Janus Sistema Administrativo da Pós-Graduação

Discipline Information

The following dates are in (dd/mm/yyyy) format.

Code: RAL5872 - 4 Type: POS
Name: Clinical Trials for Nonpharmacologic interventions
Concentration area: Ciências da Saúde Aplicadas ao Aparelho Locomotor (17142)

Approval dates:
CCP: 30/09/2024 CPG: 19/11/2024 CoPGr:

Activation date: 19/11/2024 Inactivation date:

Workload:
Total: 60 h Theory: 2 h Practice: 5 h Study: 8 h

Credits: 4 Duration: 4 weeks

Professors: 1288302 - Marcelo Riberto - 19/11/2024 until today

Objectives:

Critically discuss the concept of evidence-based medicine, its strengths and limitations associated with the use of criteria that are easily applied to pharmacological trials but are not operational with other forms of clinical intervention.

Present the methodological aspects of observational and experimental clinical studies that should be observed during the process of planning research projects and reading their results.

Rationale:

The rate of growth of scientific knowledge in the health areas has been rapidly increasing, which makes it impracticable to follow all available literature. It is therefore necessary to use criteria to define the quality of scientific production, according to the value of the aggregate contribution in making diagnostic, therapeutic, preventive and rehabilitation decisions.
These criteria are very clear for pharmacological interventions but are often not followed with the same rigor in investigations with other therapeutic interventions, such as the use of therapeutic devices, techniques or media which active principle is not chemical. The observation of this phenomenon by the agencies of control of health resources in clinical practice has determined, also, differentiated parameters of evaluation of scientific evidence for the release of equipment or techniques. In addition, the groups involved in the review of the non-pharmacological literature have established criteria for weighing the scientific evidence when not all the corollary of the pharmacological investigation can be followed.
The discipline has a formative character, since it brings to the student the reflection on medicine based on evidence, careful revision of the literature and techniques of synthesis of knowledge.

Content:

The topics of classes will be:
1. Evidence-based medicine versus excellence-based medicine
2. Levels of evidence
3. Methodological evaluation instrument for clinical trials
4. Systematic reviews: formulating and recording the research question
5. Search strategies, indexing sources, definition of limiters
6. Extraction and synthesis of data in systematic reviews
7. Critical appraisal tool: Number needed to process, number needed for damage, relative and attributable risk

Bibliography:

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1. Cleophas TJ, Zwinderman AH. Modern Meta-analysis: review and updated methodologies. Springer, 2017.
2. Sherman KJ.The Trials and Tribulations of Selecting Comparison Groups in Randomized Trials of Nonpharmacological Complementary and Integrative Health Interventions. J Altern Complement Med. 2020 Jun;26(6):449-455.
3. Mbuagbaw L, Lawson DO, Puljak L, Allison DB, Thabane L. A tutorial on methodological studies: the what, when, how and why. BMC Med Res Methodol. 2020 Sep 7;20(1):226.
4. Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to metanalysis. Jonh Wilwy & Sons, 2009.
5. Portney LG, Watkins MP. Foundations of clinical research: applications to evidence-based practice (4th edition), Prentice Hall, 2020.
6. Gupta SK. Basic principles of clinical research and methodology. Institute of Clinical Research (India), 2007.
7. Fletcher, Grant S. Epidemiologia clínica: elementos essenciais [recurso eletrônico] / Grant S. Fletcher; tradução: André Garcia Islabão; revisão técnica: Airton Tetelbom Stein. – 6. ed. Porto Alegre: Artmed, 2021.
8. Fregni F et al. Challenges and recommendations for placebo controls in randomized trials in physical and rehabilitation medicine. Am J Phys Med Rehabil 2010;89(2):160-172.
9. Vickers AJ. Placebo controls in randomized trials of acupuncture. Eval Health Prof 2002;25:421.
10. Kang M, Ragan BG, Park JH. Issues in the outcome research: an overview of randomization techniques for clinical trials. J Athletic Train 2008:43(2):215-221.
11. Speich B. Blinding in surgical randomized clinical trials in 2015. Ann Surg 2017;266(1):21-22.
12. Chan S, Bhandari M. The quality of reporting of orthopedic randomized trials with use of a checklist for nonfarmacological therapies. 2007;89(9):1970-8.
13. Whyte J, Dijkers MP, Fasoli SE, Ferraro M, Katz LW, Norton S, Parent E, Pinto SM, Sisto SA, Van Stan JH, Wengerd L. Recommendations for Reporting on Rehabilitation Interventions. Am J Phys Med Rehabil. 2021 Jan 1;100(1):5-16.
14. Pocock SJ. Travison TG, Wruck LM. How to interpret figures in reports of clinical trials. BMJ 2008;336:1166-1169.

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Type of Assessment:

Attendance at 75% of the theoretical classes (3 of the 4 classes of the discipline)
• Preparation of a reflection on the clinical research project itself, covering the following aspects (minimum grade = 7.0):
• Definition of the methodological design of the study with its advantages and disadvantages (2.5 points)
• Critical analysis of eligibility criteria, randomization method, masking, assessment methods (2.5 points)
• Outline of the presentation of results (2.5 points)
• Identification of potential sources of bias (2.5 points)
• Proposals for modification of the initial project (2.5 p

Note:

This course will be taught in person during the first and last weeks of activities. On these days, classes will be held at the FMRP-USP or PPG Health Sciences Applied to the Locomotor System facilities. In the second and third weeks, activities will be carried out remotely with exercises and activities available in the Moodle system and synchronous classes via teleconference. To register, students must present their clinical research projects, since the main item to be assessed at

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the end of the course is the ability to perceive weaknesses and possibilities for improvement in these projects with learnt content.

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