could receive acupuncture, Chinese herbs, dietary and/or life-style recommendations as appropriate, and acupuncture before and after ET (N=119); (2) Acupuncture (ACU) group elected adjuvant acupuncture only before and after ET (N=370); and (3) Usual Care group (UC) received no additional treatment (N=580). Outcomes were compared using logistic regression with covariates of antral follicle count and number of embryos transferred.

Results: Live births were higher in the WS-TCM group (N=73, 61.3%) compared to the ACU group (N=188, 50.8%; OR=1.53, 95%CI 1.01–2.34), and the UC group (N=280, 48.3%; OR=1.77, 95%CI 1.15–2.72). Biochemical pregnancies were lower in the WS-TCM group (N=3, 2.5%) compared to the ACU group (N=35, 9.5%; OR=0.24, 95%CI 0.07–0.82), and UC group (N=49, 8.4%; OR=0.28, 95%CI 0.09–0.91). There was no difference in miscarriages between the WS-TCM group (N=7, 5.8%) and the ACU group (N=27, 7.3%; OR=0.53, 95%CI 0.24–1.21), or the UC group (N=62, 10.7%; OR=0.65, 95%CI 0.29–1.46).

Conclusion: WS-TCM may improve the odds of live birth in fresh, non-donor IVF cycles, and reduce biochemical pregnancies compared to usual care or acupuncture on the day of ET alone. More rigorous research is needed to confirm these findings.

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Oral Abstract Session 08: Research Methodology

OA08.01

Improving the Patient-Reported Outcome Experience for Participants and PI's: Feasibility and Validity of PROMIS

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Purpose: Patient-reported outcomes (PROs) quantify a person's experience with their health and the effect of treatment on how they feel or function. As the patient is the only reliable source of this information, PROs are important research outcomes. Because traditional clinical outcomes are often unavailable or inappropriate for many complementary and alternative medicine (CAM) trials, PROs are particularly valuable for CAM clinical research. However, administering and scoring questionnaires requires considerable effort and time. The Patient Reported Outcomes Measurement Information System (PROMIS) could considerably reduce administrative obstacles and lessen survey burden for participants. The purpose of this study was to assess the feasibility and validity of PROMIS compared to commonly used pen and paper legacy measures for collecting PROs in clinical research.

Methods: Cross-sectional survey; 133 participants with confirmed MS completed legacy surveys and PROMIS Computerized Adaptive Tests (CATs) for depression, anxiety, pain, fatigue, and physical function. A multitrait-multimethod analysis was conducted and verified with confirmatory factor analysis.

Results: PROMIS surveys asked fewer questions and required substantially less time to complete than legacy scales. Correlations between PROMIS and corresponding legacy measures were large (0.67 to 0.87). Multitrait-multimethod criteria were generally well met, providing good evidence of convergent and discriminant validity of PROMIS measures. Confirmatory factor

analysis returned a chi-squared statistic of $\chi^2(25)=43.22$, $p=0.013$; a Goodness-of-fit index of 0.940; and RMSEA index of 0.074; indicating good fit to the observed MTMM matrix.

Conclusion: Results provide evidence of construct validity for a variety of PROMIS questionnaires. Several aspects of PROMIS CATs make them an important resource for CAM clinical trials, including: 1) substantially less time required to complete, 2) reduced missing data, and 3) automatic scoring referenced to the general population. Findings support the use of PROMIS in clinical research with MS and may have broader implications for other research populations, as well.

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OA08.02

Mixed Methods in CAM Research: A Systematic Review of Studies Published in 2012

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Purpose: Mixed methods research uses qualitative and quantitative methods together in a single study or a series of related studies. This systematic review aimed to review the prevalence and quality of mixed methods studies in complementary medicine.

Methods: All studies published in the top-10 integrative and complementary medicine journals in 2012 were screened (n=2349). The quality of mixed methods studies was appraised using a published tool designed for mixed methods studies, the Mixed Methods Appraisal Tool. Two researchers conducted the screening and quality appraisal.

Results: 4% of papers (95 out of 2349) reported mixed methods studies, 80 of which met criteria for applying the quality appraisal tool. The most popular formal mixed methods design was triangulation (used by 74% of studies), followed by embedded (14%), sequential explanatory (8%) and finally sequential exploratory (5%). Quantitative components were generally higher quality than qualitative components; when quantitative components involved randomized clinical trials they were of particularly high quality. Common methodological limitations were identified. Most strikingly, none of the 80 mixed methods studies addressed the philosophical tensions inherent in mixing qualitative and quantitative methods.

Conclusion: Research published in complementary and alternative medicine journals could benefit from more use of mixed methods research designs. The quality of mixed methods research in these journals would be enhanced by addressing philosophical tensions and improving reporting of (a) analytic methods and reflexivity (in qualitative components) and (b) sampling and recruitment-related procedures (in all components).

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OA08.03

Measuring the Healing Context in CAM: Progress on Developing Patient-Reported Measures of Nonspecific Contributors to Treatment Outcome

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Purpose: In its 3rd strategic plan, NCCAM identified goals for future research, including “better understanding of the contributions of both specific and nonspecific effects influencing outcomes.” We present progress to date on our NCCAM-funded project, The Healing Context in CAM: Instrument Development and Initial Validation, which will measure nonspecific factors from the patient’s perspective.

Methods: We used PROMIS® methodology to develop patient-report measures of nonspecific factors that may influence healing, such as perceptions of the provider and healthcare environment, treatment expectations, and spirituality and optimism. We conducted 6 focus groups of CAM and conventional medicine patients, interviewed 22 CAM experts, and evaluated existing questionnaires. Through an iterative approach involving writing, rewriting, and revising items based on feedback from patients, we developed a set of item banks containing a total of 296 items. The items were tested on an Internet sample of 1400 adults who had experienced CAM or conventional treatments, and on a Pittsburgh sample of 257 patients who had started a CAM or conventional treatment for any non-acute condition within the previous 4 months. Data analysis included exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and item response theory (IRT). Additionally, 221/257 of the Pittsburgh sample rated their Clinical Global Impression (CGI) of improvement 6 weeks after completing the item banks.

Results: EFA and CFA retained 250 items and identified 5 factors: 1) Patient-Provider Relationship+Healthcare Environment, 2) Optimism, 3) Spirituality, 4) Pro-CAM Attitudes, and 5) Treatment Expectations. IRT analyses resulted in retaining Healthcare Environment as a separate construct. Patients’ IRT theta scores for all factors except Spirituality were significantly but modestly correlated with CGI, with Treatment Expectations showing the highest correlation with CGI (Spearman’s $Rho = .358$, $p < 0.01$).

Conclusion: The project has successfully created item banks to measure nonspecific factors in healing, with most item banks exhibiting significant associations with patient reports of improvement. Further validity studies are forthcoming.

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OA08.04

Determinants of Responders in a Dose-Response Trial of Spinal Manipulation for the Care of Chronic Low Back Pain

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Purpose: The aim of this secondary analysis is to identify determinants of success of spinal manipulation (SMT) for the treatment of chronic low back pain (cLBP).

Methods: We randomized 400 cLBP patients to receive 18 sessions of lumbar SMT or a light massage control scheduled over 6-weeks; with SMT at 0, 6, 12, or 18 of the visits. Patients were followed for 52-weeks. Successful response to treatment is defined as a 50% improvement in pain measured with the 100-point modified Von Korff Pain Scale. Three-quarters of the data-set is used to develop the predictive models with stepwise logistic regression. Investigated determinants of successful response are baseline measures of pain, disability, outside care,

health status, age, gender, relative confidence in SMT/massage, any previous SMT/massage care, and time-point. Secondly, models are validated on the remaining data with sensitivity and specificity.

Results: Determinants associated with improvement across all time points included number of weeks since baseline, dose, number of comorbidities, number of treatment visits, confidence in physician’s ability to treat cLBP, and the EuroQol question about self-care at baseline with p-values of 0.048, <0.001 , 0.020, 0.080, 0.100, and 0.046 respectively. 50%-improvement in pain, across all time points, was predicted best, using forward stepwise selection, by treatment and lower number of comorbidities. An increase in dose increased successful recovery with an OR per increase of 6 treatments of 1.32 95%CI[1.11, 1.57, $p=0.002$]. And an increased count of the number of comorbidities prevented recovery at an OR per 1 comorbidity of 0.82 95%CI[0.69, 0.97; $p=0.025$].

Conclusion: These findings will assist with developing models for predicting which cLBP patients would especially benefit from SMT.

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Oral Abstract Session 09: Clinical Trials

OA09.01 LB

Mindfulness Training Versus Sleep Hygiene for Insomnia Symptoms in Older Adults: A Randomized Controlled Comparison Trial

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Purpose: Adequate sleep is vital to our survival, yet sleep problems grow common with age. About 50% of people aged 55+ years experience insomnia weekly. Given that sleep problems often go untreated in older adults, and untreated sleep problems increase the risk for morbidity and all-cause mortality, effective treatments for sleep problems are a priority to improve the health of our aging population. This randomized controlled comparison trial examined the relative efficacy of two 6-week interventions (mindfulness meditation training, MT vs. sleep hygiene, SH) on sleep, inflammatory markers, and brain morphology.

Methods: Participants (N=49) were ages 55–90 (M=66.27, SD=7.43). Inclusion criteria: currently active insomnia symptoms, age in years > 55 , and agreeing to randomization. Exclusion criteria: current inflammatory disorder, illness, or infection, current practice of meditation, depression, cognitive impairment, class II or greater obesity, current sleep apnea diagnosis, inability to speak English, and current smoking and/or substance dependence. The UCLA IRB approved study procedures. Measures included self-reported sleep, fatigue, and peripheral blood mononuclear cell levels of Nuclear Factor-kappa B. Brain images were acquired on a 1.5T Siemens Sonata scanner using an 8-channel head coil and a T1-weighted MPRAGE sequence.

Results: Forty-three (88%) participants completed the trial. ITT analyses showed that both groups reported improved sleep and NF-kB levels post-intervention. Sleep improvements in the MT condition were significantly greater than SH ($p < .02$). Fatigue symptoms improved only in the MT group ($p < .01$). Significant