US-English speaking and 16 US-Spanish speaking participants with primary or secondary insomnia. Data for the validation of the SIS were collected alongside a North American 4-week multicenter, double-blind, placebo-controlled, randomized, parallel-group study in primary and secondary insomnia patients. Item level analyses including assessment of missing data, item-item correlations, Principal Components Analysis, and clinical validity were conducted. Items with floor or ceiling effects were candidates for deletion, as were items which did not load with any particular domain. Once domains were determined, validity of the domains was assessed through internal consistency reliability, item-domain concurrent and divergent validity, clinical validity, concurrent validity and confirmatory factor analysis. Additionally, responsiveness and minimal important difference estimates were determined. **RESULTS:** Patient interviews resulted in 55 items in 8 domains. During item reduction and validation, 18 items were deleted based on their content validity, high ceiling effect (>40%), redundancy (Inter-item Pearson correlation > 00.80) no or multifactor loading and/or failure to meet the Item-level discriminant validity criterion. After reduction, the final SIS consists of 35 items in 7 domains. **CONCLUSION:** The SIS was developed to account for US-English and US-Spanish cultural differences. The validation study provides evidence on the psychometric properties of the SIS. The SIS has been shown to adequately meet the criteria for a validated measure to be used in clinical trials.

PMH56

A REVIEW OF INSTRUMENTS USED TO ASSESS THE IMPACT OF ALCOHOLISM ON QUALITY OF LIFE

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OBJECTIVES: To comprehensively explore existing quality of life (QoL) measures in alcoholism (alcohol abuse and alcohol dependence). **METHODS:** Systematic searches of Scopus (1990–2007) were conducted using terms synonymous with alcoholism combined with terms associated with measuring QoL. **RESULTS:** In total, 618 abstracts were identified detailing the use of 16 generic patient-reported measures to assess QoL in alcoholism. Upon further examination (ie searching Scopus using the QoL measure as a search term from date of development) nine measured health status and seven assessed generic QoL, with varying definitional criteria and domain focus. The SF-36 and EQ-5D, in particular, have been used widely but frequently misinterpreted as measures of QoL rather than health status. One alcohol-specific QoL measure was identified; the AlQoL 9, a scale that the authors have claimed to epitomise alcohol-related QoL. However, the AlQoL 9 was developed by reducing the SF-36 (French version) to the nine items most relevant to alcoholism. The methodology for determining the relevance of the existing items of the SF-36 was comprehensive but the adapted measure does not include assessment of additional concepts (such as sleep and social isolation) of particular importance for alcohol-related QoL. **CONCLUSION:** There is a lack of research and assessment of QoL in alcoholism. Individuals need to be given the opportunity to determine the extent to which their QoL is impaired by alcoholism based upon their own criteria for what constitutes good QoL. There is a need for an alcoholism-specific QoL measure, which focuses on the domains that are most salient to people with such problems. Furthermore, research that includes an assessment of the impact of alcoholism on the QoL of friends, family and colleagues of the person abusing alcohol would also be valuable. Only then will we be able to assess the full impact of alcoholism (and its treatment) on QoL.

PMH57

EFFECTIVENESS OF A PSYCHOSOCIAL INTERVENTION PROGRAM FOR CAREGIVERS OF PATIENTS WITH ALZHEIMER'S DISEASE IN THE PREVENTION OR REDUCTION CAREGIVER BURDEN EDUCA STUDY

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OBJECTIVES: Caregivers's patients with Alzheimer's disease (AD) experience physical and psychical stress due to the caring. This study evaluated the benefits of a Psychosocial Intervention Program (PIP) on caregivers' burden **METHODS:** A epidemiological, prospective, randomized, multicenter study was conducted by psychiatrists who recruited 115 primary caregivers's of patients with AD (DMS-IV criteria and MMSE score = 10–26) and at least 2 impaired instrumental activities of daily living (IADL score) by Lawton & Brody Test. Caregivers were randomized to receive either PIP (intervention group (IG), n = 60) or standard care (control group (CG), n = 55). PIP consisted on individual sessions (scheduled every 1–2 weeks during 4 months) of teaching strategies to reduce caregiver burnout. Caregivers stress, quality of life (QoL) and perceived health were measured using validated scales (Zarit, SF-36, GHQ-28) at baseline, after a 4-month and a 10-month follow-up period **RESULTS:** The profile of patient with AD was a 77-years-old woman, with moderate dementia (MMSEscore = 18.74) and high impairment of daily living activities (mean IADLscore = 2.17). The caregiver profile was a 60-years-old woman, wife or adult daughter, who is being careing for 3 years and care daily time was >12 hours, without refund. Changes in caregiver burden (baseline Zaritscore–final Zaritscore) showed an improvement in the IG (−8.09 points) and a worsening grouping the CG (+2.08 points), with statistically significance (p = 0.0083). The IG showed significant improvements in all the well-being perception areas measured by the SF-36scores and significantly lower score in the GHQ-28score (p = 0.0004). Caregivers and therapists considered PIP "useful/very useful" in a 97.7% and 88.6% respectively at the end of PIP, and in a 93.2% and 86.3% at 6 moths after PIP ending. **CONCLUSION:** Caregivers' psychosocial training can minimize caregiver distress and may help to develop strategies for coping problems. PIP improves QoL and the perceived health of caregivers of patients with AD.

PMH58

IMPROVED SLEEP IMPACT IN GENERALIZED ANXIETY DISORDER WITH ZOLPIDEM TARTRATE EXTENDED-RELEASE

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OBJECTIVES: Insomnia is frequently associated with generalized anxiety disorder (GAD) and affects the patient's day to day life. The Sleep Impact Scale (SIS) was developed to assess the impact of insomnia; however it has not been used in GAD. Therefore, a study was conducted to validate the SIS and evaluate the impact of zolpidem tartrate extended-release on insomnia in GAD. **METHODS:** Validation and efficacy data of the SIS were collected alongside a randomized, placebo-controlled trial of escitalopram + placebo or zolpidem tartrate extended-release in adults with insomnia associated with GAD. The validation consisted of evaluation of the validity and reliability, the responsiveness and the MID of the SIS domains to ensure the questionnaire was acceptable in a GAD population. The efficacy analysis was performed on the ITT population, consisting of general linear models to evaluate changes from baseline at each timepoint, with study endpoint as the primary change score analysis. Longitudinal analyses were also performed to evaluate the effects of

treatment through time using repeated measures ANCOVA. **RESULTS:** The SIS was found to meet psychometric standards for a valid questionnaire in a GAD population. The efficacy analysis found four domains (Daily Activities, Emotional Impact, Energy/Fatigue and Satisfaction with Sleep) consistently demonstrated significantly greater improvements in the zolpidem tartrate extended-release group at each timepoint. A quick onset of treatment effect was evident in all domains of the SIS by Week 2, with all domains statistically significantly demonstrating greater improvement than placebo. Longitudinal analyses found all SIS domains to be statistically significantly superior to placebo. **CONCLUSION:** The SIS adequately meets the criteria for a validated measure to be used in GAD. The SIS was responsive to treatment effects in this clinical trial and able to demonstrate improvements in patient reported outcomes, favoring zolpidem tartrate extended-release.

PMH59

LINGUISTIC VALIDATION OF THE HADS FOR USE IN INTERNATIONAL STUDIES

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OBJECTIVES: Prior to use in an international study, the Hospital Anxiety and Depression Scale (HADS) underwent linguistic validation in 30 languages. The original scale was developed in UK English to detect states of anxiety and depression in and outside hospital and also community settings. A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** The translation process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators who were native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country; 3) backward translation by a native English speaker; 4) comparison of source and backward version; and 5) review by the developer. The linguistic validation methodology for some languages deviated slightly from what is described above, as a translation already existed; the translation process started at the backward translation step on the existing version. **RESULTS:** The translation process revealed linguistic and conceptual challenges. Translating idiomatic expressions often required paraphrasing to convey the intended meaning whenever a literal equivalent was not conceptually equivalent and culturally relevant. In addition, while in most language versions it was possible to retain the same tense as in the original instrument without alteration of meaning in a few translations it proved necessary to use a different tense to achieve clarity and equivalence of concept. **CONCLUSION:** The language versions of the HADS were established according to a rigorous translation methodology. The process aims to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.

PMH60

A PHARMACOECONOMIC COMPARISON OF ESCITALOPRAM AND DULOXETINE IN TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD) IN THE UNITED KINGDOM

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OBJECTIVES: To evaluate cost-effectiveness of escitalopram vs. duloxetine in MDD and to identify key drivers of costs in treatment of depression with escitalopram and duloxetine. **METHODS:** An economic evaluation was conducted alongside a double-blind, randomized study (escitalopram 20 mg/day and duloxetine 60 mg/day) in outpatients with MDD, aged 18–65 years, with Montgomery Asberg Depression Rating Scale (MADRS) ≥26 and Clinical Global Impression Severity (CGI-S) ≥4, and with reported baseline duration of depressive episode of 12 weeks-1 year. The main cost-effectiveness (CEA) analysis was conducted on the full analysis set (FAS), with all patients having ≥1 valid post-baseline health economic assessment. Additional analyses were conducted on completers set (CS) with complete follow-up data. Outcomes included Sheehan Disability Scale (SDS), MADRS total score, treatment response (MADRS decrease ≥50%) and remission (MADRS≤12), and health care resource use and absenteeism from work evaluated by Health Economic Assessment. Unit costs of health care services were obtained from UK published standard sources. **RESULTS:** In the main CEA analysis on FAS, escitalopram appears to be more effective on the SDS scale (95% CI 0.10–3.74) and less costly than duloxetine (95% CI ≤–1.544 to –247). In additional analyses on CS, patients on escitalopram had 49% lower total cost compared to duloxetine ($p = 0.002$), with sick leave contributing >73% of the total disease cost. Escitalopram was associated with 58% shorter sick leave duration compared to duloxetine ($p < 0.001$). Patients with treatment response had 46% shorter sick leave ($p = 0.008$), and those achieving remission, sick leave was 53% shorter (0.002). **CONCLUSION:** Escitalopram dominates duloxetine on the SDS scale, and is associated with significant cost savings compared to duloxetine. Treatment with escitalopram may reduce sick leaves duration through improved treatment response, and result in cost savings compared to duloxetine. The results are in line with other economic studies showing cost-saving with escitalopram compared to venlafaxine, another SNRI.

RESPIRATORY DISORDERS—Clinical Outcomes Studies

PRS1

ACUTE EFFECTS OF SILDENAFIL ON ECHOCARDIOGRAGHIC PARAMETERS IN PATIENTS WITH PRIMARY PULMONARY HYPERTENSION

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OBJECTIVES: Primary pulmonary hypertension (PPH) is a disorder with limited treatment options. Sildenafil, an oral phosphodiestrase type-5 (PD-5) inhibitor and a pulmonary vasodilator, is likely to be beneficial in patients with primary pulmonary hypertension,. we hypothesized that a single dose of Sildenafil could acutely reduce peak pulmonary artery pressure and improve echocardiographic diameters of right heart. **METHODS:** We studied 12 consecutive patients with PPH (10 patients with New York Heart Association functional class ^{222}, and 2 patients with functional class^{22}). After initial echocardiographic evaluation, a 100 mg oral single dose of Sildenafil was added to previous