

# POP90119 Design of Randomised Controlled Trials

<b>Credit Points:</b>	12.5									
<b>Level:</b>	9 (Graduate/Postgraduate)									
<b>Dates &amp; Locations:</b>	2015, Parkville This subject commences in the following study period/s: Semester 2, Parkville - Taught online/distance.									
<b>Time Commitment:</b>	Contact Hours: None Total Time Commitment: 170 hours									
<b>Prerequisites:</b>	- <table border="1"> <thead> <tr> <th>Subject</th> <th>Study Period Commencement:</th> <th>Credit Points:</th> </tr> </thead> <tbody> <tr> <td>POP90016 Epidemiology</td> <td>Semester 1, Semester 2</td> <td>12.50</td> </tr> <tr> <td>POP90015 Mathematics Background for Biostatistics</td> <td>Semester 1, Semester 2</td> <td>12.50</td> </tr> </tbody> </table>	Subject	Study Period Commencement:	Credit Points:	POP90016 Epidemiology	Semester 1, Semester 2	12.50	POP90015 Mathematics Background for Biostatistics	Semester 1, Semester 2	12.50
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POP90015 Mathematics Background for Biostatistics	Semester 1, Semester 2	12.50								
<b>Corequisites:</b>	None									
<b>Recommended Background Knowledge:</b>	None									
<b>Non Allowed Subjects:</b>	None									
<b>Core Participation Requirements:</b>	None									
<b>Coordinator:</b>	Prof John Carlin									
<b>Contact:</b>	<p><a href="mailto:john.carlin@unimelb.edu.au">john.carlin@unimelb.edu.au</a> (<a href="mailto:john.carlin@unimelb.edu.au">mailto:john.carlin@unimelb.edu.au</a>)</p> <p><b>OR</b></p> <p>Academic Programs Office Melbourne School of Population and Global Health Tel: +61 3 8344 9339 Fax: +61 3 8344 0824 Email: <a href="mailto:sph-gradinfo@unimelb.edu.au">sph-gradinfo@unimelb.edu.au</a> (<a href="mailto:sph-gradinfo@unimelb.edu.au">mailto:sph-gradinfo@unimelb.edu.au</a>)</p> <p><b>OR</b></p> <p>Biostatistics Collaboration of Australia Email: <a href="mailto:bca@ctc.usyd.edu.au">bca@ctc.usyd.edu.au</a> (<a href="mailto:bca@ctc.usyd.edu.au">mailto:bca@ctc.usyd.edu.au</a>) Website: <a href="http://www.bca.edu.au">www.bca.edu.au</a> (<a href="http://www.bca.edu.au">http://www.bca.edu.au</a>)</p>									
<b>Subject Overview:</b>	Topics include: ethical considerations; principles and methods of randomisation in controlled trials; treatment allocation, blocking, stratification and allocation concealment; parallel, factorial and crossover designs including n-of-1 studies; practical issues in sample size determination; intention-to-treat principle; phase I dose finding studies; phase II safety and efficacy studies; interim analysis and early stopping ; multiple outcomes/endpoints, including surrogate outcomes, multiple tests and subgroup analyses, including adjustment of significance levels and P-values; missing data; reporting trial results and use of the CONSORT statement.									
<b>Learning Outcomes:</b>	To enable students to understand and apply the principles of design and analysis of experiments, with a particular focus on randomised controlled trials (RCTs), to a level where they are able to contribute effectively as a statistician to the planning, conduct and reporting of a standard RCT.									

<b>Assessment:</b>	Three written assignments submitted during the semester; Two worth 30% each (approx 10 hours work each) and one worth 40% (approx 12 hours work).
<b>Prescribed Texts:</b>	Piantadosi, S. Clinical Trials: A Methodological Perspective, 2nd ed, John Wiley & Sons, New York, 2005 (ISBN 978-0-471-72781-1) Resources Provided to Students: Printed course notes and assignment material by mail, email, and online interaction facilities.
<b>Breadth Options:</b>	This subject is not available as a breadth subject.
<b>Fees Information:</b>	Subject EFTSL, Level, Discipline & Census Date, <a href="http://enrolment.unimelb.edu.au/fees">http://enrolment.unimelb.edu.au/fees</a>
<b>Generic Skills:</b>	Independent problem solving, critical appraisal of research literature, clarity of written expression, sound communication of technical concepts
<b>Links to further information:</b>	<a href="http://www.sph.unimelb.edu.au">http://www.sph.unimelb.edu.au</a>
<b>Notes:</b>	This subject is not available in the Master of Public Health.
<b>Related Course(s):</b>	Master of Biostatistics Postgraduate Certificate in Biostatistics Postgraduate Diploma in Biostatistics