



EAPM 2018

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TO PROMOTE MENTAL AND PHYSICAL HEALTH
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Conducting randomized, controlled intervention trials in Psychosomatic Medicine

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Randomized, controlled clinical trials are considered the gold standard for establishing the efficacy of a therapeutic intervention. This workshop will use a short description of one such trial as a springboard to a broader discussion of the design, conduct, and reporting of clinical research. Most of the time will be devoted to interaction and discussion among the participants. The discussion may consider how to think through and formulate testable hypotheses; how to go about designing a study to test the hypotheses; how study design influences the choice of methods and procedures, and the selection of the study instruments; thinking through the basics of data analysis; and how to write up and publish studies. If participants are interested, we can also discuss the grant application process and the search for funding.

I will begin the session by summarizing a recently completed randomized, controlled intervention trial (Fallon BF, Ahern, DK, Pavlicova M, Skritskya N, Barsky AJ. A randomized controlled trial of medication and cognitive-behavioral therapy for hypochondriasis. *American Journal of Psychiatry* 2017; 174: 756-764). This clinical trial compared hypochondriacal volunteers randomized to fluoxetine, cognitive behavior therapy, combined treatment with both, or pill placebo. They were carefully screened to meet eligibility criteria, and assessed at baseline, 12 weeks and 24 weeks after treatment. An intent-to-treat analytic design was used. The results indicated that fluoxetine but not CBT was significantly effective in reducing hypochondriacal symptoms. Joint treatment provided a small incremental benefit.

It would be helpful background for our workshop if the participants would submit several topics or specific questions they would like to discuss. In addition, a brief summary of studies that they may have conducted or are currently planning would be helpful to have in advance.

CONGRESS PRESIDENT EAPM 2018

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