J Clin Trials 2015, 5:3
http://dx.doi.org/10.4172/2167-0870.S1.008

OMICS International
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International Conference on
Clinical Trials

July 27-29, 2015 Orlando-FL, USA

Follow-up study of chronic pain patients: A clinical and health psychology approach

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Background: Our research was focused on (1) effect of resilience on quality of life and mood outcomes in chronic pain patients using longitudinal data (2) comparison of effect of resilience to other illness and demographic variables as well as other adjustment factors (e.g. life events).

Methods: The sample consisted of 300 patients with chronic pain treated at National Center for Spinal Disorders. At entry into the cohort, patients had been diagnosed with chronic pain within the last 5 years. Baseline measures were administered between 1996 and 2000. Psychological test battery consist of psychosocial parameters such as demographic (objective) variables of adjustment (work and family status), quality of life, depression, anxiety, resilience, spiritual orientation were measured.

Results: No significant differences were found between either depression or anxiety scores at baseline and follow-up. Trait anxiety, depression and quality of life scores differed significantly from standard data available for the general population, deteriorated with time but were unrelated to age or gender. Resilience scores of the patients did not differ significantly from the Hungarian preliminary standards. Four variables explained 57.1% of variance in quality of life outcomes, resilience being the most powerful predictor of all. Anxiety and depression were also strongly predicted by resilience (r square=0.59 for anxiety and r square=64% for depression). Further predictors were pain symptoms and some spirituality variables. No life event or other health/illness variable effects emerged.

Conclusions: Illness and life event effects are buffered by resilience, a very powerful predictor of adaptive outcomes. Though there is deterioration in quality of life and mood through the course of illness, outcomes are remarkably better in resilient patients. The impact of this variable may result from through successful emotional regulation and more effective recovery from stress events.

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Assessment instruments for drug safety management during clinical trials conduction

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Drug safety is investigated during different phases of clinical development, aimed to establish a risk-benefit ratio that allows registration and marketing. The management of drug safety during the conduct of clinical trials is considered a key to success and for the overall results of the pharmaceutical company that sponsors the product under study process; which has, among its strategic goals, registration and subsequent marketing of its products, based on the efficient collection of reliable data on efficacy and safety. This work constitutes the first stage of a project to implement a safety information management system of our pharmaceutical company. Starting with criteria of structure, process and outcome; 23 indicators with their respective standards were identified. From these, 9 instruments were designed and validated, to assess the management of safety information which is generated at the sites of research, where clinical trials with Molecular Immunology´s Center products are conducted. The feasibility, internal consistency, and content validity of the instruments were investigated. Assessment was based on statistical methods. As results, the 9 instruments are feasible to use, that produced low missing data. Cronbach'salpha coefficient ranged from 0.79 to 0.89 for all of them. The 9 instruments showed good psychometric properties thus, are reliable tools for examining drug safety management during the conduct of clinical trials.

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