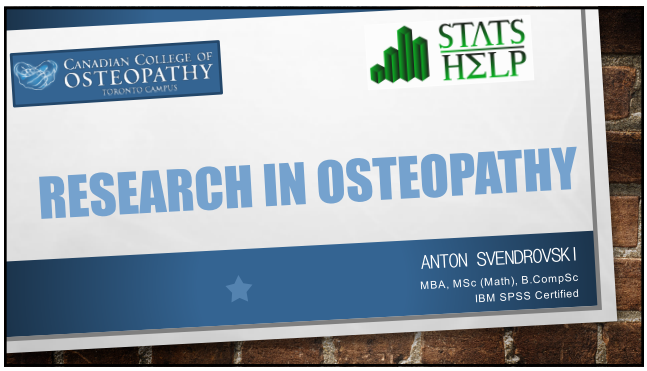


AGENDA

- REVIEW OF MATERIAL
  - HYPOTHESIS/RESEARCH QUESTION
  - P-VALUE
  - STUDY DESIGNS
  - VARIABLES AND MEASUREMENTS
- 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 OSTEOPATIC 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 (Ho):

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

Alternative Hypothesis (Ha):

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

$p < 0.05$	0.05	$p > 0.05$
Reject null and accept an alternative hypothesis.		Failed to reject the null hypothesis.
There is statistically significant reduction of acne skin redness as a result of osteopathic treatment.		There is insufficient evidence to conclude that osteopathic treatment is effective.

p-value

UNDERSTANDING RESEARCH ARTICLES

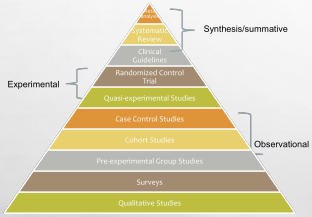
Table 2 Comparison of the VAS, MOV and ROM values between OMT and CCT groups ($n = 25$) at T0, T1 and T2.

		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://pdfs.semanticscholar.org/849d/3c122af15a27b3dc59de93a76dde196e52a4.pdf

REVIEW: STUDY DESIGNS



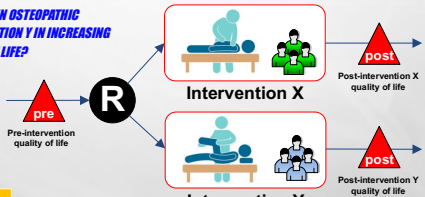
Acceptable Forms of Student Research:

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)

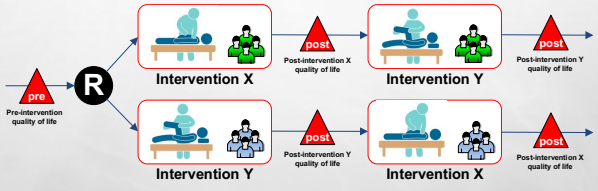
RESEARCH QUESTION:

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: QUASI-EXPERIMENTAL (CROSSOVER)



R	O	X_1	O	washout	O	X_2	O
R	O	X_2	O	washout	O	X_1	O

REVIEW: QUASI-EXPERIMENTAL (WITHIN SUBJECT)

RESEARCH QUESTION:

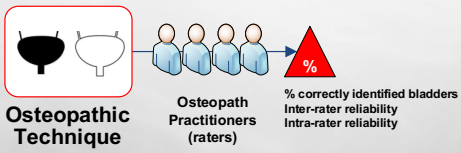
DOES OSTEOPATHIC INTERVENTION X EFFECTIVELY REDUCE PATIENTS' PAIN AFTER 5 SESSIONS?

O X O

REVIEW: RELIABILITY STUDY

RESEARCH QUESTION:

HOW RELIABLE IS A PARTICULAR TECHNIQUE IN DIFFERENTIATING EMPTY VS FILLED BLADDER?



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.

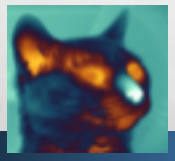
Dependent Variable – the outcome of interest, what we are hoping to change or alter.

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.

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



In the last 4 weeks have you	No Problem	Slight Problem	Moderate Problem	Marked Problem	Extreme Problem
1. Had difficulty moving?	☐	☐	☐	☐	☐
2. Had difficulty walking?	☐	☐	☐	☐	☐
3. Had problems with your balance?	☐	☐	☐	☐	☐
4. Had difficulty standing up without support?	☐	☐	☐	☐	☐
5. Had difficulty speaking?	☐	☐	☐	☐	☐

Visual Analogue Scale

Choose a Number from 0 to 10 That Best Describes Your Pain

No Pain — Distressing Pain — Unbearable Pain

0 1 2 3 4 5 6 7 8 9 10

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) — 0.05 for most social/business studies
- Effect size (d) — estimated from large studies
- Desired power (1-β) — typically 80% is considered acceptable
- Rule-of-thumb — depends on analysis being conducted

→ **Sample size (n)**

G*Power

http://www.psycho.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 CCO STUDENTS' THESIS
- THE JOURNAL OF THE AMERICAN OSTEOPATHIC ASSOCIATION
  HTTP://JAOA.ORG/
- INTERNATIONAL JOURNAL OF OSTEOPATHIC MEDICINE
  HTTP://WWW.JOURNALOFOSTEOPATHICMEDICINE.COM/
- THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
  HTTPS://WWW.LIEBERTPUB.COM/LOI/ACM
- INTERNATIONAL JOURNAL OF OCCUPATIONAL MEDICINE AND ENVIRONMENTAL HEALTH
  HTTP://IJOMEH.EU/
- INTERNATIONAL JOURNAL OF PHYSIOTHERAPY
  HTTPS://WWW.IJPHY.ORG/

Google Scholar

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SAMPLE SIZE – RULES-OF-THUMB

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

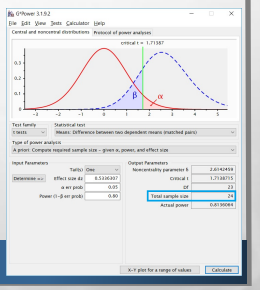
Final notes on sample size:

- 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.

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., Buttafuoco, 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-ricerche.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

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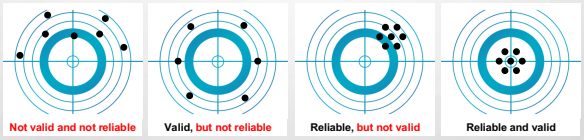
Examples:

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



INSTRUMENT RELIABILITY AND VALIDITY

Reliability:

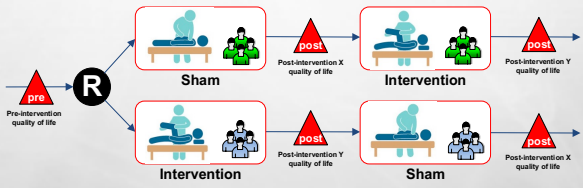
Internal consistency reliability (Cronbach's α > 0.8)
Test-retest reliability correlation (r > 0.7)
Inter-rater (inter-observer) reliability (Kappa > 0.4 or interclass correlation coefficient > 0.7)

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

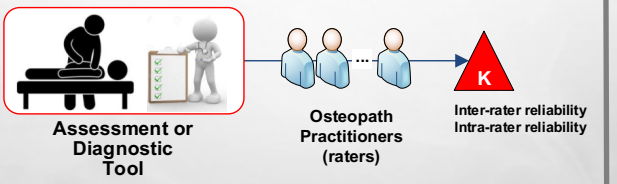
QUASI-EXPERIMENTAL (WITHIN SUBJECT)

O	X	O						
O_1	O_2	O_3	X	O_4	O_5	O_6		
O_1	X_1	O_2	O_3	X_2	O_4	O_5	X_3	O_6

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



Example:

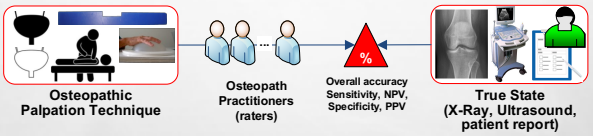
Consorti et al. (2017) study explored inter-rater reliability of Osteopathic Sacral Palpatory Diagnostic Test using 52 patients and 3 trained osteopathy students (raters). Fleiss Kappa ranges between 0.06 to 0.34 (Table 3).

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 Reiach study)
- Evaluating palpation technique to determine knee problems (validate through radiographs)
- Palpation sensitivity study using a hydrodynamic model (Monica Ney 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

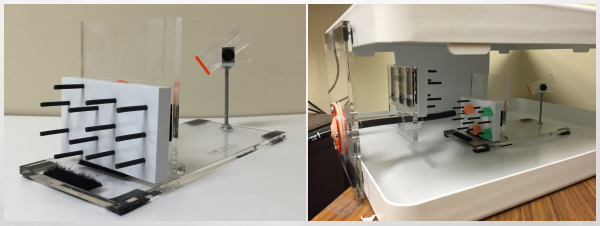
Post-intervention accuracy

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



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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**
- **INFO@STATSHELP.CA**

STATS HELP

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