RISEUP-PPD

TRAINING SCHOOL #2

PRINCIPLES AND PRACTICES IN CLINICAL TRIALS

NOVEMBER· 23-25 · 2020

cost EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Funded by the Horizon 2020 Framework Programme of the European Union

RISEUP-PPD

OVERVIEW

Training School in Principles and Practices in Clinical Trials

23 to 25 November 2020

Introduction

The Training School "*Principles and Practices in Clinical Trials*" is organised by Riseup-PPD COST Action, Workgroup 1 - Prevention and Treatment Strategies of Peripartum Depression Disorder (PPD).

The main goal of this workgroup is to synthesise current knowledge concerning diagnosis and management of PPD, including well-established interventions and new lines of research, and to disseminate this knowledge by providing training to researchers and health professionals working in perinatal settings. This Training School offers an introductory approach to the principles and practices of clinical trials, which are the gold standard to gather evidence about new diagnostic, preventive or treatment tools for PPD. This training school is also designed to foster valuable skills to highly motivated young researchers who might be interested in conducting research in the field of perinatal mental health.

Main Objectives

To understand the differences between clinical studies/clinical trials and distinctive clinical trials' designs;

To recognize important methodological and process decisions, their association with the distinctive statistical models and their impact on the strength of the study results;

To understand the requirements behind information systems for clinical studies/trials;

To recognize best practices in data entry, validation, security and sharing.

Target Audience

Researchers, lab managers, PhD and master's students, other science professionals.

No previous experience is required.

Organisers

Riseup-PPD's Working Group 1 (Prevention and Treatment Strategies in PPD)
Mijke Lambregtse-van den Berg, Ana Ganho Ávila, and Ana Fonseca

Trainers

Astrid Kamperman - Erasmus Medical Centre, Rotterdam, The Netherlands
Daniel Faria - INESC-ID and Biodata.pt, Lisbon, Portugal
Emília C. Monteiro - Portuguese Clinical Research Infrastructure Network (PtCRIN)
Joana Batuca - European Clinical Research Infrastructure Network (ECRIN)/PtCRIN

Local sites

Faculty of Psychology and Educational Sciences, University of Coimbra, Portugal
European University of Cyprus, Nicosia, Cyprus
Col·legi Oficial Infermeres I Infermers, Barcelona, Spain

Online access

You can attend the Training School online through the following Zoom link:

https://videoconf-colibri.zoom.us/j/82292557341

Made possible with support of

Funded by

Funded by the Horizon 2020 Framework Programme of the European Union

RISEUP-PPD

SCHEDULE AND TRAINERS
Training School in Principles and Practices in Clinical Trials
23 to 25 November 2020

23 November	
Time (CET)	**What**

9:30 am - 11:15 am	**Introduction (Emília C. Monteiro, Joana Batuca)**
	• Types of clinical studies
	  ○ Observational studies
	  ○ Clinical trials
	• Clinical trials
	  ○ Stakeholders involved and particularities of the studies according to the type of sponsor
	• Practical exercises

11:15 am - 11:30 am	*Break*
11:30 am - 1:30 pm	**Clinical Trial Design I (Emília C. Monteiro, Joana Batuca)** • Gap analysis • Research question (FINAR criteria) • Types of Clinical trials (phases) • Structure • Clinical trials registries databases • Clinical trial dossier ○ Key elements of a clinical study protocol • Practical exercises
1:30 pm - 2:30 pm	*Lunch break*

2:30 pm - 3:30 pm	**Study Design II (Astrid Kamperman)**
	• Assignment/randomization
	  ○ Procedures
	  ○ Importance
	• Blinding
	  ○ Definition
	  ○ Types of blinding
	  ○ Protection and assessment of blinding
	  ○ Drugs (blinding procedure, matching, coding, su
	  ○ Unblinding procedure
	• Study treatment
	  ○ Active intervention versus control/comparison t
	  ○ Placebo/sham
	• Interactive practical exercises

3:30 pm - 3:45 pm	*Break*

3:45 pm - 5:00 pm	• Study population
	  ○ Target population
	  ○ Selection criteria
	  ○ Recruitment
	• Sample size/power
	  ○ Statistical principles
	  ○ Techniques (dichotomous versus continuous)
	  ○ Estimating sample size parameters
	• Measurements
	  ○ Baseline
	  ○ Follow up
	  ○ Treatment compliance
	• Interactive practical exercises

END - 5:00 pm

24 November	
Time (CET)	**What**
9:30 am - 11:15 am	**Clinical Trial Design II (Astrid Kamperman)** • Types of bias • Pros and cons of RCT design • Specifics of clinical trials for women in peripartum period
11:15 am - 11:30 am	*Break*
11:30 am - 1:30 pm	**Interactive Practical Exercises**
1:30 pm - 2:30 pm	*Lunch break*
2:30 pm - 3:30 pm	**Information Systems for Clinical Studies and Trials (Daniel Faria)** • Domain modelling and database design • Case Report Forms (CRF) • Data entry and validation • Data security • Data sharing
3:30 pm - 3:45 pm	*Break*
3:45 pm - 5:00 pm	**Ethical issues (Emília C. Monteiro, Joana Batuca)** • Legislation and Good Clinical Practice Guidelines • Clinical trials registries databases • Informed consent and patient information • Vulnerable population • Practical exercises

END - 5.00 pm

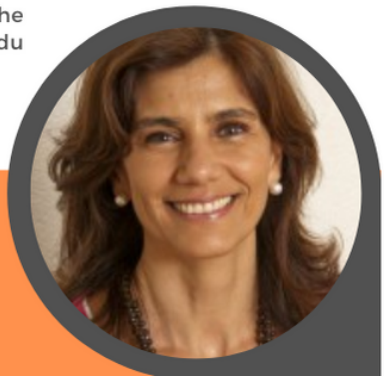
25 November	
Time (CET)	**What**
9.30 am - 11.15 am	**Poster session I**
11.15 am - 11.30 am	*Break*
11.30am - 1.30pm	**Poster session II**
END - 1.30 pm	

Dr. Astrid Kamperman is an assistant professor, has over ten years of working experience as a quantitative researcher at the department of Psychiatry at Erasmus University Medical Center in Rotterdam, The Netherlands. Over the years she has been an author of over 50 peer reviewed papers. As a psychologist and epidemiologist, her experience is centered around the methods and statistics often used in clinical psychiatry and clinical epidemiology. Recently, she added machine learning techniques and big data research to her interests. She applies her skills on topics related to women's mental health and persons with severe psychiatric disorders. She loves to find the sweet spot between valid methodology and clinically relevant research questions. In this course, she will discuss important features of a valid research design, and how to tackle the dilemma's that arise from conducting research on clinical care for women with mental illness.

ASTRID KAMPERMAN

Erasmus Medical Center, Rotterdam, The Netherlands

Prof. Emília C. Monteiro, MD by University of Navarra / Spain and PhD in Pharmacology by ICBAS/Universidade do Porto. Full Professor of Pharmacology at NOVA Medical School (NMS|FCM), Universidade NOVA de Lisboa. Principal Investigator at Chronic Disease Centre from NMS|FCM. Coordinator of the Portuguese Clinical Research Infrastructure Network (PtCRIN) and national representative of PtCRIN in the European Clinical Research Infrastructure Network (ECRIN/ERIC). She is also Senior Clinical and Scientific lead of the academic clinical trial unit NOVA CRU (http://novacru.unl.pt/), and presently member of the National Ethics Committee for Clinical Research, Member (CEIC), external consultant of the SCReN", (Spanish Clinical Research network) Advisory Committee and member of the scientific council of the ANSM "Agence Nationale de Sécurité du Medicament et des Produits de Santé" (France).



EMÍLIA C. MONTEIRO

Portuguese Clinical Research Infrastructure Network (PtCRIN)

Dr. Joana Batuca is a Biochemistry and holds a PhD in Pharmacology by Universidade NOVA de Lisboa. She worked as a clinical research associate for pharmaceutical industry and she has over 15 years' experience working in scientific translational/clinical research in the field of autoimmune diseases, cardiovascular disease and dyslipidaemia. During this period, she participated in several investigator-initiated clinical trials and also in the teaching of pharmacology at the NMS|FCM. Presently she is the Portuguese European Correspondents for ECRIN/ERIC and at national level she acts as manager of the PtCRIN and of the CLIC program (Clinical Research Certificate http://clic.pharmaceutical-medicine.pt/).

JOANA BATUCA

European Clinical Research Infrastructure Network (ECRIN);
Portuguese Clinical Research Infrastructure Network (PtCRIN)

Dr. Daniel Faria holds a PhD in Informatics with specialization in Bio-Informatics by Universidade de Lisboa. He is a researcher at INESC-ID and the interoperability and data management coordinator of BioData.pt, the Portuguese node of ELIXIR, which is the European distributed research infrastructure for biological data. As a computer scientist with a life science background, he has often carried out research applied to the life sciences, spanning from data analysis to data and knowledge management and information systems. He is the author of more than 25 peer reviewed publications.

DANIEL FARIA

INESC-ID; Biodata.pt, Portugal