

CAHS Research Education Program Research Skills Seminar

Sample Size Calculations

2nd August 2024



Presented by

Michael Dymock

Biostatistician

Telethon Kids Institute







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Child and Adolescent Health Service, Department of Research

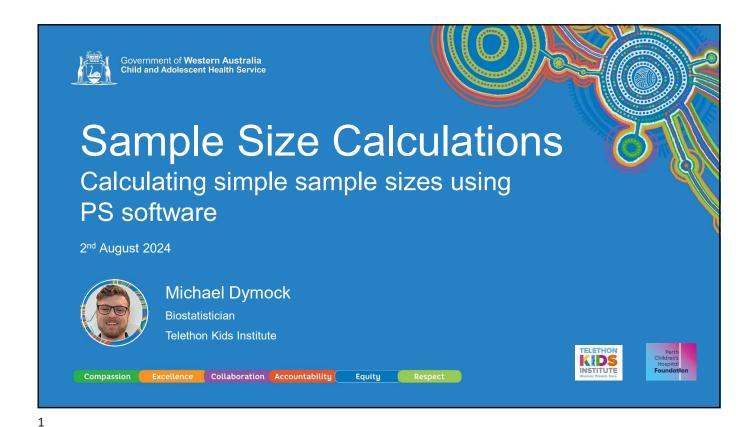
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Sample Size Calculations

PRESENTATION SLIDES

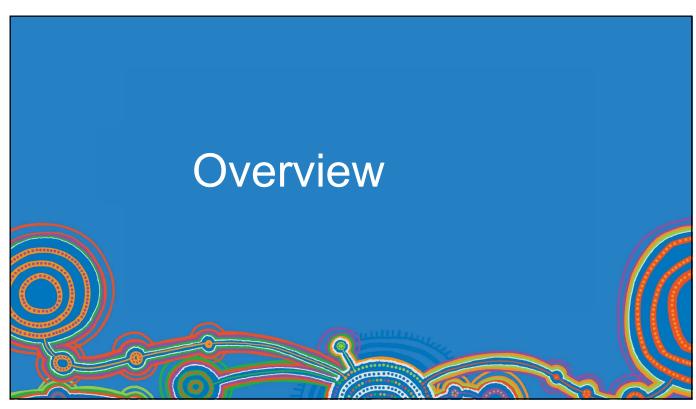




Research Skills Seminar Series

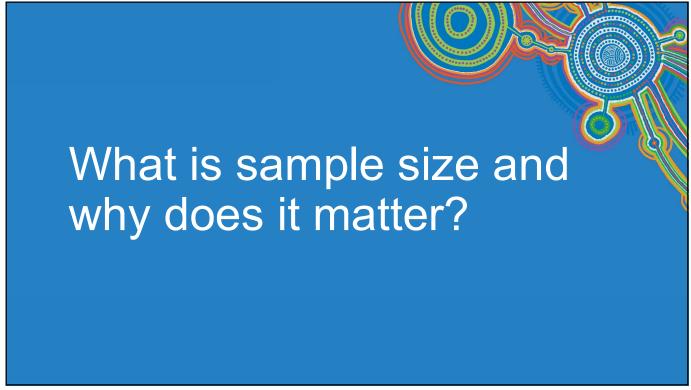
- Over 25 topics across the research process
 - 1h overview
 - o Handouts are provided
- Recorded and uploaded
- Feedback
 - Back of handout
 - o Emailed link
- Please hold questions to the end
 - Use provided microphone

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Overview

- What is a sample size and why does it matter?
- A little theory
- · Calculating sample sizes using the PS software
- · Considerations for clinical trials
- Where can I get more statistical help?



What is a sample size?

- To answer a research question effectively we should design a study carefully
- We need to decide how many subjects (participants, patients, etc.) to include and how many observations (measurements) to make on each subject

- The **sample size** is the total number of subjects*
 - *But we must consider the number of observations per subject: E.g., measuring blood pressure two times on three subjects may be considered a sample size of six

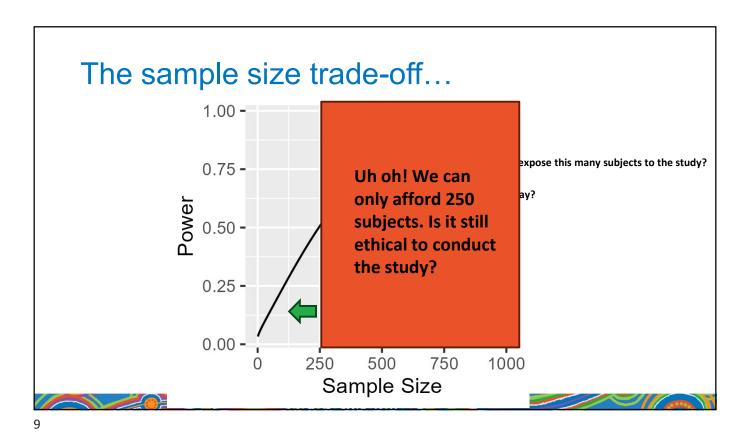
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Why does everyone care so much?

- Before conducting a study, the research team must demonstrate that it will be feasible and ethical, and this requires estimating the sample size
 - Do we have the resources to conduct the study at this sample size?
 - Are we likely to be able to draw objective conclusions (i.e., power)?
 - O What is the burden/risk to the subjects?
- Small studies are not always unethical (pilot studies, contribute to meta-analyses, low risk, etc.)

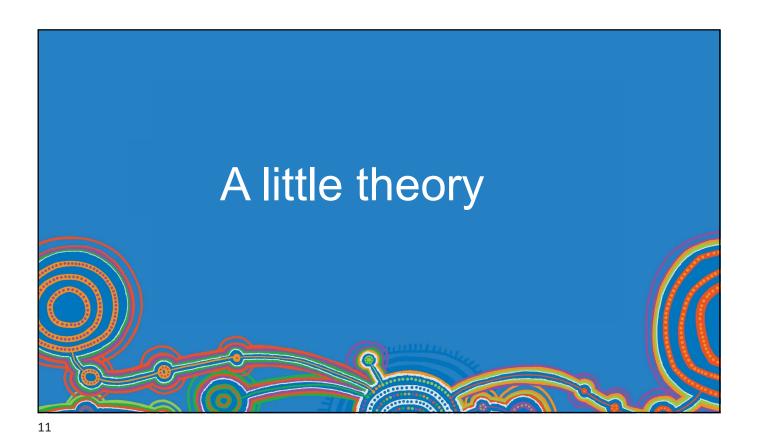
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Unfortunately, often the sample size is determined by the resources available



What does the statistician think?

- After contemplating the ethical considerations, in general, the larger the sample size the better
- A larger sample size means:
 - Reduced variability in our results (increased precision)
 - May be able to detect a smaller effect size
 - o More likely to make objective conclusions



Two errors, one study

- When answering a scientific question (e.g., does the treatment work?) you can be wrong in **two** different ways:
 - o False positive: declaring the treatment works when it doesn't
 - o False negative: declaring the treatment doesn't work when it does



You have the power!

- Probability of declaring the treatment/intervention effective (with assumptions)
- Need a (hopefully) clinically meaningful effect size
 - i.e., if the treatment has an effect size of X units, then I will declare the treatment effective Y% of the time in a series of hypothetical trials



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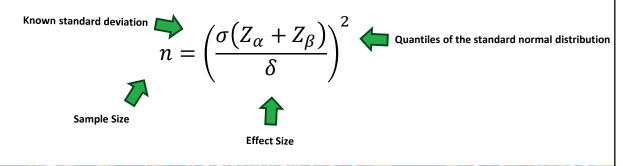
The generic problem

- We want to minimise the probability of making a Type I or Type II error
- Power = 1 Type II error (want to maximise)
- We usually choose the Type I error and Type II errors and hold them constant and compute the required sample size
 - o e.g., significance level = 5%, power = 80%

YOU CAN CHOOSE YOUR OWN VALUES

Calculating a sample size

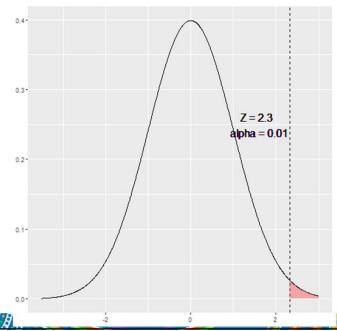
- What sample size do I need so that Type I error = X and Type II error = Y?
- We use formulas! (Or simulations when it is too hard!)
- For example, one sample Z-test sample size formula:



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A quick note on the standard normal distribution

- A probability distribution (something that allocates probabilities over a set of possible outcomes)
- Mean = 0 and Variance = 1
- Z_{α} is the point on the x-axis where there is α probability to the right (upper tail)



What factors will affect the sample size?

• Recall:
$$n = \left(\frac{\sigma(Z_{\alpha} + Z_{\beta})}{\delta}\right)^2$$

- Significance level (Type I error)
- Power (1 Type II error)
- · Data variability (standard deviation)
- Detectable effect size (delta)
- · Statistical method

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An example

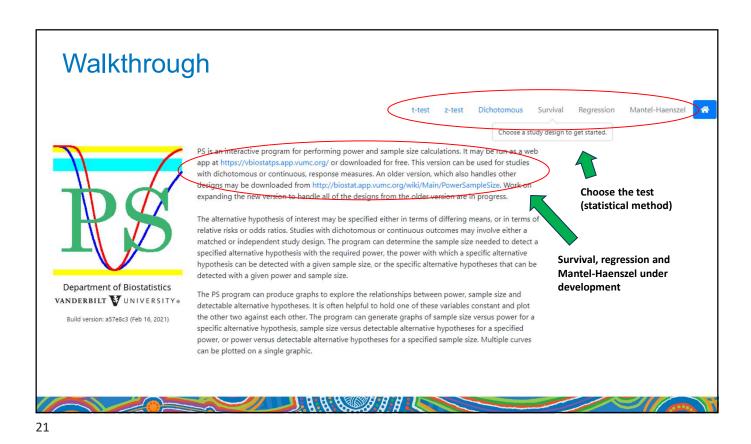
- Recall: $n = \left(\frac{\sigma(Z_{\alpha} + Z_{\beta})}{\delta}\right)^2$
- Suppose that we wanted to conduct a one sample Z-test on an outcome with known standard deviation of 3 units. Using a significance level of 5% we want 80% power to detect an effect size of 0.5 units.

$$n = \left(\frac{3 \times (Z_{0.05} + Z_{0.2})}{0.5}\right)^2 = \left(\frac{3 \times (1.64 + 0.84)}{0.5}\right)^2 = 222.6 = 223$$



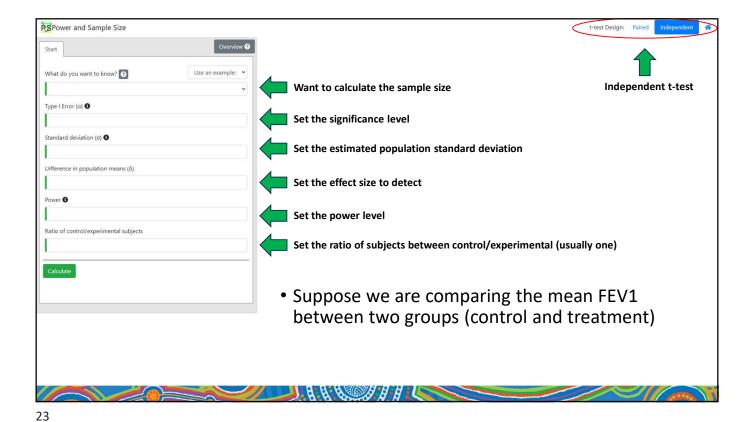
Who needs formulas anyway...

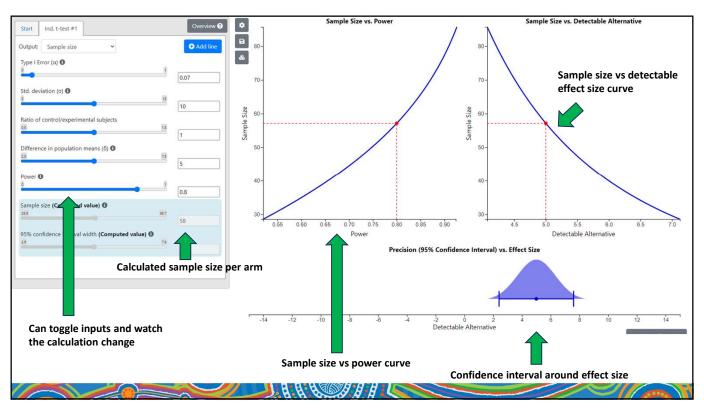
- PS: Power and Sample Size Calculation v3.1.6, 2018
 - William D Dupont and Walton D Plummer, Jr.
 - http://biostat.app.vumc.org/wiki/Main/PowerSampleSize
- PS is an interactive program for performing power and sample size calculations for free
- Can be downloaded or used via a web browser (recommended)



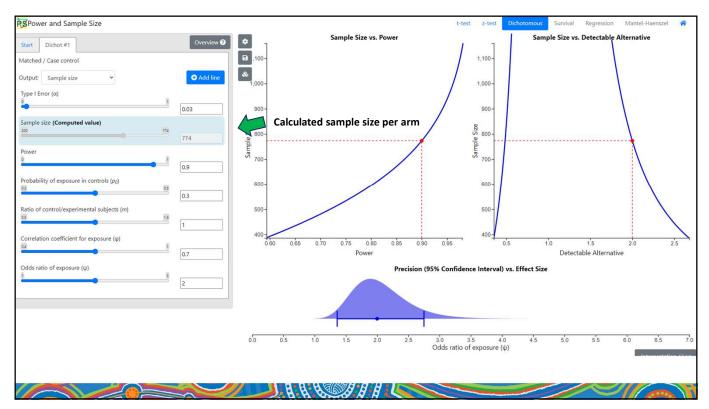
What study designs can it evaluate?

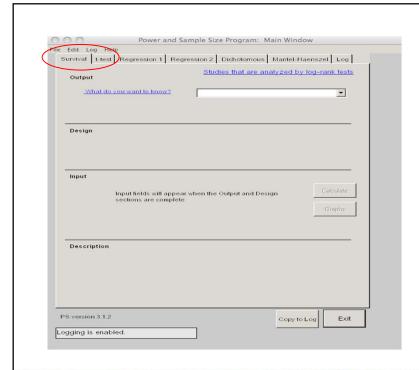
- PS can calculate the power and sample size for a range of study designs including those that require a:
 - t-test (continuous variable, two groups)
 - z-test (t-test with normality assumption)
 - binary analysis (odds ratios, matched case-control etc.)
 - survival analysis (time to event, e.g., remission, death)
 - linear regression (continuous variable, covariates)
 - Mantel-Haenszel test (2 x 2 tables, odds ratios etc.)



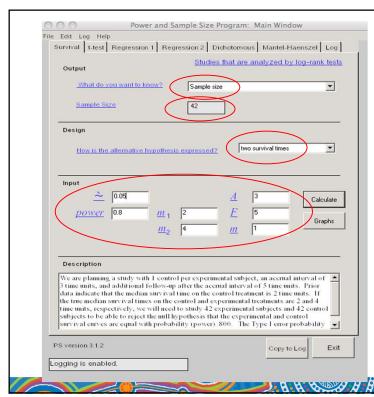


- Suppose we are comparing a binary outcome between two groups (control and treatment)
 - Are the groups matched case-control?
 - What is the probability of exposure in the control group?
 - What is the correlation coefficient for exposure? (2 x 2 table)
 - What is the odds ratio of exposure?

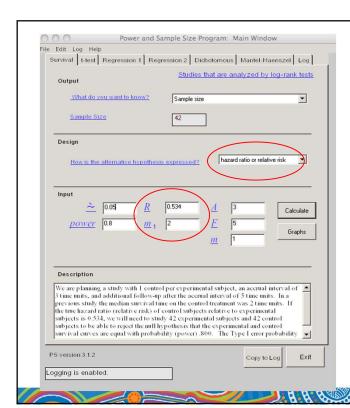




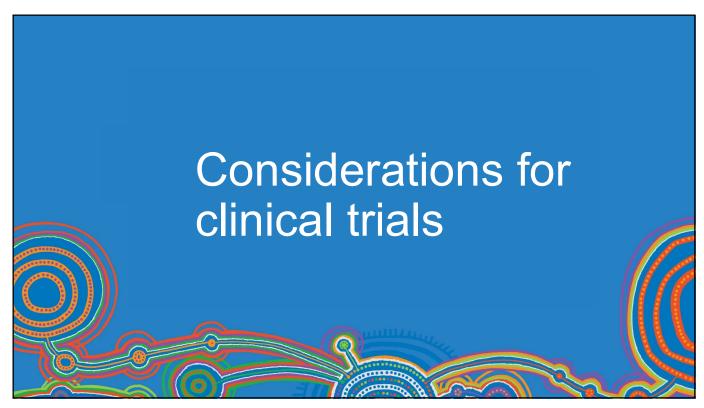
- Suppose we were comparing time to death between two groups (control and treatment)
- Each participant has two outcomes:
 - Dead/alive
 - Time to death (may be censored)



- significance = 0.05
- power = 0.8
- **m** = 1 (ratio of control/treatment)
- m_1 = 2 (median survival time control)
- m_2 = 2 (median survival time treatment)
- *A*= 3 (accrual time)
- *F*= 5 (follow up time)
- Make sure the time units are consistent between parameters!
- Sample size = 42 units per arm



- Alternatively specify alternative hypothesis using a hazard ratio / relative risk
- m_1 = 2 (median survival time control)
- **R**= 0.534 (hazard ratio)
- Sample size = 42 units per arm



Observational studies vs randomised designs

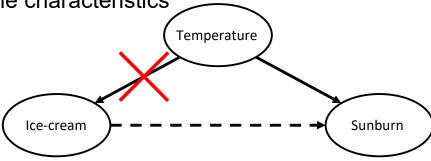
- In an observational study the independent variable (such as a treatment) is not under the control of the researcher
- In a randomised design (such as an RCT), the independent variable is randomly allocated to participants
- This "breaks" the links with any uncontrolled variables

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Randomised controlled trials

- Randomised controlled trials (RCTs) are the gold standard in clinical research
- The goal of randomisation is to break the link between treatment assignment and confounders and to balance the baseline characteristics



How do I estimate the variability?

- Previous research work (pilot study?)
- · Similar published clinical studies
- Animal studies (although humans tend to be more heterogeneous than lab animals)
- For studies restricted by resources you may want to consider a more homogeneous sample with lower variability (but beware of generalisability)

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What about inclusion/exclusion criteria?

- Inclusion/exclusion criteria determines the generalisability of the results
- The standard deviation is directly affected as it is a function of how homogeneous your target population is
- Should the study be pragmatic?



Where can I find a statistician?

Perth Children's Hospital:

Free advice through Telethon Clinical Research Centre

Telethon Kids Institute (consultancy service): Biometrics@telethonkids.org.au

UWA (consultancy service):

consulting-cas@uwa.edu.au

The Centre for Applied Statistics, UWA, offers free advice to UWA postgraduate research students

More in handouts

Checklist for talking to a Statistician

- Clear hypothesis
- Proposed study design
- Primary endpoint & estimate of variability
- Clinically relevant effect size
- Estimate of feasible sample size based on budget or potential annual patient recruitment
- Important confounders & source of bias
- Similar publications or systematic reviews

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How can I learn more about statistics?

 In the absence of large, randomised, well-controlled clinical trials to address every research question we all need to increase our statistical literacy

In person at Perth Children's Hospital:

Attend Research Skills Seminars.

In person at UWA:

The Centre for Applied Statistics provides short courses in statistics which are heavily discounted for students.

Joint Clinical-Statistical Supervision:

If one of your supervisors is a statistician, then you will have "unlimited" access to statistical knowledge/training.

How can I learn more about statistics?

Online: Data Science Specialization
Johns Hopkins University

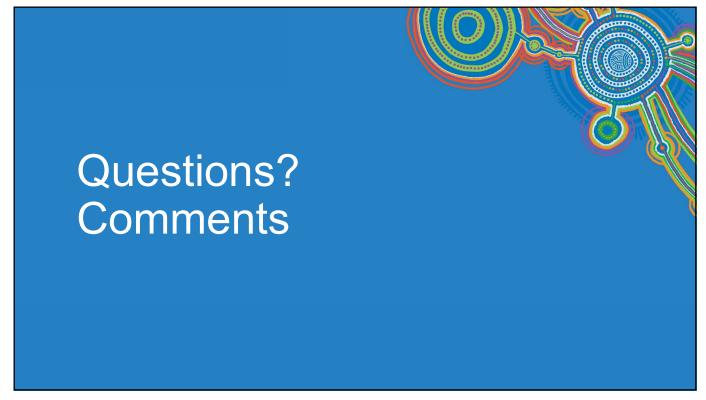
FAQ: You can access the course for free via

https://www.coursera.org/specializations/jhu-data-science#courses

This will allow you to explore the course, watch lectures, and participate in discussions for free. To be eligible to earn a certificate, you must either pay for enrolment or qualify for financial aid.

Links in your handouts

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9 Aug Rapid Critical Appraisal of Scientific

Literature - Dr Natalie Strobel, ECU

16 Aug Conducting Systematic Reviews

- Prof Sonya Girdler, Curtin University

Register -> trybooking.com/eventlist/researcheducationprogram

We love feedback

A survey is included in the back of your handout, or complete online https://tinyurl.com/surveySampleSizeCalc

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Sample Size Calculations

RESOURCE NOTES

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1. Additional reading

- Ethics in Sample Size (2004) American Journal of Epidemiology, by Bachetti et al. https://academic.oup.com/aje/article-lookup/doi/10.1093/aje/kwi014
- PS: Power and Sample Size Calculations v3.1.2 (2014) by William D Dupont and Walton D Plummer, Jr.

https://biostat.app.vumc.org/wiki/Main/PowerSampleSize

2. Statistical support contacts

2.1. Perth Children's Hospital

Telethon Clinical Research Centre (TCRC)

Department of Research, Child and Adolescent Health Service

Phone: (08) 6456 0124

Email: <u>CAHS.TCRC@health.wa.gov.au</u>

Website: https://cahs.health.wa.gov.au/Research/For-researchers/Research-

suites-at-Perth-Childrens-Hospital

Biostatistics and Data Management Support through TCRC

https://cahshealthpoint.hdwa.health.wa.gov.au/directory/research/researchers/Pages/Biostatistics.aspx

(WA Health employees only)

2.2. Telethon Kids Institute

Consultancy Service

Email: Biometrics@telethonkids.org.au

2.3. University of Western Australia

The Centre for Applied Statistics

Offers free advice for UWA postgraduate research students

Email: consulting-cas@uwa.edu.au



2.4. WAHTN Clinical Trial and Data Management Centre

The Clinical Trial and Data Management Centre is a WAHTN enabling platform which aims to enhance clinical trials and related data management in Western Australia.

The platform is a WAHTN-wide entity sharing expertise in clinical trial study design (including novel designs), clinical trial conduct, data management, data-linkage, analytical techniques for clinical trial datasets, bio-repository techniques and clinical registry datasets. It facilitates the pursuit of large-scale clinical trials and translational healthcare research in WA.

Phone: (08) 9266 1970

Email: <u>CTDMC@curtin.edu.au</u>

Website: https://wahtn.org/platforms/clinical-trials-data-centre/

2.5. WAHTN Clinical Research Support Service – EMHS Sessions

The WAHTN are offering a Clinical Research Support Service for anyone currently involved or interested in conducting clinical research in WA. WAHTN's Clinical Trial and Data Management Centre (CTDMC) can meet onsite with staff from WAHTN Member Partners, including EMHS.

The CTDMC staff can provide advice on various aspects of clinical research including:

- how to get started with your project
- a brief primer on research ethics & governance
- setting up essential documents for your project
- data management and database design
- protocol development and other research related documents
- assistance connecting with research partners and working with universities

Sessions can:

- be one-on-one or with a small group, such as a research team
- tailored to the areas you need help

Contact: General enquiries to

EMHS.REG@health.wa.gov.au

or

Sharon Oddy, Business Support Officer

Sharon.Oddy@health.wa.gov.au

(08) 9224 3771

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Research Skills Seminar Series

A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

2024 Seminar Schedule

Interactive in pdf format Last updated 30/7/24

#	DATE	TOPIC	PRESENTER	ENROL	WATCH
1	9 Feb	Research Fundamentals	Dr Kenneth Lee, UWA	-	2024
2	16 Feb	Introductory Biostatistics	Michael Dymock, TKI	-	<u>2024</u>
3	8 Mar	Social Media in Research	Dr Amy Page, UWA	-	<u>2024</u>
4	22 Mar	Introduction to Good Clinical Practice	Alexandra Robertson, CAHS	-	<u>2024</u>
5	19 Apr	Research Governance	Dr Natalie Giles, CAHS	-	2024
6	3 May	Scientific Writing	A/Prof Tony Kemp, UWA	-	<u>2024</u>
7	17 May	Project Management	Melanie Wright, SMHS	-	2024
8	7 Jun	Research Impact	Dr Tamika Heiden, Vic	-	2024
9	21 Jun	Consumer & Community Involvement in Research	Belinda Frank, TKI	-	<u>2023</u>
10	19 Jul	Getting the Most out of Research Supervision	Dr Timothy Barnett, TKI	-	2022
11	26 Jul	Enrolling Incapacitated Patients into Medical Research in WA	Prof Daniel Fatovich and Mark Woodman, EMHS	-	2024
12	2 Aug	Sample Size Calculations	Michael Dymock, TKI	-	2023
13	9 Aug	Rapid Critical Appraisal of Scientific Literature	A/Prof Natalie Strobel, ECU	REGISTER	2023
14	16 Aug	Conducting Systematic Reviews	Prof Sonya Girdler, Curtin Uni	REGISTER	<u>2023</u>
15	23 Aug	Knowledge Translation	Prof Fenella Gill, Curtin/CAHS	REGISTER	2023
16	30 Aug	Media and Communications in Research	Peta O'Sullivan, CAHS	REGISTER	2023
17	6 Sep	Involving Aboriginal Communities in Research	Cheryl Bridge, TKI and co.	REGISTER	2023
18	11 Oct	Grant Applications and Finding Funding	Dr Tegan McNab, TKI	REGISTER	<u>2023</u>
19	18 Oct	Oral Presentation of Research Results	Dr Giulia Peacock, CAHS	REGISTER	2023
20	25 Oct	Statistical Tips for Interpreting Scientific Claims	Michael Dymock, TKI	REGISTER	2023
21	1 Nov	Survey Design and Techniques	Dr Giulia Peacock. CAHS	REGISTER	2023
22	15 Nov	Ethics Processes for Clinical Research in WA	Dr Natalie Giles, CAHS	REGISTER	<u>2023</u>
23	22 Nov	Qualitative Research Methods	Dr Lorna Davin, Uni Notre Dame	REGISTER	<u>2023</u>
24	29 Nov	Innovation and Commercialisation	Dr Helga Mikkelsen (Brandon BioCatalyst) & Ashley Schoof (TKI)	REGISTER	2022
25	6 Dec	Data Collection & Management (REDCap)	Dr Giulia Peacock, CAHS	REGISTER	2023

Register via Trybooking.com

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Research Skills Seminar Series

A free, open-access resource designed to upskill busy clinical staff and students and improve research quality and impact.

Rapid Critical Appraisal of Scientific Literature



9th August 2024

12.30 -1.30pm

Given the sheer volume and variable quality of published papers even in high impact journals, it is essential to have skills to target and rapidly appraise relevant literature to answer current clinical questions. This seminar provides simple strategies to help focus your reading, examine validity of results, and decide whether to accept and apply them in your setting.



Meet the presenter



A/Prof Natalie Strobel
Associate Dean (Research), Kurongkurl Katitjin, Edith Cowan University

Natalie is the team leader on the evidence synthesis stream for the Centre for Improving Health Services for Aboriginal and Torres Strait Islander Children and Families (ISAC) at the Edith Cowan University. She has been working in health services research and epidemiology to improve service delivery to children, in particular Aboriginal and Torres Strait Islander children. Dr Strobel has been consulting with WHO on various neonatal guidelines including for preterm and low birth weight infants. Her work has had a strong focus on ensuring projects delivered are needs based and inform policy and practice.

Perth Children's Hospital Auditorium

Level 5, 15 Hospital Ave Nedlands Accessible via pink or yellow lifts

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Access online via Teams or Avaya or Watch from a hosted video-conferencing site

- Fiona Stanley Hospital
- Lions Eye Institute
- Pathways in Shenton Park
- Royal Perth Hospital









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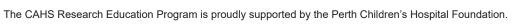
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A light lunch is provided for our in-person attendees. Bookings are essential.





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Conducting Systematic Reviews

16th August 2024

12.30 -1.30pm



Systematic reviews play an important role in health research. They provide a high level summary of studies and can inform policy and practice relevant to a particular area of inquiry. Understanding review methodologies is useful for those who wish to undertake a systematic review, or just read one. This seminar provides an overview of several types of reviews, along with simple strategies to focus a review and support review methodology.



Meet the presenter

Curtin University

Prof Sonya Girdler Director of the Curtin Autism Research Group (CARG) Director of Program 3 of the 'Living with Autism' CRC

Sonya has published over 100 papers, including publishing more than 20 reviews (Systematic and Scoping), supervised 12 PhD students to completion and has extensive experience in conducting research in health and community settings.

Sonya is active in advocating and supporting other women in research in STEMM related fields.

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- Lions Eye Institute
- Pathways in Shenton Park
- Royal Perth Hospital









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A light lunch is provided for our in-person attendees. Bookings are essential.











The Research Education Program - supported by the Perth Children's Hospital Foundation and the Telethon Kids Institute - offers a series of hands-on workshops that focus on the most integral features of REDCap and its application to your research project data. Workshops aim to directly build user skills in a guided environment, with time to ask questions and work on your own project.

Dates below are still being finalised so check back again for latest version.

Presented by: Research Education Program Research Fellow Dr Giulia Peacock

Location: PCH, TKI Seminar Room, Level 5 (West).



Topic	Day	Date	Time	Max No (in person)
Workshop 1 – Basic Walkthrough	Tuesday	27 Feb	2:30pm to 4:30pm	<u>Watch</u>
Workshop 2 – Intermediate Walkthrough	Tuesday	12 March	1:00pm to 3:30pm	Watch
Workshop 3 – Advanced REDCap - Creating Surveys	Tuesday	30 April	1:00pm to 3:30pm	Watch
Workshop 4 – REDCap Troubleshooting Workshop	Tuesday	28 May	2:00pm to 4:00pm	cancelled
Workshop 5 – Basic Walkthrough	Tuesday	16 July	1:00pm to 3:30pm	40 Register
Workshop 6 – Intermediate Walkthrough	Tuesday	20 Aug	1:00pm to 3:30pm	40 Register
Workshop 7 – Advanced REDCap - Creating Surveys	Tuesday	10 Sep	2:00pm to 4:30pm	40 Register
Workshop 8 – REDCap Troubleshooting Workshop	Tuesday	15 Oct	1:00pm to 3:30pm	40 Register

IMPORTANT

Attendance is open to all Department of Health and Telethon Kids Institute staff.

Places are strictly limited and offered on a first-come, first-serve, basis. If you are not able to attend a workshop for which you have registered, please contact Research Education Program support via phone or email to cancel your reservation and/or be placed in another workshop or on the waitlist.

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Contact Us or Register here

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REDCap Workshop 6: Intermediate Walkthrough

20th August 2024 1.00 - 3.30pm

Beyond the basics

- This level offers a more comprehensive look at creating a database and using surveys, and builds upon the topics in the REDCap Basics Workshop.
- Those who attend this workshop should be familiar with navigating and using REDCap for project set-up and it will be most beneficial to those who have identified an upcoming need for the advanced functionality covered in this workshop.
- Do you already know how to create a project from scratch and use branching logic? If no, please register for a Basics Workshop. This workshop is for users who are already familiar with the REDCap interface. Open to all WA Health and TKI staff only.



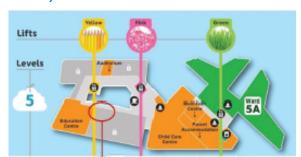
Meet the presenter

Dr Giulia Peacock CAHS Research Education Program Research Fellow

Giulia graduated medical school from the University of Notre Dame Fremantle in 2014. She supplements her clinical work as an Advanced Paediatric Trainee by conducting and publishing research in paediatric cardiology and through active involvement in medical education.

She is currently completing her Masters in Clinical Science, Child Health Research at the University of Western Australia. She hopes to ensure easy accessibility to research education and support, to create best outcomes for all patients.

PCH, TKI Level 5 Seminar Room



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Places are capped at 40. Laptops are available if required



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2024 Research Skills Workshop Series



The Research Education Program (REP) Research Skills Workshop Series, supported by the Perth Children's Hospital Foundation and the Telethon Kids Institute, offers a series of interactive workshops that focus on building the most fundamental research skills required to undertake clinical research projects.



Workshops aim to directly build user skills and knowledge in a guided environment, with time to ask questions specific to your own project.

Presented by: CAHS Research Department and invited guests Location: PCH, TKI Seminar Room, Level 5 (W)

Topic	Day	Date	Time	Max (in-person)
Workshop 4 - Navigating Research Ethics and Governance in WA If you are undertaking a research project or are thinking about becoming involved in research, understanding the review and approval requirements for your research project may appear intimidating. This workshop aims to help you understand the process of ethical and governance review for research approvals at CAHS - includes PCH, CACHS, CAHMS and Neonatology.	Tue	23 April	2.00pm - 4:00pm	40 Watch
Workshop 1 - Setting up Clinical Trials Clinical trials are the benchmark for testing interventions in healthcare. This workshop aims to provide practical advice to clinical researchers who want to gain insight on how to develop and complete their clinical trial on time and within budget. Come learn practical aspects of the steps involved in developing a clinical trial from the research idea to protocol development and execution.	Mon	20 May	12.00 noon - 2.00pm PCH level 6 TKI Manda	40 <u>Watch</u>
Workshop 2 - Manuscript Writing Journal publications are an integral part of dissemination of research findings. However, it can be overwhelming to convert several months of research into a succinct manuscript that will be loved by peer-reviewers and attract readers. This workshop is designed to give those who have completed their research projects, practical skills to transform their research data into publishable peer-reviewed literature.	Tue	11 June	2.00pm - 4:00pm	40 Recording coming soon
Workshop 3 - Oral Presentation of Research Results Dissemination of research findings is integral in knowledge translation and clinical practice change. Oral presentations provide rapid dissemination of research findings to a target audience. We invite you to a practical session that will provide useful tips, practice sessions and personalised feedback to help deliver an adequate depth of your research findings to various research stakeholders.	Tue	22 Oct	2.00pm - 4:00pm	40 Register

IMPORTANT

Places are strictly limited and offered on a first-come, first-serve, basis. If you are not able to attend a workshop for which you have registered, please contact Research Education Program support via phone or email to cancel your reservation and/or be placed on the waitlist.



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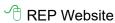
Contact Us

(08) 6456 0514

researcheducationprogram@health.wa.gov.au \bowtie

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Child Health Research Symposium

Empowering Futures: Advancing Child Health

4 - 7 November

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You are invited!

Monday 4 November at 5pm PCH Collegiate Lounge

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pch.symposium@health.wa.gov.au

Poster Opening Night



Research Skills Seminar Series

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	u ioi you	r interest in	uns semina	31		
Please complete this 1-minute evaluation. Your feedback will help guide future presentations and educational activities.						
How did you attend the seminar? Live seminar at Perth Children's H Hosted video-conference on-site (o Online via Avaya or Teams Viewed online recording		Lions Eye, F	RPH etc.)			
Please rate your agreement with the fol	llowing s	tatements:				
	N/A	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
The aims and objectives were clear	\bigcirc	\circ	0		\bigcirc	\circ
The session was well structured	\circ	\circ	\circ	\circ	\circ	0
Presentation style retained my interest		\circ	\circ	\circ	\circ	\circ
The speaker communicated clearly	\circ	\circ	\circ	\circ	\bigcirc	\circ
The material extended my knowledge	\circ	\circ	\circ	\circ	\bigcirc	\circ
The additional resources were helpful	0	0	0	\circ	\circ	0
What were the best aspects of the semi	nar?					
What changes or improvements would y	VOLL SILIGO	est?				
muc changes of improvements would j	you sugg					
How did you hear about the seminar? you can select multiple answer)						
Email invitation from Research Ed		_				
CAHS Newsletters e.g. The Headli "Health Happenings" E-News	ines, The	View, CAHS	Research N	lewsletter		

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