Collecting Treatment Data Efficiently in Large Trials of Acupuncture: STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) meets Technology

Karen J. Sherman, PhD, MPH*, Arya Nielsen, PhD±, Doug Kane, MS1 for the BackInAction Trial

*Kaiser Permanente Washington Health Research Institute, ±Department of Family Medicine & Community Health, Icahn School of Medicine at Mount Sinai, New York

Background

- Clinical trials typically reported using the CONSORT (Consolidated Standards of Reporting Trials) statement, which includes a 25-item checklist and a trial flow diagram, to assist in high quality reporting of trials.
- CONSORT is augmented by specific extensions for various types of trials.
- STRICTA (STandards for Reporting Interventions in Clinical Trials of Acupuncture) is an extension of the CONSORT statement providing guidance on how to clearly describe the acupuncture treatments administered in a trial.
- To prepare for launching the “BackInAction” 4-site pragmatic trial of acupuncture for chronic low back pain in older adults, we developed a standalone database to capture the aspects of the intervention we expected to vary among treatment visits.

Results

Introduction to STRICTA

The STRICTA checklist includes the rationale for the type of acupuncture (Item 1), details of needling (Item 2), treatment regimen (Item 3), other components (Item 4) and practitioner background (Item 5).

Overall Acupuncture Treatment Regimen:
- Standard Treatment: between 8 and 15 treatment visits during 90-day treatment period.
- Maintenance Treatment: up to 6 additional treatment visits during 90-day maintenance period.

Methods

- We used a modified Delphi Process1 to develop a flexible acupuncture intervention protocol for this trial.
- Our protocol explicitly addressed all five components (and 15 subcomponents) of the STRICTA checklist.
- Our treatment visit form captured needling details, treatment regimen and other components of treatment (in this case, lifestyle components).
- We built a password-protected, HIPAA compliant SQL server database that used the treatment form as a template for the database interface.
- We added additional questions on the details of treatment (see Fig. 1, Item 4) that allow us to monitor treatment fidelity, whether and how protocol restrictions impacted the acupuncturist’s ability to deliver what they felt would be the best acupuncture treatment, and the patient’s status at the end of the treatment (e.g., treatment continuing, treatment completed).

Conclusion

It is possible to build a database to securely capture treatment information in a pragmatic trial of acupuncture to describe the acupuncture provided as required by the STRICTA extension to the CONSORT statement.