# REVISIÓN



# Didactic strategy for the training of skills in clinical trials of Stomatology residents

# Estrategia didáctica para la formación de habilidades en ensayos clínicos de residentes de Estomatología

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# ABSTRACT

**Introduction:** Primary Health Care is the first point of contact that specialists in stomatological sciences provide to the population.

**Objective:** to develop a didactic strategy for training skills in clinical trials for dentistry residents.

**Method:** descriptive, cross-sectional study on the Isle of Youth, 2022-2023. Intentional non-probabilistic sampling was used, with the sample consisting of 39 residents, 20 academic committee professors, 17 provincial coordinators and 7 research methodology professors.

**Results:** a survey was applied to explore knowledge on the topic and it was found that 89,7 % had a low level. The main difficulties identified were in the questions related to knowledge about the researcher's portfolio and the elements necessary to start a clinical trial, with percentages of 7,7 % and 12,8 %, respectively. The proposed strategy was submitted to expert judgment, with scores predominating: very appropriate and moderately appropriate, with values of 64,8 % and 25,6 %, respectively, which represented 90,3 % for the evaluated criteria. The strategy was made up of four stages and actions structured in a coherent manner for its application, which can be enriched from the teaching reflection and the practice of the academic committee of each specialty.

**Conclusions:** the diagnosis of the current situation of the training of Stomatology specialists on the subject of clinical trials revealed potentialities and shortcomings in the conception, the process and the current level of its development.

Keywords: Clinical Trials; Stomatology; Skills.

# RESUMEN

**Introducción:** la Atención Primaria de Salud es el primer punto de contacto que los especialistas de las ciencias estomatológicas proporcionan a la población.

**Objetivo:** elaborar una estrategia didáctica para la formación de habilidades en ensayos clínicos para los residentes de estomatología.

**Método:** estudio descriptivo, de corte transversal en la Isla de Juventud, 2022-2023. Se utilizó el muestreo no probabilístico intencional quedando constituida la muestra por 39 residentes, 20 profesores del comité académico, 17 coordinadores provinciales y 7 profesores de metodología de la investigación.

**Resultados:** se aplicó una encuesta para explorar los conocimientos sobre el tema y se constató que el 89,7 % tenían un nivel bajo. Las principales dificultades identificadas estuvieron en las preguntas relacionadas con

© 2024; Los autores. Este es un artículo en acceso abierto, distribuido bajo los términos de una licencia Creative Commons (https:// creativecommons.org/licenses/by/4.0) que permite el uso, distribución y reproducción en cualquier medio siempre que la obra original sea correctamente citada conocimientos sobre la carpeta del investigador y los elementos necesarios para iniciar un ensayo clínico, con porcentajes de 7,7 % 12,8 %, respectivamente. La estrategia propuesta se sometió a criterio de expertos, predominando las puntuaciones: muy adecuada y moderadamente adecuada, con valores de 64,8 % y 25,6 %, respectivamente, lo que representó el 90,3 % para los criterios evaluados. La estrategia quedó conformada por cuatro etapas y acciones estructuradas de manera coherente para su aplicación, que pueden ser enriquecidas a partir de la reflexión docente y la práctica del comité académico de cada especialidad. **Conclusiones: e**l diagnóstico de la situación actual de la formación de los especialistas de Estomatología sobre la temática de ensayos clínicos, reveló potencialidades y carencias en la concepción, el proceso y el nivel actual de su desarrollo.

Palabras clave: Ensayos Clínicos; Estomatología; Habilidades.

# **INTRODUCTION**

Scientific research is an activity with a cognitive purpose. It comprises a set of planned actions undertaken with the purpose of totally or partially solving a given scientific problem. In higher education it has a double function: it contributes to the formation of the professional and it is also a way to solve complex problems that arise in society.<sup>(1)</sup> The process of scientific research in universities is developed as a service offered to society, to improve production and services; to enrich science, deepening man's knowledge of his surroundings.<sup>(2)</sup>

The university is one of the pillars of the country's science and technological innovation subsystem, and it is responsible for stimulating the scientific training of the professionals it trains to meet their needs and guarantee their full development. That is why the need to raise the research preparation of health science graduates, especially of graduating physicians, is a present and debated challenge. The university center should take the lead in conducting research that contributes to raising the quality of medical care provided.

Primary health care (PHC) is the central function and main core of the National Health System (NHS) in Cuba; it represents the first level of contact of individuals, the family and the community with it, and brings health care as close as possible to the place where people live and work; it is the first element of a permanent process of health care. Research conducted in this setting provides knowledge relevant to other disciplines, which is essential to achieve a comprehensive understanding of health problems and contribute to their improvement. Clinical research is undertaken taking into account the health problems identified in the population and is developed with high scientific rigor, allowing results to be obtained that can contribute to decision making in the field of public health.<sup>(3)</sup>

Clinical trials (CT) are a fundamental procedure for the generation and incorporation of proprietary knowledge in PHC.<sup>(4)</sup> Their performance in this context brings with it numerous advantages.<sup>(3)</sup> Diseases can be detected in their earliest stages, a large number of patients can be recruited early, resulting in a much faster and more efficient process, work is achieved in multidisciplinary teams that include the psychological and social care of patients, among others.

In 2004, the National Clinical Trials Coordinating Center (CENCEC) implemented a strategy that included all the provinces of the country, except for the Isle of Youth. The improvement plans in the last 10 years do not include the subject among their learning needs. Due to the antecedents previously exposed, the authors posed as a scientific problem: How to contribute to the formation of skills in clinical trials for residents of stomatological specialties? The objective was proposed as: to elaborate a didactic strategy for the formation of skills in clinical trials for Stomatology residents. This will contribute to the formation of a professional, able to investigate, include patients and actively participate as a member of this type of research from primary health care.

# **METHODS**

A descriptive, cross-sectional study was conducted in the Special Municipality Isla de Juventud from January 2022 to October 2023.

#### Universe and sample

The study universe consisted of all the residents and the professors of the academic committee of the specialty at the Faculty of Medical Sciences of that municipality, in addition to the provincial coordinators of clinical trials (CPEC) of the CENCEC and the professors who taught research methodology at the national level in the 2022-2023 academic year.

Non-probability and purposive sampling was used. The sample consisted of 39 residents, 20 academic committee professors, 17 CPECs and 7 research methodology professors.

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#### Techniques and procedures

The research was also carried out with experts who were selected according to the following criteria: 10 years of experience or more in CE and a high or medium competence coefficient (between 0,8 and 1).

The main variables were: expert competence and level of knowledge.

Documents on undergraduate and postgraduate medical-stomatological education, current curricula for undergraduates, current curricula for specialists, subject and course syllabi, as well as the model of the professional were examined.

The results of the diagnosis made it possible to identify the most appropriate actions to be taken. Actions aimed at professional development were proposed (seminars, workshops, specialized conferences and others). Strengths and weaknesses were identified, which made it possible to establish the different alternatives to be applied. The resources needed to implement each action in the short, medium and long term were specified.

First, the first stage of the strategy (diagnosis) was validated in practice through a pilot test that made it possible to evaluate its viability and improve its design, and secondly, expert criteria were used as a theoretical assessment.

A group interview was conducted with professors of the academic committee of postgraduate specialties: to learn about the training received on the subject of clinical trials and the treatment of research skills in the development of their teaching activities. In addition to specifying the criteria about the need for preparation in the subject, as well as the limitations that influence them to teach it.

A survey was designed to measure the level of knowledge on the subject of clinical trials in residents. As a starting point, elements provided by the literature review were used to determine the variables and indicators, which made it possible to determine the research needs on the subject. This instrument consisted of seven questions and a high level of knowledge on the subject was considered when the evaluation was excellent, medium when the qualification was good or regular and low when the qualification was poor.

Interviews were conducted via email with CE CPECs and research methodology professors to learn about the training pathways that are in place in each province for the preparation of residents in CE.

The expert criteria were used in two moments, first to validate the survey applied to the residents, and second, for the approval and theoretical validation of the didactic strategy presented.

The statistical methods used were the percentage analysis, which allowed the processing and summary of the information, and the Delphi method to process the experts' criteria.

The SPSS 22.0 program was used to create the database for processing and analyzing the information. The ethical considerations established in scientific research were taken into account for obtaining and processing the information, as well as for disseminating the results. The information obtained was not used for other purposes outside the framework of the research.

# RESULTS

The diagnosis of the current situation of undergraduate and postgraduate specialist training on the subject of CE yielded the following results:

In the analysis of the undergraduate study plan,<sup>(5)</sup> in the opinion of the authors, there is no systematic and integrated work of the subjects and disciplines in terms of the creation of common strategies for the development of a scientific culture, which constitutes a curricular limitation. This finding coincides with previous research.<sup>(6,7,8,9)</sup>

In the analysis made by the authors of the undergraduate program,<sup>(5)</sup> to identify the contents of CE present in it, eight subjects were identified that present topics that can facilitate the general training of this professional in experimental studies.

Once again, the research methodology module in the postgraduate program deals with research skills, emphasizing that, unlike the undergraduate program, it is taught in all the years that make up the specialization, but not in the CE content. It was also pointed out that the subject is not addressed in the rest of the modules, and in the contents that the resident must acquire, the development of research skills as a system is not enhanced, using the space offered by the practice activities in the medical sciences. When analyzing the contents of the courses and skills to be developed, it was observed that they do not provide effective options to promote knowledge related to the subject of CE. There are no curricular spaces committed to the formation of these skills and to learning in this sense.

The proposed strategy is defined as didactic, since it is fundamentally aimed at improving the training process of future postgraduate specialists. It presents a logical order and is characterized by the interrelation between the stages that compose it. Due to its integral and systemic character, it facilitates the establishment among all participants, the developmental approach of the training process of research skills and the improvement of their professional performance. The proposed strategy is shown graphically (figure 1).



Figure 1. Didactic strategy proposed for the formation of research skills in clinical trials of Stomatology residents Source: Own elaboration (The original Spanish language version).

The group interview with the teachers showed that 95 % (19) reported not having received any preparation related to CE, either in their initial or continuous training. It was evidenced that the prominence of this topic in professional development has been poor, which was demonstrated in the projection of actions. The authors believe that this is due to the fact that those in charge of developing these skills are mostly the teaching specialists themselves, who also state that they have limitations in this regard.

The level of mastery they have to correctly assume the training and development of research skills with their residents is low, referred by 100 % of the interviewees. Likewise, 100 % considered that CE is research that can be performed in PHC because it is the first point of contact that health services provide to the population, regardless of socioeconomic level, age, sex, health status or disease.

The diagnosis of learning needs provides the necessary elements to develop the activities required to meet those needs, as has been shown in several studies.  $^{(8,10,11,12,13,14,15)}$  When exploring the residents' knowledge of the subject, it was found that most of them had a low level of knowledge, 89,7 % (35). The main difficulties were in the questions related to knowledge about the researcher's folder and the elements necessary to initiate a CE, with percentages of 7,7 % (3) and 12,8 % (5) respectively. The highest number of correct answers was related to the concept of CE with 37 for 94,9 %.

CENCEC has a total of 32 CE CPECs distributed in all provinces of the country according to data provided by the postgraduate department of that institution. An e-mail interview was sent to each of them, and 17 (53 %) replied. Of these, only two (11,7 %) said they were aware of the existence of a course and that they agreed that it included the methodological pillars of CE, the phases of drug development, GCP, research ethics and the protocol.

None of the research methodology professors interviewed reported knowing neither the course nor its contents, although 2 (18 %) pointed out that in the classes on classification of research, ECs are addressed in the experimental type.

The degree of expertise of the specialists participating in the evaluation of an instrument has a decisive influence on the accuracy and reliability of the criteria they offer.<sup>(16,17,18,19,20,21,22)</sup> In the present research, the experts' criteria were needed to verify the scientific validity of the survey applied in the diagnosis and of the didactic strategy proposed for the latter; the very adequate and moderately adequate scores predominated with values of 64,8 % and 25,6 %, respectively, which represented 90,3 % for the criteria evaluated.

Among the recommendations issued by the experts for the improvement of the proposal were the following:

- To take advantage of the remaining two years of the specialty to deepen aspects addressed as part of the proposed course.
- Control, together with the methodological teaching department, that the ethical elements of clinical research are addressed in the Research Methodology module, as well as in the Philosophy and Society module.
- Include all members of the multidisciplinary work team in the improvement activities.
- Establish effective coordination with the different teaching scenarios in which specialists and teachers are inserted, in order to promote improvement in CE.

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By performing a comprehensive analysis of the instruments used, it was understood the need to deepen the development of research skills for the development of CE of the stomatology specialist, to find the potentialities to improve the current situation and contribute to mitigate the existing limitations in the training of this professional.

# CONCLUSIONS

The diagnosis of the current situation of undergraduate and postgraduate training on CE revealed potentials and deficiencies in the conception, process and current level of development of the subject in Stomatology specialists. The proposed didactic strategy is made up of four fundamental stages and a set of actions structured in a coherent manner that make its application possible, being evaluated as very adequate by the experts' criteria.

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# CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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