

Pragmatic approaches to studying wholistic therapies

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Today's presentation

- Introduction
- Study designs for the clinical setting
 - Case studies
 - Single subject study
 - N-of-1 randomized trials
- Inclusive study approaches
 - Whole systems research
 - Patient oriented research
- Pilot study of acupuncture to treat adolescent anxiety
 - Waitlist control trial using individualized acupuncture protocol



Introduction

Why pragmatic approaches?

- Vignette: Mary, a 35 y.o. female
 - Chief complaint of insomnia; other complaints: anxiety, constipation, heartburn, HBP, leg cramps
 - Treatment plan: acupuncture, melatonin, meditation, eliminate caffeine
- How to study complex case and multifaceted treatments?
 - How to shift from a reductionistic model to a model that considers the totality of care?



Study design: Case studies

- *Non-experiment descriptive* research that seeks to identify explanatory patterns for phenomena and generates hypotheses for future research.
- Systematically recorded observations and narrative description of an individual's characteristics and response to treatment
 - Involves careful, *preplanning* observation, of individual or group
 - More *systematic* documentation than case report
 - May be basis for making plausible inferences and generate *hypothesis* for future research



Study design: Single subject study

- *Quasi-experimental* approach to investigating causal relationships between independent and dependent variables.
- Characterized by repeated measures of an observable and clinically relevant target behavior throughout at least one pretreatment (baseline) and intervention phase.
- Consists of systematic observation, measurement, graphing and analysis of defined outcome using repeated measures
 - Repeated measures establish trend of outcome over time
 - Data can be plotted on a graph and analyzed for changes by level, trend, variability between baseline and intervention phrases

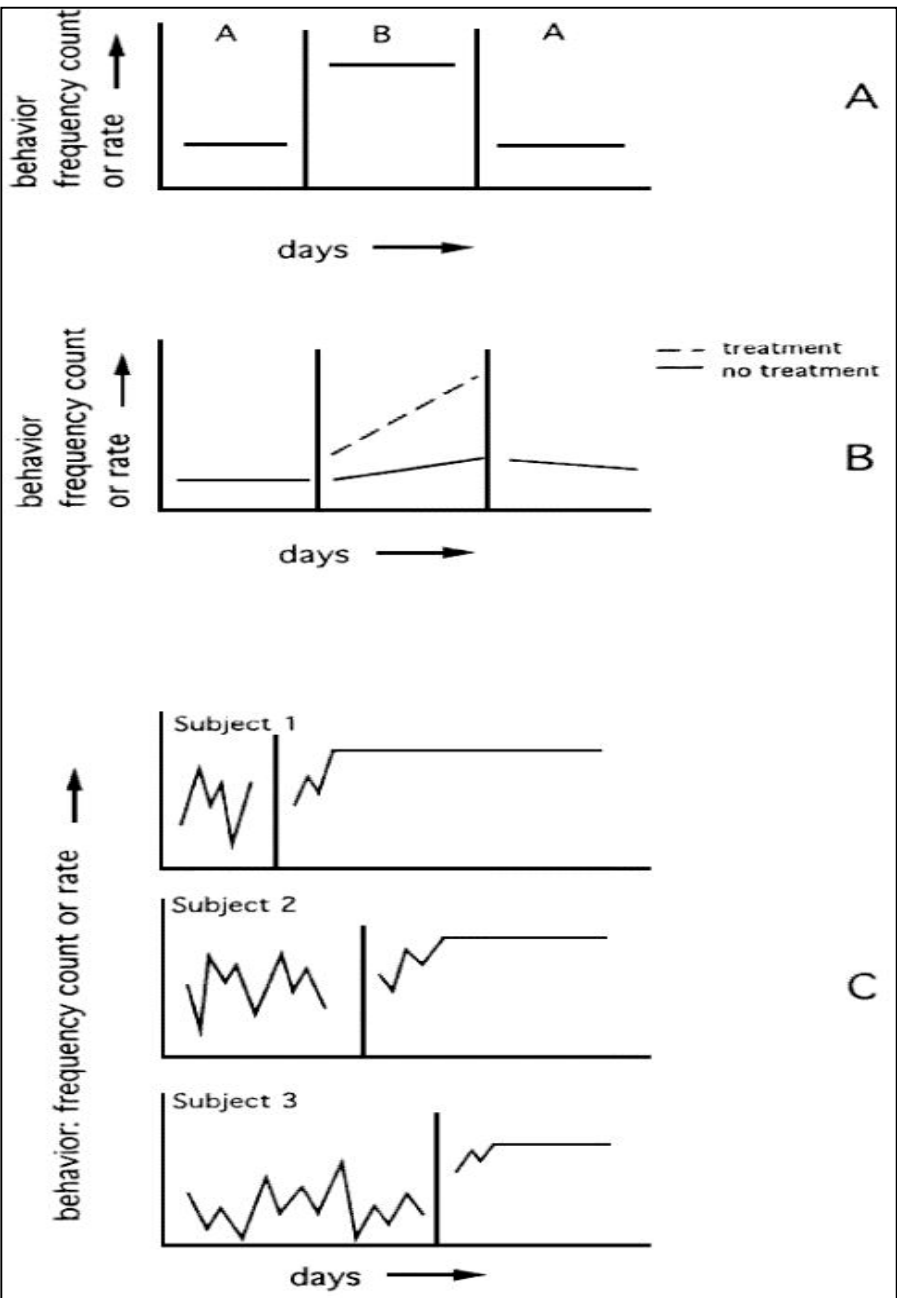


Figure 1 . Examples of changes in level, trend, and variability in the visual analysis of single-subject research designs.

- A. Change in level in an ABA design.
- B. Change in trend in an alternating treatments design.
- C. Change in variability in a multiple baseline design across three subjects.

CASE STUDIES, SINGLE-SUBJECT RESEARCH, AND N OF 1 RANDOMIZED TRIALS: Comparisons and Contrasts¹.

Backman, Catherine; MS, OT; Harris, Susan; PhD, PT. American Journal of Physical Medicine & Rehabilitation. 78(2):170-176, March/April 1999.



Study design: N-of-1 randomized trials

- *Experimental*, randomized controlled trial
- Compares a therapeutic procedure with placebo OR compares two treatments
- Uses a predetermined random order
- Clinician and patient are blinded to treatment status

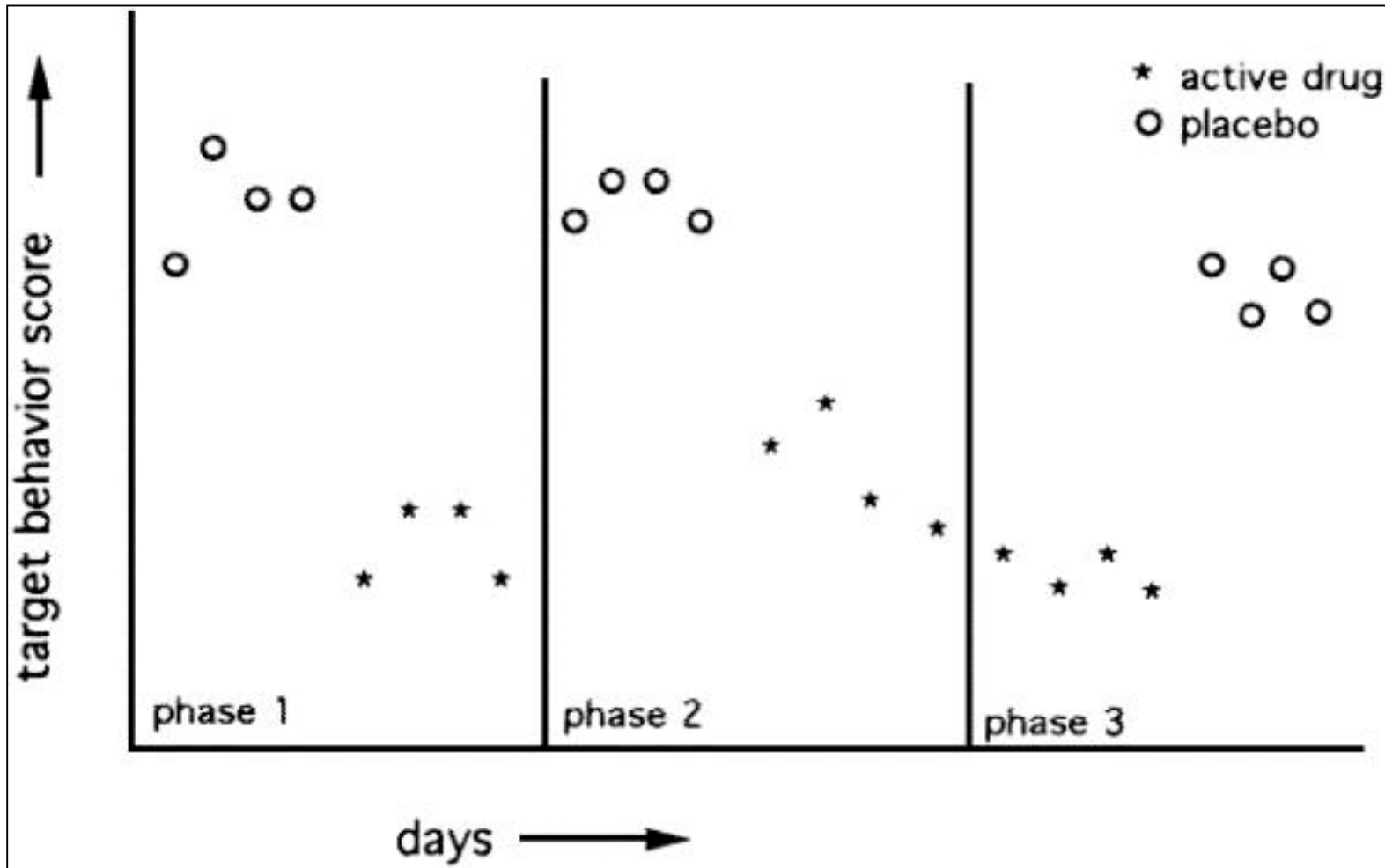


Figure 2 . Results from a hypothetical N of 1 trial. In this trial, the desirable outcome is for the frequency of the target behavior to be as low as possible.

CASE STUDIES, SINGLE-SUBJECT RESEARCH, AND N OF 1 RANDOMIZED TRIALS: Comparisons and Contrasts1.

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Questions to consider to do N-of-1 RCT

- Is a N-of-1 RCT indicated for the patient?
 - Is effectiveness of treatment testable?
 - Will the treatment, if effective, be continued long term?
 - Will the patient cooperate, collaborate on the design of the n-of-1 RCT?
- Is the n-of-1 RCT feasible in this patient?
 - Does the treatment have a rapid onset?
 - Does the treatment cease to act soon after it is discontinued?
 - Is an optimal treatment duration feasible?
 - Can a criteria for stopping the trial be established?
- Is the n-of-1 RCT feasible in my practice setting?
 - Is there a colleague/pharmacist to help me (i.e. maintain randomization sequence or blinding)?
 - Can the data be interpreted?
- Is the study ethical?

Whole Systems Research

- To study whole systems of practice such as Chinese medicine
 - i.e. multiple treatment modalities prescribed concurrently [such as acupuncture, diet, botanicals, massage, meditative activity, among others], individualized diagnosis, patient–practitioner interactions, techniques for changing patient behavior.
- Acknowledges *unique* characteristics and perspectives of the *patient*, the clinical experience and other external factors.
- Design: mixed methods preferred – ideally, large clinical trial testing the “whole system”, collecting quantitative and qualitative data.

Whole Systems Research

Pros

- Beyond testing a single agent (variable), more in keeping with holistic practices;
- Inclusion of metrics that assess quality of life
- Pragmatic trials provides the best true estimates of “real world” expectations
- More patient centred, using patient reported outcomes
- greater external validity (generalizeability)

Cons:

- Expensive, resource intensive
- Complex statistical analyses, and interpretation
- Finding appropriate comparator e.g. the usual care practices within the same clinical setting, i.e., the status quo

Patient Oriented Research

- Refers to a continuum of research, from the initial studies in humans to comparative effectiveness and outcomes research to inform the health care system and clinical practice.
- Engagement of the patient in all aspects of the research process, from developing research question(s) to recruitment and data collection/interpretation to knowledge dissemination
 - o Patient Reported Outcome Measures (PROMS)
 - o Patient Reported Experience Measures (PREMS)
- POR lends well to WSR and pragmatic designs as it takes into account outcomes that are important to patients

Patient Oriented Research

Patient Reported Outcome Measures (PROMs)	Patient Reported Experience Measures (PREMs)
Measures impact of an illness or health condition from the patient's perspective	Captures the patient's view of what happened during their healthcare visit (process of healthcare)
Examples: quality of life, symptom severity, functional status, health status	Examples: Communication and trust in staff, cleanliness, timeliness
Used to monitor the progress of a health condition or whether a treatment has been effective by comparing results over time	Used to evaluate and monitor service delivery
Measured from the patient's perspective, usually via questionnaires	
Used together to assess quality of care and services from patient's viewpoint	

Synopsis

Why pragmatic approaches?

- Vignette: 35 y.o. female
 - Chief complaint of insomnia; other complaints: anxiety, constipation, heartburn, HBP, leg cramps
 - Treatment plan: acupuncture, melatonin, meditation, eliminate caffeine

Applying pragmatic approaches:

- Case study →
- SSRD →
- N-of-1 →

A pilot study of acupuncture in the treatment of adolescent anxiety.

Brenda Leung and Wendy Takeda

Why study this topic?

What is already known on this topic

- Anxiety in children and adolescent is a growing health concern.
- Psychotherapy has been the first-line treatment, and medication use has increased drastically.
- There is growing interest in the use of complementary therapies for children's psychiatric disorders.

What this study adds

- There are potential benefits of acupuncture for paediatric anxiety.
- Minor side effects and no adverse events associated with acupuncture were reported.
- Acupuncture was well tolerated by participants.

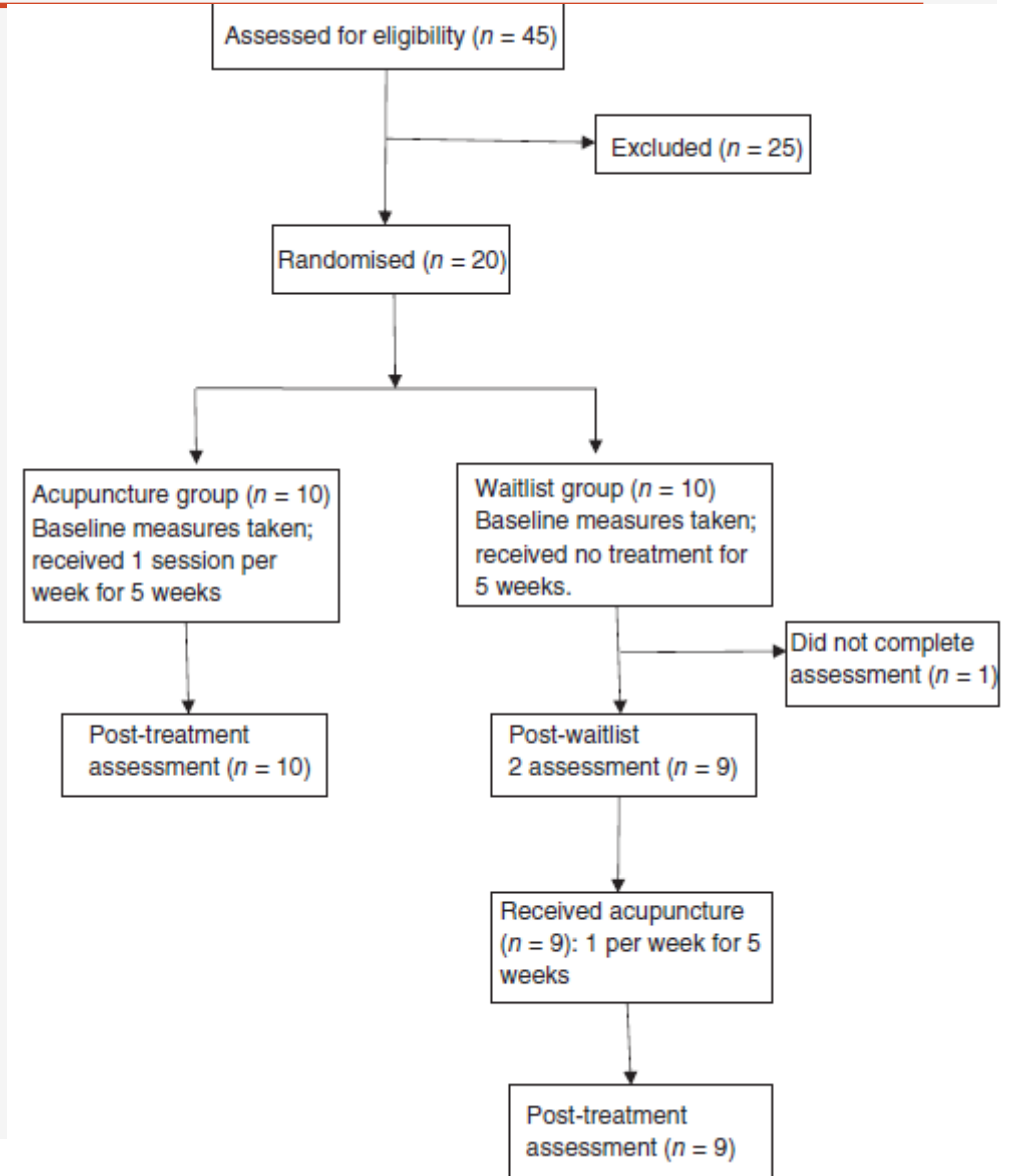


Background

- Anxiety disorders are the most common mental health complaint in the paediatric population, with prevalence estimated to range from 2.6 to 41.2%
- Current treatments include: cognitive behavioural therapy (CBT), Medications such as anxiolytics and anti-depressants
- Evidence suggest safety and feasibility of acupuncture in children and adolescents.
- **Purpose** of this pilot study was to evaluate acupuncture as a potential treatment for paediatric anxiety.
- **Hypothesis** participants who received acupuncture would experience reductions in measures of anxiety compared to baseline and to the waitlist control group.

Method

- Randomized (waitlist) controlled trial of children with general anxiety, aged 8–16, living in Lethbridge, Alberta, and surrounding communities
- Measures:
 - Hamilton Anxiety Rating Scale for children and adolescents with generalised anxiety disorder (HAM-A);
 - Multidimensional Anxiety Scale for Children 2nd Edition (MASC-2)
 - Clinical Global Index – Symptom scale



Acupuncture Intervention

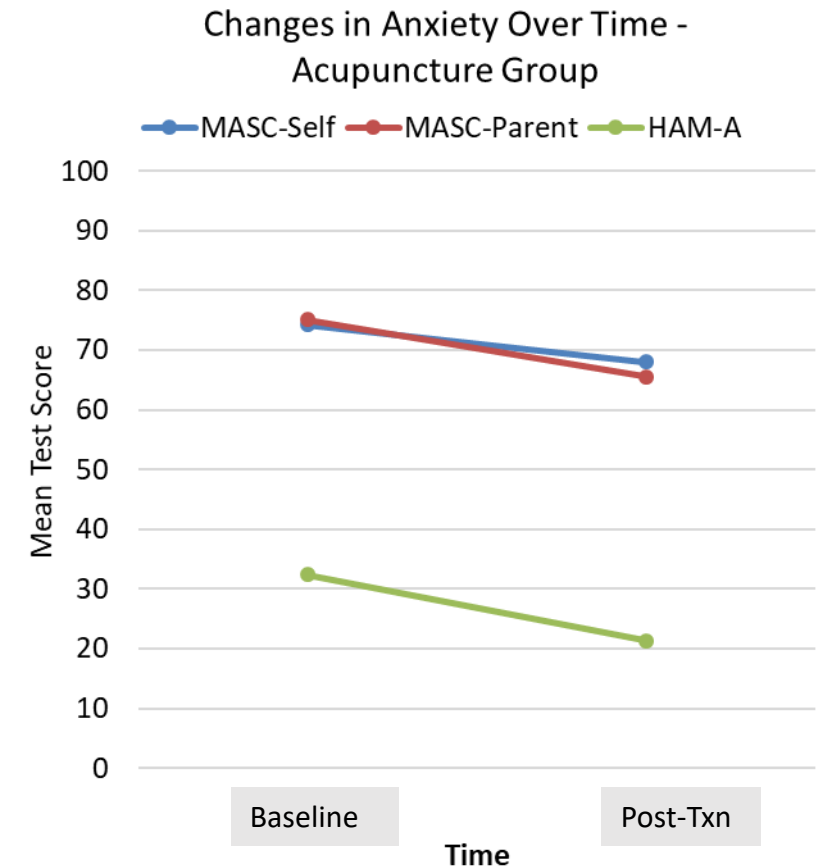
- Acupuncture involved the application of needles, suction cups (cupping) and/or herbal ear seeds (tiny pellets).
- A child may be given any of the three techniques over the course of the acupuncture treatments.
- Acupuncture points were selected based on the principles of traditional Chinese medicine syndromes, Zhang fu organ diagnosis, tenderness on palpation of Japanese Hara points, tenderness on palpation over traditional acupuncture points for anxiety and Mu/Shu points.
- Participants received a total of five acupuncture sessions, 30 min per session, one per week for 5 weeks.

Results

Table 3 Pre- and post-anxiety measure differences for acupuncture group

	Baseline		Post-treatment		P value†	Mean difference	Effect size Cohen's <i>d</i>
	Mean	SD	Mean	SD			
MASC self	74.30	10.79	68.00	12.07	0.070	6.30	NA
MASC parent	75.10	9.67	65.60	15.00	0.008	9.50*	0.75
HAM-A	32.40	8.04	21.30	7.72	<0.001	11.10*	1.4

* $P < 0.05$ is statistically significant. † P value from paired samples t-test. Baseline, before acupuncture treatment 1; HAM-A, Hamilton Anxiety Rating Scale; MASC, Multidimensional Anxiety Scale for Children; NA, not available; Post-treatment, after acupuncture treatment completion; SD, standard deviation.



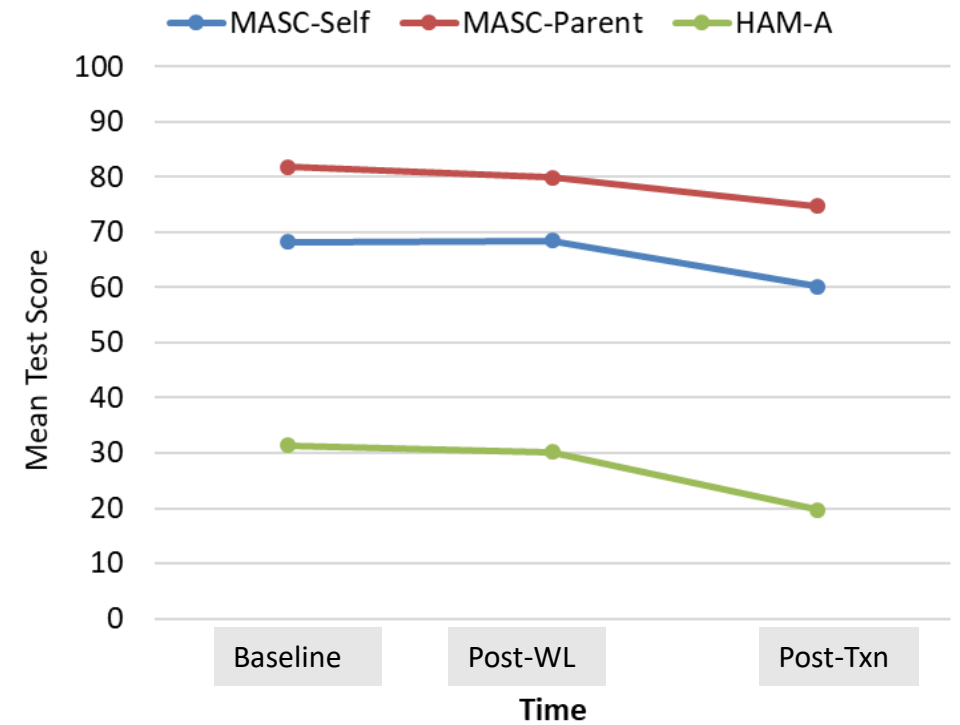
Results

Table 4 Waitlist group anxiety measure at three data collection time points

	Baseline		Post-waitlist		Post-treatment		Post-txn effect size		
	Mean	SD	Mean	SD	Mean	SD	P value†	Mean difference	Cohen's d
MASC self	67.88	9.61	68.50	9.15	NA	NA	0.772	-0.62	NA
MASC parent	82.25	8.75	79.88	12.18	NA	NA	0.355	2.37	NA
HAM-A	33.63	10.38	30.13	9.94	NA	NA	0.087	3.50	NA
MASC self	NA	NA	68.50	9.15	60.13	12.72	0.022*	8.37	0.75
MASC parent	NA	NA	79.88	12.18	74.75	13.53	0.048*	5.13	0.40
HAM-A	NA	NA	30.13	9.94	19.75	7.01	0.007*	10.38	1.21

*P < 0.05 is statistically significant. †P value from paired samples t-test. HAM-A, Hamilton Anxiety Rating Scale; MASC, Multidimensional Anxiety Scale for Children; NA, not available.

Changes in Anxiety Over Time - Waitlist Group



Summary

- Our study results demonstrated acupuncture reduced symptoms of anxiety and the treatments were acceptable to children in this age group.
- We incorporated pragmatic approaches into our study:
 - Randomization, blinding, (waitlist) control
 - WSR design – customized acupuncture treatments
 - Based on TCM diagnosis & practice for symptom picture.
 - POR element – clinician driven process in treatment and outcome
 - Exit interview captured patient's perspectives and reported experiences.

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- Leung BM, Takeda W, Holec V. A pilot study of acupuncture in the treatment of adolescent anxiety. *Journal of Paediatrics and Child Health*. February, 2018. doi:10.1111/jpc.13910.



Questions?

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