education program to better understand which is the most effective online teaching method to update nursing students' knowledge in the field of genomics science.

1.1.2 Theoretical and Conceptual Framework of the Study

This study is guided by E.M. Rogers' Diffusion of Innovation Theory (Rogers, 2003). According to this theory, adoption of an innovation (in this case, genomic education for nurses), is a process that takes time, as people gradually adopt the innovation. When promoting an innovation, it is essential to understand the target population's characteristics (Rogers, 2003). The role of genes and the genomes in health and disease has been well understood with the advancement of genetics and the sequencing of the human and other genomes (Kumar & Antonarakis, 2016). To date, however, genomic science is still new in the nursing profession, compared to other disciplines like medicine where this field of science has been widely adopted. Despite current evidence that genomics technology can contribute to delivering safer and higher quality healthcare service, there are gaps—particularly among nurses—in their education, research, and clinical practice. There is a demand for ensuring the adequate education of health professionals like nurses, especially since research increasingly indicates a rise in ethical dilemmas associated with emerging technologies such as genome sequencing (Lopez-Correa & Patrinos, 2018).

Conceptual Framework of the Study

The conceptual framework of this study (**Fig. 1**) illustrates the integration of three different disciplines: biomedicine sciences, biobank, and nursing sciences. The paradigm shift for nursing career development with a “Genomic Nursing Care Approach” is a sensible response to biomedicine and biobank advanced science that is rapidly and remarkably changing the way we provide care to our clients (Kosma, Mannermaa, & Kujala, 2019; Sanner et al., 2013; World Health Organization, 2020). The conceptual framework of this study is in line with the conceptual model created by Hickey (2018), which illustrates the overlapping sources on which one can build a career as a nurse in the field of genetics-genomics (**Fig.**

2). The conceptual framework of Genomic Nursing Care comprises of three essential elements: education, research, and clinical practice.

2 THE STUDY

2.1 Aim

The aim of this paper is to describe a randomized controlled trial protocol that will evaluate the effectiveness of two web-based genomic nursing education interventions designed to improve the undergraduate nursing student's knowledge of genetics-genomics concepts.

2.2 Objectives

The objectives formulated are:

1. To assess the knowledge gaps of genetics-genomics concepts among nursing students using the Genomic Nursing Concept Inventory (GNCI© 2011) beta-revised version.
2. Evaluate the effectiveness of two web-based nursing education intervention on the outcomes (GNCI scores) of nursing students (baseline, post-test-1, post-test-2).

2.3 Hypotheses

The trial is designed to test the hypotheses at 0.05 level of significance. The hypotheses formulated are:

H1. There will be significant statistical differences in the pre-test, post-test, and repeated post-testing of GNCI scores among nursing students in the intervention arm compared to the control arm.

H2. There will be significant statistical differences in the effectiveness of the newly designed web-based genomics nursing education program compared to the standard web-based genomics nursing education.

2.4 Design and Methodology

A randomized control trial (RCT) with two groups, with a pre-test and repeated post-test will be used in this study. An RCT is preferred to reduce selection bias (Moher et al., 2010). Participants in this study will be randomly allocated to either the control or intervention group. The control group will receive the standard web-based nursing education intervention, while the intervention group will receive the newly

developed web-based nursing education intervention. A single-blind technique will be used, so that participants are not aware if they are in the control group or intervention group. Outcome measures include the level of knowledge of nursing students in nursing genetics-genomics concepts. Data will be collected electronically. This RCT study is unique as it will use the Flipped Classroom Model, which ought to communicate the vital importance of lifelong learning, the taste of learning new things and translating passions and interests into actual knowledge (Talbert, 2017).

2.5 Participants

The target population of this study are undergraduate nursing students at all levels (years 1-4) enrolled in a bachelor level government-established educational institution in either Finland or the Philippines. This includes any educational institution, university, or university of applied sciences fully or partially financed by the government and established by law. Due to the complexity and diversity of participating countries, this study is limited to nursing students who are studying in government-established educational institutions to allow comparison of collected data.

The reason for choosing undergraduate nursing students as a target population is to initiate and ignite students' interest in the field of genomics science at an early stage of their nursing career. As the future frontline of the healthcare workforce, these students play a vital role in the sustainability and career advancement of the nursing profession, and they will bridge the existing knowledge gaps in precision medicine.

Finland and the Philippines were chosen as the two countries participating in this current study as they are both similarly placed with respect to genomics science and nursing and are both relatively new to this rapidly advancing field. In Finland, utilization of genomic data is well positioned as Finnish biobank laws are very progressive and supportive in scientific fields (Ministry of Social Affairs and Health, 2015). In the Philippines, many genetics-genomics services are available and delivered to the whole country

which makes it one of the most active countries in Southeast Asia with respect to genetics and genomics (Padilla & Cutiongco-de la Paz, 2016).

The partnership between a developed and developing country is one of the strengths of this study and it is hoped that this collaboration will be an impetus to achieve the benefits of genetics-genomics transformation in each country's health. The Finnish and Philippines' nursing curricula have some differences as well as similarities. Recent research from a qualitative analysis on the directive and formative stage of Finnish and Philippines nursing curricular shows that nursing education in Finland is 3.5 to 4 years while in the Philippines it is 4 years (Dumo, 2017). While there are differences in terms of the number of nursing courses, academic credits, and clinical practice hours, both countries share the same philosophy and theoretical design in nursing education, and characteristics of nursing graduates (Dumo, 2017). Nursing curricula in both countries also emphasizes provision of care on individuals across settings, families and communities, the roles of nurses in promotion and restoration of health, prevention of diseases, and providing holistic care (Dumo, 2017). Finding strategies to apply genetics-genomics technologies in the healthcare system and integrate genomics science into the nursing curriculum is only beginning in both countries (Ministry of Social Affairs and Health, 2015; Padilla & Cutiongco-de la Paz, 2016). Another strength of this current study is an established international partnership of Finnish, American, New Zealand, and Australian experts who have the background and experience in this field of genomic science and in educating nursing students in genetics-genomics concepts.

Inclusion and Exclusion Criteria

The following are the inclusion criteria for participants: (1) undergraduate nursing students of any year level (1-4years) who are (2) studying in government institutions like a university or university of applied science; and (3) willing to participate in the study. The exclusion criteria include: (1) graduate nursing students (2) students studying in private institutions, and (3) working staff nurses.

2.5.1 Sample size determination

Sample size will be determined based on a G*Power analysis, using the t-test, to measure the difference between two independent means (two groups) to achieve a medium effect size of 0.5. A minimum sample size of 200 undergraduate nursing students will be needed to achieve a power of 94% at 0.05 level of two-sided significance (Cohen, 1992; Faul, Erdfelder, Lang, & Buchner, 2007). In the actual recruitment we anticipate that some participants will drop-out. To reach a meaningful result from the analysis of data, we added a buffer of 50 additional students (n=250) to ensure the validity and robustness of the results.

2.5.2 Randomization

Randomization

The computer random number generator “Research Randomizer” (Urbaniak & Plous, 2018) will be used in the sequence generation process to generate a random sample using the block randomization technique. To give all participants an equal chance of being allocated to the control group or intervention group, the Research Randomizer will generate two sets of 250 unique, sorted numbers from the least to the greatest, with a range from 1 to 2 (1 representing the control group and 2 representing the intervention group). Single-blinding technique will be used to conceal the allocation. Participants will not know if they are given the standard web-based education platform or the newly designed web-based education platform. Using a central allocation web-based-controlled randomization, only the principal investigator will be aware of who belongs to the control and intervention groups. Both nursing education interventions will be delivered via an online platform to reduce the bias anticipated due to knowledge of the allocated interventions. This also means that the blinding of the outcome assessment will be safeguarded, and the time exposure will be controlled. Participants will join the web-based education interventions at the same time during the period of 12 weeks (3 months) and the follow-up time at 24 weeks (6 months).

2.6 Outcome measures

The primary outcome in this study is the level of knowledge of nursing students of genetics-genomics concepts. The Genomic Nursing Concept Inventory (GNCI) will be used to measure the primary outcome variables. The GNCI tool, consisting of 31 multiple item questions, will be used to assess students' knowledge and will determine what learning outcomes are appropriate in designing a new web-based nursing educational intervention. The secondary outcome in this study is the participants' feedback to measure the effectiveness of the online platforms. We will use questionnaires to evaluate participants' self-assessment of learning and program evaluation. In addition, participants will be asked about their preferences in course delivery and how they would like to develop the course. The results of the study will be used to develop and design a course or curriculum to prepare nurses in the field of genomics science.

2.7 Validity and reliability

2.7.1 Study protocol

A panel of experts which consisted of the research team reviewed and finalized the study protocol. The protocol is registered in ClinicalTrials.gov with ID number NCT03963687. URL: <https://clinicaltrials.gov/show/NCT03963687>.

Data collection

Data will be collected electronically using the university's electronic platform. The English version of the GNCI will be used in the Philippines because it is the main language used in teaching and the second native language of the country. In Finland, both English and Finnish versions of GNCI will be used to accommodate both the local and international students. A survey questionnaire will be used to collect feedback from the participants with their learning experiences in utilizing the standard and new web-based genomic nursing education interventions.

2.7.2 Psychometric testing of the instruments

The Genomic Nursing Concept Inventory (GNCI© 2011) beta-revised version is a 31-item scale with demonstrated validity and reliability (Cronbach's alpha values between 0.73 and 0.83). The GNCI will be used in this study to determine the level of knowledge of the participants in nursing genetic-genomic concepts (Ward et al., 2014). The GNCI tool maps particular concepts that are useful to measure the understanding of individual genetic-genomic concepts. Furthermore, because item distractors reflect misunderstandings of particular concepts, analysis of response data identifies specific targets for continuing or remedial education (Ward et al., 2014).

2.8 The Study Procedure

Research Design

Figure 3 represents our research design. First, an introduction of the research study to the research participants will be presented. Consent will be secured electronically; and sociodemographic data will be collected prior to pre-testing of GNCI. The results of the GNCI will be used in the development of a new web-based genetics-genomics nursing education intervention. Research participants at each site will be randomly assigned into two groups: group 1 will be given the standard educational intervention, while group 2 will receive the new educational intervention. Exposure to the educational intervention will be concurrent for both groups over a period of 12 weeks (3 months) to control the time exposure. After 12 weeks of exposure, a post-test using the GNCI will be performed. A follow-up with another post-test of the GNCI will be completed at 24 weeks (6 months). Figure 4 illustrates the Consort Flow Diagram of this RCT study.

2.8.1 Intervention arm

Intervention group: Based on the results from the pre-test of Genomic Nursing Concept Inventory (GNCI), the research team will design a new Web-based Genetics-Genomics Nursing Education which will be given to the intervention group.

2.8.2 Control arm

Control group: The control group will be given the standard education intervention which is available online for more than 20 years to educate nurses in Genetics Education Program for Nurses (GEPN).

2.9 Intervention

In this study, the research team will design a new web-based Genomic Nursing Education based on the preliminary result of the pre-test of the GNCI tool. We will use the Flipped Classroom Methodology as an online education platform. The Flipped Classroom shifts teaching methodology from the traditional teacher-centered approach to a more student-centered learning environment (Talbert, 2017). Using this pedagogical teaching method, the research team will first identify the intended learning outcomes to plan what will happen during the course. After that, analysis will be completed, consisting of comparing the performance between the two groups based on the GNCI scores of the nursing students from the pre-test, post-test (after 12 weeks) and repeated post-testing (after 24weeks). Finally, we will evaluate students' learning experiences and instruction based on the desired results of learning.

2.9.1 New Web-based Genomic Nursing Education (WGNE) Description:

The new WGNE will be a free online course especially designed for undergraduate nursing students. This flexible online course will use video-lectures, quizzes, games, and a literature review and can be completed at home or any other location where the student feels comfortable and has internet access. The web-course will be designed so that there will be no gateways between the different areas of content and students will be able to move forward and backward. At the end of this twelve-week course, students will: (1) understand the genetic/genomic principles, concepts, and mechanisms of how genes influence health; (2) know genomic competencies expected of nurses; (3) be aware of the practical nursing applications of genetic-genomic concepts; and (4) understand ethical, legal, and social implications of genomic nursing practice.

2.10 Data analysis

To evaluate the students learning outcomes, the Revised Bloom's Taxonomy (Anderson et al., 2001) will be utilized. Item-analysis will be used to see what proportion of students answered each GNCI item correctly and among those who answered incorrectly, which wrong ideas students thought were true. Data from the experimental and control groups at each study sites will be analyzed separately. The IBM SPSS (version 25) will be used in data analysis. Demographic variables and other pertinent respondents' characteristics will be summarized using descriptive statistics. Relevant tests of differences will be used to compare the outcomes of the control and intervention groups, as well as differences in the sample from Finland and the Philippines. A university statistician will be consulted.

3 DISCUSSION

The discipline of genomics science is still new to the nursing profession. Most studies in genomic nursing education have been descriptive, few are qualitative studies and most measure perceived knowledge rather than actual knowledge. This study is the first to measure actual knowledge using a RCT. Opportunities and challenges abound to develop effective strategies to integrate genomics into nursing education, research, and clinical practice. To our knowledge, this is the first RCT study within nursing education that compares two online educational platforms. This trial will provide evidence of the effectiveness of these strategies to bridge genetic-genomic knowledge gaps among nursing students. The findings of this RCT will add to the scientific and practical knowledge of the nursing profession and support career advancement in the era of genetics and genomics. Furthermore, by generating a training program, this study will enhance current nursing education in response to the demand to transform healthcare through application of genomics technology and precision medical care.

The Importance of Genetics-Genomics Concepts in Nursing Profession

Genomics technology creates novel approaches for disease prevention and targeted care and brings new opportunities to identify the causes of human health and diseases and enhance healthcare outcomes, quality, safety, and cost savings (McCormick & Calzone, 2016; Ministry of Social Affairs and Health,

2015; Williams et al., 2017). Increasingly, an individual's genetic makeup is used as basis for making better decisions and individualized choices. Genomic information allows healthcare providers to identify the most effective care, precisely-targeted disease screening, and more accurate diagnosis (Bancroft, 2013; Calzone et al., 2013; Chuang, Hsiu Hsieh, & Addullah Charles, 2013; Finnish Institute for Health and Welfare (THL), 2019; McCormick & Calzone, 2016; Santos et al., 2013; Weitzel, Blazer, MacDonald, Culver, & Offit, 2011).

According to the Finnish Institute for Health and Welfare THL (2019), it is important to strengthen healthcare professionals' capacity to apply genome-based information. The effective use of genomic information to improve peoples' health can be done by empowering strategies such as teaching about genomics as part of health education, reforming secondary education curricula, and training healthcare professionals to ensure fair access to genomics services (Camak, 2016; Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Jenkins & Calzone, 2007; Ministry of Social Affairs and Health, 2015; National Geographic Society, 2019; World Health Assembly, 2004). It is essential that nurses acquire adequate knowledge and be equipped with the basic competencies of genetics, genomics and the use of genetic information regardless of academic degree, role, or clinical specialty (Chair, Waye, Calzone, & Chan, 2019). It is necessary to utilize versatile online education to update genetics-genomics education in the curricula, basic training, and continuing professional development of nurses and other healthcare professionals (Camak, 2016; Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Jenkins & Calzone, 2007).

Role of Nurses in the Genomic Era

Research has shown that progress in genetic-genomic knowledge has led to an expanded role for nurses as genetic counselors (Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Hickey et al., 2018; Jenkins & Calzone, 2007; World Health Organization, 2020). Further, the nursing profession can play a crucial role for successful adoption of genetics-genomics discoveries in health care services

(Bancroft, 2013; Beery et al., 2018; Calzone et al., 2010, 2013). As the most trusted healthcare profession, nursing has the responsibility for integrating and translating genomic care into practice (Calzone et al., 2010; Hickey et al., 2018). It is essential for nurses to develop roadmaps on how to include genetics-genomics into nursing practice, education, and research (Calzone, Jenkins, Bakos, et al., 2013; Chuang et al., 2013; Kirk, Calzone, Arimori, & Tonkin, 2011; Lea, Skirton, Read, & Williams, 2011; Williams et al., 2017). In this genomic era, nurses are expected to be competent on the following skills: obtaining comprehensive family histories, assessing which family members are at risk of developing a genomic influenced condition, identifying genomic influenced drug reactions, helping people make informed decisions, understanding the results genetics-genomics tests and therapies, and referring at-risk people to the appropriate healthcare professionals and agencies for specialized care (Calzone et al., 2010; Hickey, 2018; International Society of Nurses in Genetics, 2020; Kirk et al., 2011).

3.1 Strengths and Limitations of the Study

One of the strengths of this study is that it represents a collaboration between Finland and the Philippines and develops a partnership between a developed and developing country. Both countries are similarly placed with respect to genomics science and nursing. It is hoped that this will be an impetus to stimulate the benefits of the genetics-genomics transformation in their respective health systems and lead to improvements in health for each countries' populations. Another strength of this study is the benefit of having a research team which includes research collaborators from the USA, New Zealand and Australia who have already embarked on genomic nursing education in their respective countries. Their expertise can guide and help us in our genomic nursing education programs. Another strength is that this study protocol can also be used for nurses working in other clinical settings like hospitals, the public health sector, and academia. Study findings can also be applied to other healthcare disciplines to determine what basic concepts are needed to support genomics science in their settings. There is also the possibility that the study could also be conducted in other countries in the future.

A limitation of this study is that it is not possible to use the double-blinded technique, as the researchers will know which participants are in the intervention and control groups. We also anticipate that the different nursing curricula in the two countries might affect the results of the study and affect how we compare our data. The complexity of the education systems and research systems could also affect the research timeframe and getting students to participate in the research in a timely manner is also another challenge. To encourage participants to enroll and complete the study, they will be given a certificate of appreciation for participating in the research at the end of the study.

3.2 Generalizability

This study protocol can be applied to other non-academic settings e.g., hospitals and public health sector agencies. The findings of this study can also be applied in other healthcare disciplines particularly defining the concepts needed to support genomics science. In the future, the study can also be feasibly done in other countries.

3.3 Ethical Considerations and Approval

The researchers will adhere to the EU's General Data Protection Regulation (2016/679, GDPR). The Committee on Research Ethics of the University of Eastern Finland reviewed the trial protocol and issued ethical approval STATEMENT 21/2018 in October 2018. Administrative permissions were obtained from the Heads of the participating institutions and universities. To secure safe data transfer from the Philippines to Finland, all data will be encrypted. Participants will be provided a unique identifying code to secure their identities.

3.3.1 Consent process

The participants will be informed about the study and written informed consent will be secured. Participants will have the right to withdraw their participation at any time with no consequences to their academic study, assured by the participating institutions. Participants' privacy, anonymity, and confidentiality will be secured throughout the study.

3.4 Harms

The study does not involve any significant risks and is considered to be low risk. Participants are unlikely to experience any serious harm from participating. However, participants will be encouraged to contact their local student counselling services if they feel distressed during or after completing the surveys and web-based intervention. The results of the 31-item scale Genomic Nursing Concept Inventory (GNCI© 2011) will not affect the academic performance of the students. The purpose of using the test questionnaires is purely for research purposes only.

4 CONCLUSIONS

This study which describes an RCT testing the effectiveness of two online educational interventions will provide evidence-based findings that can guide the design of an online nursing educational program. Nursing leaders, educators and policy makers must include genomics/genetics concepts in the education of the nursing profession to meet the anticipated increasing demand for genomic based nursing care. Upon completion of this study, the most effective educational intervention can then be recommended as an integral part of the future undergraduate nursing curriculum.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the author(s).

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (<http://www.icmje.org/recommendations/>)]:

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

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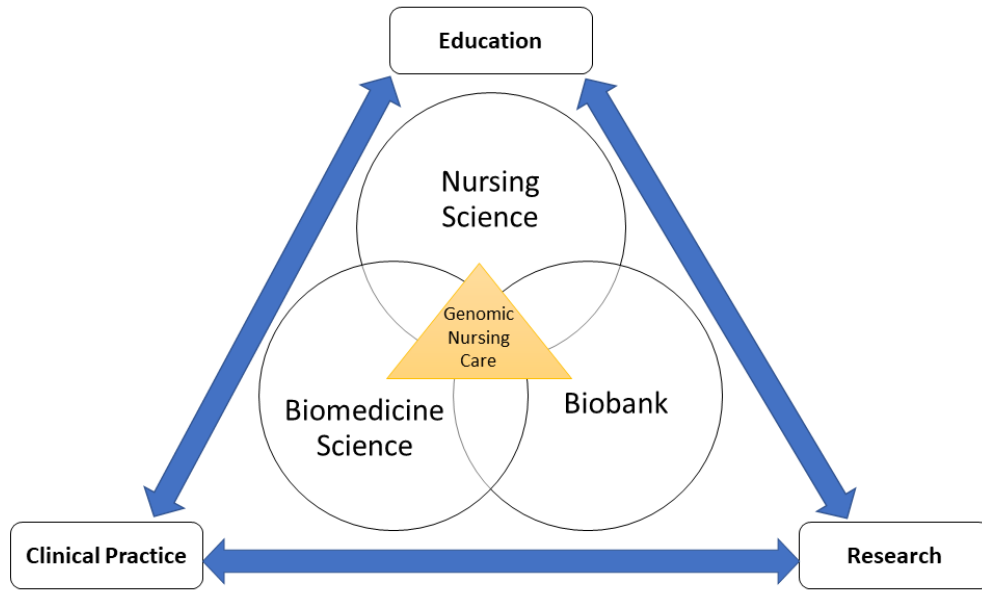


Figure 1. Conceptual Framework of Genomic Nursing Care. Three overlapping disciplines—nursing science, biomedicine science, and biobank—build a career in Genomic Nursing Care, which is central to the circles representing the complex concepts and skills necessary to nursing career development.

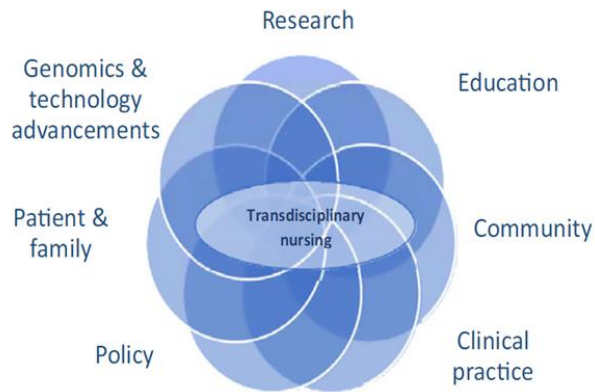


Figure 2. Model of the elements that intersect to develop a career as a transdisciplinary nurse scientist - © Hickey, 2018.

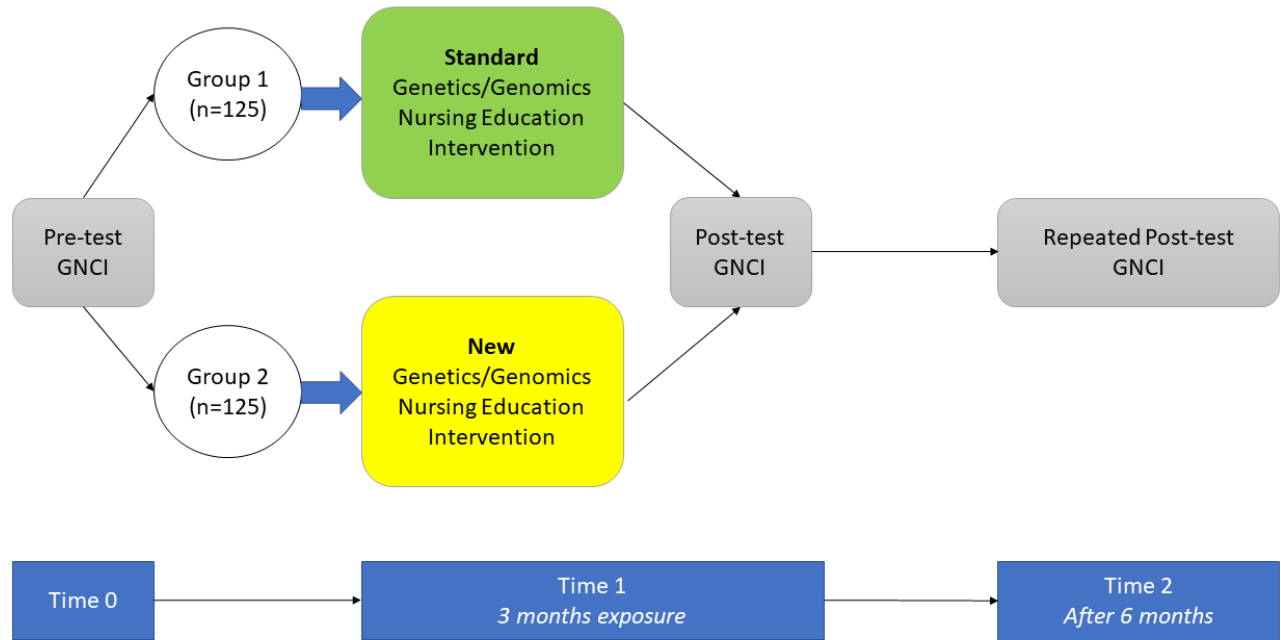


Figure 3. Research Design, RCT of two-group pretest and repeated posttest.

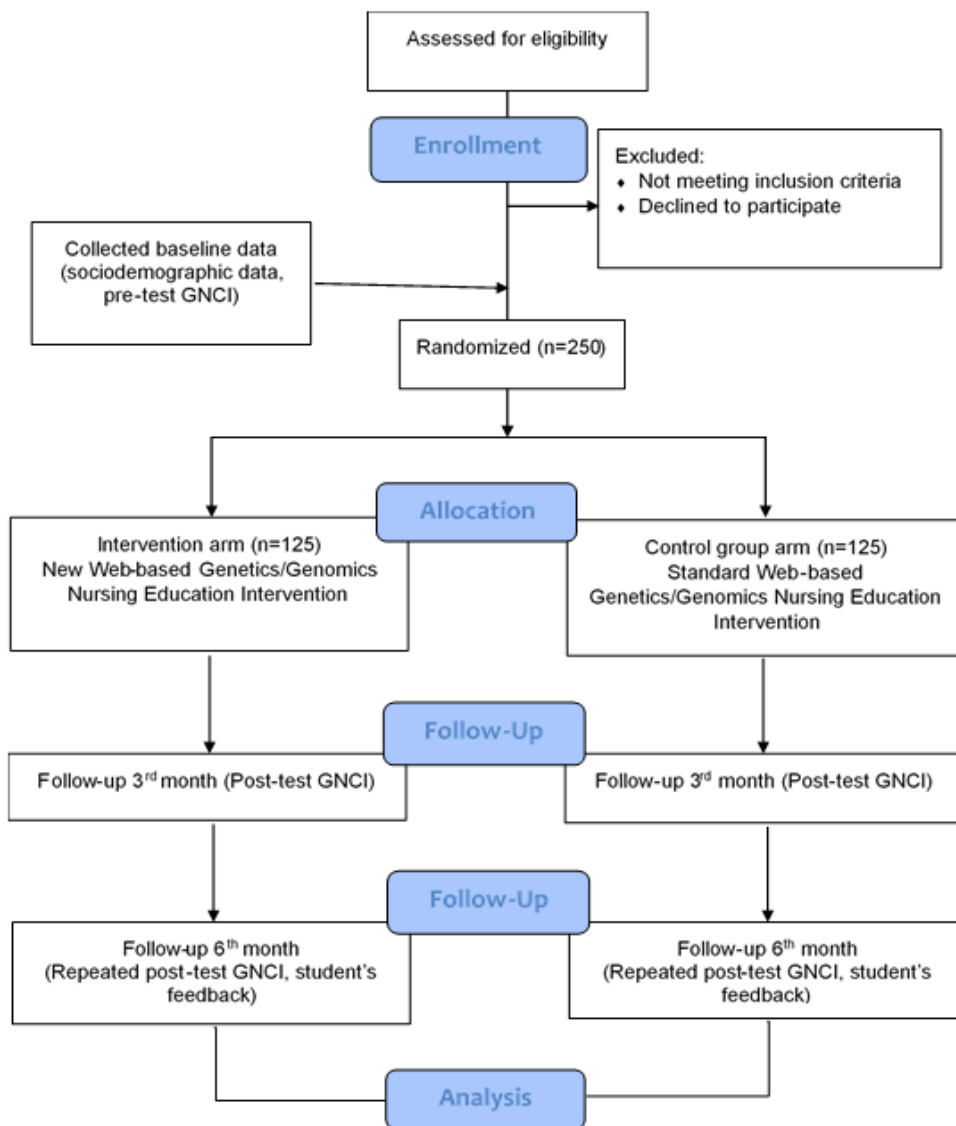


Figure 4. The Consort Flow Diagram of RCT in this study



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title Page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 1
Introduction Background and objectives			
	2a	Scientific background and explanation of rationale	Page 3-6
	2b	Specific objectives or hypotheses	Page 7
Methods Trial design			
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 8-9
Participants			
	4a	Eligibility criteria for participants	Page 9
	4b	Settings and locations where the data were collected	Page 8-9
Interventions			
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 9-13
Outcomes			
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 10-11, 13-14
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size			
	7a	How sample size was determined	Page 9-10

	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 9-10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 9-10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 9-10
	11b	If relevant, description of the similarity of interventions	Page 12-13
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 13-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 4
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 4
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Figure 4
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	-

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	-
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 9-10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 17-18
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 16-17
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 14-17
Other information			
Registration	23	Registration number and name of trial registry	Page 1, 11
Protocol	24	Where the full trial protocol can be accessed, if available	Page 1, 11
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title Page, and Page 18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological

treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.