

Using Normalization Process Theory to Evaluate Providing Pediatric Palliative Care at End-of-Life as Web-Based Training Intervention for Nurses: Study Protocol for a Randomized Controlled Trial

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Abstract

Background: Palliative care is a rather concept that new in Iraq, there is no training intended for both health care specialists and the overall public. The lack of education and training programs is the most important barrier. Intermediate training is needed for individuals regularly at work with patients with life-threatening diseases. The End-of-Life Nursing Education Consortium-Pediatric Palliative Care meant for nurses with an interest in providing care for those children with a life-limiting disease or in the event of accidents and unexpected passing.

Objective: The present paper is intended to evaluate the effect of a web-based course using the Normalization Process Theory, which focuses attention on how complex interventions become routinely embedded in practice and training of the sample academic nurses' staff in the application of the pediatric palliative care in routine daily practice. It hypothesizes that nurses' specialists will help after passing the training in providing palliative care for the pediatric population.

Methods: In a Multicenter, parallel, Pragmatic trial, five health care settings spread over a single city of Babylon Province. Participants will be recruited and stratified to two strata (critical care units and non-critical care units). In the experimental condition, the (n = 86 academic nursing staff) will be trained in the application of the pediatric palliative care, for two weeks as web-based training course powered by Relais platform through inviting the nurses to participate via email, or instant messaging instruct WhatsApp, telegram, Viber account of participants to provide End of life care in addition to usual care to children and adolescents with life-limiting conditions. In the control condition (n=86), continue usual care. The program's effectiveness will be assessed at the level of nurses only. The statistical analyses will compare the baseline assessment for each participant (before the intervention) with a post-intervention assessment (after passing the training course). Moreover, a continuation assessment will occur three months after the course end. As around numerous unidentified factors influencing the effect of the course training, a progress evaluation to evaluate selection sample, application, and intervention value besides difficulties and organizers to implementation will as well be present comprised in the study analysis. The staff of nursing might not be the intervention blinded, nonetheless were blinded for the results.

Results: The study trial recruitment opened in July 2020. The first outcomes are predicted to be available in December 2020.

Discussion: Study object to determine the training effect of the academic nurse staff of multicenter departments\ units with a training course in the application of new pediatric palliative care. The study strengths are the usual practice setting, the staff training, the readiness of staff to participate in the study, and the random allocation to the intervention. Possible drawbacks may drop out because of staff of nursing may well transfer to another department throughout the study period.

Trial Registration: <https://clinicaltrials.gov/ct2/show/NCT04461561>

Keywords: ELNEC-PPC, implementation, Iraq, life-limiting illnesses, pediatric palliative care, pragmatic trial, web-based training

Introduction

Palliative care (PC) is the comprehensive active care for children and young adults, which is considered globally recognized priority in caring for whom with life-limited conditions of death. This recognition was justified by high rates of mortality from cancer specifically. Therefore, a need for skilled, supportive care, pain management, and symptom control at the end of life is approved for PC provision [1,2].

Annually 7 million families could benefit from pediatric palliative care, but those in low- and middle-income countries seldom have such access, while approximately 1.2 million children globally who were more males than females; And they desperately need this type of care and die; for the reason for multiple and varied problems such as birth defects, Malnutrition diseases, meningitis, AIDS, as well as cardiovascular diseases [3].

Universally, in 2011, more than 29 million individuals from a diverse age groups pass away from diseases demanding PC, as the biggest proportion of adults rather than children less than fifteen. Each year in the world, which concerns the age of the present study, just 63 children out of 100,000 population under 15 years old will require palliative care at the end of life [3].

The WHO Presents palliative care as integrated approaches: rules, opioid availability, facilities obtainability, and educational platforms, plus palliative care certified activity, which must be existed in 15, Eastern Mediterranean countries. Saudi Arabia had the maximum number of PC agendas, in addition to Iran, and Lebanon, who awards official licensing for their physicians, followed by Egypt and Jordan, and a more four countries (Oman, Jordan, Egypt, and Qatar) have established other advanced programs for training (for example, Masters or Diploma), though Iraq and the occupied Palestinian areas stated no care ever [4].

Despite some physicians and nurses have attended essential and advanced workshops on PC, since 2011, but it is still considered as a new concept in Iraq and no formal policies or guidelines relating to this field; that the main contributors for introducing PC are nongovernmental organizations and Middle East Cancer Consortium [4,5]. The number of qualified doctors is very low as trained physicians flee the country's political instability. There are no degree programs in palliative medicine that the number of qualified doctors is very low as trained physicians, and a quarter of nurses are college graduates; most lack primary education [5].

Not any actual policy alters have happened in the previous 10 years, nonetheless, in the previous 6-years, nearly new opioids were presented, but it not ever permissible for outpatients besides not available by any means; only medics in governmental hospitals can recommend it, income is for oncology however not for PC. Though, approximately individual funders have stated appeal in supplying support for oral morphine if permitted by the ministry of health. In attendance is no instant announcement morphine and no continued release morphine. Injectable morphine and codeine, transdermal fentanyl patches became available in 2013, which are brought for free, and deliberated as an area for upgrading [4].

Obstacles to PC can be divided into three parts: 1) Deficit of health policies in the sustenance of PC improvement; 2) Nonexistent of the significant trained healthcare workers; 3) Reduced accessibility of essential palliative care drugs [6,7]. All these barriers can be overcome through guiding the greatest important barriers delaying the PC development in Iraq are the public responsiveness lack, education, and training programs lack inadequate opioid accessibility, and the disappointment to identify PC as a field [3,4]

The political state and uncertainty in the nation show the main roles in postponing awareness of the public. Furthermore, the greatest pediatric care providers consider that PC is a good means to disclose that more cannot be complete [4].

Because of, the present PC condition in many countries in the Middle East, with a big need to emphasis on the professional staff members teaching, to rise by a consistent, renewed experts' nucleus, who would be accountable for the modern PC team's development [8-10].

Palliative care education is desired at three levels which must be included in English, curricula: 1) basic palliative care preparation for all health professionals; 2) intermediate training for those consistently working with patients with life-threatening illnesses; 3) professional palliative care training managing patients with more than routine symptom management needs [3].

Without appropriate End of Life (EOL) education, it is incredible for nurses to afford adequate care in issue related. As well, it is vital to balance education with attention to personal understanding and attitudes toward death and dying to allow students opportunities to become knowledgeable about death and grief, to deal with their feelings, and to develop [11]. From 1997 to 2000, the investigation verified a lack in the overall nursing texts in EOL care content in addition to dissatisfy faculty of nursing EOL content knowledge [12,13]. These efforts include the development and dissemination of new educational recommendations, training materials, and educational requirements at both the medical school and residency levels and for nursing students and other health professionals, which should address the need for palliative care education [14].

Nevertheless, to detect the rational shortage of knowledge existed, researchers at the City of Hope USA, National Medical Center conducted a 3-year project titled "Strengthening Nursing Education to Improve End-of-Life Care," which was supported by The Robert Wood Johnson Foundation. The brought together professional nursing organizations, expert clinicians, and educators in palliative/hospice care to improve a curriculum to enhance nursing care at the end of life. The project revealed chief insufficiencies in nursing education, and its role in end-of-life care, including lack of content in nursing texts, insignificant content in the nursing curriculum, insufficient nursing faculty knowledge, and many other educational barriers that inhibit good nursing practice in this area [15-17].

[18] have a project on "The End-of-Life Nursing Education Consortium-Pediatric Palliative Care (ELNEC-PPC)" based on the original training, intended to study the concern of nurses in providing care for life-threatening illness to children or accidents/sudden death. Perinatal and neonatal palliative care is one module [19]. The ELNEC-PPC training stayed upgraded as a two and (1/2) daytime, program that is train-the-trainer, with the dedicated that those whom ELNEC-PPC qualified would develop active competencies in its distribution through the information taking to clinical practice or college locales meanwhile first training module was opined in 2003, 8 nationwide train the trainer programs have been run with more than 700 nurse's attendance from varied pediatric locations crossways the United States and Canada.

Anticipating many children die from life-threatening illnesses such as congenital malformation, chromosomal abnormalities, accidents, low birth weight, and sudden infant death syndrome, which appraised as 50 out of every 100,000 children living today; Could be assisted from palliative care services, but there is little consideration delivered to decline the suffering faced by children, and their families [7, 18].

As long as pediatric nurses that considered as more than any other healthcare professionals occupied and have a distinctive opportunity to assess and come across the needs of children with their families, who feel the pain to die suddenly, or shortly after birth or die in utero with perinatal death. By the time, those nurses may have little knowledge about the principles of caring for terminally ill children at different ages for various causes of death [20,21].

On the other hand, a problem could take place on the attainment of new means in complex supplying and consolidating healthcare into practice, which is extensively used in the health service, in community health practice, and in areas of social policy that has important health consequences, such as education, transport, and housing. The UK Medical Research Council's framework for designing and evaluating complex interventions recommends conducting a process evaluation in order to illuminate inconsistencies between predictable and detected outcomes to understand how context impact outcomes, and to afford insights to assist implementation [22,23].

[24-26] mentioned that a certain problematic translational gap continues steadily to exist between demonstrating the positive impact of a complex healthcare intervention in a study environment, as well as the utilization of this intervention into routine daily practice. As a result, Normalization Process Theory (NPT) [27], as well as its predecessor, the Normalization Process Model [28,29] provides a framework, which conceptually helps in understanding and explaining the dynamic processes which can be encountered through the utilization of complex interventions and technological, or organizational innovations in the medical career.

[30,31] specified four key analytical domains as non-linear and cooperate energetically to afford broad enlightenment of the implementation processes, which anticipated if participants do not understand, sustain, or consider an intervention valuable, or compatible with their current work, then the likelihood of successful integers. The NPT was designed to be applied flexibly, can be used at one or more points in a qualitative study, has been successfully used, following NPT [29,31], the process of implementing a complex intervention can be described and explained by employing four central theoretical constructs:

- Coherence, the method, and work of sense-making and comprehending that individuals and organizations need certainly to proceed through so that you can promote or inhibit the embedding this is certainly routine of practice.
- Cognitive Participation, the procedure, and work that people and organizations need certainly to proceed through so that you can enroll people to build relationships the practice this is certainly new.
- Collective Action, the task that people and organizations want to do to enact the practice this is certainly new. (“Collective Action” was primarily labeled as a normalization process model and contained 4 sub-components (for example. “Contextual Integration”, “Relational Integration”, “Interactional Workability”, and set of skills Workability).
- “Reflexive Monitoring”, the task characteristic into the practice appraisal that is informal and formal this is certainly new it is being used, so that you can measure the benefits and drawbacks, and which develops users’ knowledge of this practice aftereffect.

The NPT has become a widely used theory for analyzing the implementation of complex interventions and has previously been applied to a wide range of health topics and empirical settings, including chronic health care, maternity care, e-learning and telemedicine. This comprises eight papers in the e-health and telehealth care field, and the 21 remaining studies in several other healthcare fields, which entirely concluded that the NPT was a complete and a valuable model to drive the process of implementation in the settings of a health facility [31].

Presently, a quantitative design in a palliative care health context has not confirmed the validity of the NPT model yet. An NPT tool has newly been established Normalization Measure Development (NoMAD) [32] for use in quantitative research. Similar to the Conceptual Model of Implementation Research [33], the elements are formulated to feature at application with hindsight. Besides, the NoMAD tool measure is suitably unclear toward allowing its custom across several contexts, these acts to restrict its practical usage in selected settings, E.g., A single element of the NoMAD tool tests whether “sufficient resources are obtainable to maintain the intervention” [32]. Nevertheless, to our knowledge, no NPT studies have concentrated on evaluating a web-based training program in pediatric palliative care at the end of life for nursing interventions in hospital settings.

Training, and has been recognized as a key implementation approach for enlightening provider knowledge and skills with an interest in the use of web-based training methods [34,35]. The indication is accumulating that Web-based training can be a working educational instrument aimed at bringing and appraising curricular content through numerous organizations and training levels. In the role of high-speed internet access computers have shown off universal at home and in the clinic, a disseminated healthcare professional can effortlessly access Web-based resources, regardless of their setting and at periods that do not exertion with their clinical tasks or responsibility hour restrictions [36].

The original policy for providing consistent behavioral interventions in a series of situations is the Web-based interventions, which has the ability to access behavioral maintenance at any time, greater confidence, and lower cost compared with a clinician-delivered group, compared with old-fashioned face-to-face training methods[35,38] ,

Surveys, qualitative studies recommended that EOL care research is feasible and ethical but funding of EOL care research is poor [39,40]. Thus, randomized trials of EOL care treatments and services persist to be uncommon, often limited by poor enrollment, high attrition, unfairness, confusing and small sample [41,42].

Specifically, a pragmatic multicenter randomized controlled trial is recommended for the evaluation of complex health care interventions to enrich enrollment, broadcasting, and upsurge the external validity of trial results [43]. Nevertheless, pragmatic RCTs are intended to evaluate treatments in real-world (as opposed to idealistic) conditions, directly enlightening decision-making by the patients, providers, and health care policymakers [44].

Comparator

Comparators often used to decide the work level of an intervention related to a clinically relevant substitute. The choice of the comparator (control group) is always a serious decision in a manipulative a clinical trial, which have one major purpose: to allow the perception of patient outcomes (for example, changes in symptoms, signs, or other morbidities) triggered by the test treatment from outcomes caused by other factors, such as the natural advancement of the disease, observer or patient potentials, or other treatment.

The comparator experience to predict the alterations would have ensued to patients if they had not established the test treatment or if they had received a different treatment is known to be operative [45].

The present knowledge regarding the absolute value of the anticipated experimental and control interventions is considered as one of the factors that regulate the appropriate choice of a comparator for a trial [46]. The research question type is the main ideal comparator determining factor. Significantly related comparators contain ones that duplicate existing clinical or public health performs or facilities (for instance, Care that are usual or care standard), other implementations (for example, A firm, evidence-based practice intervention by way of a comparator aimed at an intervention that up-to-date), and clinically pertinent variations on the trial implementation (for instance, the similar intervention excluding provided employing alternate way, (for example once a face-to-face intervention is associated to the similar intervention brought by distant technology of telehealth) [47].

Though, the Pragmatic Model intended for Selection of Comparator assures investigators toward choosing clinically important instead of non-natural comparators that are unlikely to continually be situated utilized in clinical practice, the Pragmatic Model for Comparator Selection offers a mode on the way to resolve the incongruities numerous and influences that edge the comparators that are used in intervention trials behavior [47].

As a clarification, typical care is the comparator of choice for this trial, which is considered as a treatment or service that is consistently providing in the sites after which experimental members are joined. Often differs across individuals and settings, and in some trials may be heightened or delimited for trial participants [47]. According to [48], customary care is the favorite comparator among researchers. Substitute as a comparator or constituent of the comparator, which was found in 99 (49.5%) studies, often appearing under numerous synonymous terms (e.g., Standard treatment, care, as usual, standard care, treatment as usual, standard of care). Even though [49] stated that it may vary considerably between centers and countries confounding comparator choice. Using clinical guidelines to define usual care can help standardize comparator treatments; conversely, this may decrease the applicability of the results to actual settings.

Hereafter, the selection of the typical care for this trial follows Clinical Practice Guideline recommendations, as well as the organized appraisal of the significant literature that seemed in effect on palliative care services, which is not accessible to pediatric patients in Iraq owing to deficiency of knowledge and training of healthcare professional or short care supply [4,10,46].The trial aims to explain the provision of palliative care at the-end-of life through the implementation of the ELNEC course, as WBT Program using the Normalization Process Theory. Its emphasis on interventions complexity, which becomes routinely embedded in practice. In addition to, identify the changes implemented by the participant nurses (intervention group) in their clinical practice, after participating in WBT Program to provide Palliative Care alongside with usual care versus usual care only (control group) for children with life-limiting conditions or in the case of accidents or/sudden death, at the end of life. Finally, provide findings that will assist in the interpretation of the trial results.

Objectives

Primary Objectives:

- Holding a short course ELNEC-PPC WBT program at selected Hillah city hospitals, Iraq by July 2020;
- Evaluating the impact and effectiveness of this project through using NPT theory, at the beginning of WBT course, after the end of WBT course 2 weeks, and finally at 3 months for both groups examine, defining PC advocacy activities, operating the principles found in ELNEC-PPC WBT program for their work at selected Hillah city hospitals, Iraq by August 2020.

Secondary Objective:

- Monitoring participants for 3-months post-course in a try to raise their PPC to improve their self-efficacy levels and attitudes concerning pediatric palliative care at selected Hillah city hospitals, Iraq by August 2020.

Methods

Trial design

This study is designed as a multicenter, investigator-blinded, parallel, 3-month, pragmatic, two-arm, superiority (the provision of Pediatric PC with usual care is superior to the usual care only), randomized control trial in which different units from multiple hospitals are stratified and randomized, randomization will be performed as block randomization with a 1:1 allocation, which will be conducted according to the

CONSORT guidelines. The Consolidated Standards of Reporting Trials (CONSORT) statement is a guideline designed to improve the transparency and quality of the reporting of randomized trials [50,51].

Study setting

The trial will be taking place in the selected Hillah City Hospitals, as a local government organization that holds numerous various pediatric and adult sections. In Iraq, there are 273 public hospitals spread all over the country [52]. The Hillah City, of Babylon Province, hosted four hospitals and one Babylon Oncology Center, the recruitment of participants will be conducted in these five sets, which is: "Imam Sadiq" Teaching Hospital (general hospital) consists of 492 beds, Babylon Maternity and Children Teaching Hospital (obstetric and pediatrics hospital) with a capacity of 323 beds, Morgan-Teaching Hospital (specialized centers tertiary health care), Al-Noor Hospital for children (pediatrics hospital), and Babylon Oncology Center [53].

Participants will be recruited and stratified to two strata included: 1) Critical care units that included (one Artificial kidney, one Resuscitation emergency, one Catheterization unit, two Children's emergency, one Emergency Department, one Maternity Emergency, one Morning-resuscitation, one Operations room, and one Pediatric Surgery); 2) Non-critical care units included (one blood disease, one Chemo injection, one Health insulation, one Private Suite, and five pediatric lobby), that the smaller structural units within the selected hospitals. It is a structural component by its organization and specialized unit. Staff in selected hospitals do not employ in two areas at the same time, each section, pediatric clients with several diagnostic classifications are preserved and provided usual care. Recruitment for the current study started in July 2020. A 2-year outline plans for the research, with likely changes along with the primary analysis outcomes (see below).

Eligibility criteria

Participants must meet all the following eligibility criteria:

Inclusion Criteria

- The health care centers where the intervention will be administered include 1) Imam Sadiq (peace be upon him) Teaching Hospital; 2) Babylon Maternity and Children Teaching Hospital; 3) Al-Noor Hospital for Children; 4) Morgan Teaching Hospital, and 5) Babylon Oncology Center.
- The study population will be included, all nurses who completed their bachelor's degree and who have (master's or doctorate) degree in nursing sciences, that existence working used for at least 3 months and non-expected to be moved to another unit in the interior the research period all through either morning or evening shifts and provides nursing care for both male and/or female of hospitalized patients ≤ 18 years.
- Using a computer (desktop or laptop) with access to the internet at home or work (phone line or internet access), or use a smartphone (with at least Android 6.0+ or iOS 11.0+) with internet access (Wi-Fi and/or mobile data) to join the online training course.
- Have a working email address and/or a working mobile number and have access to a computer or smartphone with internet access to complete questionnaires in a web browser.

Exclusion Criteria

Presence of the following criteria will exclude participants from enrolling in the RCT:

- Not interested.
- Not being employed for at least three months.
- Academic nurses who employed and continuing to work with other than selecting units, due to the carefully chosen only units that provide nursing care for both pediatric and adults or for pediatric, in order to achieve the study objectives.
- Enrolled in another experimental trial.

The evaluation of whether the exclusion criteria are ruminated is achieved via the investigator during the recruitment phase or by the participant self - report during the day of the interview.

Screening for eligibility and enrollment

The recruitment period is planned to start in July 2020. A total of on a participant consisted of 172, participants are who have to be recruited to the in RCT. Of these Part of them represented as, 46% (n=80) will be recruited in a selected setting (1), 26% in a selected setting at (2) (n=45), 8% (n=13) will be recruited in a selected setting (3), 16% (n=28) in a selected setting at (4), while 4% (n=6) will be recruited in a selected setting at (5), collaborations with the selected setting would be established to facilitate

recruitment. The number of participants needed to ensure a sufficient recruitment rate has been informed by the sample size (see sample size section).

The recruitment process is outlined in the box with the blue framework in (Figure 1). The main investigator will be submitting the official approval form for researching the continue continuing nursing education units in the selected hospitals, (Appendix 1), with the approval form for the training course (Appendix 2, Appendix 3), for a WBT course hosted by Nursing Faculty- Continuing Nursing Education Unit.

Eligible nurses will be invited to participate in the trial by the Continue Continuing Nursing Education Unit (CNEU) team in selected settings. The unit will refer potentially eligible participants depend on a quick eligibility explanation that the main investigator submits to the unit included:

- Nomination form for the training course (Appendix 4) for recruitment. Each participant should fill it out, this, forms which will be used for contact with each participant, that This form included: (his/her name, email address, telephone number with Telegram or Viber or WhatsApp service, current duty, type of practice unit inside the selected settings, date, job description, academic qualification, a text box for random numbers in the upper left side of forms, and participants signature), the number of this printed forms is according to the size of the estimated sample for the research (see sample size section).
- Table of the estimated sample, and their type types of practice unit inside the selected setting (Appendix 5) according to this table the persons, who in charge of CNEU in each selected setting used it to select eligible participants.
- Informed consent form (Appendix 6).

The referral to the trial will be taken place after the CNEU in each selected setting has performed selected by the participants according to the table of estimated sample size that will submit to the CNEU and their current practice unit (the usual procedure). Participants are recruited engaged through the unit team recruitment in selected settings. Participants are seeing an invitation letter including written information about the project and numbered, opaque, sealed, and stapled envelopes contain a nomination form for the training course. The written information describes two ways to contact the researcher, if the participant is interested in the project: 1) by email, 2) telephone (call or instant message by Telegram or Viber or WhatsApp message). Nomination form for the training course filled out by the candidates are placed in a sealed (A4) large sealed envelope and sent to the unit for CNEU in the faculty of Nursing that will host the WBT course.

The study started by preparing the formal and essential approvals through the academic professor (H J) / responsible for the continuing education unit in the Faculty of Nursing and coordinator with the Babylon Health Department, to obtain the official agreements for the sample collection according to study criteria. The candidates collected in a closed envelop, till emptied them for the training course in an Excel participant, ' spreadsheet by using a laptop. The information entered of each form in the sequence and making a backup copy of the Excel spreadsheet, printing it and keeping it in a safe, and close location, then sent via email a copy of the participants' spreadsheet to the main investigator to contact with participants via provided emails or via (Telegram, Viber, or WhatsApp) The enrollment process is outlined in the box with the red framework in (Figure 1). If eligible and willing to participate; the informed consent will be signed in each selected setting to participate, then the main investigator contact with each participant and are sent, by sending an email or via a certain means of social communication like Telegram, Viber, or WhatsApp instant message with a link to the web-based baseline questionnaire. The randomization performed via a web-based randomization system (see randomization section).

The participants can return the signed informed consent in a pre-stamped envelope as provided by the unit or the participant they can take a picture of the signed consent form and send it via a text message to the main investigator. Subsequently, the main investigator will contact the participants, inform them about the results of the random distribution, and give instructions accordingly to the group that was randomly chosen, whether it was a control or intervention group. All instructions are completed on the phone or via text message, and on the other hand, the participant receives a link to the design of the website by the main investigator on Google site (Appendix 7), which provides all instructions and details of participation in the training course which shown also in Arabic language.

In the CNEU, hereafter next to the randomization is performed. If (randomized to A) ELNEC-PPC WBT Course in addition to usual care, participants are sent the link of the website contain all instruction to enrolling in for registering in the training course and assistance on how to keep access by to contact with the participants via instant messaging or via email. Moreover, the participant is given information about their follow-up assessments, and information on how to contact the main investigator if needed. If a

participant declines participation, the main investigator will ensure that the information from the baseline questionnaire is deleted. If (randomized to b) usual care, participants are instructed in the principles of usual care and are given the same information as the ELNEC-PPC WBT Course intervention group about the follow-up assessments and how to get in touch with the main investigator if needed. The flow of participants through the trial is described in (Figure 1).

Insert figure 1 around here.

Randomization

Participants are randomized to either (a) ELNEC-PPC WBT Course as well as usual care or else (b) only usual care. The randomization is done as block randomization plus permuted blocks of random size 172 known to the researcher and stratified by type of unit (i.e. Critical care unit, noncritical care unit). The allocation ratio between the ELNEC-PPC WBT Course as well as usual care and the usual care groups is 1:1. Randomization will be generated by using the Website (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>).

Randomization performed by not involve volunteer nurses (S A) generates random numbers using the computer; distributes and writes it on the nomination form for the training course in the text box on the top of the form. According to the sample size, for example, the first random number represents the intervention group, will be written on a form (Symbolize it as T) format, and the format (Code C) represents the random number of the control group, the nurse puts these forms in a sealed envelope and mixing it to put them in a big, sealed envelope (A3) (Appendix 8). The previous steps represent the randomization processed by the nurse; a videotape made in the process of the sealed envelope with a participant details visible.

A second researcher' (A Y, N M) later viewed videotapes to ensure the process. Corresponding envelopes will be opened only by the participants who select it and it was timing to allocate the intervention. The enrolled participants completed all baseline assessments.

Blinding

The research is single-blinded research, concerned with the participants that are not blinded to group allocation. The examination and the study result interpretation will be achieved by investigators blinded to group to allocation. Once the study is completed, a copy of the data will be extracted in a pseudonymized form for statistical analyses. The information concerning the group allocation will be added to the dataset by the intervention, and control group randomly categorized as T and C. This work is done under control by camera prepared for documentation later (by supervisors) that the full data entry was done without the main researcher knowing. The randomization key (i.e. Document entailing information on which group) is kept at the supervisors (A Y, N M). They will provide the randomization key to the researchers once a blinded interpretation of the results is finalized.

Interventions

The experimental and intervention are labeled ensuing the SPIRIT recommendation [54] and CONSORT E-health extension [55].

Usual care:

Participants nurses deliver usual care as his/her role appropriate to neonates, infants, toddlers, preschoolers, school-age, and adolescents in the selected unit of perinatal, neonatal, and pediatric settings. This comprises at all treatment management, diagnostic procedure, or referral process, which they discovery relevant as the case history, clinical results, and practical, everyday practices that are not included PPC. Later the trial completion, participants in this group are accessible a WBT course similar to the group given to the ELNEC-PPC WBT course group.

Providing of Palliative care with usual care

Course:

The online ELNEC-PPC course is being developed in collaboration with Relias Learning Systems [56]. The ELNEC Pediatric PC, complete nationwide work to advance palliative end of life care delivered through health care experts in perinatal, newborn, and pediatric contexts. The mission is depending on the unique ELNEC care course training, which is cooperation among "The City of Hope" and the American association of colleges of nursing. This design may be a combination of investigation and knowledge in PC and is meant to help with applying evidence-based practice. Taken the American association of schools of nursing Peaceful Death: Recommended Competencies and Curricular Guidelines for End-of-Life PC and so the 1997 drugs report Organization. The electronic training course is going to be included in two and 1/2-day modules, with the, determined that those that qualified in ELNEC Pediatric PC would become vital

services in its supply by taking the knowledge to clinical practice [18]. The curriculum involves 9, modules that are specific to the care of children, and their families challenging life-limiting illness [57]:

module 1, nursing care of the pediatric palliative introduction

module 2, perinatal and neonatal PC

module 3, pediatric PC communication

module 4, pediatric PC ethical/legal issues

module 5, pediatric PC cultural and spiritual considerations

module 6, pediatric PC pain management

module 7, management of symptom

module 8, pediatric PC loss, grief, and bereavement

module 9, pediatric PC care at the time of death

Each module will cover about twenty minutes of PowerPoint slides and data text gaining and 40 activity sessions minutes for clinical application. The application of clinical will comprise case management studies, film vignettes including critical thinking questions, and “stop and think” queries that want the scholar to answer so as to continue through the module. By the top of each training module, the participant is going to be requested to reply to 10 NCLEX-format questions to complete mastery. The importance of this interactive online module buying is roofed through the funding for all participants in selected Hillah City hospitals.

There are 8 main themes surrounded within each of those modules. They include of (1) The family because the unit of care; (2) The important role of the nurse as an advocate; (3) The culture importance as an influence in PC; (4) The critical demand for notice to special populations like ethnic subgroups, the deprived, and then the uninsured; (5) PC influences altogether care systems crossways wholly contexts; (6) Critical monetary matters impact PC; (7) The PC isn't limited to cancer or AIDS, but it's temperately vital through altogether serious diseases, and in sudden death cases; and (8) Care interdisciplinary is vital intended for value EOL care [18].

Hypothesized that NPT theory would be a useful conceptual tool because it provides a strong analytic framework for understanding the organization and operationalization of tasks (their implementation), of creating them routine elements of lifestyle (their embedding), and of sustaining embedded practices in their social contexts (their integration) [28].

The process of implementation

Institutional review board approval will be obtained from Babylon University/ Nursing Faculty and from selected hospitals in Babil Province Health Department, where the study took place. Informed consent will be submitting to the selected hospitals, and the nurses were given 1 week to decide if they wished to participate. Relating to those nurses who decided to participate, the Arabic-NoMAD pre-test electronic questionnaire will be provided.

The intervention group received the ELNEC-PPC training course through the Relais Academy website. The main investigator sent a link of e-questioner to all participants via their emails or via (Telegram, Viber, or WhatsApp), as it includes questioned that describe the experience and role of each participant in providing PPC, and within 2 weeks, each one should return to their appropriate routine practice. The time frame from pretest to ELNEC-PPC training course /intervention to clinical to posttest will be 2 weeks and after 3 months.

Main investigator then will send a link of the website that provides details of participation in the training course and enrolling at Relias Academy (see link in Box 1). Website also provides support in the Arabic language to all participants of the intervention group (T). For enrolling at Relias Academy (Textbox 1) The participants should follow this process to get started on Relias Academy:

Textbox 1. The Enrolling at Relias Academy

1. Go to www.reliasacademy.com
2. Select, “Sign In” from the top right corner of the screen
3. Type in your email address and password
4. Email: (provide for participants)
5. Password: (provide for participants)
6. Confirm that the ELNEC-PPC course you are looking for is present
7. Once logged in, click on “Manage Account” select, “Courses.”

Each participant login to the site link to them, and read the steps necessary to complete the course, (on our website will provide to them) This site, which was designed for research purposes by the researcher, to

deliver the content of the course that was on Relais academy platform and providing the required survey to the participants to facilitate the process of implementation, as it was created using google site, a service provided by Google to build websites. The way it works is similar to the way a wiki works.

Each participant in (T) group should complete all of the ELNEC-PPC training course nine modules. Meanwhile, the main investigator will follow the participants entering the website link and ask them via an instant message or e-mail about the completion of steps and Uploads of one screenshot for each model to Google Form URL provide to them, to reach the course and complete it.

After 2 weeks has passed, the main investigator makes sure that all participants in the intervention group have accomplished the tasks assignments to them during the course, by asking the participants via an instant message or via email, also send all certificate there gets it for each module. Then the electronic questionnaire (Arabic-NoMAD) is sent again to be filled out for the second time by the (T) group that participated in the course, the main investigator will make sure that all the forms have been completed within two weeks after the training course, where all participants in the intervention group (T) will have participated in the pediatric palliative care course submitted through the Relias platform. After that, the participants will be monitored at their workplaces for 3 months in order to measure the impact of the training course on the work of the nurses who participated in the training course, as well as to measure the changes that affect their roles, as well as their experiences using the NPT toolkit, through interviewing participants at their workplaces the units in their selected hospitals.

After 3 months, the main investigator measures the variables of the interview using the NPT toolkit to create a viewpoint for the PPC delivery at the end-of-life via nurses, also, the modality of working in the hospital units that will be chosen to carry out the trial. Simultaneously, the NoMAD link is sent to all participants for the two trial arms to complete it for the last time to evaluate the long-term impact of the training course to provide palliative care.

Outcomes

All outcomes of the study are accumulated at a starting point, two weeks, also three months, particularly the participant's characteristics and demographic variables are collected at baseline. Participant characteristics include age, gender, and relevant comorbidities, whereas the demographic variables include job category, work experience, academic qualification, job title, and the number of local training courses that participated in the computer pediatric palliative care. The outcomes included in the trial was based on recommendations for NPT theory, and its four related constructs [58].

Primary outcome

The primary outcome is the RCT process evaluation of ELNEC-PPC aimed at providing PC in a range of healthcare contexts by Arabic-NoMAD questionnaire, and observation of routine clinical care.

Secondary outcomes

A secondary outcome of the interview, operating context examination, knowledgeable via NPT toolkits.

Interview Procedure

Semi-structured face-to-face interviews will be conducted by all nurses on how successful passing the ELNEC-PPC WBT course from the selected setting. All participants had direct contact with patients, through three rounds of interviews will be conducted after 3 months. After consenting, participants will be interviewed by the main investigator (MA). All interviews will be audio-recorded and transcribed. If participants didn't demand to be recorded, the main investigator made assenting notes and then transcribed an in-depth discussion account. Some nurse's participants are going to be interviewed in team-up, or small nurses' groups. They're going to be asked was about the significant feeling of change, and method of application, if any, the training had donated. Throughout the next interviews round, nurses' participants are going to be inquired about the foremost significant developments since the program start; they're going to be asked to disclose their opinions around PPC and to clarify the degree to which they were implementing the method, and else, why not. Theme directors were learnt by NPT [59] and were reviewed to include problems that developed at the same time as a significant in initial meetings. This assisted the researcher to explore participants' views on the simplest models of care.

Consequently, it will be used the interactive NPT toolkit. It contains 16 questions, for thinking through an implementation problem. The work was embedding improved and edited statements and explanations into a web-enabled tool.

Sample size

The study is designed as a superiority trial with two parallels groups, ELNEC-PPC WBT; as well as usual care against only usual care. The calculation of the appropriate sample size, the main researcher uses the

following assumptions: the five selected settings consist of 254 nursing staffs on average eligible for inclusion, through surveying all including setting to determine the total number of nurses that work in a selected setting appropriate for inclusion before the study. Based on these assumptions and reinforced a two-sided meaning $P < .05$ level, a 0.90 power and a traditional predictable correlation between two measurements of 0.5, and an intraclass $P < .05$ coefficient of correlation that needed about 86 sample size of nursing employees' members of the intervention group and 86 within the control group, for t-tests analysis. Supported equal sample sizes which mean, including units of selected setting analysis. so as to account for intra stratified correlations of units, Analysis of Multilevel is going to be used. Nursing staff that transfers to a dissimilar organization unit are going to be exchanged, the sample of nursing staff, changing them will take part in the course. To catch up on nursing staff not changed in time, the researcher will insert an added organization unit, consequently employing using additional critical care units for intervention and control units this finish in 172 staff of nursing members. All power analyses were performed using the 'GPower' package (version 3.1).

Data collection

The NoMAD Instrument

Participants will be completed two data collection forms at the beginning, and after T group complete their ELNEC-PPC training in both the intervention and the control group. The main data collection instrument was NoMAD [33]. The original form of this instrument was translated into Arabic and adapt to Arabic conditions to evaluate the normalization potentiality of the PPC, which provided by WBT intervention concept.

The NoMAD was translated into the Fusha dialect in translation steps outlined by [60] who were used to translate the NoMAD from English to Arabic and then back- translate it to English. The validity of content and translated NoMAD acceptability was measured in a reiterative procedure by four recognized steps, including translation forward and translation backward; first tests of the target language instrument content validity, counting meeting with specialists, and more revision; last content validity test of the studied tool. The finalized tool implementation into an electronic form. The Arabic-NoMAD prime version, following as of step two of the clarification and process of adaptation, was applied in a pilot study that was the implementation start line Q of the PPC provide by WBT intervention. The Arabic-NoMAD is split into three sections. It starts with 12 items on the respondent in section (A), after that 3 general items on the intervention with section (B). the last section (C) covers twenty identifiable items on the intervention, alike the NPT four concepts, with "Coherence" and "Cognitive Participation" has four respectively, seven questions for "Collective Action" also five questions for "Reflexive Monitoring."

The Arabic-NoMAD scale consists of 31 Likert-type items, however, the questions in section B are responded with a Likert scale that 10-point beginning from "Not at all" to "Completely", however, the items in part (C) are responded employing a Likert scale 5-point, beginning from "Disagree Strongly" to "Agree Strongly." "Neutral" and "Not applicable" were also assumed as choices to explain respondents' experiences of using the intervention within the workplace (Appendix 9). Participants of 30 members complete the Arabic-NoMAD survey, which provided a reply 100% rate. Content validity computed for the Arabic-NoMAD Scale-CVI of 0.91, which is significantly over the suggested level of 0.80, and an I-CVI starting from 0.71 to 1.00. Scale reliability was also strong, with Cronbach's Alpha coefficient of (0.77 to 0.86) post-course analysis. During a newer study, the NoMAD demonstrated indoor consistency score (alpha coefficient) reached as of 0.76 to 0.83, [61], and may be considered as representative reliable.

The NoMAD questionnaire is translated into seven languages [62]. The Arabic-NoMAD is made to supply a versatile "bank of items" [63], with an honesty aimed at wide versions regarding items which are used also expressed, for instance, to supply more anticipatory assessments. The NoMAD designers propose that the tool must be examined as a "pragmatic measure" of an intervention [64,65] and motivate adaptation multipurpose function by the investigators at their particular application study also clinical practice requirements.

Consequently, the Arabic-NoMAD is displayed as four building item groups, by data of reliability and validity; in addition, doesn't proposal definite scoring instructions or making construct procedures, which should be used in each research.

Time to complete the baseline questionnaire is approximately 20-25 minutes, the follow-up questionnaires are shorter and time to complete is approximately 20 minutes. As a starting point, two weeks, and three-month follow-up, participants will be sent an email with a link that directs them to complete the Arabic-NoMAD questionnaire. To ensure as a high a response rate as possible in the follow-up questionnaires, several reminders' e-mails will be sent, the first after three days,

and the second after six days, and so on. If yet no response, the investigator going to be communicating the nurses' participant via text message or by phone call and inquire if he or she remains readied to reply to the survey on the telephone.

The Interview

Semi-structured face-to-face interviews will be conducted with all nurses to detect the level of successfully passing the ELNEC-PPC WBT course from the selected setting. All participants had direct contact with patients, based on three rounds of interviews will be conducted after 3 months. After consenting, participants will be interviewed by the main researcher (MA). All interviews were audio-recorded and transcribed. If participants did not interest in recording, the researcher made contemporaneous notes and subsequently wrote a detailed account of the discussion. Some participants will be interviewed in pairs or small groups. They will be asked about their feeling of significant change.

To do that, it will be used the interactive NPT toolkit. It contains 16 questions, for thinking through an implementation problem. The work was embedding improved and edited statements and explanations into a web-enabled tool.

Access to data

All personally identifiable data collected in the trial will be kept for five years. These data are kept to be able to track any adverse events reported post completion of the trial. After these five years, the data set will be fully anonymized. The anonymized full data set will be kept for up to 30 years for research purposes and will be used to create a data model that can inform the further development of potential research of the ELNEC-PPC WBT. Data will be stored at the Postgraduate Department of Nursing College/Babylon University.

Statistical analysis

Results will be stated consistently with the Consolidated Standards of Reporting Trials (CONSORT) declaration concerning health [50,51]. The analysis of primary data will follow the principle of intention-to-treat and relate the alterations in the overhead outcome measures between the intervention group and the control group. The SPSS V. 26.0 software will be used for the data analysis. Descriptive statistics were presented by percentage distributions and indicators describing the location (arithmetic mean = M) and deviation (range, standard deviation = SD). The analysis of primary data will be predicted the mean difference by a about 95% confidence interval in NoMAD score at three months follow-up between groups (ELNEC-PPC WBT as well as usual care against only usual care).

This model comprises altogether accessible data aimed at the entire nurses' participants at whenever point (i.e., Starting point, 2-weeks, in addition, 3-months). Within the regression model, distinct participants are going to be stated using a random effect, accounting for the inside topic covariance construction. The group and time effect are going to be stated asset effects using a combined intervention and time variable. At this time, starting point levels are collected over the two research collections supposing that somewhat starting point alterations are due toward coincidental [66]; this as well contains aimed at a little starting point changes in the variable of the outcome. Both groups going to be primarily be labeled concerning their starting point features, that the analysis of first data is going to evaluate the ELNEC-PPC WBT effectiveness in the intervention group with the alterations in the control group, followed by the alterations proceeding NPT theory. The analysis going to be inspected in the intervention effect by way of continuous over time, as well as an interaction between period and group allocation. The difference between the groups is going to be valued both for the period of a basic model, and attuned for the mutable intended for stratification in the randomization category of unit ex. Critical care unit, noncritical care unit [68].

Repeated measures of ANOVA are going to be wont to check the multivariate main intervention effects (associated by control) besides pre, post, follow-up time, as well as their interface effect. A $P < .05$ two-sided is going to be deemed as important. Besides, will calculate the standardized effect size (Cohen's d) as well. Analysis of Mediator as well will be controlled to discover which subgroups would benefit further as of the intervention, with outcome variables regressing on variables that independent as age group, sex, state of education, and starting point the Arabic-NoMAD grades. Secondary outcomes are going to be analyzed using a similar approach as described above for the primary outcome with linear mixed models for repeated measures. Analyses of data from 2weeks- and 3 months follow-up will also be analyzed according to the above description for the primary outcome.

Pilot testing

A pilot study was conducted, starting March 2020 and July 2020, by using the initial Arabic-NoMAD version, following as of step two of the clarification and process of adaptation, which was applied in a pilot study that was the implementation start line of the PPC provide by WBT intervention.

The purpose of the WBT intervention was to provide a source for the provision of pediatric palliative care in-hospital by staff nurses including the application and development of further adaptable and improved operating approaches for facilities of health care.

While the purposes of the pilot study were to try out the instruments, making revisions where necessary, and trying them out again. Piloting other aspects of the research, such as how to gain access to respondents [69]. Also, test a process of implementing ELNEC-PPC WBT as well as to gain information about practical procedures regarding recruitment and screening as described in this protocol. Accordingly, the pilot study identified challenges in the recruitment process that could be adjusted before the RCT. The pilot was conducted with the methods described for the RCT in this protocol. Recruitment ran until had been tested from all described channels. All participants in the pilot study were contributing to the ELNEC-PPC WBT, in addition to usual care (intervention). Outcomes were collected at Baseline and after 2 weeks. The outcome data collected will not be included in the RCT analysis.

Research ethics approval

Approvals for the pilot study, RCT, and process evaluation has been obtained from the relevant ethics committees in Nursing College/Babylon University. The approval was sought from the Committee on Scientific Research Ethics (NO.291 Date/01/29/2020) and Babel Health Director (No.124 Date 01/30/2020). Correspondingly, approval from institutional review boards either or both protection of data activities has been gained within Nursing College.

The trial is registered with <http://www.clinicaltrials.gov> (NCT04461561).

For this trial, serious adverse events are not expected. Consequently, as serious adverse events are unexpected, no interim analysis or a priori defined stopping rules are defined or implemented for this trial. All inquiries from participants reporting technical or medical problems are registered. The website for providing training course contains a link to a webpage with frequently asked questions that can guide participants with technical issues. All inquiries will be documented conferred in an internal review also described utilizing the research outcomes.

Results

The RCT results will be stated in compliance with the CONSORT 2010 writing recommendation in addition to the 2013 modification CONSORT-EHEALTH list aimed at writing RCTs that are mobile-based and web-based [51,55]. Collection of data occurs expected near to be completed with March 2021 then trial results distribution is intended after then.

Discussion

To the best of our knowledge, current RCT is the first trial study that clarifies the delivery of PC at the end-of-life by the implementation of ELNEC-PPC as a WBT course among Iraqi nurses population of pediatric; in addition, it is as well one of the only some papers that evaluate enhancement in palliative care as a result of ELNEC-PPC WBT program. It will also evaluate the impact and effectiveness of this project by using NPT theory, which focuses attention on how complex interventions become routinely embedded in practice. The study design has another strength, including the random allocation to dissemination conditions, Inclusion of data on reach, implementation under different conditions, the willingness of staff to participate in the study and the highly pragmatic nature of the protocol, planned via the Pragmatic Explanatory Continuum Indicator Summary (PRECIS)-2 guidelines [70] summarizes in (Figure 2) that show the characteristics of the ELNEC-PPC as a WBT study. The mean score amongst the altogether 9-domains of PRECIS is 4.22, which shows a somewhat protocol that is pragmatic, the training of the sample staffs that work in pediatric units and mixed units in the experimental condition. Intervention strengths are also, making the intervention to the requirements and wishes of the healthcare association to overawe hindrances also benefit from organizers in the healthcare administration. To increase the nursing staff motivation, the WBT course will be provided to the units that control when finished of the study.

The trial has approximately limitations that must be specified. The first weakness is that employees of nursing will be conscious of the intervention receiving, which might cause bias. One more limitation, since it will primarily practice the self-data collect report method, this may cause bias of recall. For this study, the likely high dropout rate, even with self- choice and additional strategies to reduce it (for instance, e-mail notices in addition to further incentives). Another weakness, not able to experiment with the outcomes

longer than 3-months. The last study weakness is that associated with group-based training, while the interventions that are web-based self-administrated it may be less efficient.

Up to now, the staff's readiness to join in the ELNEC-PPC WBT course is outstanding. The first training was given in March 2020 for the pilot study, and the last training will be assumed about August 2020. The results will be accessible in December 2020. The study involved numerous various departments. Whatever altogether units have in shared is that they have a bottom-up demand aimed at offering palliative care for life-limiting illnesses children. The selected design be situated for study purposes. The design permits evaluating the training program's influences on normalization also adaptation in supplying the new care during daily routine practice promptly afterward the training course, in addition to brief, three months by performing one additional measurement.

If through this study, it will hope that the findings of this study will show the intervention also not only active in recovering the providing the new care in addition to usual care of employers, but also bringing positive impact for providing high-quality nursing care in the pediatric governmental healthcare organization, also provide knowledge about recovery in life-limiting illness children in addition assistance in scheming improved convalescence plans toward attending this method. The health worker will help original info intended for adapting manner interventions toward their patient's needs. Lastly, the results will benefit decision-makers for healthcare in order to decide whether to expend ELNEC-PPC as course training program for the full nursing staff of the country.

Insert figure 2 around here.

Acknowledgments

The ELNEC-PPC WBT program has received no funding.

Drs Amean and Nuhad had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Professor. Dr. Amean, Assistant. Professor. Dr. Nuhad, M.S.N Mustafa.

Critical revision of the manuscript for important intellectual content: Professor. Dr. Amean, Assistant. Professor. Dr. Nuhad, M.S.N Mustafa.

Statistical analysis: Main researcher M.S.N. Mustafa Ali and Hussein J. Mohammad.

Administrative, technical, or material support: Main researcher M.S.N. Mustafa Ali and Hussein J. Mohammad

Study supervision: Professor. Dr. Amean, Assistant. Professor. Dr. Nuhad.

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The associates included in the ELNEC-PPC WBT plan incorporate:

- Babylon University-Nursing Faculty: is leading the overall project.
- The RCT is a multi-center trial, participants are recruited at:
 1. Imam Sadiq (peace be upon him) Teaching Hospital;
 2. Babylon Maternity and Children Teaching Hospital;
 3. Al-Noor Hospital for Children;
 4. Morgan Teaching Hospital; and
 5. Babylon Oncology Center

Which can be leading into running in the planning and conducting of the RCT.

Conflict of interests

"none declared"

The overall aim of the ELNEC-PPC WBT project is to evaluate the providing of PPC as new care instilling in daily nurse's practices, also to support participants to self-manage their virtual course. The results and experiences from the pilot and RCT will inform the further development of the PPC in the healthcare setting. In order to secure an unbiased interpretation and dissemination of the RCT.

Abbreviations

CNEU: continue nursing education unit

CONSORT: consolidated standards of reporting trials

CVI: content validity index

ELNEC: end-of-life nursing education consortium

ELNEC-PPC: end-of-life nursing education consortium-pediatric palliative care

EOL: end of life

FINER: feasible, interesting, novel, ethical, and relevant

I-CVI: item-content validity index

NoMAD: Normalization Measure Development

NPT: normalization process theory

PC: palliative care

PICOT: population, intervention, comparator, outcomes, timing

RCT: randomized controlled trial

SPIRIT : standard protocol items: recommendation for intervention trials

WBT: web based-training

WHO: world health organization

Multimedia Appendix

Full copyright and citation information see <http://dx.doi.org/10.2196/jmir.23783>

Multimedia Appendix 1

Official approval form for conducting research

[Image file (PNG), 4MB]

Multimedia Appendix 2

Approval form for hold the training course

[Image file (PNG), 1MB]

Multimedia Appendix 3

Nomination form for the training course

[Image file (PNG), 2MB]

Multimedia Appendix 4

Nomination form for the training course

[Image file (PNG), 23KB]

Multimedia Appendix 5

Table of details of estimated sample needed

[xlsx file (MS Excel), 27KB]

Multimedia Appendix 6

Full web site page screen (In the English Language)

[Image file (PNG), 1015KB]

Multimedia Appendix 7

Informed consent

[PDF file (Adobe Acrobat), 187KB]

Multimedia Appendix 8

NoMAD questionnaire

[PDF file (Adobe Acrobat), 295KB]

Multimedia Appendix 9

Randomization process by nurse

[Image file (PNG), 161KB]

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