Monitoring cognitively-disabled subjects in an interactive Internet-based clinical trial of a multi-factorial treatment based on a molecular model of chronic disease

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The validity of a clinical trial is enhanced when all segments of a study population are represented. Based on this author's experience on an NIH data, safety and monitoring board, we were aware that most clinical trials exclude many of the sickest patients because they have diminished cognitive abilities, e.g. memory loss, poor communication skills, questionable judgment.. Therefore, we designed a trial of a multi-factorial treatment for many chronic diseases based on a molecular model of Th1 inflammatory processes in which cognitively-disabled patients could be adequately represented. The open trial of this therapy has resulted in the inclusion of a large number of patients with significant cognitive impairment. Nurses who are charged with monitoring the progress of these cognitively impaired subjects are well-grounded in the molecular science to help them accurately assess the effects of the recovery process. The trial is being conducted using an interactive, Internet-based format. Instruction of subjects and their participating physicians is done online. All communication between subjects and the Nurses who monitor them is done in writing using a standard report form to collect data. Using the computer, which is a new and daunting endeavor for many of the participants adds a unique aspect to cognitive assessment. A standardized report form is used to facilitate accurate assessment and collect data. Regular reporting is expected by subjects to monitor comprehension and compliance with the protocol (which includes several medications) and to ensure early detection of medication error or unexpected treatment effects. Pertinent questioning solicits any important information that is excluded from the subject's report due to cognitive deficit and rapid feedback by the Nurses ensures subject safety. The ongoing written reports are used to assess patient progress, especially in the area of improved cognitive abilities. We describe the observational skills needed, the techniques used and the limits/advantages of monitoring subjects using this format. This unique method of observation has provided a level of monitoring equal to, and superior in some respects to that done via traditional methods (e.g. phone interviews or in-person visits) and has resulted in a fair representation of the cognitively-disabled patient in a ground breaking study.
