The evaluation of self management of health problems and the value of Randomized Clinical Trials

In this issue of Patient Education and Counseling, Landsman-Dijkstra et al. [1] present the short-term effects of a body awareness program; in fact they evaluate self-management of health problems. In short, they treated patients who suffered from medically unexplained physical and psychological problems (Chronic A-specific Psychosomatic Symptoms), for a period longer than three months. It is important to note that they had a clear theoretical basis for their intervention, the Body Awareness Program (BAP). It is certainly one of the strengths of this study that it concerns a theory-driven evaluation. The ingredients of BAP are related to theoretical notions relevant to the adaptation to stress and to behavior change and are expected to change as a result of the intervention. In view of the fact that there is a high necessity to design effective psychosocial interventions to treat distress related to (chronic) somatic diseases, we would like to underline the strategy of explicitly translating theoretical notions into intervention protocols. In the long run it will advance our knowledge with respect to the mechanisms and the outcomes of interventions under study.

In accordance, Landsman-Dijkstra et al. studied both the process target variables of the intervention (such as increase in body awareness, self-efficacy, and change-of-behavior change) and the endpoint variables (e.g. reduction in psychosomatic symptoms and increase in other quality of life indicators). By and large, the three-day program resulted in positive effects in the short-run. There is clear evidence that the program is influencing the process variables as well as the quality of life. Interestingly, spouses of the patients confirm the positive results, and, of importance is the finding that half of the patients who were on sick leave returned to work after the program.

So far so good, but let us turn to the interpretation of the results and the ecological validity of the study, at least two issues are at stake: (1) the fact that a group of motivated patients entered the study, and (2) the fact that a non-treatment control group is missing.

Quite often experimental studies have to deal with non-representative samples; i.e. including patients who do not resemble the patients who usually get a treatment in daily practice. Hence, quite often researchers in experimental (RCT) studies include patients who do not represent the average patient; i.e. patients are often not included on the basis of their motivation to get treatment, but rather on the basis of strict inclusion and exclusion criteria, singling out many patients who, in daily practice, might be motivated to get treatment. Hence, methodological rigor may hamper clinical significance and therefore it’s ecological validity. Furthermore this may lead to an underestimation of the effect the intervention can have for the ultimate target group, while the intervention will not be very effective for a part of the patients included in that experiment. Clearly, experimental studies do have to resemble everyday clinical practice and this idea may hold even stronger for psychosocial interventions than more medical oriented work (like drug studies).

The second issue deals with the lack of a non-treatment control group. We believe that the principle of the Randomized Clinical Trial (RCT) and outcomes of studies of that nature is overrated when compared to the experimental non-control group design. This holds specifically when it concerns psychosocial outcome studies. Evidently, it is difficult to study people in an unobtrusive way. We know that when people know that they are monitored (for example being subject in the control group), they tend to react. Hence, when patients are distressed and are willingly to enter in an intervention study to get help for their psychosocial distress, being in a non-treatment or waiting-list control condition, may very well effect their behavior and for that reason may be of influence on the variables under study. This process may hamper the assessment of the ‘real’ effect. In fact we have to do here for some part with placebo effects and for this very reason one includes a control group. However, this effect may interact with condition (control vs experimental), by which we refer to the possibility that the placebo effect may be different in the two conditions. In our opinion when one studies psychosocial distress this may specifically complicate to unravel the true intervention effect. Con- cato et al. [2] published a very interesting study in which they compared (medical oriented) RCT-studies with cohort or case-control studies that assessed the same intervention.

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Quite surprisingly they reported that “well-designed observational studies do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials”. The study is very convincing in challenging the current consensus that RCT’s are the best way to test interventions.

In conclusion, we have to judge the results from studies like the one from Landsman-Dijkstra on its own merits and take into account that careful designed studies, not necessarily with a RCT design [2], may help us to learn about the value of (new) therapeutic tools which are relevant in clinical practice. At the same time we stress the importance to carry out cross-validation, preferably by other researchers. In addition, randomization is of course warranted when possible and relevant, for example when testing which of two therapies is the most effective one.

References


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