PIH63

TURKISH CULTURAL ADAPTATION AND VALIDATION OF GLASGOW HEALTH STATUS INVENTORY

Oksuz E, Malhan S, Tekin R, Yilmaz F, Baytar S

Baskent University, Ankara, Turkey

OBJECTIVES: The Glasgow Health Status Inventory, (GHSI) measures the effect of a health problem on the quality of life of a person and allows cross-comparison among many health conditions, among different health interventions, and among demographic and cultural subgroups. The GHSI contains 18 health status questions, which ask specific questions about how the health problem has affected their quality of life. This study aims to adapt the GHSI into Turkish culture and check the reliability and validity of the inventory culturally. **METHODS:** The original instrument was translated and back translated by two independent translators. a small sample consisting of 40 people was used to check the initial comprehension and factibility. Cronbach's Alfa was used to assess reliability and factor analysis to assess dimensionality. The EuroQol questionnaire and corresponding Visual Analogue Scales were used for concurrent validity. **RESULTS:** A total of 163 people participated in this study. 52% of them were female, 48% of them were male. Mean age was 24.3. The internal consistency coefficient (Cronbach's alpha) of GHSI was 0.86. Factor analysis of the scale revealed that it was composed of four factors with Eigenvalues >1.0, accounting for 62.2 % of the total variance. Correlations were moderate with EuroQol and VAS. **CONCLUSIONS:** The culturally adapted GHSI has good validity and reliability, making it a potentially useful outcome measure in the determining the effect of health problems on the quality of life of people in Turkey.

PIH64

A CONCEPTUAL FRAMEWORK FOR A PATIENT REPORTED OUTCOMES MEASURE OF ATTITUDES TOWARD COMPLEMENTARY AND ALTERNATIVE MEDICINE IN MENOPAUSE

Bunsiriluck S, Williamson EM, Donyai P

Reading University, Reading, UK

OBJECTIVES: Menopause may cause hot flashes, night sweats, mood swings and other symptoms. Although hormone replacement therapy (HRT) is prescribed in severe cases, it is not suitable for all women, and increasing numbers of women refuse or discontinue HRT because of side effects, or real or perceived health risks. The use of complementary and alternative medicine (CAM) in menopause has been increasing, with women perceiving CAM as safer than HRT, but this is not supported by clinical evidence. Biased decisions occur when an individual's cognition is affected by factors that include attitudes, preferences, and moods. Cognitive bias affecting women's perception of CAM can impact on decisions and ultimately CAM usage in the menopause. Yet, no validated questionnaire exists to measure attitudes towards CAM in menopause, in line with accepted patient reported outcome (PRO) methodology. Our aim was to develop a conceptual framework of attitudes to CAM in the menopause to inform the development of a PRO tool. **METHODS:** A systematic review of the literature was conducted April-May 2010 using Medline and PsycINFO databases with the MESH terms attitude, menopause, complementary therapy, and perception. a total of 122 papers were retrieved, with 91 excluded on the basis of abstract review and 13 after full-text analysis, resulting in 19 studies suitable for inclusion. The papers were analyzed in line with qualitative review methodology to produce a number of themes that were later grouped together to produce the dominant categories. **RESULTS:** A conceptual framework was developed to reflect attitudes to CAM in the menopause. The dominant categories of perception related to menopausal symptoms, optimism about CAM, pessimism about HRT, cure-control with CAM, and relationship with physician. **CONCLUSIONS:** This research has identified key domains relevant to women's attitudes towards CAM in the menopause, from which a relevant PRO instrument could be developed.

PIH65

USING A GENERALIZED ADDITIVE MODEL TO EXAMINE THE RELATIONSHIP BETWEEN BODY MASS INDEX AND HEALTH-RELATED QUALITY OF LIFE IN THE ELDERLY POPULATION—RESULTS FROM THE POPULATION-BASED GERMAN KORA-AGE STUDY

Hunger M, Thorand B, Döring A, Peters A, Schunk M, Holle R

Helmholtz Zentrum München—German Research Center for Environmental Health (GmbH), Neuherberg, Germany

OBJECTIVES: Numerous cross-sectional studies reported that high body mass index (BMI) is associated with poorer health-related quality of life (HRQL), while only few studies also provide evidence for impaired HRQL in underweight individuals. Our objective was to investigate the nonlinear relationship between BMI and HRQL in an elderly general population sample using semiparametric regression methods. **METHODS:** We analyzed data from 4562 individuals aged 65 years or older, living in the region of Augsburg, Southern Germany. The data come from the KORA-Age study which is based on a postal follow-up of individuals who participated in the population-based MONICA/KORA surveys S1-S4. Health-related quality of life was measured using the German EQ-5D index. For our multivariable regression analyses, we used a generalized additive model (GAM) to estimate the functional form of the relationship between BMI and HRQL after adjusting for confounding factors. **RESULTS:** We found a significant nonlinear (inverse U-shaped) relationship between BMI and HRQL after adjusting for gender, age, sociodemographic factors and comorbid conditions. The maximum HRQL was observed at a BMI of about 25 kg/m^2. Our estimates indicate that going from a BMI of 25 to 35 is associated with a EQ-5D utility loss of about 5.2 units (corresponding to 0.28 of standard deviation). On the other hand, underweight individuals with a BMI of 18 had an average impairment of 5.8 units compared to a BMI of 25. Subgroup analyses showed that the inverse U-shaped relationship is more pronounced in individuals ≥75 years than in individuals aged 65–74 years. In particular, the effect of low BMI on HRQL is more important in the older age group. **CONCLUSIONS:** Generalized additive models are an adequate method to estimate the nonlinear relationship between BMI and HRQL in the elderly population. With increasing age, low BMI has similar impairments in HRQL as overweight.

PIH66

IDENTIFYING APPROPRIATE COMPARISON GROUPS IN GLOBAL PREGNANCY REGISTRIES

Albano JD[1], Roberts SS[2], Brown VD[3]

[1]Kendle International Inc., Durham, NC, USA; [2]University of North Carolina, Wilmington, Wilmington, NC, USA; [3]Kendle International Inc., Wimington, NC, USA

BACKGROUND: Pregnancy exposure registries are valuable for studying the teratogenicity of drugs used in the post-marketing setting. However, their limited sample size and potential for selection bias can make data interpretation challenging. While enrolling an internal comparison group is ideal, this is often not feasible. To ease these limitations, pregnancy registries commonly use a population-based background rate as the primary comparison group. **OBJECTIVES:** The objectives of this research are to evaluate appropriate population-based birth defect surveillance systems, cohorts, and other studies from a variety of geographic areas and to systematically assess their utility as a comparison group for global pregnancy exposure registries. **RESULTS:** Among the 14 studies evaluated, study designs include observational cohort studies, case control studies, population-based surveillance registries, and population-based active surveillance systems. Catchment areas are somewhat diverse geographically and range in scope from a metropolitan city, single state/province, or individual country, to multi-national/multi-continental networks of organizations contributing to a single data source. All identified studies have been ongoing for at least a decade. Studies range in size from several thousand participants in total to more than 1 million participants enrolled annually. Data reporters vary and include patients, physicians, and other health care personnel. Some studies ascertain infant outcome and birth defect status at the time of birth only, while others involve pediatricians and include follow-up for one to several years. **CONCLUSIONS:** There are many potential sources of comparison data for overall birth defect rates; however, the sources vary greatly in design, data collection methods, birth defect coding systems, clinical review procedures, and equation for calculating birth defect prevalence rate. Utilizing a population-based background rate can be useful, but care should be taken in selecting an appropriate comparison group. The differences between the individual pregnancy registry and the population-based comparator should be evaluated and recognized.

NEUROLOGICAL DISORDERS – Clinical Outcomes Studies

PND1

INDIRECT COMPARISON OF ADVERSE EVENTS AND DROPOUT RATES FOR EARLY PARKINSON'S DISEASE (PD) MONOTHERAPY TRIALS: PRAMIPEXOLE, ROPINIROLE AND RASAGILINE

Zagmutt FJ[1], Tarrants ML[2]

[1]Vose Consulting, Boulder, CO, USA; [2]Teva Pharmaceuticals, Kansas City, MO, USA

OBJECTIVES: Pramipexole, Rasagiline, and Ropinirole are approved for monotherapy in early PD. Understanding the comparative safety profiles of these products can be important information to choose an optimal therapy. As no direct comparisons of the safety profile of these products are available, our objective was to perform an indirect comparison of Adverse Events (AEs) and Dropout Rates (DRs). **METHODS:** Articles were selected and reviewed via Cochrane Guidelines. Placebo-controlled randomized clinical trials were eligible for review. Data collected for analysis included total AEs, Cognitive, Gastrointestinal (GI), and Sleep/Fatigue AE categories and dropout rates. We used indirect meta-analysis to calculate the pooled Relative Risk (RR) of each product against placebo, and then used pairwise comparisons. Frequentist and Bayesian methods were used to compare sensitivity of findings. **RESULTS:** 208 studies were identified and reviewed, 6 were determined eligible via established criterion. The RRs and [95%CIs] from the fixed-effects model for Rasagiline, Pramipexole, and Ropinirole respectively were total AEs: .97 [.87, 1.07], 1.05 [1.00, 1.1], 1.07 [1.00, 1.14]; Cognitive: .78 [.43, 1.44], 5.56 [2.35, 13.13], 1.56 [.83, 2.94]; GI: .9 [.49, 1.63], 2.00 [1.57, 2.53], 2.43 [1.81, 3.27]; Sleep/Fatigue: .84 [.53, 1.35], 1.63 [1.35, 1.97], 3.24 [2.08, 5.05]; and DR: .60 [.39, .91], 1.01 [.66, 1.56], 1.77 [1.14, 2.76]. AEs were no worse than placebo for all Rasagiline AEs and for Ropinirole cognitive AEs. DRs for Rasagiline were significantly lower than placebo. Rasagiline had the lowest RRs with ≥90% confidence for all categories. Results were comparable across statistical models tested. **CONCLUSIONS:** This indirect treatment comparison suggests that subjects with early PD treated with Rasagiline have less risk for adverse events and treatment dropouts than patients treated with Pramipexole or Ropinirole. Ropinirole exhibits the highest risk for GI AEs, Sleep/Fatigue AEs and DRs, while the risk for Cognitive AEs is higher for Pramipexole.