

## **Monitoring recovery of an aging cohort with an adaptive, Internet-based clinical trial, based on a molecular model of chronic disease.**

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Based on this author's experience on an NIH monitoring board, we devised and conducted an Internet-focused, community-based, phase II clinical study of a VDR-agonist antibacterial therapy, which demonstrated proof of concept of a novel biological description of the chronic disease process[1]. We collected evidence that restoring competence of the innate immune system will reverse the progression of much chronic disease[2]. This multi-factorial therapy activates the Vitamin D Nuclear-Receptor, enabling the innate immune system to attack the intracellular microbiota which dysregulates the Vitamin D metabolism. Additionally, it reduces elevated 1,25-dihydroxyvitamin-D and reduces co-morbid cognitive impairment [3]. Nurses who counsel and monitor the subjects' progress are well-grounded in molecular science to help them accurately anticipate immunopathology, and the measures of recovery. Instruction of subjects and/or their participating physicians occurs online. All communication is done in writing using a standard report form to facilitate accurate assessment and collect objective data. Ongoing, regular reports and rapid feedback by Nurses ensures early detection of unexpected treatment effects. We describe the observational skills needed, the assessment techniques used and the limits/advantages of monitoring a cohort via the Internet. As a result of the therapy, subjects experienced diminishing levels of relapse and remission of disease symptoms[4]. Over 3-6 years this typically resulted in symptomatic recovery, invigoration, and return to the family and/or workplace.

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