

**CANADIAN COLLEGE OF OSTEOPATHY**  
TORONTO CAMPUS

**STATS HELP**

# RESEARCH IN OSTEOPATHY

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## AGENDA

- **ELEMENTS OF RESEARCH**
  - RESEARCH QUESTION / HYPOTHESES
  - P-VALUE
  - STUDY DESIGNS
  - VARIABLES AND MEASUREMENTS
- **DESCRIPTIVE STATISTICS**
- **INFERENCE STATISTICS**
- **SAMPLE SIZE DETERMINATION**
- **CHOOSING MEASUREMENT INSTRUMENT/TOOL**
- **RESEARCH PROPOSAL**
  - CASE SERIES
  - IDEAL STUDY CONSIDERATIONS
- **WORKING TOGETHER**

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## 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?

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# HYPOTHESIS

Hypothesis = Research Question + **Measurement Tool** + "**p ≤ 0.05**"

Examples of Hypothesis formulation:

1. Osteopathic treatment will significantly reduce the redness associated with acne as measured by **infra-red photography**, **p ≤ 0.05**.
2. Five sessions of osteopathic intervention X will result in significant reduction in patients' pain as measured by **Visual Analog Scale**, **p ≤ 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 ≤ 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 ≤ 0.05**.

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# HYPOTHESES

**Null Hypothesis (H<sub>0</sub>):**

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

**Alternative Hypothesis (H<sub>a</sub>):**

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

p < 0.05

0.05

p > 0.05

Reject null and accept an alternative hypothesis.  
There is statistically significant reduction of acne skin redness as a result of osteopathic treatment.

Failed to reject the null hypothesis.  
There is insufficient evidence to conclude that osteopathic treatment is effective.

→ p-value

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

<sup>a</sup> The visual analogue pain scale was scored from 0 to 10.

<sup>b</sup> Measure in millimeters.

<sup>c</sup> 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>

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# 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

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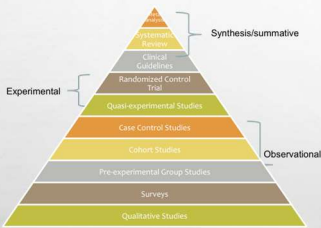
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# STUDY DESIGNS



## 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

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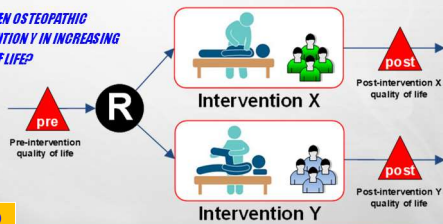
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# EXPERIMENTAL (RCT)

## RESEARCH QUESTION:

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



R	O	X <sub>1</sub>	O
R	O	X <sub>2</sub>	O

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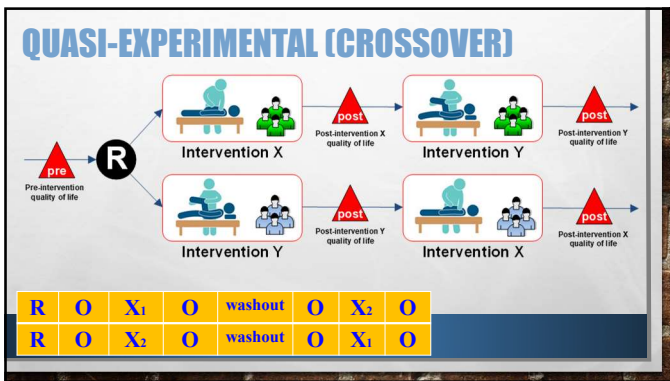
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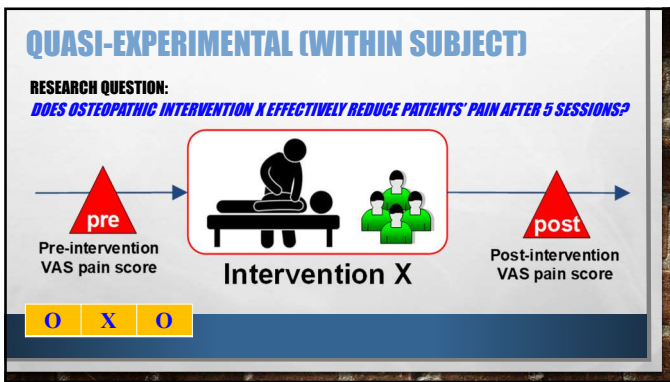
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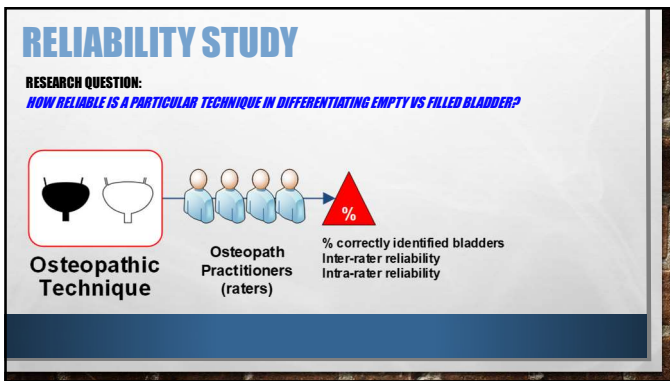
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## VARIABLES

**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)

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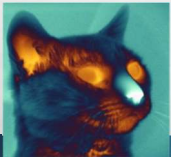
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## MEASUREMENTS

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

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



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"/>




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## 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

### INFERENCEAL 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

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## 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 ( $\alpha$ )  
outs for most social/business studies

Effect size ( $d$ )  
estimated from large studies

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

**Sample size (n)**

Rule-of-thumb  
depends on analysis being conducted



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

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## 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)

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## 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)
- **INTERNATIONAL JOURNAL OF OCCUPATIONAL MEDICINE AND ENVIRONMENTAL HEALTH**  
[HTTP://JOHMER.ED/](http://johmer.ed/)
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[HTTPS://WWW.IJPHT.ORG/](https://www.ijpht.org/)

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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.

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## 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 determine the **effect size** and calculate sample size needed for a large study
- Recommendations for future large-scale study

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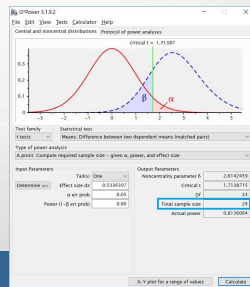
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## SAMPLE SIZE DETERMINATION EXAMPLE

### 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., & Cocco, 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>

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## SCIENTIFIC RESEARCH

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

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## 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**



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## 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).

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## INSTRUMENT RELIABILITY AND VALIDITY

Not valid and not reliable

Valid, but not reliable

Reliable, but not valid

Reliable and valid

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## 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

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## CCO RESEARCH PROPOSAL

**Case Series**

- Study you will actually conduct
- Subjects are existing patients or friends
- Sample size  $n = 6$
- All subjects (one group) will receive treatment
- Numerical outcome to be assessed using validated and reliable tool
- Collecting data on adverse events

**Ideal Study**

- Hypothetical, but realistic study
- Subjects are recruited from the target population
- Sample size determined by statistician
- Usually two arms/groups (control and treatment)
- Subjects randomly assigned to groups
- Blindness (single-blind in osteopathy)
- Objective measurements and assessments
- Team of researchers (multiple roles)

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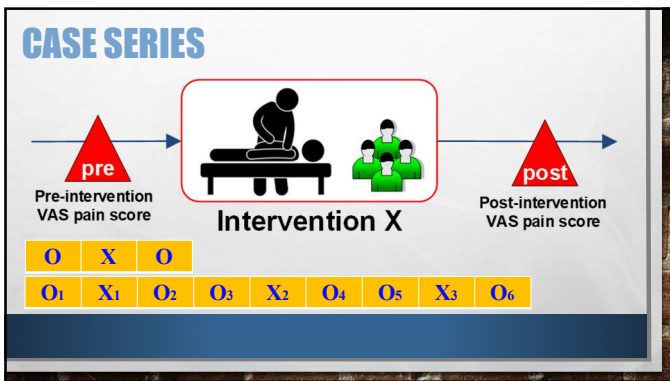
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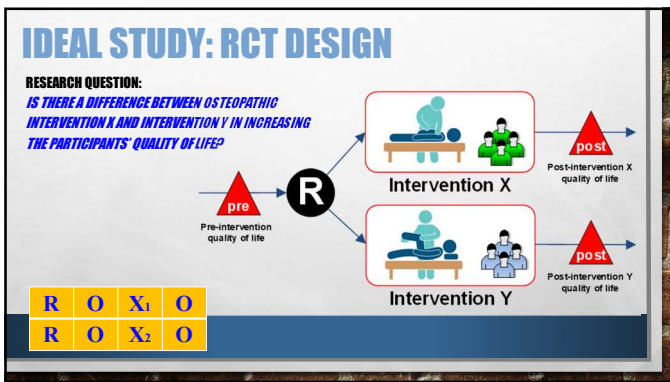
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### STUDY PARTICIPANTS

#### Recruitment of study participants

- Specialized clinics, medical offices
- Osteopathic/manual therapy 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

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## WORKING TOGETHER

### Preparation [your part]

- Decide on research **topic**
- Formulate research **question** and **hypotheses**
- Decide on **intervention** to be used and **control group(s)** for ideal study
  - global/local OMT, # of sessions/frequency, use of sham in control group
- Think through applicable/relevant **outcomes** to be assessed (primary, secondary)
- Identify valid/reliable **instruments** to be used to measure the outcomes
- Narrow down **target population** and sampling for ideal study
  - inclusion/exclusion criteria, recruitment strategy, intake process
- Identify a couple of quantitative studies (or CCO theses) that can be used to estimate the **effect size**
  - similar target group, similar intervention, similar outcome
- Think through the methodology details of ideal study
  - team and different roles, randomization/blindness, logistics

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## WORKING TOGETHER

### Initial consultation

- Review and discuss the proposal
  - wording for research question and hypotheses
  - research methodology, instruments, outcomes, groups, target population
  - study logistics, team and roles, data collection forms
  - identify any flaws and potential biases/risks (and ways to mitigate them)
- Examine the selected studies to ensure suitability for effect size extraction
  - determine if additional studies are needed

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## WORKING TOGETHER

### Statistician provides [my part]

- Power analysis (sample size calculation)
  - required sample size for ideal study is calculated based on effect size from selected studies
- Randomization sequence for ideal study
- Write-up for statistical methodology section
  - both case series and ideal study
- Letter of statistical support
- Additional reviews for the proposal [if required or if there are changes]
  - research and statistical methodology
- Data analysis for case series study [when data is completed]



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## QUESTIONS? COMMENTS? THOUGHTS?

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

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