

## P05.10

### The Fuzzy Edge of CAM Use: Challenges in What Constitutes CAM Use in Self-Administered Questionnaires

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**Purpose:** Whether certain practices like “prayer,” “supplements,” or “special diet,” constitute CAM is an important debate when measuring CAM use. We sought to determine the degree of variation in self-reported CAM use in self-administered patient questionnaires based on what patients consider CAM.

**Methods:** We extracted patient-reported CAM use data using a broad and inclusive definition from the first 177 patients enrolled in a cancer communication study that had completed a follow-up survey. We identified those patients that reported any history of CAM across 15 CAM modalities derived from existing NIH definitions. We then calculated self-reported CAM use rates using a narrower definition of CAM. The narrow definition excluded disputable or “fuzzy” categories (“prayer,” “supplements,” “special diet,” and “other practitioner”).

**Results:** When we used a broader definition of CAM that included the fuzzy categories, 154 patients (63% female with a variety of cancers at various stages) self-reported CAM use at some point in their life (87%). From these patients, CAM category usage rates varied from 2.6% (hypnotherapy) to 79.2% (prayer). Of all CAM-users, 13.6% reported prayer as their only type of CAM. Supplement use, special diet, and other practitioner were the only types of CAM reported in 1.9%, 1.9%, and 0.6% of cases, respectively. One third of all CAM use under this broader definition was attributable to modalities in the fuzzy categories 54/154 (35%). Conversely, when we used a narrower definition of CAM, 100 out of 177 used CAM (56%).

**Conclusion:** Accepted definitions for what qualifies as “CAM” are not concrete and pose measurement challenges in self-administered questionnaires, even if clear definitions are presented. Exclusion or inclusion of “prayer” alone as a type of CAM will change self-reported CAM usage rates by as much as 12%. Excluding or including all types of “fuzzy” CAM categories can affect CAM self-report rates by as much as 31%.

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## P05.11

### Controlling for Placebo Effects in Clinical Trials of Craniosacral Therapy: Blinding Success and Credibility of a New Sham-Control Protocol

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**Purpose:** Determining efficacy and controlling for non-specific effects in complementary and alternative medicine (CAM) re-

quire valid placebo or sham control groups that generate similar levels of expectancy, credibility and therapist attention and ensure successful patient blinding. To differentiate specific effects of Craniosacral Therapy (CST) from non-specific, placebo-related mechanisms a new sham-control procedure was developed and tested for its credibility.

**Methods:** Patients from a randomized controlled trial on chronic neck pain (NCT01526447) completed the Credibility/Expectancy Questionnaire and the Helping Alliance Questionnaire as well as questions about compliance and safety. Patients in the treatment group received 8 individual CST sessions once a week whereas sham group patients received light touch of the same extent. Complete (N=50) and multiple imputed data (N=54) were analyzed separately using a logistic regression model with patients’ ratings as independent predictors and group assignment as dependent variable. An additional t-test for analysis of the overall compliance/attendance was computed.

**Results:** Patients’ ratings of treatment expectancy, treatment credibility and therapeutic alliance were not found to have a significant power for classifying cases into CST or sham group ( $p \geq .05$ ). Only satisfaction with treatment revealed a significant adjusted odds ratio (AOR: 6.83; 95% CI: [1.54; 30.24];  $p = .011$ ) in the analysis of the complete cases, but was not stable for the imputed dataset (AOR: 4.09; 95% CI: [0.94; 17.76];  $p = .060$ ). Compliance of both groups was comparable ( $p = .054$ ) as were reasons for non-attendance. No serious adverse events were reported.

**Conclusion:** Study results indicate that blinding patients to treatment allocation was successful; patients’ expectancy, credibility and alliance to the therapist did not appear to affect study outcomes, and sham manipulation was tolerable and safe. The design can therefore be regarded as a credible means to control for placebo effects in future CST clinical trials.

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## P05.12

### Avoiding Unrealistic Results When Analyzing Influencing Factors Associated with CAM Use: Introducing the Idea of Multilevel Modeling

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**Purpose:** Many researchers explored the possible influencing factors from individual’s perspective for selecting or rejecting CAM among individuals in different health conditions all over the world. In order to reveal the factor levels (individual or population) and statistical methodologies which were used in the previous studies, we conducted this review.

**Methods:** MEDLINE, CNKI and VIP electronic databases were searched till Oct. 2013. Surveys which presented evidences on associations between CAM use and various influencing factors were included this review.

**Results:** 67 articles were identified. After reading titles and abstracts, 29 of these articles were excluded because they were duplicates, reviews, or their objectives different from this review. Data in 31 (81.6%) of surveys had the hierarchical structure, but none of them were analyzed using multilevel models. of articles demonstrated that many individual level characteristics (such as elder age, female, higher income or education level,