

Re: "FARADARMANI" on Patients in Waiting List for Liver Transplantation: A Double-Blinded Randomized Controlled Clinical Trial

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To the Editor

Approaching to Dr. Daneshfard et al. article there are two complete different major aspects: First dealing with "Faradarmani" (Beyond or Super-natural therapy) which is presented as a CAM sub-modality (under the mind-body category) and have been emphasized several times to have positive effects and therapeutic abilities; And second the scientific validity and limitation of the current study as a "double blinded randomized controlled clinical trial".

For the first part, to be brief and concise, "Faradarmani" is more a personal idea than a type of Complementary and Alternative Medicine (CAM), as the founder (MA Taheri) has written: "Then suddenly, on November 1st, 1978, several inspirations and revelations occurred to me" [1]. The current evidences for utility of this approach in medicine is so limited and mostly based on case reports and some non-analytic studies [1-10].

Apart from the origin, meaning and plausibility of this title "Faradarmani", Dr. Daneshfard et al. has presented a study that is supposed to be a scientific proof for its efficacy on a disease. But, despite its primary aim, acceptable design (RCT) and so much beautiful written structure, because of several fundamental faults and limitations in this study, the mentioned survey is not eligible for producing some causal or analytical conclusions and can just report the results that they have gained. The main clues are:

1. The study groups are not matched properly; the age and sex distribution among the study groups aren't similar ($p=0.01$ and $p=0.002$, respectively). These mismatching can greatly affect the outcome measures. For instance, the percentage of females in the test group was 14% compared to 61% in control group ($p=0.002$) which appears the main reason for their lower Hgb and consequently their poorer energy/fatigue, physical or even social functioning status. On the other hand opposite to the authors claim about the age discrepancy: "which is not normally considered to be a favourable parameter for any practitioner", while facing end-stage diseases like cirrhosis, having a control group with a mean age more than a decade (11 years) less than the test group ($p=0.01$), simply means that either the background cause/s of their diseases were more morbid or the severity of a same initial causal disease was more in control group which more rapidly brought them to an end stage status.
2. There is no data about the important confounders such as the primary causes of cirrhosis, the drug history of patients and their additional health or medical impairments which can totally alter the comprehension of the study results. Bearing in mind that the patients were registered with an end stage liver disease in the biggest academic center of liver transplant at least in the Middle East, such "lack of data" is not acceptable.
3. The large number of withdrawers ((31 out of 70 (44.3%)), that

we do know nothing about the reason/s of their withdrawal, their age, sex and other information, is the next drawback. Meanwhile, incongruently, the authors addressed the starting sample size of the study was 80:

"The sample population consisted of two 40-member groups on whom randomization was done on the spot", which can drop the response rate even more (less than 49%). These weak completion rates (48.8% to 55.7%) especially for a study with that limited sample size, can consequently impact the study normality, randomness, independence, power and even the accuracy of the used statistical tests [11].

As mentioned earlier these are main confounding factors which seriously affect the ability of this study as a standard RCT. This article has also much general speaking and other misleading claims such as: MELD score differences of the study groups "As observed throughout the data laid out in Table 3, that the level of worsening in the test group has been less than that of the control group at the end of the study." ($p=0.72$) or explanations about social functioning "whereas some decrease of social functioning has been witnessed in the control group." ($p=0.548$) and repeatedly claims about safety and efficacy of Faradarmani "In view of the positive effects of this method of therapy, in addition to its being totally without costs and danger, over and above the fact that it never interacts with any other of the conventional treatments that the patients might have been undergoing," which upon the study results and/or the existing evidences none of them are proven.

To sum up neither this article nor any other study/ies yet has not shown anything on safety or efficacy of so called "Faradarmani" in a scientific context. However, it is an essential duty of scientists and researchers to investigate new and fresh claims apart from their bizarre or even implausible affirmation- especially in academic centers, these investigations should be done by correct scientific methods and as much as possible away from fanaticism and extremism to be able to help us to achieve our goal: "The Real Science".

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