Study Protocol and Statistical Analysis Plan

Determining the Effectiveness of the Geriatric Pain Measure in Older Adults Attending a Gynecology Clinic

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STUDY PROTOCOL

Universe and Sample of the Study

Many studies have noted that the prevalence of pain in adults is generally high, and women in particular experience more pain (Damico et al., 2018; Dahlhamer et al., 2018; Ferrell et al.,2000; Larsson et al., 2017; Jackson et al., 2015; Woo et al., 2009). Therefore, the study population was chosen among female patients. The universe of the study consisted of 917 female patients aged 65 and over who attended the gynecology outpatient clinic of Training and Research Hospital in the four months from 1 August 2018. The sample consisted of 100 female patients who met the inclusion criteria and agreed to participate in the study.

Inclusion Criteria

Patients aged 65 and over who scored 23 and above on the SMMSE, who did not have any disability preventing them from answering the questions, who were not addicted to alcohol or other substances, and who had no history of trauma in the previous six months, were included in the study.

Data Collection and Management

The data of the study were collected using the Patient Identification Form prepared by the researchers, the GPM, and the SMMSE. The GPM is a 24-item multidimensional scale developed by Ferrell et al. (2000), for elderly individuals treated on an outpatient basis. Its validity and reliability in Turkish were confirmed by Dursun and Bektaş (2017). The Turkish version of the scale has five sub-dimensions: withdrawal due to pain *(Factor 1; Items 19, 20, 22, 23)*; pain intensity *(Factor 2; Items 1, 2, 3, 4, 5, 6)*; pain with movement *(Factor 3; Items 9, 10, 11, 12)*; pain with strenuous activities *(Factor 4; Items 7, 8, 18, 21, 24)*; and pain with other activities *(Factor 5; Items 13, 14, 15, 16, 17)*. The total score is calculated by adding the "Yes" answers, and each item is multiplied by 2.38 and the total is converted into a score of between 0 and 100. Scores between *0 and 29* are considered to indicate mild pain, scores

between *30 and 69* are considered to indicate moderate pain, and scores of *70 and above* are considered to indicate severe pain.

The SMMSE measures the degree of cognitive impairment. The SMMSE was validated in Turkish by Güngen, Ertan, Eker, & Yaşar (2002) in patients with mild dementia. The SMMSE consists of five parts: orientation, memory, attention/calculation, recall, language and motor function, and perception. Each question is worth 1 point. The maximum score obtainable is 30; a score of 24 to 30 points indicates normal cognitive function, a score of 18 to 23 points indicates mild dementia, while a score of 17 points or fewer indicates severe dementia. The threshold for the diagnosis of mild dementia in the Turkish population has been reported as 23/24 (Güngen et al., 2002).

There is no data security monitoring board in the study.

STATISTICAL ANALYSIS PLAN

Data obtained from the study were processed and analyzed using SPSS 24 software. For the data determined to be abnormally distributed, the Mann-Whitney U test was used to compare two independent groups, and the Kruskal Wallis test was used to compare three or more independent groups. Spearman correlation coefficients were used to evaluate whether there was a linear relationship between variables. The Cronbach's alpha coefficient was calculated to determine the internal consistency of the scale. Statistical significance was accepted as $p< 0.05$ (Christensen, Johnson, & Turner, 2015).