

Pragmatic Clinical Trial: Nursing interventions for the transformation of public health policies

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Abstract

Objective: To describe the phases of a Pragmatic Clinical Trial (PCT) as a methodology for the transformation of health policies. **Development:** The Pragmatic Clinical Trial (PCT) not only considers clinical scenarios, it involves visits in real contexts such as communities and homes. It also implies administrative management, cultural feasibility, socioeconomic study and political proposal to improve health services. The phases of a PCT are: (1) Description of the phenomenon, (2) Feasibility study, (3) Implementation, (4) Clinical utility, (5) Public policy and (6) Evaluation. **Final considerations:** The contribution of nursing interventions to society (derived from scientific evidence) could be considered by political actors, who can assess the external validity of a PCT, because the data is translatable and usable in real life, at a lower cost and with less expensive interventions
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Introduction

The construction of public health policies must be based on scientific evidence. However, the results of nursing research involving technical care procedures for the prevention and treatment of health problems are not regularly used to propose health reforms or take many years to be applied. Under the premise that indicates: If experimental designs in nursing are not yet a fully used resource to improve health systems, then the impact of the results of typical clinical trials are not reflected in changes in health policy.

A typical clinical trial is understood to mean randomized controlled clinical trials (RCT), recognized as the designs with the highest reliability within the scientific evidence.¹ However, there is evidence that when RCT interventions are translated into practice, there is a decline in efficacy² and inadequate usefulness for reforming government health programs³. Then what is missing to have the desired impact? Considerable challenges have been identified for the translation of RCT results to be effective in practice.^{2,3} For example, the lack of a previous economic study, the cultural characteristics that prevent reproducibility, the characteristics and resources of the medical service that prevent the practice of nursing care, and the lack of political will.⁴ A recent review of the literature argued that the methodological procedures with which nursing

RCTs have been carried out have presented poor evaluations according to the CONSORT^{5,6} criteria. It is argued that an average of 27,000 clinical trials are published per year, The vast majority of systematic reviews conclude that there is not enough evidence to inform about a good clinical decision. In addition, an average of 17 years is required for only 14% of the knowledge obtained through research to be translated into practice.³ This is where the realization of the Pragmatic Clinical Trial (PCT) becomes important, which can be used by nursing science to build evidence-based interventions, not only to transmit knowledge, but to translate it in different latitudes in a short period. The structure of an PCT must have the necessary elements to be able to replicate it in other similar contexts to test its adaptation and contrast its effectiveness, under the framework that considers clinical, sociocultural, economic and political feasibility to achieve the maximum possible generalization, measuring a wide range of results.

Aim: To describe the phases of a Pragmatic Clinical Trial (PCT) as a methodology for the transformation of health policies.

What is a Pragmatic Clinical Trial?

The PCA is based on the RCTs, but not only consider the clinical scenarios, the cognitive implications and the statistical

contrast, the PCT goes beyond the internal validation of a controlled experiment. The sample is large enough to gain power and detect small effects,³ including visits to the community, to the home, to the settings where the study phenomenon is developed to solve real problems for health care based on human responses. It also implies administrative management, verification of cultural feasibility, socioeconomic study for implementation and political proposal to improve health services.^{2,8,9}

To improve "fast and relevant short time" nursing research, it is necessary to propose a research model based on a more pragmatic intervention. The procedures must contemplate a balance between internal and external validity, which denotes a more effective adherence to the real conditions of the health problem in question and not be limited to a controlled scenario.² The PCT is particularly relevant because it considers evidence-based interventions developed in other countries, adapting to different cultural contexts or healthcare settings.^{1,9}

In general, the development of an PCT is long and rigorous, it requires a budget for materials, scenarios, instruction of facilitators or providers of the intervention to guarantee the service to the patients that make up the groups to be manipulated. In fact, the PCT can be used as a nursing research model to try to make interventions more effective and more generalizable. Achieve the effect of an effective and efficient intervention (with respect to cost) of nursing care in: adherence to pharmacological treatment of diabetes patients at home, continuity of care in the healing of chronic wounds, use of contraceptives in adolescents, self-breast examination, exercise practice at home and nutritional education for weight control; These are just a few examples that can more quickly influence health policies and health decisions in priority public health problems.⁴

Phases of a Pragmatic Clinical Trial

The development of an PCT follows the same phases and tests of a typical test, however the size of the sample can improve the generalization and the relevance of the interventions for the nursing practice due to the cultural adaptation it is more precise. Among the various authors there are some differences regarding the phases of an PCT.^{1,2,8} However, many have carried out their work under the CONSORT extension for PCT^{10,11} and the PRECIS-2 instrument, which assesses how pragmatic a clinical trial is^{3,12} based on the different authors and assessment tools, next, the stages or phases to manage and implement an PCT until it is translated into a political proposal are presented.

Phase one. Description of the phenomenon under study, exploring the concept and the implicit theory of the published evidence. In this phase, it is necessary to justify the research question, through the review of the literature (especially systematic reviews, meta-analyses and previous RCTs) that justify the type of intervention of the PCT. Derived from the literary review, the research question is formed and the objectives are formulated. During this phase it is necessary to determine the content of the intervention, which includes the "dose of the active ingredient", with which the variable will be manipulated; the control of this dose is the core point in the study sub-

jects, otherwise, it can provide methodological biases due to the possible interference of confounding variables.¹³

Phase two. This phase refers to the feasibility of implementing the PCT and the application of the pilot test. Once the active ingredient is obtained with respect to the expected dose-response (derived from the literature), the objective is to attract groups interested in the development of the research, not only patients and researchers, but also clinics or health centers. Feasibility refers to the possibility of carrying out the intervention (if something very complicated is proposed to the health system, it does not make sense). Carrying out the feasibility study increases the chances of success, because the interests of the community and its leaders are included. In other words, in the feasibility study, people from the community and the authorities should be interviewed to find out their interests or needs; This facilitates the call to form focus groups of interested parties or patients who wish to enter the study.

To verify the feasibility of the study, an exploratory test or pilot test must be carried out, to prove the test methods and procedures, explore possible effects and associates¹⁴. Carrying out a pilot test benefits in the degree of knowing the preliminary barriers that could arise in the scenarios to implement the intervention, knowing the barriers implies knowing the facilities of clinical, physical-structural and human resources to reduce the methodological bias.¹³

Phase three. This phase refers to the effectiveness of the PCT in a real context, where the intervention is properly implemented in subjects distributed in parallel groups called control and experimental¹⁵, the intervention model that was structured to dose the active component that manipulates the dependent variable is established, controlling other variables that are identified as mediating, intervening or confounding¹³, derived from phase one corresponding to the review of the literature and subsequently identified in the pilot test. In this phase, the costs and the magnitude of the results are established to determine the potential of the intervention in terms of acceptability and clinical effect, validity and analysis of results from a qualitative and statistical perspective.

Phase four. This phase refers to the usefulness of the PCT, where the external validity is evaluated based on the contrast of its results with other similar clinical trials. The most important thing in this phase is the replication in other contexts with a sufficiently robust sample to improve the scientific explanation, contrast the results from the clinical and statistical field, with which the impact in the different clinical scenarios of different latitudes (regional, national or international).¹⁶ The fidelity of the intervention to both the patient receiving the active ingredient and the care provider is verified. To do this, check sheets are used or interviews are conducted during or at the end of the time the intervention lasted, with the purpose of identifying, on the one hand, that the patient uses the strategies learned and, on the other, verifying the degree of compliance.

Treatment by the caregiver. It is in this phase, according to the findings, that the dose of the active ingredient in the intervention must be fine-tuned, to ensure the integrity of the

treatment in a real context, not only in the laboratory or in limited contexts such as in an RCT.^{17,18}

Phase five. This phase refers to the generation of public policy, where the implementation is requested from the authorities that regulate the laws of the local health system. The objectives and strategies for the implementation of the PCT must be presented within a regulatory framework for its execution.

Each country has its own policy evaluation councils for social development, which are usually autonomous and, due to their technical capacity, are part of the dictation of the public policies presented. It is recommended that the issue addressed by the PCT must be adapted to the national development plan of the government in turn, that is, to the priorities or previous programs prioritized by the government, under a planning and financial framework. The institutions that make decisions must be identified, be they Congress of the Union, State Legislature, Federal Audits, Chamber of Deputies or Sendores, all political actors that have to do with public spending for science and technology that are interested by the health service of society.^{4,19}

Phase six. Under the reasoning that all knowledge must be updated, this phase is evaluation, where the results derived from the implementation of public policy are fed back. The evaluation can provide elements for changing or updating the dose of the active ingredient. The evaluation concludes with reforms to the regulations originally established with the purpose of improving the public health of the population to whom the benefits are directed^{4,20}. The phases can be seen in Table 1.

To identify the order and cohesion of the management phases for the creation and implementation of an PCT and the

specifications in the delivery of the intervention, the following Figure 1 is presented.

Final considerations

In the services of a first level of health care, nursing interventions are complex and multiple, most of them are educational, not only to prevent diseases, they are fundamental to promote health. Nursing care works with human responses to manipulate them positively and favor adherence to treatment, pharmacological, nutrition, physical activity and stress control; situations that alleviate suffering and strengthen the trust of families.

It is recognized that the nursing position in the community is valued as professionals with great leadership, a situation that gives them control over the scenarios to test the effectiveness of health interventions in the real world. The nurse interacts like no other health professional with society, a situation that gives them an advantage to apply the PCT, a situation that results in the achievement of maximum external validity in many settings and not only in a valid laboratory very high internal

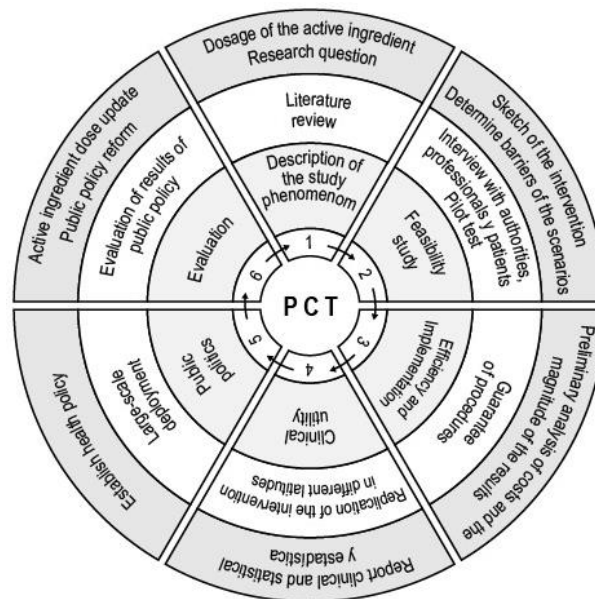
In short, pragmatic trials are experimental designs that allow, due to their usefulness, to support with their results, decisions to generate public policies. The interventions are built based on scientific evidence and are applied in robust samples, in order to gain external validity that favors collective health. Professional participation is multidisciplinary, where nursing has a privileged role due to its direct proximity to the community.

Table 1. Development phases for the creation and implementation of a PCT

Phase	Strategies	Expected Outcomes
1. Description of the phenomenon to be studied.	Literature review to identify systematic reviews, meta-analysis and clinical trials.	Justification of the PCT. Proposal of the active ingredient dosage Research question Creation of Objectives.
2. Feasibility study and pilot test.	Feasibility: Interview with authorities, professionals and patients. Calculate recruitment rate. Pilot test Train the facilitators of the intervention.	Develop an outline of the intervention. Determine barriers of the scenarios. Improve the intervention design derived from the results of the pilot test.
3. Efficacy and implementation	Form the research team. Calculate the sample by buffering for the drop-out rate (attrition). Randomize the study subjects into the groups. Guarantee the delivery of procedures in the intervention.	Analyze the results from a clinical and statistical perspective. Determine the magnitude of the intervention's effectiveness Preliminary cost analysis and magnitude of the results.
4. Clinical utility	Replica of the intervention in different latitudes: regional, national or international	Report clinical and statistical testing. Discover at an early stage if the intervention has potential.
5. Public Policy	Determine the effects on public health programs, large-scale implementation.	Establish health policies.
6. Evaluation	Evaluation of public policy results. Recognize current scientific evidence to revolutionize	Active Ingredient Dosage Update Public Policy Reform

Source: Adapted from the CONSORT extension for ECP¹¹, PRECIS-2^{12,16} and Landeros et al.⁴

Figure 1. Phases from pragmatic clinical trial



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