sharp health deterioration with age. Nevertheless, moderate health problems are considered as acceptable in advanced ages. These findings intend to support compliance research and health gain valuations.

PMS57 PRELIMINARY PSYCHOMETRIC VALIDATION OF THE SLEEP DISTURBANCE AND SLEEP ADEQUACY SUBSCALES OF THE 1-WEEK RECALL MEDICAL OUTCOMES STUDY SLEEP SCALE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: Sleep issues have been reported by patients with rheumatoid arthritis (RA) and recently recommended as a clinical trial endpoint. The objective of this study was to conduct a quantitative validation of the sleep disturbance and sleep adequacy subscales of the 1-week recall Medical Outcomes Study Sleep Scale (MOS-SS) in patients with RA.

METHODS: Participants with self-reported RA were recruited via newspaper or online advertisements in two regions of the US. Participants completed measures in-person, then completed a one-week retest via mail. Internal consistency of the MOS-SS subscales was evaluated using Cronbach’s α; test-retest reliability was assessed using Intraclass Correlation Coefficient (ICC). Pearson’s correlation coefficient was calculated to assess convergent validity of MOS-SS 1-week subscales with a Sleep Numeric Rating Scale (SRS). Known-groups validity was assessed using ANOVA to compare MOS-SS mean subscale scores with self-reported sleep disturbances and adequacy.

RESULTS: Participants (N=50) were 76% female, 72% White, mean age (SD) 49.4 (13.2) years and mean disease duration (SD) 13.7 (12.0) years. Cronbach’s α for sleep disturbance and adequacy subscales were 0.73 and 0.71, respectively. Sleep disturbance and adequacy subscales demonstrated good general health status group differences, but correlation coefficients were not significantly different. CONCLUSIONS: The MOS-SS sleep disturbance and sleep adequacy subscales demonstrated good internal consistency and test-retest reliability, modest convergent validity, and trended but did not significantly discriminate based on RA severity or general health. Further psychometric analysis in a larger sample of RA patients is needed to determine if these subscales could be useful in clinical trials.

PMS58 PILOT VALIDATION OF THE BRIEF FATIGUE INVENTORY ‘FATIGUE AT ITS WORST’ ITEM IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: Fatigue was a term they would use to describe their symptom affirmed the use of fatigue (71.4% in US and 90% in UK). A total of 32 participants were recruited (19 in US, 13 in UK), of which the majority were female (74% in US, 77% in UK) and White (68% in US, 77% in UK). Mean age (SD) of the US and UK participants was 65.1 (6.9) and 47.7 (14.7), respectively. Descriptions of RA in both populations were similar and included pain (n=32) and fatigue-like effects of RA (n=17), which impacted daily activity and psychological well-being. Descriptions of pain were similar in US and UK populations: “dull,” “shooting,” “nagging” and “growing.” The term “fatigue” was mentioned spontaneously by some (n=5, 26%) of US participants, and was not mentioned spontaneously by any UK participants. The majority of those asked whether fatigue was a term they would use to describe their symptom affirmed the use of fatigue (71.4% in US and 90% in UK). CONCLUSIONS: This small, qualitative, study identified few differences in experiences of RA in US and UK patient populations. Qualitative research is useful for identifying whether the use of identical PRO measures is acceptable in multi-national clinical trials.

PMS61 RAPID REDUCTIONS IN FATIGUE AND SLEEP PROBLEMS AND CORRELATION WITH IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IN PATIENTS WITH ACTIVE RA TREATED WITH CERTOLIZUMAB PEGOL IN THE REALISTIC 12-WEEK PHASE IIIB RANDOMISED CONTROLLED STUDY

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OBJECTIVES: To determine the impact of CZP on patient-reported outcomes (PROs), including fatigue and sleep problems, among patients (pts) with active RA who participated in the REALISTIC (RA EvALuation In Subjects receiving TNF Inhibitor Certolizumab pegol) [CZP] study. METHODS: A total of 1,063 eligible pts were randomised 4:1 to CZP 40mg at WK 0, 2, and 4 followed by 200mg every 2 wks or placebo injection (control) every 2 wks added to current therapy. PROs included fatigue (Fatigue Assessment Scale [FAS]), sleep quality and quantity (Sleep Problem Index II domain, Medical Outcomes Study sleep scale [MOS-SPI]), pain (visual analogue scale [VAS]), and pts global assessment of disease activity (PGA, VAS). The % of pts reporting minimal clinically important differences (MCID) were determined: ≥1 FAS, ≥6 MOS-SPI, and ≥10mm pain-VAS and PGA. Correlations between FROS and DA28 were assessed (Pearson ρ, CZP group only). NCT00717236.

RESULTS: Baseline (BL) characteristics were similar for both groups. Significant, meaningful improvements, compared with placebo (PL), in fatigue and sleep control from the first time point at WK 2 (1.1 vs –0.2; p<0.001) to WK 12 (–1.3 vs –0.5; p<0.001). Sleep problems were significantly reduced with CZP vs control from the first assessment at WK 6 (7.6 vs –4.8; p<0.05) to WK 12 (–7.6 vs –4.2; p<0.01). CZP significantly reduced pain and PGA from WK 2 (pain: –15.3 vs –9.7; p<0.01; PGA: –2.5 vs –0.001) to WK 12, more CZP pts had improvements in FAS in 56.4% vs 46.2%, p<0.001, MOS-SPI (49.7% vs 42.5%, p=0.058), pain (59.0% vs 42.0%, p<0.001) and PGA (59.5% vs 42.5%, p<0.001). Correlations between FROS and DA28 were moderate (0.3–0.4; rho=0.6). CONCLUSIONS: CZP was associated with clinically meaningful reductions in fatigue and sleep problems, and improvements in pain and PGA, in a diverse group of RA pts reflecting those seen in daily clinical practice.