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Effectiveness of a Computerised System of Patient Education in Clinical Practice: a Longitudinal Nested Cohort Study

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Abstract

Introduction: Developing electronic medical record information systems is an international trend for promoting the integration of medical information and enhancing the quality of medical services. Patient education is a frequent intervention in nursing care and recording the amount and quality of patient education have become essential in the nursing record. The aims of this study are: (1) to develop a high quality Patient Education Assessment and Description Record System (PEADRS) in the electronic medical record; (2) to examine the effectiveness of the PEADRS on documentation and nurses' satisfaction; (3) to facilitate communication and cooperation between professionals.

Methods and Analysis: A quasi-experimental design and purposive sampling will be used. The participants are nurses who are operated the PEADRS. A prospective longitudinal nested cohort study will be conducted to compare the effectiveness of PEADRS, including: (1) the length of nurse documentation; (2) satisfaction with using READRS; and (3) the benefit to professional cooperation.

Ethics and dissemination: Patient privacy will be protected according to Electronic Medical Record Management Practices of the hospital. This study develops a patient education digital record system, which would profit the quality of clinical practice in health education. The results will be published in peer-reviewed journals and will present at scientific conferences.

Keywords: Health informatics, Education and training

Word count: 3477

Strengths and limitations of this study

- We develop Patient Education Assessment and Description Record System (PEADRS) that is first linkage of patient education into nursing records digitally in the electronic medical information system.
- A prospective longitudinal nested cohort design was chosen to evaluate the effectiveness of PEADRS in the quality of patient education and professionals' cooperation.
- A potential limitation of the study is the small sample size, when patients with invasive procedures or examinations and operation that may affect the generalizability and external validity of the result of study.

Introduction

The use of computerised systems in healthcare has been significantly growing globally. Electronic medical records are computerised systems that allow storage, retrieval and sharing of information among professionals. [1] Electronic medical record information systems standardise specific content, including documentation standards, storage, labelling and certification. Such records promote the integration of medical information to enhance the quality of medical services. [2]

Paper copies of medical records require large amounts of storage space. In addition, they increase the operating and personnel costs of hospitals. Medical records produced and stored in electronic format may preclude writing and storage of paper copies. Electronic records not only make access to medical records faster but also enhance the quality of service and improve the efficiency of medical resources. [3] To fulfil the requirements of the Electronic Medical Record Adoption Model (EMRAM) Stage 6 Award Survey in April 2017, our hospital had to achieve a near-paperless environment that harnesses technology to support optimised patient care. [4]

Patient education is an important nursing intervention [5] and an important aspect of the nursing documentation. Patient education has been viewed as an important part of providing quality healthcare that respects and safeguards the rights of patients. Research has shown that patient education provides knowledge regarding healthcare, establishes healthy behaviour, shortens hospitalisation and reduces re-hospitalisation. [6] Patient education is foundational for improving compliance with and success of patient engagement initiatives. [7, 8] Patient education affects the patient's health status and reduces healthcare costs. It has also been recognised as an independent function of the nursing profession and is a planned, systematic and logical process. [6, 10] Patient education is an important component of good quality

healthcare. One of the teaching methods follows the ASSURE (Assessment, Select materials, Utilise materials, Require learner response, Evaluation) model, which provides guidelines to organise appropriate teaching for achieving health education. [10, 11, 12]

Health insurance in Taiwan has nationwide coverage, which provides a comprehensive package of preventive measures and medical services. [13] It allows equal access to healthcare for all citizens by monitoring financial expenditures and improving healthcare outcomes. This high insurance rate results in an extremely high nurse-to-patient ratio in Taiwan compared with other countries and involves providing health education to patients when they are hospitalised. [14] Providing patient education requires time based on patient's needs and involves one-on-one discussion. Also, in clinical practice, patients need repeated education.

Since the Electronic Signature Act was enacted in 2001, the process of maintaining electronic and digital medical records has been rapidly developed. [15] The legal elements and effects of electronic medical records and signatures have become well-established under the act. These aspects have made electronic medical records popular and have accepted and included safe and reliable internet, electronic records and unduplicated signatures. Moreover, identification of health providers involved in patient care would benefit communication among healthcare professionals. [16] Therefore, electronic medical records store patient data, strengthen record quality and enable interprofessional cooperation to achieve the goal of providing optimum patient healthcare.

Currently, health education is recorded under the content of caring activities in the nursing record section of the electronic medical record. Records of patient education were not easy to identify in the document. Professional health providers in different units are unaware of the type of health education the patient or the patient's family has received. Furthermore, it is difficult to follow-up patients' compliance with treatment after health education if the patient education details are not recorded. Thus, the development of a health education

informatics system would fill the gap between the actual patient education and continued patient healthcare.

Developing a computerised system for patient education is not only to maintain a record but also to improve the working process of clinical practice, which includes appropriate methods, equipment and a computerised system for nurses. Developing an electronic patient education record system would be the last stage in completing nursing records digitally. Despite the benefit of storage space and the ease of transport, little is known about the effectiveness of documenting, nurses' satisfaction level and professional cooperation with the use of the Patient Education Assessment and Description Record System (PEADRS).

Methods

Study aims

The aim of this study is to develop a PEADRS and evaluate the effectiveness of the system on documenting, nurses' satisfaction level and professional cooperation. The study will be conducted in two phases. The first phase is to establish the PEADRS. In the second phase, a quasi-experimental study will be conducted to evaluate the effectiveness of PEADRS. To investigate the outcomes, the following research questions will be asked:

1. How does the patient education care service influence the quality of patient education?
2. How does the PEADRS affect the length of nursing documentation and extent of completed patient education?
3. Is the satisfaction level of participants using the PEADRS different from those using traditional nursing records?
4. How does the PEADRS benefit professional cooperation?

Study conceptual framework

Converting the written records into electronic records (electronic medical records) is a developmental approach in the field of medical science. It can transform patient healthcare management into knowledge and information sharing through the processes of information transferring, integrating, classifying and supporting decision making of patients and healthcare providers for enhancing patients' quality of healthcare. PEADRS provides a model that is based on the ASSURE teaching model (Figure 1). The development process of a PEADRS includes technology, planning and management systems.

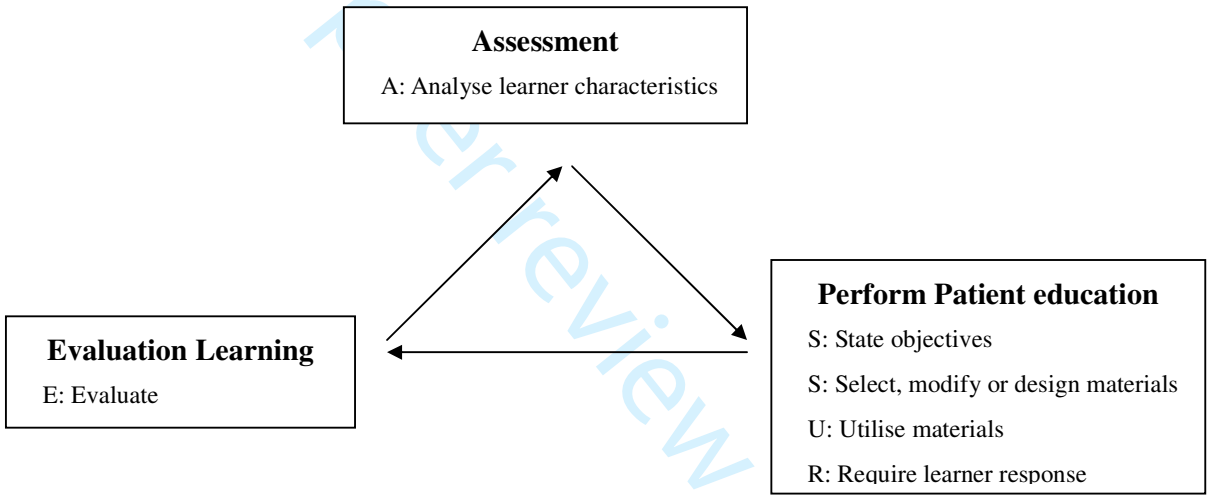

Figure 1. Structure of PEADRS based on ASSURE Systematic Teaching Model

Design

The project involves a quasi-experimental design. The study will be conducted in two phases. In the first phase, the PEADRS will be established, developed and built. In the second phase, the effectiveness of the PEADRS will be evaluated, for which a non-synchronous design will be implemented. Subjects for the study will be recruited by purposive sampling of nurses providing education to patients admitted in a hospital or preparing for invasive examination or surgery. The study will be conducted in a medical centre in central Taiwan. A

total of 220 nurses will be recruited in each of the control group and the experimental group. The control group will use the traditional method of maintaining records in patient education, whereas the experimental group will apply the PEADRS for patient education and records.

Independent variables

To assess the effectiveness of the PEADRS in patient education related to those admitted for invasive examination or surgery preparation, the following outcomes will be measured:

1. PEADRS application: applying the ASSURE teaching model to the system.
2. The length of the nursing documentation process: observing and recoding the time taken by nurses in documenting health education.
3. Record the integrity of health education: assessing the completion rate of nurses' record.
4. Satisfaction level of nurses using the PEADRS: questionnaire to evaluate satisfaction levels in nurses using the PEADRS.
5. Interprofessional cooperation: is the PEADRS a platform for cognate professionals.

Setting

The study will be conducted in a medical centre in central Taiwan. The hospital is one of the nation's premier teaching hospitals with a capacity of 2111 beds. The hospital has 2980 health education materials in different languages, including brochures, posters and films. In the past decade, the average occupancy rate of hospitalised patients was 85% in this hospital. Many nurses are occupied in implementing health education and recording data.

Participants

The participants include nursing staff who are recruited through convenience sampling from the medical centre in central Taiwan. The inclusion criteria are that they should be registered nurses, have a work experience of more than 3 months and should be working in a general ward. Participants will be excluded if they are working as assistant personnel. The

optimal sample size was calculated using G*Power 3.1., with a mean difference of $\alpha = 0.05$ and effect size of 0.2 in one sample case with pre-test and post-test. Overall, 199 participants will be required to achieve a power of 80% to detect statistically significant differences. A total of 220 participants will be recruited, with 10% possibly missing in data collection. The same number of participants will be recruited for the control group. The control group will use the original method of recoding patient education in nursing records, and the experimental group will use the PEADRS.

To determine the effectiveness and stability of the PEADRS, the following procedures will be included: (1) PEADRS interface design guidance to guide the operation of priority steps; (2) the consistency of data linking to the nursing care system, assisting nurses to determine patient facts and amendments; (3) set the content of professional care aspects and their description, meeting the needs of health education records; (4) the convenience for users (nurses); and (5) stability of informatics system. A pilot study was conducted to identify the barriers to and operation of using the PEADRS. A group of 30 nurses was recruited to make appropriate amendments.

Developing and establishing PEADRS

1. Establishing a system-developed project team: The team members included a primary investigator, two co-primary investigators (patient education committee chairman, director of nursing), two clinical health educators with more than 10 years of experience, five clinical nurses with 15 years of experience of working in a medical centre (internal medicine, surgery, obstetrics and gynaecology, paediatrics and emergency department), four senior technicians (internal medicine, surgery, rehabilitation and haemodialysis) and one informatics programmer. Several clinical observations of patient education were arranged for the informatics programmer to understand its implementation to reduce the cognitive gap and meet the needs of the users.

2. Regular meeting: The team met twice a week for discussion. The nursing department was responsible for collecting information and setting up computer screen interfaces for the system and reviewing and analysing the current status of the implementation of the records. Relevant health education for different departments was encouraged by setting up procedures for patient education, including assessment and implementation, developing education content and documenting methods.
3. Setting up the projects: The system includes five professional care aspects: outpatient care, adult patient care, paediatric patient care, examination and treatment care and Chinese traditional medicine care. The content and procedure of health education can be divided into steps. For example, taking care of a wound would involve the following procedures: (1) keeping the wound clean and dry; (2) observing for signs of infection, including swelling, soreness and abnormal secretions; (3) taking wound-dressing precautions and knowing when to call for the nurse; (4) knowing how to use Steri-Strip/Adhesive Skin Closure; (5) using waterproof cover on the wound before shower; (6) having information regarding care of wound caused during removal of arterial catheter; and (7) knowing how to use Tegaderm Hydrocolloid Dressings.
4. Applying the ASSURE systematic teaching model: The process of ASSURE includes assessment prior to health education, implementation of health education and evaluation of health education on the functional interface of the PEADRS. The design and development of the assessment contents are based on the literature review and recommendations of clinical practice experiences and the experts' advices. It includes an assessment lens related to patient characteristics and the ability to learn, formulating the strategies to implement health education instruction and evaluating the learning outcome based on learners' understanding level (Figure 2).

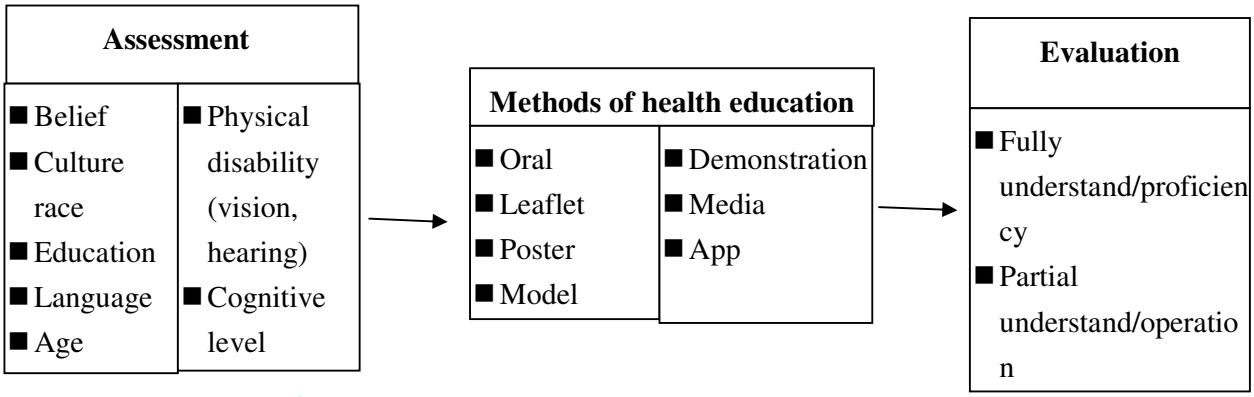

Figure 2. PEADRS Design

5. Operation system: The development of simple input interface was designed by the information programme engineer who also integrated the interface control software. To delaminate implementation of the ASSURE systematic teaching model, the following were the operation guidelines with priority steps: 'assessment of patients'; 'implementation of health education'; and 'evaluation of learning'. The components embedded into the design along with health education items allow addition of all types of special components or integration of system functional elements. To simplify the process, after clicking on the data entry, 'Nursing Integration System' of the 'assessment of patient', this will be linked to 'electronic medical record system'. All functions within the Nursing Integrated System automatically generate patient records, resulting in the associated data, functional window prompts and feedback. Nurses in different duty shifts can use the 'inquiry' function to find any related health information and know about the patient/family members who have received health education and the type of health education.
6. Confidentiality and stability: According to the regulation of electronic medical records, the establishment of information management system will ensure the stability, reliability, system confidentiality and security of the overall system operation.

Instruments

There are several methods to evaluate the study outcomes, including clinical data, nursing record review, observation and questionnaire. To ensure reliable and unbiased extraction of data from the observation, research assistants will be trained in observing, recording and accounting data. Inter-rater reliability of the study will be noted.

A self-report questionnaire will help to measure the satisfaction level of nurses using the

PEADRS. Questions will be based on the users' adoption and implementation of the PEADRS. The questionnaire includes 15 questions that are answered on a 5-point Likert scale, ranging from 'very good' to 'very bad'. To have an in-depth understanding of the constructive views of nurses, their attitude and their demands, two open-ended questions will be added: 1) enhancing factors in adopting the PEADRS; and 2) impeding factors in adopting the PEADRS.

Professional cooperation will be measured by the PEADRS system. The system would provide the choice of a date range (seven or all), on which health education items implemented through the system can be queried across departments (professionals). Nurses can choose the 'query' option to understand what type of information was already provided to the patient/family members and can continue to follow-up on their response (reaction/adherence).

Data Collection and Analysis

After the PEADRS is established, baseline data regarding the time of implementing health education and record will be collected, for which a total of 220 nurses providing health education to inpatients with various invasive examination and surgery will be enrolled. The time taken by the nurses for documenting patient education will be observed and recorded. Data on the satisfaction level of nurses using the PEADRS will be collected using a questionnaire. The results of professional cooperation will be measured by checking the record on the PEADRS and the questionnaire.

The data will be analyzed using descriptive and inferential statistics. To evaluate PEADRS, the McNemar and paired t tests will be used to calculate the means of length of the nursing documentation between pretest and post-test responses. Next, a t-test will be conducted to compare the two groups in recording the integrity of health education, satisfaction level and

interprofessional cooperation. An alpha level of 0.05 will be designated as statistically significant.

Ethics and dissemination

Procedure for protecting individual information confidentiality will be followed by electronic medical record management practices of hospitals in accordance with the national medical law and personal data protection law. The ethical approval has been processed in the Institutional Review Board of China Medical University Hospital. The study excludes all individual identification of participants or demographics data. Participants' privacy will be protected according to Electronic Medical Record Management Practices of the hospital.

Discussion

Informatics system have contributed to healthcare. [15] The development and application of the PEARDS is an important stage in promoting a smarter medical care. It is the first act in integrating health education resources into a computerised system in electronic medical records. The study is expected to achieve the following: (1) establishing an assessment, description and record informatics system on patient education for clinical practice in electronic medical records; (2) guiding nurses to provide patient education with the ASSURE systematic teaching model. The results of this study will help nurses to assess the needs of patients/family members for education, such as physical and psychological barrier and emotional status. Thus, it would help nurses to choose an appropriate method for the learner based on assessment and evaluation of learning outcomes; (3) enabling nurses, easily, to review patient data related to health education, which will not only reduce repetition of teaching but also emphasise the evaluation of learning to provide efficacious education. The nurses will recognise the type of patient education that patients/family members have already received, thus facilitating coordination, communication and cooperation between healthcare

providers. This would reduce the transmission time and help follow-up patient's adherence so that the patient could enjoy continuity and integrity of healthcare; (4) improving data consistency, recording integrity and minimising storage space for medical records; and (5) facilitating functional window prompts and feedback. The records cannot be saved until the data entry is completed; this improves the completion of patient education, which helps improve quality of care.

Limitations

Although the steps of the research process have been followed, there are limitations based on staffing, time and economic constraints: (1) education is a highly complex activity, which combines interactive situations with humanities, ethics and educational context. The relationship between the nurses and learners is subjective. The experimental research emphasises standardisation and repeated verification, but education is often unique and cannot be repeated; hence, the cause and effect in health education still has limitations; (2) the study involved conducting a survey on the nurses' implementation of patient education and digital record, as a representative of patients with invasive procedures or examinations and operation; thus, the results of this study may not be inferred to different types of patient education. (3) Although the nurses are willing to cooperate with the implementation and response, the variation in quality, teaching ability and system operation skills may have an impact on the effectiveness of the validity of the new system.

Conclusion

This study aims to study whether the PEADRS has a positive effect on the quality of health care. This study develops a PEADRS, which could help promote the quality of clinical practice. There is a significant gap in the electronic medical record information system. The quality of the caring process in patient education documentation is evident. The teaching

models such as assessment, teaching methods and evaluation of learning provide a guideline for nurses in patient education, which enhances the nurses' capability in health education. A study of nurse-end users of the PEADRS should be conducted for yielding more information about barriers, frustrations, quality needs and preferences of nursing staff. Also, a further study is needed to study the effect of the PEADRS on interprofessional cooperation. A follow-up study is planned to assess effects of user-designed system changes based on the results of this study. Further work following PEADRS improvements will explore the satisfaction of paramedical staff, including teamwork cooperation, integrated care and sustainability. This study will provide new information specific to patient education and will assist in providing an evidence-base for this innovation at a level that has not yet been established.

Contributions: CHS is the principal investigator of the PEADRS. Study concept was given by CHS and DYC. CHS, TSL, WFM, THL, YSC and LCH contributed to design of the study and/or to the implementation of the Intervention. CHS wrote the manuscript and LCH revised for important intellectual contents. All authors approved the final manuscript.

Competing interests: None

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors

Ethics approval: The ethical approval has been processing in the Institutional Review Board of China Medical University Hospital.

Data sharing: This manuscript describes the study protocol for research that do not yet begin the data collection.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	16
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	16
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	3
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

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Effectiveness of a Computerised System of Patient Education in Clinical Practice: a Longitudinal Nested Cohort Study

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Effectiveness of a Computerised System of Patient Education in Clinical Practice: a Longitudinal Nested Cohort Study

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Abstract

Introduction: Developing electronic health record information systems is an international trend for promoting the integration of health information and enhancing the quality of medical services. Patient education is a frequent intervention in nursing care and recording the amount and quality of patient education have become essential in the nursing record. The aims of this study are: (1) to develop a high quality Patient Education Assessment and Description Record System (PEADRS) in the electronic medical record; (2) to examine the effectiveness of the PEADRS on documentation and nurses' satisfaction; (3) to facilitate communication and cooperation between professionals.

Methods and Analysis: A quasi-experimental design and random sampling will be used. The participants are nurses who are involved in patient education by using traditional record or the PEADRS at a medical center. A prospective longitudinal nested cohort study will be conducted to compare the effectiveness of PEADRS, including: (1) the length of nursing documentation; (2) satisfaction with using PEADRS; and (3) the benefit to professional cooperation.

Ethics and dissemination: Patient privacy will be protected according to Electronic Medical Record Management Practices of the hospital. This study develops a patient education digital record system, which would profit the quality of clinical practice in health education. The results will be published in peer-reviewed journals and will present at scientific conferences.

Keywords: Health informatics, Patient education, Patient education record system

Strengths and limitations of this study

• We develop Patient Education Assessment and Description Record System (PEADRS) that is first linkage of patient education into nursing records digitally in the electronic medical information system.

• A prospective longitudinal nested cohort design was chosen to evaluate the effectiveness

of PEADRS in the quality of patient education and professionals' cooperation.

• A potential limitation of the study is the small sample size, when patients with invasive procedures or examinations and operation that may affect the generalizability and external validity of the result of study

Word count: 3308

Introduction

The use of computerised systems in healthcare has been growing globally. Electronic health records are computerised systems that allow storage, retrieval and sharing of information among professionals. [1] Electronic health record information systems standardise specific content, including documentation standards, storage, labelling and certification. Such records promote the integration of health information to enhance the quality of health services. [2]

Paper copies of health records require large amounts of storage space. In addition, they increase the operating and personnel costs of hospitals. Health records produced and stored in electronic format may preclude writing and storage of paper copies. Electronic records not only make access to health records faster but also enhance the quality of service and improve the efficiency of medical resources. [3, 4] To fulfil the requirements of the Electronic Medical Record Adoption Model (EMRAM) Stage 6 Award Survey in April 2017, our hospital had to achieve a near-paperless environment that harnessed technology to support optimised patient care. [5]

Patient education is an important nursing intervention [6] and an important aspect of the nursing documentation. Patient education has been viewed as an important part of providing quality healthcare that respects and safeguards the rights of patients. Research has shown that patient education provides knowledge regarding healthcare, establishes healthy behaviour, shortens hospitalisation and reduces re-hospitalisation. [7] Patient education is foundational for improving compliance with and success of patient engagement initiatives. [8, 9,10] Patient education affects the patient's health status and reduces healthcare costs. It has also been recognised as an independent function of the nursing profession and is a planned, systematic and logical process. [7, 11] Patient education is an important component of good quality healthcare. One of the teaching methods follows the ASSURE (Assessment, Select materials,

Utilise materials, Require learner response, Evaluation) model, which provides guidelines to organise appropriate teaching for achieving health education. [11, 12, 13]

Health insurance in Taiwan has nationwide coverage, which provides a comprehensive package of preventive measures and health services. [14] It allows equal access to healthcare for all citizens by monitoring financial expenditures and improving healthcare outcomes. This high insurance rate results in an extremely high nurse-to-patient ratio in Taiwan compared with other countries and involves providing health education to patients when they are hospitalised. [15] Providing patient education requires time based on patient's needs and involves one-on-one discussion. Also, in clinical practice, patients need repeated education.

Since the Electronic Signature Act was enacted in 2001, the process of maintaining electronic and digital health records has been rapidly developed. [16, 17] The legal elements and effects of electronic health records and signatures have become well-established under the act. These aspects have made electronic health records popular and have accepted and included safe and reliable internet, electronic records and unduplicated signatures. Moreover, identification of health providers involved in patient care would benefit communication among healthcare professionals. [18, 19] Therefore, electronic health records store patient data, strengthen record quality and enable interprofessional cooperation to achieve the goal of providing optimum patient healthcare.

Currently, health education is recorded under the content of caring activities in the nursing record section of the electronic health record. Records of patient education were not easy to identify in the document. Professional health providers in different units are unaware of the type of health education the patient or the patient's family has received. Furthermore, it is difficult to follow-up patients' compliance with treatment after health education if the patient education details are not recorded. Thus, the development of a health education informatics system would fill the gap between the actual patient education and continued

patient healthcare.

Developing a computerised system for patient education is not only to maintain a record but also to improve the working process of clinical practice, which includes appropriate methods, equipment and a computerised system for nurses. [20] Developing an electronic patient education record system would be the last stage in completing nursing records digitally. [21] Despite the benefit of storage space and the ease of transport, little is known about the effectiveness of documenting, nurses' satisfaction level and professional cooperation with the use of the Patient Education Assessment and Description Record System (PEADRS). [22]

Methods

Study aims

The aim of this study is to develop a PEADRS and evaluate the effectiveness of the system on documenting, nurses' satisfaction level and professional cooperation. The study will be conducted in two phases. The first phase is to establish the PEADRS. In the second phase, a quasi-experimental study will be conducted to evaluate the effectiveness of PEADRS. To investigate the outcomes, the following research questions will be asked:

1. How does the patient education care service influence the quality of patient education?
2. How does the PEADRS affect the length of nursing documentation and extent of completed patient education?
3. Is the satisfaction level of participants using the PEADRS different from those using traditional nursing records?
4. How does the PEADRS benefit professional cooperation?

Study conceptual framework

Converting the written records into electronic records (electronic health records) is a

developmental approach in the field of medical science. It can transform patient healthcare management into knowledge and information sharing through the processes of information transferring, integrating, classifying and supporting decision making of patients and healthcare providers for enhancing patients' quality of healthcare. PEADRS provides a model that is based on the ASSURE teaching model (Figure 1). The development process of a PEADRS includes technology, planning and management systems.

Design

The project involves a quasi-experimental design. The study will be conducted in two phases. In the first phase, the PEADRS will be established, developed and built. In the second phase, the effectiveness of the PEADRS will be evaluated, for which a non-synchronous design will be implemented. Subjects for the study will be recruited by random sampling of nurses providing education to patients admitted in a hospital or preparing for invasive examination or surgery in the general wards. The study will be conducted in a medical centre in central Taiwan. A total of 220 nurses will be recruited in each of the control group and the experimental group. The control group will use the traditional method of maintaining records in patient education, whereas the experimental group will apply the PEADRS for patient education and records.

Independent variables

To assess the effectiveness of the PEADRS in patient education related to those admitted for invasive examination or surgery preparation, the following outcomes will be measured:

1. PEADRS application: applying the ASSURE teaching model to the system.
2. The length of the nursing documentation process: observing and recoding the time taken by nurses in documenting health education.
3. Record the integrity of health education: assessing the completion rate of nurses' record.

4. Satisfaction level of nurses using the PEADRS: questionnaire to evaluate satisfaction levels in nurses using the PEADRS.
5. Interprofessional cooperation: is the PEADRS a platform for cognate professionals.

Setting

The study will be conducted in a medical centre in central Taiwan. The hospital is one of the nation's premier teaching hospitals with a capacity of 2111 beds. The hospital has 2980 health education materials in different languages, including brochures, posters and films. In the past decade, the average occupancy rate of hospitalised patients was 85% in this hospital. Many nurses are occupied in implementing health education and recording data.

Participants

The participants include nursing staff who will be recruited through random sampling from the medical centre in central Taiwan. The inclusion criteria are that they should be registered nurses, have a work experience of more than 3 months and should be working in a general ward. Participants will be excluded if they are working as assistant personnel. The optimal sample size was calculated using G*Power 3.1., with a mean difference of $\alpha = 0.05$ and effect size of 0.2 in one sample case with pre-test and post-test. Overall, 199 participants will be required to achieve a power of 80% to detect statistically significant differences. A total of 220 participants will be recruited, with 10% possibly missing in data collection. The same number of participants will be recruited for the control group. The control group will use the original method of recoding patient education in nursing records, and the experimental group will use the PEADRS.

To determine the effectiveness and stability of the PEADRS, the following procedures will be included: (1) PEADRS interface design guidance to guide the operation of priority steps; (2) the consistency of data linking to the nursing care system, assisting nurses to

determine patient facts and amendments; (3) set the content of professional care aspects and their description, meeting the needs of health education records; (4) the convenience for users (nurses); and (5) stability of informatics system. A pilot study was conducted to identify the barriers to and operation of using the PEADRS. A group of 30 nurses was recruited to make appropriate amendments.

Patient and Public Involvement

Patients and public will not be involved in this study.

Developing and establishing PEADRS

1. Establishing a system-developed project team: The team members include a primary investigator, two co-primary investigators (patient education committee chairman, director of nursing), two clinical health educators with more than 10 years of experience, five clinical nurses with 15 years of experience of working in a medical centre (internal medicine, surgery, obstetrics and gynaecology, paediatrics and emergency department), four senior technicians (internal medicine, surgery, rehabilitation and haemodialysis) and one informatics programmer. Several clinical observations of patient education are arranged for the informatics programmer to understand its implementation to reduce the cognitive gap and meet the needs of the users.
2. Regular meeting: The team meets twice a week for discussion. The nursing department is responsible for collecting information and setting up computer screen interfaces for the system and reviewing and analysing the current status of the implementation of the records. Relevant health education for different departments are encouraged by setting up procedures for patient education, including assessment and implementation, developing education content and documenting methods.
3. Setting up the projects: The system includes five professional care aspects: outpatient care, adult patient care, paediatric patient care, examination and treatment care and

Chinese traditional medicine care. The content and procedure of health education can be divided into steps. For example, taking care of a wound would involve the following procedures: (1) keeping the wound clean and dry; (2) observing for signs of infection, including swelling, soreness and abnormal secretions; (3) taking wound-dressing precautions and knowing when to call for the nurse; (4) knowing how to use Steri-Strip/Adhesive Skin Closure; (5) using waterproof cover on the wound before shower; (6) having information regarding care of wound caused during removal of arterial catheter; and (7) knowing how to use Tegaderm Hydrocolloid Dressings.

4. Applying the ASSURE systematic teaching model: The process of ASSURE includes assessment prior to health education, implementation of health education and evaluation of health education on the functional interface of the PEADRS. The design and development of the assessment contents are based on the literature review and recommendations of clinical practice experiences and the experts' advices. It includes an assessment lens related to patient characteristics and the ability to learn, formulating the strategies to implement health education instruction and evaluating the learning outcome based on learners' understanding level (Figure 2).

5. Operation system: The development of simple input interface was designed by the information programme engineer who also integrated the interface control software. To delaminate implementation of the ASSURE systematic teaching model, the following were the operation guidelines with priority steps: 'assessment of patients'; 'implementation of health education'; and 'evaluation of learning'. The components embedded into the design along with health education items allow addition of all types of special components or integration of system functional elements. To simplify the process, after clicking on the data entry, 'Nursing Integration System' of the 'assessment of patient', this will be linked to 'electronic health record system'. All functions in the Nursing Integrated System automatically generate patient records, resulting in the

associated data, functional window prompts and feedback. Nurses in different duty shifts can use the 'inquiry' function to find any related health information and know about the patient/family members who have received health education and the type of health education.

6. Confidentiality and stability: According to the regulation of electronic medical records, the establishment of information management system will ensure the stability, reliability, system confidentiality and security of the overall system operation.

Instruments

Several methods will be used to evaluate the study outcomes, including clinical data, nursing record review, observation, interview and questionnaire. To ensure reliable and unbiased extraction of data from the observation, research assistants will be trained in observing, recording, interviewing and accounting data. Inter-rater reliability of the study will be noted.

A self-report questionnaire will help to measure the satisfaction level of nurses using the PEADRS. Questions are based on the users' adoption and implementation of the PEADRS. The questionnaire includes 12 questions that are answered on a 5-point Likert scale, ranging from 'very good' to 'very bad'. To have an in-depth understanding of the constructive views of nurses, their attitude and their demands, two open-ended questions are added: 1) enhancing factors in adopting the PEADRS; and 2) impeding factors in adopting the PEADRS. The instrument's readability, accuracy, and adaptability will be determined by panel of experts and a pilot study. Face validity will be determined by expert review with a CVI calculation. Reliability will be tested internal consistency by a pilot study with a sample of 30 nurses.

Professional cooperation will be measured by the PEADRS system. The system would provide the choice of a date range (seven or all), on which health education items

implemented through the system can be queried across departments (professionals). Nurses can choose the 'query' option to understand what type of information was already provided to the patient/family members and can continue to follow-up on their response (reaction/adherence). Thus, the system will record the times when patients visit different professionals (nurses/technician/pharmacist/etc) and have health education connected in time and completed. Also, the questions about satisfaction with professional cooperation is also provided in the instrument. For the control group, the professional cooperation can be observed and counted in the traditional nursing records.

Data Collection and Analysis

After the PEADRS is established, baseline data regarding the time of implementing health education and record will be collected, for which a total of 220 nurses providing health education to inpatients with various invasive examination and surgery will be enrolled. The time taken by the nurses for documenting patient education will be observed and recorded. Data on the satisfaction level of nurses using the PEADRS will be collected using a questionnaire. And data on nurses' perspective on applying the PEADRS will be interviewed. The results of professional cooperation will be measured by checking the record on the PEADRS and the questionnaire.

The data will be analyzed using descriptive and inferential statistics. To evaluate PEADRS, the McNemar and paired t tests will be used to calculate the means of length of the nursing documentation between pretest and post-test responses. Next, a t-test will be conducted to compare the two groups in recording the integrity of health education, satisfaction level and interprofessional cooperation. An alpha level of 0.05 will be considered statistically significant.

Ethics and dissemination

Procedure for protecting individual information confidentiality will be followed by electronic medical record management practices of hospitals in accordance with the national medical law and personal data protection law. Ethical approval was obtained from the Institutional Review Board of China Medical University Hospital (CMUH107-REC2-024). The study excludes all individual identification of participants or demographics data. Participants' privacy will be protected according to Electronic Medical Record Management Practices of the hospital.

Discussion

Informatics system have contributed to healthcare.[16] The development and application of the PEARDS is an important stage in promoting a smarter medical care. It is the first act in integrating health education resources into a computerised system in electronic medical records. The study is expected to achieve the following: (1) establishing an assessment, description and record informatics system on patient education for clinical practice in electronic medical records; (2) guiding nurses to provide patient education with the ASSURE systematic teaching model. The results of this study will help nurses to assess the needs of patients/family members for education, such as physical and psychological barrier and emotional status. Thus, it would help nurses to choose an appropriate method for the learner based on assessment and evaluation of learning outcomes; (3) enabling nurses, easily, to review patient data related to health education, which will not only reduce repetition of teaching but also emphasise the evaluation of learning to provide efficacious education. The nurses will recognise the type of patient education that patients/family members have already received, thus facilitating coordination, communication and cooperation between healthcare providers. This would reduce the transmission time and help follow-up patient's adherence so that the patient could enjoy continuity and integrity of healthcare; (4) improving data

consistency, recording integrity and minimising storage space for medical records; and (5) facilitating functional window prompts and feedback. The records cannot be saved until the data entry is completed; this improves the completion of patient education, which helps improve quality of care.

Limitations

Although the steps of the research process have been followed, there are limitations based on staffing, time and economic constraints: (1) education is a highly complex activity, which combines interactive situations with humanities, ethics and educational context. The relationship between the nurses and learners is subjective. The experimental research emphasises standardisation and repeated verification, but education is often unique and cannot be repeated; hence, the cause and effect in health education still has limitations; (2) the study will involve conducting a survey on the nurses' implementation of patient education and digital record, as a representative of patients with invasive procedures or examinations and operation; thus, the results of this study may not be generalized to different types of patient education; (3) although the nurses are willing to cooperate with the implementation and response, the variation in quality, teaching ability and system operation skills may have an impact on the effectiveness of the validity of the new system.

Conclusion

This study aims to study whether the PEADRS has a positive effect on the quality of health care. This study develops a PEADRS, which could help promote the quality of clinical practice. There is a significant gap in the electronic health record information system. The quality of the caring process in patient education documentation is evident. The teaching models such as assessment, teaching methods and evaluation of learning provide a guideline for nurses in patient education, which enhances the nurses' capability in health education. A

study of nurse-end users of the PEADRS should be conducted for yielding more information about barriers, frustrations, quality needs and preferences of nursing staff. Also, a further study is needed to study the effect of the PEADRS on patient outcome such as quality of life, medication adherence). A follow-up study is planned to assess effects of user-designed system changes based on the results of this study. Further work following PEADRS improvements will explore the satisfaction of paramedical staff, including teamwork cooperation, integrated care and sustainability. This study will provide new information specific to patient education and will assist in providing an evidence-base for this innovation at a level that has not yet been established.

Contributions: CHS is the principal investigator of the PEADRS. Study concept was given by CHS and DYC. CHS, TSL, WFM, THL, YSC and LCH contributed to design of the study and/or to the implementation of the Intervention. CHS wrote the manuscript and LCH revised for important intellectual contents. All authors approved the final manuscript.

Competing interests: None

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors

Ethics approval: The ethical approval has been approved by the Institutional Review Board of China Medical University Hospital (CMUH107-REC2-024).

Data sharing: This manuscript describes the study protocol for research that do not yet begin the data collection.

Competing interests: None

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Figure legends

Figure 1. Structure of PEADRS based on ASSURE Systematic Teaching Model

Figure 2. PEADRS Design

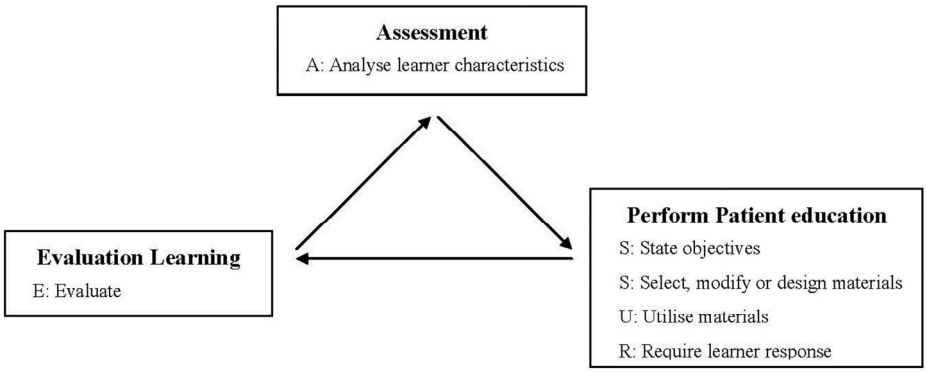

Figure 1. Structure of PEADRS based on ASSURE Systematic Teaching Model

Structure of PEADRS based on ASSURE Systematic Teaching Model

184x101mm (300 x 300 DPI)

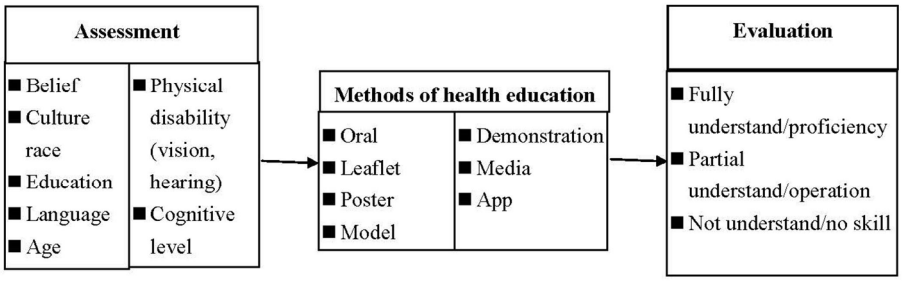

Figure 2. PEADRS Design

PEADRS Design

196x101mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	16
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	16
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.