

## Conducting clinical trials in partnership with Aboriginal and Torres Strait Islander communities

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ACTA Conference 3<sup>rd</sup> October, 2019

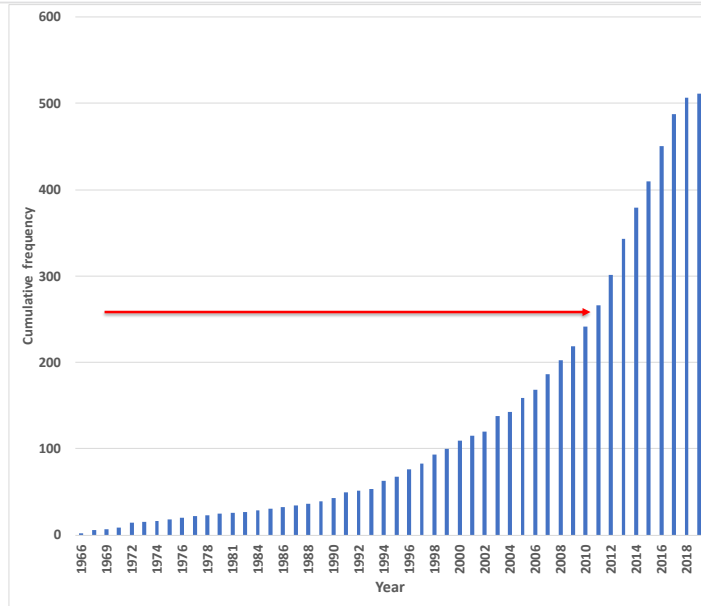


### Outline

1. Ethics
2. RCT design
3. Trial implementation



## RCT related publications in Medline involving Indigenous populations in Aus, NZ, Canada and USA 1966 - 2019



## NHMRC research funding

NHMRC Funding 2000 – 2016 for Aboriginal and Torres Strait Islander health research

| Field of research             | Number of grants | Funding awarded (millions) |
|-------------------------------|------------------|----------------------------|
| Public Health                 | 257              | \$187.7                    |
| Health Services Research      | 73               | \$50.6                     |
| Clinical Medicine and Science | 19               | \$8.3                      |
| Basic Science                 | 4                | \$1.5                      |

NHMRC Funding 2019 Investigator Grant outcomes for Aboriginal and Torres Strait Islander health research and researchers

| Research and researchers   | Number of applications | Number funded | Funded rate | Total value  | Proportion of total funding awarded |
|--|------------------------|---------------|-------------|--------------|-------------------------------------|
| Aboriginal and Torres Strait Islander health research  | 66                     | 15            | 22.7%       | \$19,370,843 | 5.3%                                |
| Researchers of Aboriginal and/or Torres Strait Islander descent  | 11                     | 7             | 63.6%       | \$8,545,900  | 2.3%                                |
| Aboriginal and Torres Strait Islander health research led by researchers of Aboriginal and/or Torres Strait Islander descent | 9                      | 5             | 55.6%       | \$5,949,861  | 1.6%                                |

There is overlap between the first two rows, as shown in the third row.



*Aboriginal Health and Medical Research Council  
of New South Wales*



**AH&MRC Ethics Committee**

AH&MRC Guidelines for Research  
into Aboriginal Health  
**Key Principles**

- Spirit and integrity
- Cultural continuity
- Equity
- Reciprocity
- Responsibility
- Net benefits for Aboriginal people and communities
- Community control of research
- Cultural sensitivity
- Reimbursement of costs
- Enhancing Aboriginal skills and knowledge

## Rights

1. To self-determination
2. To say yes
3. To say no up front
4. For Aboriginal and Torres Strait Islander ways of doing things to be respected
5. To have input into the research agenda
6. To commission research that meets priority needs
7. To negotiate a different focus for the research
8. To request more time to talk about the research proposal
9. To expect respect for culture, values, beliefs
10. To seek advice and support to negotiate a written research agreement
11. To check on the researcher's track record
12. To suspend or withdraw from a research project
13. To make a complaint if something goes wrong
14. To assert ownership of cultural and intellectual property and shared copyright

## Outline



1. Ethics
2. RCT design
3. Trial implementation



22/10/2019

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## THE CONVERSATION

Academic rigour, journalistic flair

 Search analysis, research, academics...

Arts + Culture Business + Economy Cities Education Environment + Energy **Health + Medicine** Politics + Society Science + Technology

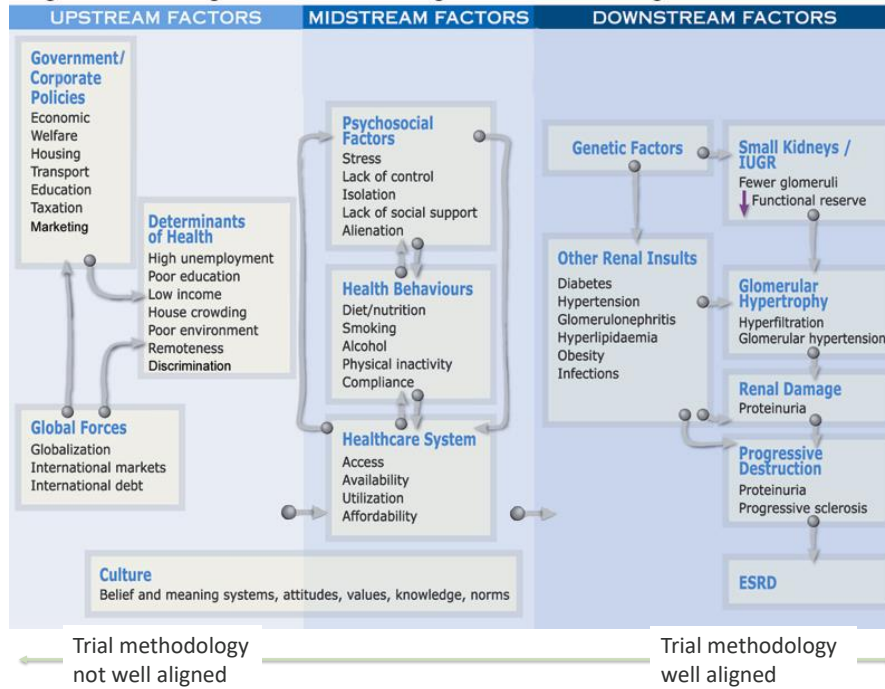


**Controlled experiments won't tell us which Indigenous health programs are working**

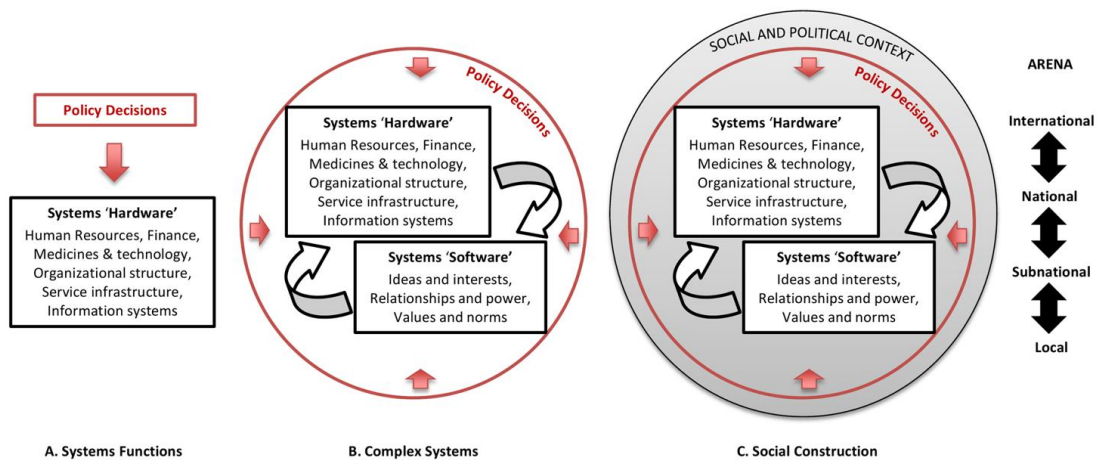
August 18, 2017 10:19am AEST



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**Figure 3 An integrated model of end-stage renal disease in Indigenous Australians**

## Health system complexity



*Sheik Plos Med 2011*

**THE LANCET**

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**Articles**

**Quarter-dose quadruple combination therapy for initial treatment of hypertension: placebo-controlled, crossover, randomised trial and systematic review**

Prof Clara K Chow, PhD, Prof Jay Thakkar, MBBS, Alex Bennett, MPhil, Prof Graham Hillis, PhD, Michael Burke, PhD, Prof Tim Usherwood, MD, Kha Vo, BSc, Kris Rogers, PhD, Emily Atkins, PhD, Ruth Webster, PhD, Michael Chou, MBBS, Hakim-Moulay Dehbi, MSc, Abdul Salam, PhD, Prof Anushka Patel, PhD, Prof Bruce Neal, PhD, David Peiris, PhD, Prof Henry Krum, Prof John Chalmers, PhD, Prof Mark Nelson, PhD, Prof Christopher M Reid, PhD, Prof Mark Woodward,

Efficacy

**Research**

**Original Investigation**

**Effects of a Fixed-Dose Combination Strategy on Adherence and Risk Factors in Patients With or at High Risk of CVD**

**The UMPIRE Randomized Clinical Trial**

Simon Thom, MBBS, MD, Neil Poulter, MB, MSc, FMedSci, Jane Finkel, BSc, Anushka Patel, MD, PhD, Dorraj Prabhakaran, MD, DM, MSc, Alice Stanton, MBBS, PhD, Diederick E. Grobbee, MD, PhD, Michel L. Boer, MD, PhD, K. Srinath Reddy, MD, DM, Raghu Cidambi, LLB, Severine Bompont, BSc, Laurent Billot, MSc, Anthony Rodgers, MD, PhD, for the UMPIRE Collaborative Group

Effectiveness

**European Journal of Preventive Cardiology**

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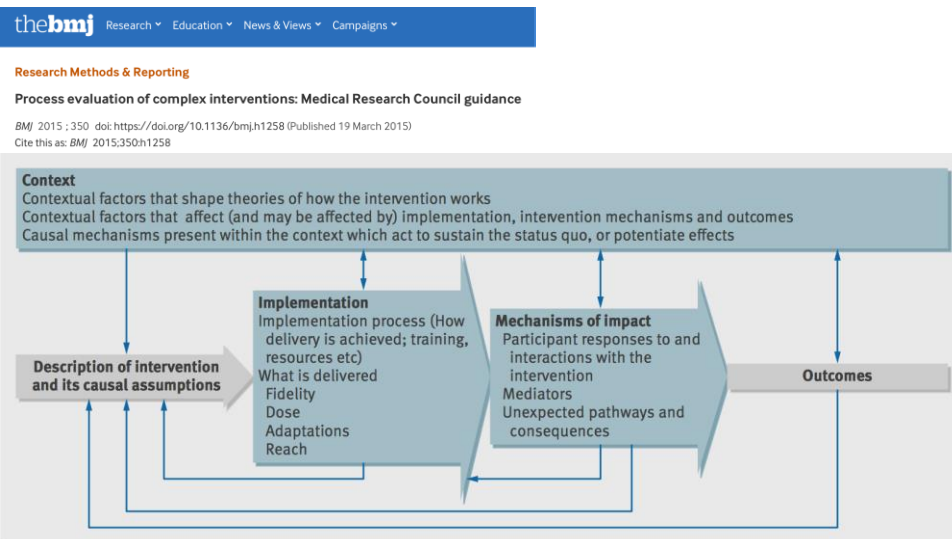
**A pragmatic randomized trial of a polypill-based strategy to improve use of indicated preventive treatments in people at high cardiovascular disease risk**

Anushka Patel, Alan Cass, David Peiris, Tim Usherwood, Alex Brown, Stephen Jan, Bruce Neal, Graham S Hillis, Natasha Rafter, Andrew Tonkin, Ruth Webster, Laurent Billot, Severine Bompont, Carol Burch, Hugh Burke, Noel Hayman, Barbara Molanus, Christopher M Reid, Louise Shiel, Samantha Togni, Anthony Rodgers, for the Kanyini Guidelines Adherence with the Polypill (Kanyini GAP) Collaboration\*

First Published March 27, 2014

Implementation trial

## Process Evaluation



## Outline

1. Ethics
2. RCT design
3. Trial implementation

THE MEDICAL JOURNAL OF AUSTRALIA

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SEARCH

THE RESEARCH ENTERPRISE

VOLUME 176 / ISSUE 6

# The demise of a planned randomised controlled trial in an urban Aboriginal medical service

Beverly M Sibthorpe, Ross S Baillie, Maggie A Brady, Sandra A Ball, Polly Sumner-Dodd and Wayne D Hall

Med J Aust 2002; 176 (6): 273-276. || doi: 10.5694/j1326-5377.2002.tb044406.x

Published online: 18 March 2002

## ARTICLE

## AUTHORS

## REFERENCES

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RANDOMISED CONTROLLED TRIALS (RCTs) are seen as the evidence "gold standard" for the effectiveness of clinical interventions. However, as a method of evaluating complex interventions in community-based settings they have significant limitations. Because of the poor uptake in Australia of secondary prevention for alcohol misuse among Indigenous people,<sup>1</sup> we set out to trial a brief intervention (involving motivational interviewing of individuals not presenting primarily with an alcohol problem<sup>2</sup>) in this population. This intervention has been subjected to a rigorous multinational trial under the auspices of the World Health Organization (WHO)<sup>3</sup> and found to help patients reduce their risk of alcohol-related harm.<sup>4,5</sup> However, there were too few Indigenous people in the Australian arm of the WHO trial to provide evidence of the effectiveness of the intervention in this population. Here we report on an attempt to address this gap through implementation of a trial in an urban Aboriginal Medical Service.



## Enablers and barriers to RCT participation

Original Article

A systematic review of barriers and facilitators to participation in randomized controlled trials by Indigenous people from New Zealand, Australia, Canada and the United States

Marewa Glover<sup>1</sup>, Anette Kira<sup>1</sup>, Vanessa Johnston<sup>2</sup>, Natalie Walker<sup>3</sup>, David Thomas<sup>4</sup>, Anne B. Chang<sup>2</sup>, Chris Bullen<sup>3</sup>, C. J. Segan<sup>5</sup> and Ngiare Brown<sup>4</sup>

### Enablers

- Relationship and partnership building
- Employment of Indigenous staff
- Drawing on Indigenous knowledge models
- Targeted recruitment techniques and adapted study materials

### Barriers

- Distrust of the research
- Inadequate addressing of practical barriers
- Lack of recognition or incorporation of Indigenous knowledge systems

Global Health Promotion 2015



## 1. Strategic alignment

### Multi-tiered consultation

- Board – leaders – frontline staff – patients and community

### Importance of the research question

### Alignment with community/health service strategic goals

### Is an RCT an acceptable design?

### Competing priorities

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Published on 02.04.19 in Vol 7, No 4 (2019): April

Preprints (earlier versions) of this paper are available at <http://preprints.jmir.org/preprint/12745>, first published Dec 06, 2018.

This paper is in the following e-collection/theme issue:

- mHealth for Wellness, Behavior Change and Prevention
- mHealth in the Developing World/LMICs, Underserved Communities, and for Global Health
- Smoking Cessation

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**Original Paper**

**A Smartphone App to Assist Smoking Cessation Among Aboriginal Australians: Findings From a Pilot Randomized Controlled Trial**

David Peiris<sup>1</sup>, PhD, MBBS, MPH ; Lachlan Wright<sup>1</sup> ; Madeline News<sup>1</sup>, MSc ; Kris Rogers<sup>1</sup>, PhD ; Julie Redfern<sup>2</sup>, PhD ; Clara Chow<sup>2</sup>, PhD ; David Thomas<sup>3</sup>, PhD

<sup>1</sup>The George Institute for Global Health, UNSW Sydney, Newtown, Australia  
<sup>2</sup>Westmead Applied Research Centre, University of Sydney, Sydney, Australia  
<sup>3</sup>Menzies School of Health Research, Darwin, Australia

## 2. 'Capacity' building

*"Within the agenda of growing an Indigenous health workforce, we hear talk of 'building capacities and aspirations' of Blackfellas via 'pathways' and 'pipelines', as if our under-representation in the health workforce is not a product of racism, but a product of us just not knowing or wanting any better. Here, we are framed as empty vessels whose 'aspirations' and 'capacities' need building to gain entry into the health system. We are to be captured and channelled through 'pathways' and 'pipelines'"*

A/Prof Chelsea Bond University of Queensland 2018

- Abandon empty vessel thinking
- Lead research team
- Early and mid-career researchers
- Project staff
- Health service staff
- Community participation

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**Effect of a Computer-Guided, Quality Improvement Program for Cardiovascular Disease Risk Management in Primary Health Care**

**The Treatment of Cardiovascular Risk Using Electronic Decision Support Cluster-Randomized Trial**

## 3. Resources

- Pressure on staff time
- Staff availability
- Competing with service delivery requirements
- Physical space
- Access to other funding initiatives
- Doing things too fast with too little

THE MEDICAL JOURNAL OF AUSTRALIA

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RESEARCH

VOLUME 203 ISSUE 1

Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services

Huaming Liu, Tracy-Lee Luba, Luciana Mace, Stephen Jin, Tim Usherwood, Anushka Patel, Noel E Hayman, Alan Cass, Anne-Marie Eades, Chris Lawrence and David P Peiris  
Med J Aust 2015; 203 (9): 24-27 | doi: 10.5694/mja14.00981  
Published online: 6 July 2015

ARTICLE

AUTHORS

REFERENCES

RESPONSES

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TOPICS

HEALTH SERVICES ADMINISTRATION

CARDIOVASCULAR DISEASES

INDIGENOUS HEALTH

**Abstract**

**Objective:** To identify facilitators and barriers to clinical trial implementation in Aboriginal health services.

**Design:** In-depth interview study with thematic analysis.

**Setting:** Six Aboriginal community-controlled health services and one government-run service involved in the Kanyini Guidelines Adherence with the Polyphill (KIGAP) study, a pragmatic randomised controlled trial that aimed to improve adherence to indicated drug treatments for people at high risk of cardiovascular disease.

**Participants:** 32 health care providers and 21 Aboriginal and Torres Strait Islander patients.

**Results:** A fundamental enabler was that participants considered the research to be governed and endorsed by the local health service. That the research was perceived to address a health priority for communities was also highly motivating for both providers and patients. Enlisting the support of Aboriginal and Torres Strait Islander staff champions who were visible to the community as the main source of information about the trial was particularly important. The major implementation barrier for staff was balancing their service delivery roles with adherence to often highly demanding trial-related procedures. This was partially alleviated by the research team's provision of onsite support and attempts to make trial processes more streamlined. Although more intensive support was highly desired, there were usually insufficient resources to provide this.

**Conclusion:** Despite strong community and health service support, major investments in time and resources are needed to ensure successful implementation and minimal disruption to already overstretched, routine services. Trial budgets will necessarily be inflated as a result. Funding agencies need to consider these additional resource demands when supporting trials of a similar nature.



## Key points

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1. Exponential growth in RCTs involving Indigenous people since 2010
2. Most trials in Australia led by non-Indigenous researchers
3. Strong frameworks, guiding principles and practical guidelines exist for conducting research
4. Community control, representation and participation in the research are the most common areas of ethical concern
5. Is an RCT design fit for purpose?
6. Trial implementation – multilevel factors to consider and often under-resourced

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