

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable

ACTIVE INGREDIENT: Not applicable

Study No: NIS-NES-DUM-2008/1 NCT00749970

Validity of the Spanish version of Subjective Well-being under Neuroleptics Scale (SWN-K) in patients with schizophrenia.

Developmental phase: Not applicable

Study Completion Date: 01/01/2009

Date of Report: 11/27/2009

OBJECTIVES:

The subjective experience of psychotic patients towards treatment is a key factor in therapeutic adherence, quality of life, and clinical outcome.

To assess the psychometric properties of the Spanish version of the Subjective Well-being under Neuroleptics scale (SWN-K), a self reported instrument designed to evaluate patients' subjective experiences regardless of their mental state and medication stabilization.

METHODS:

Spanish multicentre, non-interventional, observational, and prospective psychometric study. Eligibility criteria included outpatients being at least 18 years old, having a diagnosis of schizophrenia, schizoaffective disorder or schizophreniform disorder, being clinically stable, and taking the same single oral antipsychotic medication at least in the previous 3 months. Patients participated only if they gave written informed consent. The study was approved by Fundació Sant Joan de Deu's Institutional Review Board, Barcelona, Spain.

The SWN-K used in this study consists of 20 questions answered on a 6-point Likert ordinal scale. The total score ranges from 20 to 120 points (higher scores indicating better well-being). The original version was back-translated and a focus group was conducted to improve the comprehension of the items. Patients were evaluated with the Positive and Negative Symptoms scale (PANSS), the Drug Attitude Inventory (DAI-10), the Clinical Global Impression of Severity (CGI-S), and the SWN-K. A re-test was conducted one week after baseline.

RESULTS:

97 patients were included. Seventy-two percent of them (70) were male. Mean age was 35 years (SD = 10.0). Mean PANSS total score: 65.0 (SD = 21.4). Mean SWN-K total score: 83.5 (SD = 14.0). The SWN-K showed good acceptability. Internal homogeneity: Cronbach's α coefficient was 0.86. The mean elapsed time between test-retest assessments was 7.5 days (SD=1.9), and the symptoms remained stable (CGI-S ICC=0.96, 95% CI=0.94 to 0.97; PANSS total score ICC=0.94, 95% CI=0.91 to 0.96). Test-retest reliability was 0.88 (95% CI=0.84 to 0.93). All correlation coefficients between SWN-K and PANSS were significant but moderate, supporting an inverse association between the experience of psychotic symptoms and subjective well-being. Conversely, correlation coefficients between SWN-K and DAI-10 were close to null and none presented a significant value. SWN-K discriminated among CGI-S levels (oneway ANOVAS $p < 0.01$), showing a linear trend ($p < 0.001$).