

CANADIAN COLLEGE OF OSTEOPATHY
TORONTO CAMPUS

STATS HELP

RESEARCH IN OSTEOPATHY

ANTON SVENDROVSKI
MBA, MSc (Math), B. CompSc
IBM SPSS Certified

AGENDA

- REVIEW OF MATERIAL
 - HYPOTHESIS/RESEARCH QUESTION
 - P-VALUE
 - STUDY DESIGNS
 - VARIABLES AND MEASUREMENTS
- DESCRIPTIVE STATISTICS
- INFERENCE STATISTICS
- SAMPLE SIZE DETERMINATION
- CHOOSING MEASUREMENT INSTRUMENT/TOOL
- QUASI-EXPERIMENTAL DESIGNS
- RELIABILITY STUDIES

REVIEW: RESEARCH QUESTION

1. WHY DO PATIENTS SEEK OSTEOPATHIC TREATMENT?
2. DOES OSTEOPATHIC INTERVENTION X EFFECTIVELY REDUCE PATIENTS' PAIN AFTER 5 SESSIONS?
3. IS THERE AN ASSOCIATION BETWEEN THE AGE OF PARTICIPANTS AND THE NUMBER OF OSTEOPATHIC SESSIONS ATTENDED?
4. IS THERE A DIFFERENCE BETWEEN OSTEOPATHIC INTERVENTION X AND INTERVENTION Y IN INCREASING THE PARTICIPANTS' QUALITY OF LIFE?
5. HOW RELIABLE IS A PARTICULAR TECHNIQUE IN DIFFERENTIATING EMPTY VS FILLED BLADDER?
6. IS THERE A CONSENSUS IN PUBLISHED STUDIES REGARDING THE EFFECTIVENESS OF INTERVENTION X?

REVIEW: HYPOTHESIS

Hypothesis = Research Question + **Measurement Tool** + " **$p \leq 0.05$** "

Examples of Hypothesis formulation:

1. Osteopathic treatment will significantly reduce the redness associated with acne as measured by **infra-red photography**, $p \leq 0.05$.
2. Five sessions of osteopathic intervention X will result in significant reduction in patients' pain as measured by **Visual Analog Scale**, $p \leq 0.05$.
3. Three trained osteopathy students at the end of their curriculum could achieve at least moderate agreement on osteopathic sacral palpatory diagnostic tests, **evaluated using Fleiss K (Kappa) statistics**, $p \leq 0.05$.
4. Osteopathic treatment X is more effective than osteopathic intervention Y in increasing the participants' quality of life as measured by **WHOQOL questionnaire**, $p \leq 0.05$.

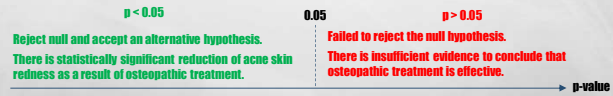
REVIEW: HYPOTHESES

Null Hypothesis (H₀):

Osteopathic treatment **will NOT** significantly reduce the redness associated with acne as measured by **infra-red photography**, $p > 0.05$.

Alternative Hypothesis (H_a):

Osteopathic treatment **will** significantly reduce the redness associated with acne as measured by **infra-red photography**, $p \leq 0.05$.



UNDERSTANDING RESEARCH ARTICLES

Table 2 Comparison of the VAS, MOV and ROM values between OMT and CCT groups (n = 25) at T0, T1 and T2.

		OMT		CCT		t	p
T0	VAS ^a	6.9	±0.88	6.40	±1.42		NS
	MOV ^b	35.1	±4.36	34.9	±34.5		NS
	ROM ^c	62.4	±10.67	64.5	±9.55		NS
T1	VAS ^a	1.5	±0.85	2.6	±0.7	-4.995	0.000
	MOV ^b	46.0	±4.78	41.3	±4.52	3.572	0.000
	ROM ^c	81.9	±10.31	71.9	±9.05	3.654	0.000
T2	VAS ^a	3.8	±1.26	4.4	±1.75		NS
	MOV ^b	42.9	±2.69	40.4	±2.41	3.461	0.001
	ROM ^c	80.5	±5.44	72.4	±2.95	6.545	0.000

^a The visual analogue pain scale was scored from 0 to 10.
^b Measure in millimeters.
^c Measure in degrees.

Source: A.M. Cuccia et al. Osteopathic manual therapy versus conventional conservative therapy in the treatment of temporomandibular disorders: A randomized controlled trial. *Journal of Bodywork & Movement Therapies* (2010) 14, 179-184
<https://doi.org/10.1016/j.jbmt.2010.03.001>

UNDERSTANDING RESEARCH ARTICLES

Table 1.—Headache Measures-Comparison of Means and *t*-Tests

Group	N	Std. Mean	Range Deviation	Range Minimum	Range Maximum	<i>t</i> -Value	Sig. df	2-tailed	
HA free days per week	C	12	.21 days	1.685 days	-3	4	-2.589	24	.016
	E	14	1.79 days	1.424 days	-1	4			
	Total	26	1.06 days	1.717 days	-3	4			
HA degree of improvement	C	12	.656	1.953	-2.58	2.36	-1.860	24	.075
	E	14	1.881	1.394	.00	4.46			
	Total	26			-2.58	4.46			

C = control group; E = experimental group.

Source: Rosemary Anderson & Caryn Seniscal (2006). A comparison of selected osteopathic treatment and relaxation for tension-type headaches. American Headache Society, doi: 10.1111/j.1526-4610.2006.00535.x

REVIEW: STUDY DESIGNS



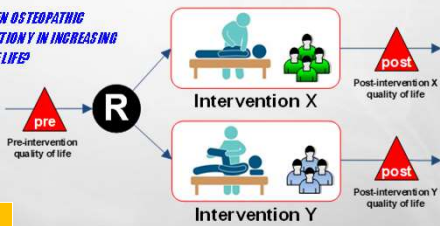
Acceptable Forms of Student Research:

1. Experimental and quasi-experimental research
2. Reliability, validity, and palpation studies
3. Technique studies
4. Case series studies
5. Fundamental studies - investigative but non-experimental
6. Qualitative studies

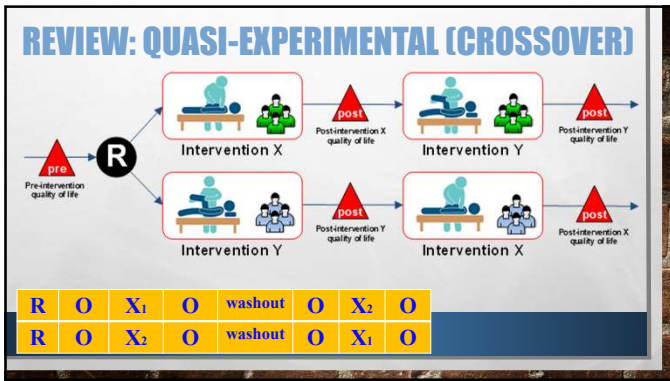
REVIEW: EXPERIMENTAL (RCT)

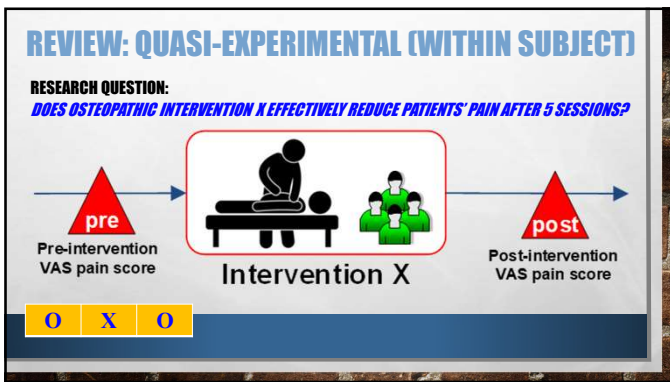
RESEARCH QUESTION:

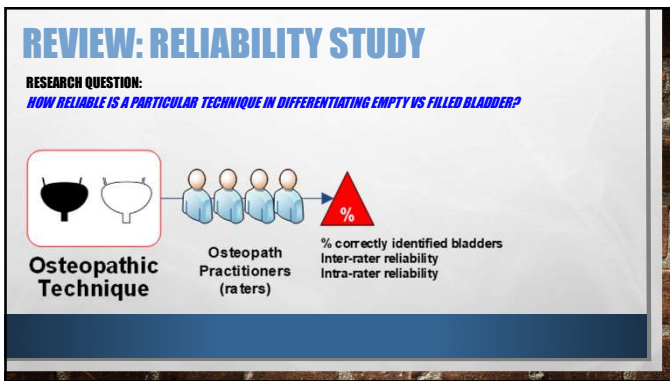
IS THERE A DIFFERENCE BETWEEN OSTEOPATHIC INTERVENTION X AND INTERVENTION Y IN INCREASING THE PARTICIPANTS' QUALITY OF LIFE?



R	O	X ₁	O
R	O	X ₂	O







REVIEW: VARIABLES

Variable is a thing that changes in experiment. A variable is any factor, trait, or condition that can exist in differing amounts or types.

Independent Variable – the variable that is changed or controlled in a scientific experiment. Usually the Treatment: technique, global or regional osteopathic intervention vs control.

Dependent Variable – the outcome of interest, what we are hoping to change or alter.

Variable type: **Numerical** (Age) or **Categorical** (Gender, Group)

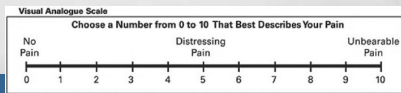
REVIEW: MEASUREMENTS

Measurement is a variable that is being assessed (quantified / measured) using a particular technique, tool or instrument.

$$\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m)}^2}$$



In the last 4 weeks have you	No Problem	Slight Problem	Moderate Problem	Marked Problem	Extreme Problem
1. Had difficulty moving?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Had difficulty walking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Had problems with your balance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Had difficulty standing up without support?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Had difficulty speaking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



TWO AREAS OF STATISTICS

DESCRIPTIVE statistics

- SUMMARIZE SAMPLE DATA
 - MEAN, MEDIAN, MODE
 - STANDARD DEVIATION, RANGE
 - FREQUENCY, PROPORTIONS (%)
- VISUALIZE DATA IN A SAMPLE
 - HISTOGRAM
 - BAR GRAPH
 - BOX-WHISKER PLOT

INFERENCEL statistics

- INFER/GENERALIZE RESULTS TO THE TARGET POPULATION
- CONFIDENCE INTERVALS (95% CI)
- STATISTICAL TESTS (P-VALUE)
 - PARAMETRIC VS NON-PARAMETRIC
- TYPE I AND TYPE II ERRORS

SAMPLE SIZE DETERMINATION

Level of significance (Type I error) – chance of finding effect if it does not exist
Effect size – expected amount of change in dependent variable (treatment effect)
Statistical power – credibility of the test, chance of finding effect if it does exist

Type (family) of statistical test
depends on data being collected


One- or two-tailed
depends on hypothesis wording

Level of significance (α)
outs for most social/business studies

Effect size (d)
estimated from large studies

Desired power ($1-\beta$)
typically 80% is considered acceptable

Rule-of-thumb
depends on analysis being conducted



Sample size (n)

<http://www.psych.uni-duesseldorf.de/abteilungen/aap/gpower3/download-and-register>


HOW DO I KNOW EFFECT SIZE?

Approaches to determine effect size:

- Previous (published) studies with similar research question
 - similar Population, Intervention, Outcome
 - look for numbers to quantify effect size (mean, standard deviation, %)
- Pilot study conducted with small group of participants ($n = 12$)
- Based on practical significance
 - Clinically important change, Minimal Important Difference (MID)
- Assume to be medium effect (*Cohen's d* = 0.5)

FINDING PUBLISHED STUDIES

- **GOOGLE SEARCH (START WITH GOOGLE SCHOLAR)**
- **PREVIOUS YEARS CEO STUDENTS' THESIS**
- **THE JOURNAL OF THE AMERICAN OSTEOPATHIC ASSOCIATION**
[HTTP://JAMA.ORG/](http://jamaa.org/)
- **INTERNATIONAL JOURNAL OF OSTEOPATHIC MEDICINE**
[HTTP://WWW.JOURNALOFOSTEOPATHICMEDICINE.COM/](http://www.journalofosteopathicmedicine.com/)
- **THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE**
[HTTPS://WWW.LIEBERTPUB.COM/LO/ACM](https://www.liebertpub.com/lo/acm)
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[HTTPS://WWW.IJPT.TANDF.CO.UK/](https://www.ijpt.tandf.co.uk/)



SAMPLE SIZE – RULES-OF-THUMB

- Experimental:** Minimum 12
- Quasi-Experimental:** Minimum 16
- Reliability Studies:** Minimum 40
- Technique Studies:** Minimum 24
- Case Series:** Minimum 6

Final notes on sample size:

- For multiple groups, aim for **balanced** design (equal number of participants in each group).
- Account for **non-response rate** during recruitment.
- Account for **attrition/drop-out rate** during the study.

PILOT STUDIES / PRE-STUDIES

Pre-study is a *small (preliminary)* study undertaken before *large* one.

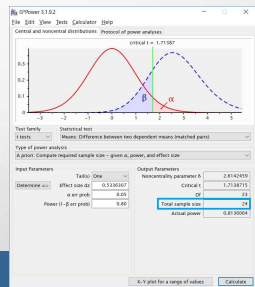
- Applicable when no previous studies are available on the research topic
- **Feasibility** assessment to validate
 - study design and research protocol
 - subjects recruitment strategy, consent rate, dropout rate
 - treatment, intervention
 - outcome measures, instruments, measurement/assessment tools
- Helpful to explore the effect size and determine sample size needed for a large study
- Recommendations for future large-scale study

SAMPLE SIZE DETERMINATION EXAMPLE

Research Question:

A global osteopathic treatment will increase urinary pH levels, as measured using urine test strips.

- crossover design
- “increase” → one-tail test
- literature search → Buscemi et al. (2015) study reported effect size
- G*Power calculation → 24 subjects
- 10% dropout rate → 27 subj to recruit



Reference: Buscemi, A., Carbone, J., Tacchi, M., Buttafoco, S., Rapisarda, A., Perciavalle, V., & Coco, M. (2015). Changes of urine pH after the compression of the fourth ventricle. *Medicina, Ricerche, Scienza della vita*. Retrieved from <http://www.scienza-ricerca.it>

STUDENTS' RESEARCH

- Proposal (PICO statement)
 - P = patient/problem (research question)
 - I = intervention (experiment design)
 - C = comparison (control)
 - O = outcome (validated instrument to measure)

MEASUREMENT INSTRUMENT/TOOL

Examples:

- Strain → Strain gauge
- Angle → Goniometer (manual or digital)
- Acceleration (3-axis) → Accelerometer (Fitbit or less expensive alternatives)
- Ground reaction force → Force platform/plate
- Object thickness → Caliper
- Time interval → Stopwatch (iPhone has one built-in)
- Weight → Scale



Clinical measurements (pulse, blood pressure, temperature, respiratory rate)

Ensure sufficient level of **accuracy/precision** and **range**



MEASUREMENT INSTRUMENT/TOOL

Google Scholar



Examples:

- Tinnitus symptoms → Tinnitus Handicap Inventory (THI)
- Quality of life → Quality of Life Scale (QOLS) questionnaire
- Pain → Visual Analog Scale (VAS)
- Feet functioning → Foot and Ankle Survey (FAOS) or Foot Functioning Index (FFI)

Good instrument is both **Reliable** and **Valid** (validated).

INSTRUMENT RELIABILITY AND VALIDITY

Not valid and not reliable

Valid, but not reliable

Reliable, but not valid

Reliable and valid

INSTRUMENT RELIABILITY AND VALIDITY

Reliability:

- Internal consistency reliability (Cronbach's $\alpha > 0.8$)
- Test-retest reliability correlation ($r > 0.7$)
- Inter-rater (inter-observer) reliability (Kappa > 0.4 or interclass correlation coefficient > 0.7)

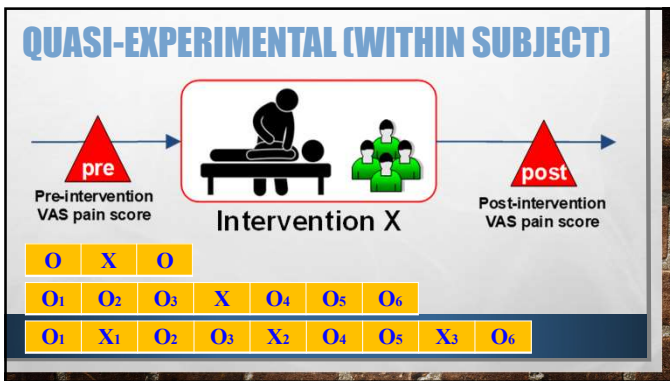
Validity:

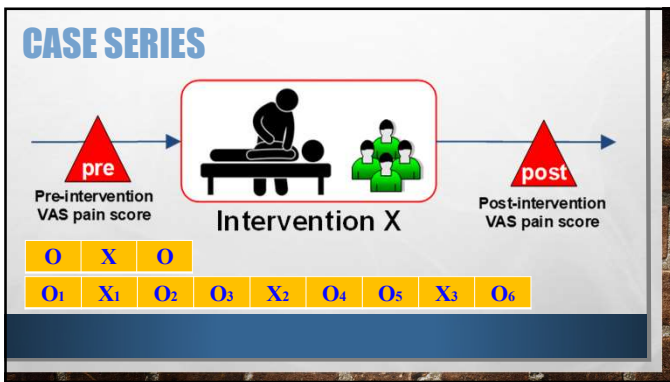
- Correlation with "gold standard" instrument ($r > 0.7$)
- Overall accuracy with respect to actual state (diagnostic accuracy, sensitivity, specificity, PPV, NPV)

< 0	0.00-0.20	0.21-0.40	0.41-0.60	0.61-0.80	0.81-1.00
Poor	Slight	Fair	Moderate	Substantial	Almost perfect

QUASI-EXPERIMENTAL (CROSSOVER)

R	O	O	washout	O	X	O
R	O	X	O	washout	O	O





- ### RELIABILITY/VALIDITY/PALPATION STUDIES
- Practical aspects
 - Live patients or objects (models)
 - Repeated trials to make a diagnosis
 - Benefits
 - Relative simplicity in design
 - Contribution to osteopathic profession
 - Improving manual skills
 - Osteopathic students as study participants

RELIABILITY STUDY EXAMPLE

Assessment or Diagnostic Tool

Osteopath Practitioners (raters)

**Inter-rater reliability
Intra-rater reliability**

Example:
Consorti et al. (2017) study explored inter-rater reliability of Osteopathic Sacral Palpatory Diagnostic Test using 52 patients and 3 trained osteopathy students (raters). Fleiss Kappa ranges between 0.06 to 0.34 (Table 3).

Categorical outcomes:
Cohen's Kappa (2 raters), Fleiss Kappa (3+ raters)

Numerical outcomes:
Cronbach's α , Interclass Correlation Coefficient

< 0	0.00-0.20	0.21-0.40	0.41-0.60	0.61-0.80	0.81-1.00
Poor	Slight	Fair	Moderate	Substantial	Almost perfect

VALIDITY STUDY EXAMPLE

Osteopathic Palpation Technique

Osteopath Practitioners (raters)

**Overall accuracy
Sensitivity, NPV,
Specificity, PPV**

**True State
(X-Ray, Ultrasound,
patient report)**

Examples:

- Assessing accuracy of palpation technique to differentiate between empty and filled bladders
- Using wax blocks to assess participants' skills in differentiating two heights (Christopher Reich study)
- Evaluating palpation technique to determine knee problems (validate through radiographs)
- Palpation sensitivity study using a hydrodynamic model (Monica Roy project)

Categorical outcomes:
Overall accuracy, sensitivity, specificity, NPV, PPV

Numerical outcomes:
Correlation coefficient, mean absolute error

PALPATION STUDY EXAMPLE

**Pre-intervention accuracy
Validity study**

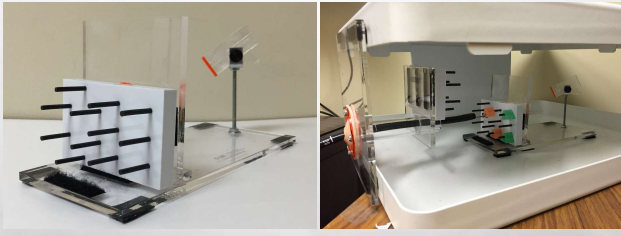
Intervention to improve palpation skills

**Post-intervention accuracy
Validity study**

Intervention examples:

- Feedback when using wax blocks
- Take home models to self-practice palpation skills
- Workshops with group practice sessions

TRAINING STATION FOR SURGEONS



Presented with the permission of Dr. Ray Habitz and Dr. Eran Shlomovitz (University Health Network)

STUDENTS' RESEARCH – PARTICIPANTS

Recruitment of study participants

- Specialized clinics
- Osteopathic practices
- Social media (Facebook, LinkedIn, Twitter)
 - Post message on your own page
 - Ask friends to re-post your message on their pages
 - Join relevant Facebook group
 - Paid advertisement
- Kijiji and other online posting sites



QUESTIONS? COMMENTS? THOUGHTS?

- ANTON SVENDROVSKI
- 647-833-3359
- WWW.STATSHelp.CA/OSTEO/
- INFO@STATSHelp.CA



Research Proposals | Sample Size Calculation | Methodology/Design | Statistical Data Analysis | Interpretation
