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DESIGN CHALLENGES IN TAIJI/QIGONG RESEARCH: RATIONALE FOR A SHAM CONTROL AND IMPLICATIONS

HOW DO WE KNOW IF TC/QG "WORKS"?

- ✘ Compare long-term practitioners to non-practitioners
- ✘ Compare some parameter before and after a series of classes for group practice
- ✘ Examine acute impact of practice, such as immediate change in biomarkers
- ✘ Randomize to a TC/QG or no intervention control
- ✘ Randomize to TC/QG or "placebo" control.



FIRST EFFORT AT "SHAM" CONTROL GROUP

- ✘ 2-group RCT to test of effects of Qigong vs sham control on hypertension
 - ✘ **Qigong** exercises targeting heart, kidney, based on **Grand Master Hong Liu's** protocol for BP
 - ✘ **Sham control intervention** based on cardiac surgery rehab exercises
- True and sham "emitted Qi from Grandmaster"



HYPOTHESES & QUESTIONS

- × **H1**: Perceptions of the SQ protocol will not differ significantly from TQ on authenticity, level of exertion, benefit, and level of relaxation.
- × **H2**: Hypertensive patients treated with TQ (True Qi emission and practicing True Qigong Exercises) will decrease blood pressure more than those treated with sham Qigong emission and exercises.
- × **RQ**: Will there be pre- to post-intervention differences between groups on biofield assessments?

DESIGN

- ✘ Twenty-two Stage 1 hypertensive patients (systolic 140-159 mmHg) (NOT randomized) to TQ or SQ. 18 completers
- ✘ Month-long intervention
- ✘ Measures of BP, cortisol, O₂sat, and GDV (biofield) pre- & post single class and full intervention
- ✘ Intervention “comparability” measures: Borg’s RPE, video raters of “relaxed movement”, perception of authenticity, perceived benefit

RESULTS--- COMPETING MECHANISMS VS PLACEBO EFFECTS

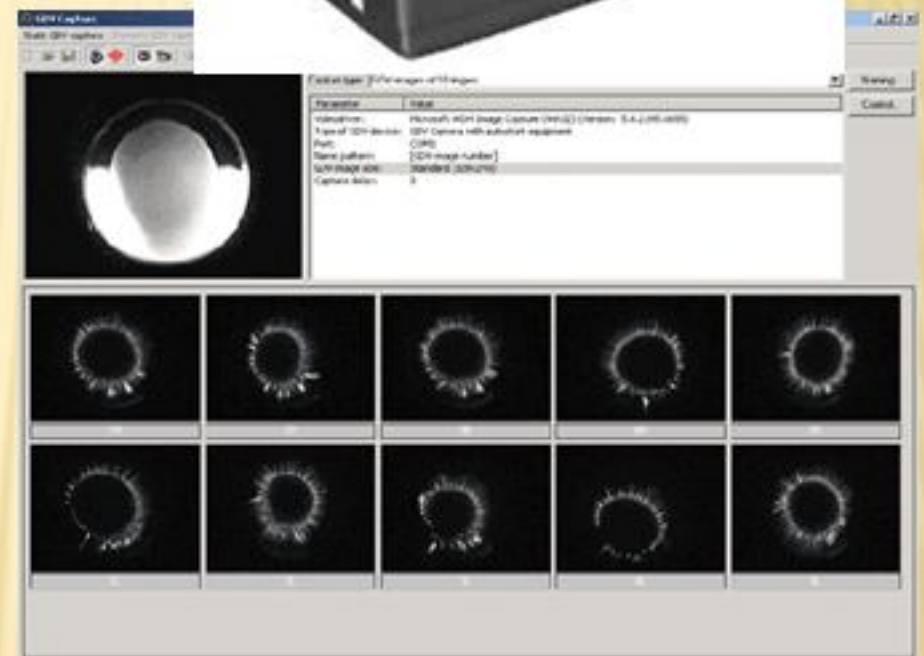
- ✘ Similar perceptions of two interventions:
 - + Perceived **level of exertion** (extremely light to light)
 - + Perceived as **beneficial** and "**authentic**" (7 vs 5/11)
- ✘ Ratings of "**relaxed movement**" similar (raters)
- ✘ Significantly lowered systolic pressure for TQ compared to SQ (diastolic only approached)



Larkey, L.K., Rizzo-Roberts N, Schwartz G. Development and assessment of a sham control protocol for cardiac Medical Qigong exercises and acute effects on hypertension. Presented at the 15th Annual Institute for the Study of Subtle Energies and Energy Medicine Conference, June, 2005, Colorado Springs, CO.

GDV ASSESSMENT OF BIOFIELD EFFECTS

- ✘ GDV (Gas Discharge Visualization Device) assessment of meridian balance (JS Integer) significant changes for TQ, not SQ
- ✘ SQ mean JSI change, .45,
- ✘ TQ mean JSI change, .80
- ✘ ($t = 3.19, df 19, p = .002$).



ISOLATE "QI" AS MECHANISM OF ACTION

GDV: MERIDIAN-BASED OUTPUT



KEY CHALLENGES IN TC/QG RESEARCH DESIGN

- ✘ **Intervention fidelity:** Set of exercises the same for everyone? **specific condition vs. general** benefit
- ✘ **Intervention fidelity:** Protocol **taught consistently** (teaching methods, teacher variation, exercise execution differences)
- ✘ **Intervention fidelity:** “You can lead them to the pill, you can even watch them swallow it, but you can’t tell what is happening inside” Not a pill...
 - + Validation of meditative state
 - + Assessment of breathing
 - + Coaching and assessment of movement

Larkey, L.K., Jahnke, R., Etnier, J. Gonzalez. (2009). Meditative Movement as a category of exercise: Implications for research. *Journal of Physical Activity and Health*, 6(2):230-238.

CURRENT STUDY: EFFECT OF QG ON FATIGUE AFTER TREATMENT FOR BREAST CANCER

- ✘ 2-group RCT comparing TCE/QG and modified Lebed for fatigued breast cancer survivors
- ✘ Measures: Fatigue, cognitive function and performance, depression/anxiety, sleep quality
- ✘ Controlling for “qi”?
 - + Eligibility: no experience with MM
 - + Music, laughter, singing
 - + Movements selected to be similar
- ✘ Preliminary examination of data...



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