Janus Sistema Administrativo da Pós-Graduação

Discipline Information

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

Code: RAL5872 - 3 Type: POS
Name: Clinical trials and metanalises for nonpharmacologic interventions
Concentration area: Ciências da Saúde Aplicadas ao Aparelho Locomotor (17142)

Approval dates:
CCP: 10/05/2018 CPG: 12/06/2018 CoPGr:
Activation date: 12/06/2018 Inactivation date:

Workload:
Total: 60 h Theory: 2 h Practice: 5 h Study: 8 h
Credits: 4 Duration: 4 weeks

Professors: 1288302 - Marcelo Riberto - 12/06/2018 until today

Objectives:

To present the most important methodologic aspects for the development of high quality clinical trials.
To critically discuss the concepts of evidence based medicine, its strengths and limitations related to criteria easily applicable for pharmacologic treatment, but not as effective in the evaluation of other clinical interventions.
To develop skills of critical reading of clinical reports as well as practice the gathering, summary, compilation and writing of systematic reviews. Also, the concepts related to quantitative analisys of this studies will be approached to present the most important aspects of metanalises.

Rationale:

The rapid increase of scientific knowledge in health sciences has in the last decades made it impracticable to follow all available literature, even in restricted areas of knowledge. In order to synthesize the available knowledge and to allow the best scientific information to be tracked on a subject, it is 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. Such 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 devices, techniques or medium whose active principle is not chemical or pharmacological. The observation of this phenomenon by the agencies of control of health resources in clinical practice has determined, also, differentiated parameters of evaluation of the scientific evidence for the release of equipment or techniques. In addition, the groups involved in the review of the non-pharmacological literature have been establishing criteria for weighing the scientific evidence when not all the corollary of the pharmacological investigation can be followed.
This course addresses a specific area of current clinical research knowledge that is not part of undergraduate courses, since for the most part the examples and discussions used in courses in this area are based on examples with drugs, which limits the critical view of the graduated as to the particularities of the research with non-pharmacological means, such as those associated with masking, loss of follow-up and obsolecence of equipment. It can also be understood as instrumental since it aims to introduce the student to the various aspects of a clinical trial that increase its quality and impact across the rest of the published literature. It can increase the quality of clinical studies and graduate projects. On the other hand, it also has a formative character, since it brings to the student the reflection on evidence-based medicine, careful review of the literature and knowledge synthesis techniques.

Content:

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The topics will be:
1. Evidence-based medicine
2. Clinical epidemiology – cross-sectional x longitudinal studies
3. Clinical trials 1: equipoise concept, developmente of a clinical question, study designs
4. Clinical trials 2: randomization and blinding
5. Clinical trials 3: recruiting and drop-out
6. Basic statistic for clinical trials: type 1 and 2 errors, hypothesis
7. Basic statistic for clinical trials: Confidence intervals, effect size, sample size
8. Systematic reviews
9. Meta-Analysis: data extraction, Forrest Plot
10. Meta-Analysis: heterogeneity, publication bias

Bibliography:

1. Friedmann LM, Furberg CD et al. Fundamentals of clinical trials. Spinger International Publishing 2015. Switzerland.
2. Boutron I et al. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update anda a CONSORT extension fof nonpharmacologic trials abstract. Ann Int Med 2017;167:40-47.
3. Moher D et al. Preferred reporting items for systematic review and meta-analyses: the PRISMA statement. Int J Sur 2010;8:336-341.
4. Stewart LA et al. Preferred reporting items for systematic review and meta-analysis of individual participant data: the PRISMA IPD statement. JAMA 2015;313(16):1657-65.
5. Moher D et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015;4(1):1
6. Bossuyt PM et al. STARD 2015: na updated list of essential items for reporting diagnostic accuracy studies. BMJ 2015;351:h5527
7. Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to metanalysis. Jonh Wilwy & Sons, 2009.
8. Portney LG, Watkins MP. Foundations of clinical research: applications to practice (3rd edition), Prentice Hall, 2008.
9. Gupta SK. Basic principles of clinical research and methodology. Institute of Clinical Research (India), 2007.
10. Beseñor IM, Lotufo PA. Epidemiologia – abordagem prática – medicina, ciência e arte 2ª. Ed. Sarvier 2011.
11. 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.
12. Vickers AJ. Placebo controls in randomized trials of acupuncture. Eval Health Prof 2002;25:421.
13. 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.
14. Pocock SJ. Travison TG, Wruck LM. How to interpret figures in reports of clinical trials. BMJ 2008;336:1166-1169.

Type of Assessment:

The evaluation criteria are:

• Presence: 70% in classes
• Mean = > 7 (of the following items):

Writing a clinical trial protocol – weight 1
Critical

Note:

This course may be administered by teleconference from FMRP-USP or HCRP, with a variable number of distance points according to the enrollment and technological resources for retransmission. Students enrolled in postgraduate programs in the health area will be accepted as long as they have a clinical research study in the process of being drafted, but data collection has not started. The main evaluation item at the end of the course is the ability to perceive the weaknesses and possibilities for improvement in these projects with the acquired content. This course can be taught in English, depending on the presence of foreign students.

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