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

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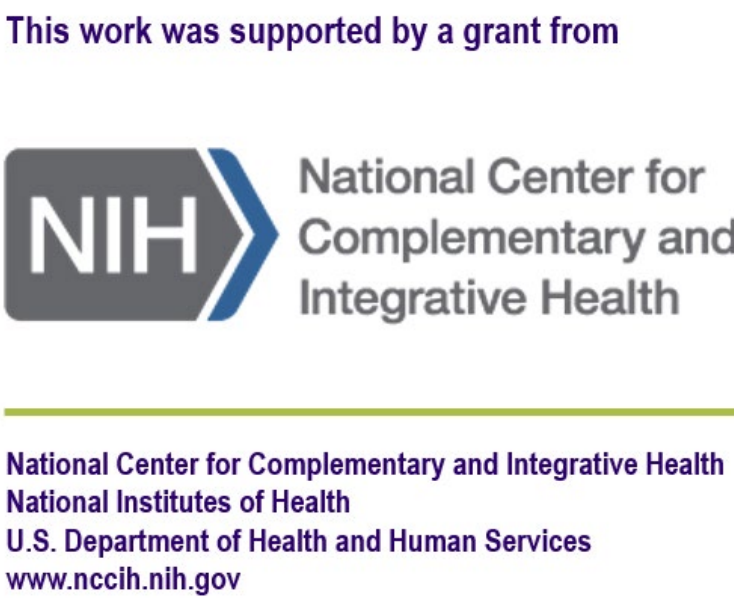
Background

- 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.

Methods

- We used a modified Delphi Process[1] 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).

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).

Of those, acupuncture rationale and practitioner qualifications were pre-determined and thus, not included in the database.

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.

STRICTA Item	Detail
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant
	2b) Names (or location if no standard name) of points used (uni/bilateral)
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level
	2d) Response sought (de qi or muscle twitch response)
	2e) Needle stimulation (manual, electrical)
	2f) Needle retention time
	2g) Needle type (diameter, length, and manufacturer material)
3. Treatment regimen	3a) Number of treatment sessions
	3b) Frequency and duration of treatment sessions
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (lifestyle advice)
	4b) Setting and context of treatment, including instructions to practitioners and information and explanations to participants

Figure 1: STIRCTA Required Elements of the Database

Number of Needles Used:_____ Local Points: ☐ No ☐ Yes   Distal Points: ☐ No ☐ Yes

Needle Retention Time (minutes):   Minimum: _____   Maximum: _____   Average: _____

De qi: ☐ No   ☐ Some ☐ Most/All   Needle Length(s):_____

Figure 2: Database details to address STRICTA Items 2a, 2d, and 2f.
[Note: 2b is represented in Figs. 6-9; 2c is based on recommendations in several texts and is prescribed to be manual]

COMPLETE THESE AT FIRST VISIT ONLY   Needle Gauge(s) (mm)_____

Needles are: ☐ Coated   ☐ Uncoated   Needle Manufacturer:_____

Figure 3: Database details to address STRICTA Item 2g

Study ID: _____   Visit Date: _____/_____/202____
Visit No (check Box) 1 ☐ 2☐ 3 ☐ 4☐ 5☐ 6☐ [etc]   Visit Start Time: ____:____   Visit End Time: ____:____

Figure 4: Database details to address STRICTA Items 3a and 3b

Self care recommendations (check all that apply):
1. ☐ None
2. ☐ Movement, activity, exercise
3. ☐ Meditative movement (QiGong, Tai Chi)
4. ☐ Food/diet/water: general
5. ☐ Guidance on breathing awareness
6. ☐ Sleep
7. ☐ Other
(specify):_____
Did you use ear seeds? ☐ No ☐ Yes

We also added some additional questions on the details of treatment 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).

Figure 5: Database details to address STRICTA Item 4a [4b uses common materials and trainings to guide acupuncturists in their treatment and interactions with patients]:
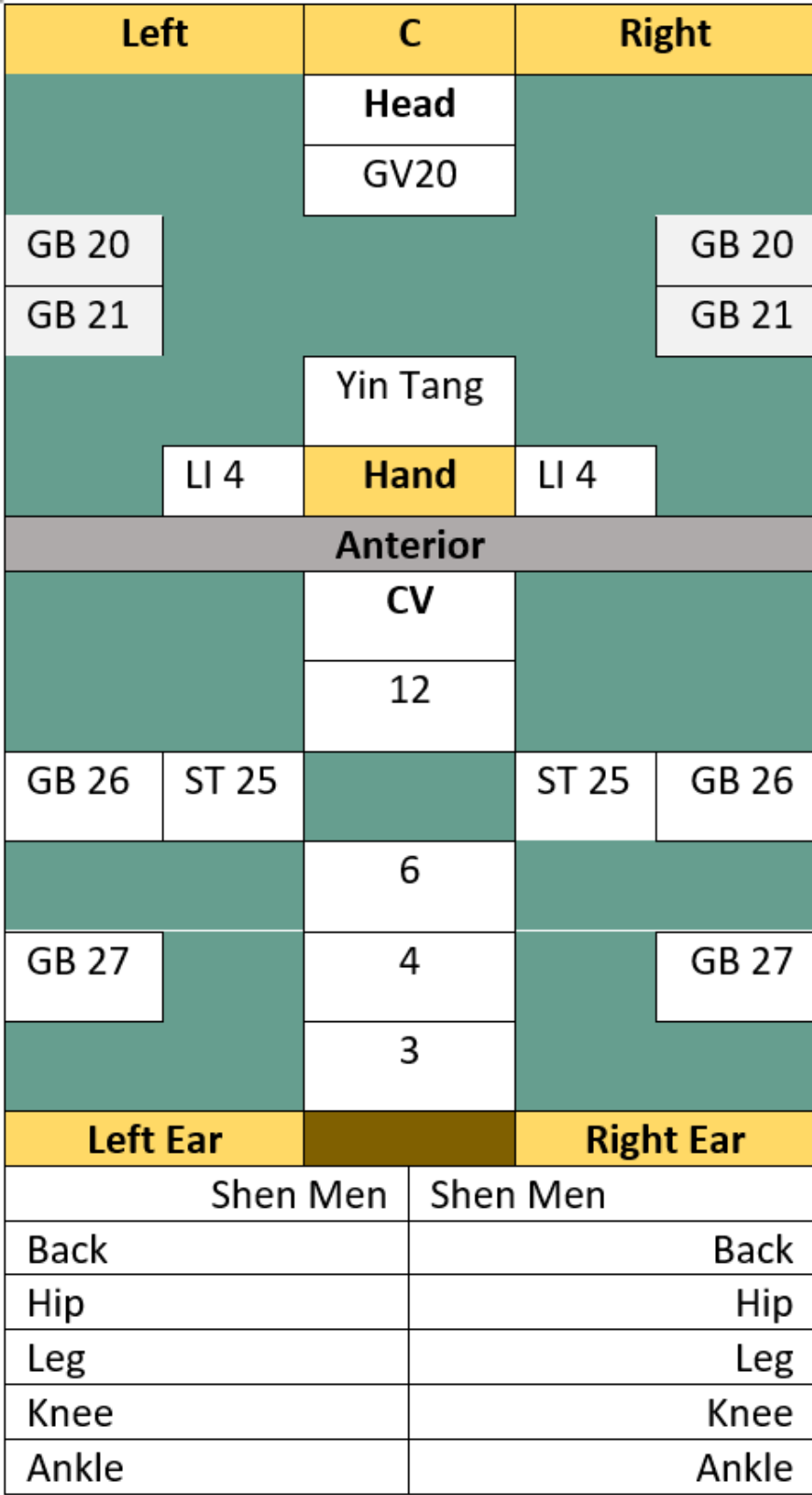

Figure 6: Recommended Acupuncture Points: Anterior of Body (except legs)
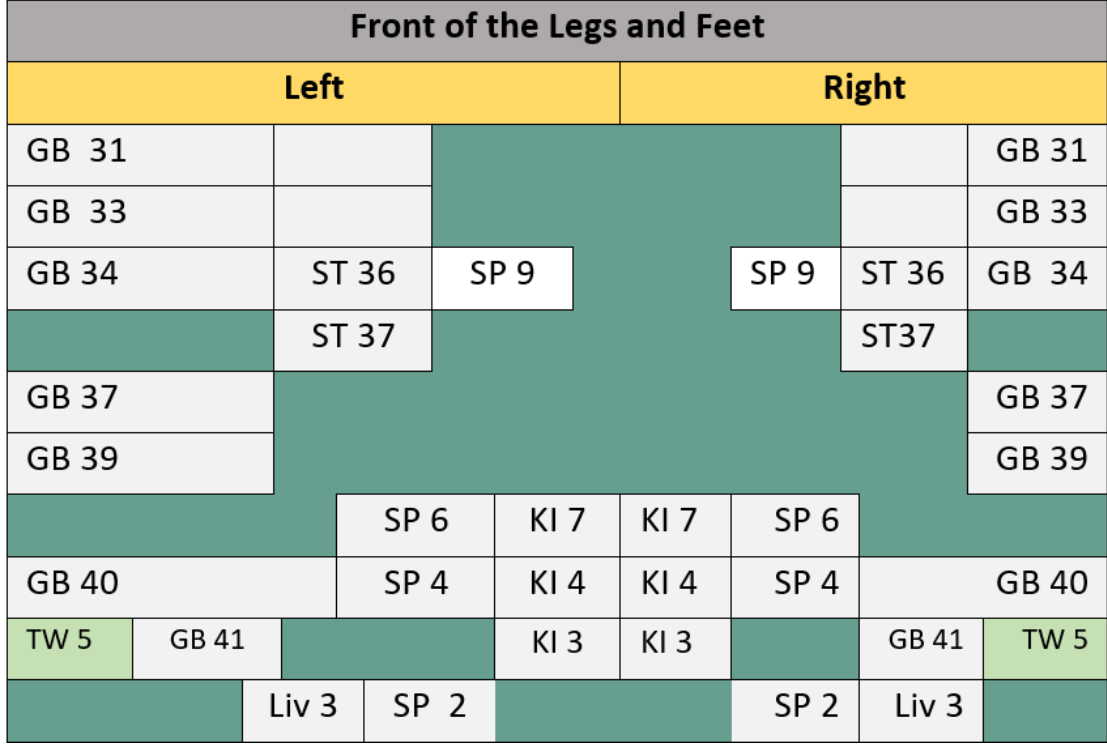

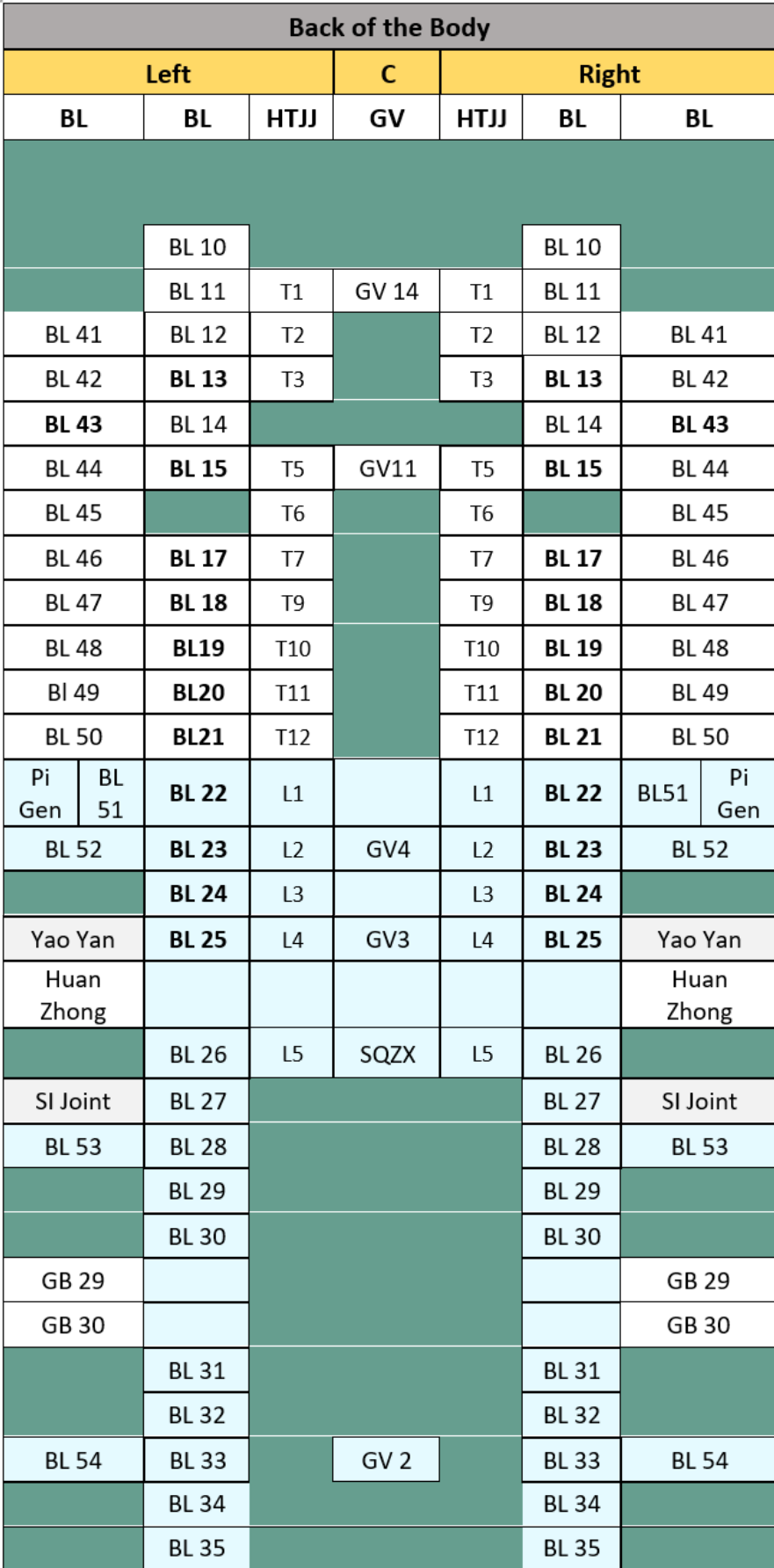*Figure 8: Recommended Acupuncture Points: Posterior of the Body (except legs)*

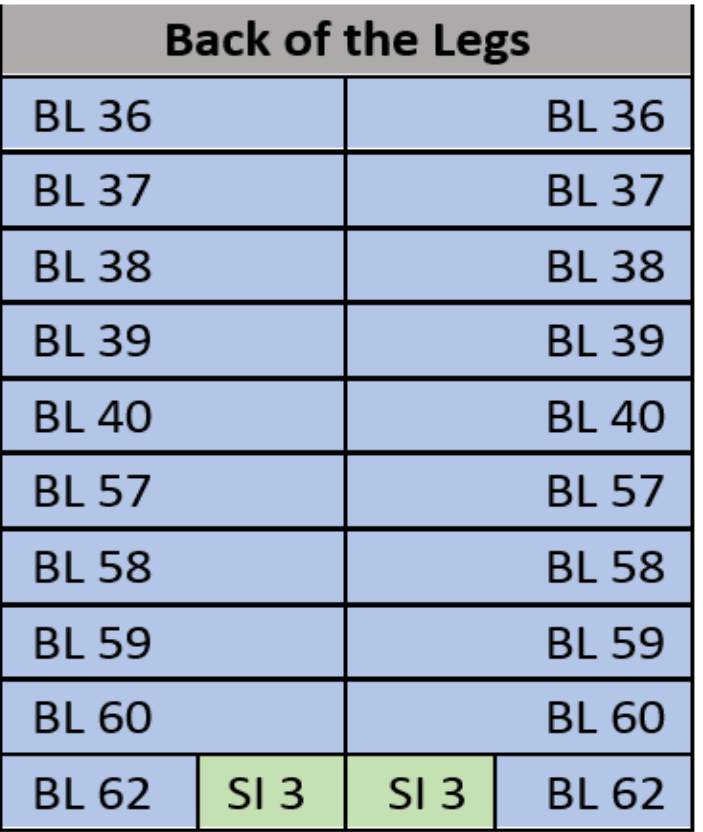*Figure 7: Recommended Acupuncture Points: Anterior of Leg*

Figure 9: Recommended Acupuncture Points: Posterior of Leg

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.

Reference

1. Nielsen A, Ocker L, Majd I, Draisin JA, Taramino K, Maggenti MT, Long J, Nolting M, Sherman KJ. Acupuncture Intervention Protocol: Consensus Process for a Pragmatic Randomized Controlled Trial of Acupuncture for Management of Chronic Low Back Pain in Older Adults: An NIH HEAL Initiative Funded Project. Glob Adv Health Med. 2021;10:21649561211007091. Published 2021 May 26. doi:10.1177/21649561211007091