CORRESPONDENCE

Mind–Body Medicine in the Secondary Prevention of Coronary Heart Disease—A Systematic Review and Meta-analysis

by Dr. rer. medic. Holger Cramer, Dr. rer. medic. Romy Lauche, Dr. rer. medic. Anna Paul, Prof. Dr. med. Jost Langhorst, Prof. Dr. med. Andreas Michalsen, and Prof. Dr. med. Gustav Dobos in issue 45/2015

Prospective Studies from Germany Are Lacking

In their article, Cramer et al. summarize the evidence relating to the subject of mind-body medicine (MBM) (1). The definition and subject matter of MBM are described in the second and third paragraphs of the introduction as “intensive [...] programs for lifestyle modification” that entail “not only nutritional advice and exercise/sport, but also relaxation techniques and psychological motivational elements.” This raises the question of whether the literature search should not have included in the analyses the prospective phase II studies of outpatient and inpatient cardiovascular rehabilitation in Germany, which are entirely consistent with the multimodal concept of MBM as presented (2–4)? This form of rehabilitation according to the 2007 German guideline for the rehabilitation of patients with cardiovascular disorders (DU-Reha) is (translated from verbatim quote) “the process by which patients with heart disease are supported by means of a multidisciplinary team in their efforts to regain at the individual level the best possible physical and psychological health and social integration and to sustain these in the long term.”

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Dr. med. Manju Guha

Deutsche Gesellschaft für Prävention und Rehabilitation von Herz-Kreislauf-Erkrankungen (DGPR) e.V.
Reha-Klinik am Sendesaal, Bremen

Prof. Dr. med. habil. Axel Schlitt, MHA

Deutsche Gesellschaft für Prävention und Rehabilitation von Herz-Kreislauf-Erkrankungen (DGPR) e.V.
Paracelsus-Harz-Klinik Bad Suderode, Quedlinburg
dr.axel.schlitt@paracelsus-kliniken.de

Conflict of interest statement

Professor Schlitt has received consultancy fees from AstraZeneca. He has received lecture honoraria and conference delegate fees and travel expenses from BMS, MSD, Novartis, Pfizer, Bayer; he has received study support (third-party funding) from Sanofi-Aventis, Novartis, and Actelion.

Dr Guha declares that no conflict of interest exists.

In Reply:

In their letter, Dr. Guha and Professor Schlitt suggest including in our meta-analysis of the effect of mind-body medicine in the secondary prevention of coronary heart disease prospective observational studies in addition to randomized studies (1).

The inclusion of non-randomized studies—such as retrospective or prospective observational studies—in meta-analyses of the effectiveness of therapeutic or preventive procedures is the subject of controversial discussion. However, the PRISMA statement (2) as well as the guidelines of the Cochrane Collaboration (3) regard the exclusion of non-randomized studies from those systematic reviews and meta-analyses as the default scenario.

The PRISMA statement assumes that non-randomized studies are primarily of interest for diagnostic or epidemiological research questions (2). Accordingly, the Cochrane Collaboration recommends the inclusion of non-randomized studies only if no randomized studies on the topic under discussion are available or if the research question cannot be answered by using a randomized study design (3).

Neither is the case for our research question. Simulation studies have shown that, although non-randomized studies are not per se subject to an increased risk of bias, it is just this variable risk of bias that brings about uncertainty regarding the study results, which may exceed the range of the confidence interval up to 10-fold (4). Furthermore, no adequate methods seem to exist for determining the risk of bias or for the statistical adjustment for the evident selection bias of non-randomized studies (4).

For these reasons, it still seems reasonable to us, in view of the available evidence from randomized studies, to refrain from including non-randomized studies. DOI: 10.3238/arztebl.2016.0373b

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Dr. rer. medic. Holger Cramer

Prof. Dr. med. Gustav Dobos
Klinik für Naturheilkunde und Integrative Medizin, Kliniken Essen-Mitte,
Medizinische Fakultät, Universität Duisburg-Essen
Essen
h.cramer@kliniken-essen-mitte.de

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The authors declare that no conflict of interest exists.