



Centre for Healthcare Randomised Trials

Mediation in RCTs: examples

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Overview

- **Opportunities missed**
- **Example (Catheters)**
- **Irons in fire**



Challenges

RESEARCH REPORTS

Clinical

J.E. Clarkson¹, S. Turner^{1*}, J.M. Grimshaw²,
C.R. Ramsay³, M. Johnston³, A. Scott⁴,
D. Bonetti¹, C.J. Tilley¹, G. MacLennan³,
R. Ibbetson⁵, L.M.D. MacPherson⁶,
and N.B. Pitts¹

Changing Clinicians' Behavior: a Randomized Controlled Trial of Fees and Education

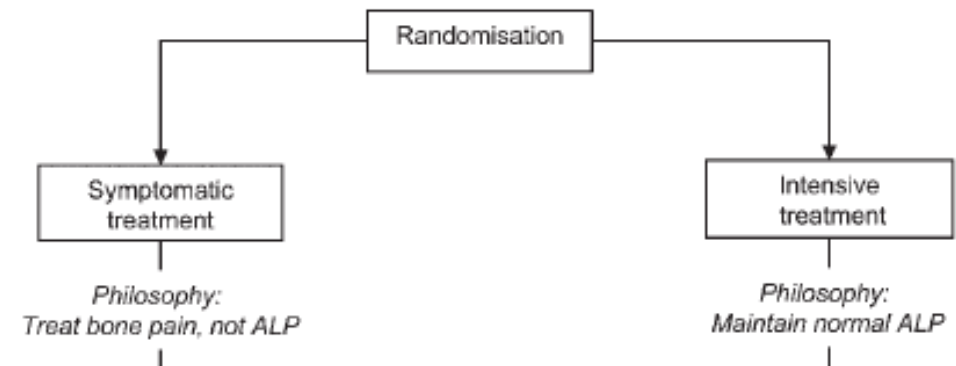
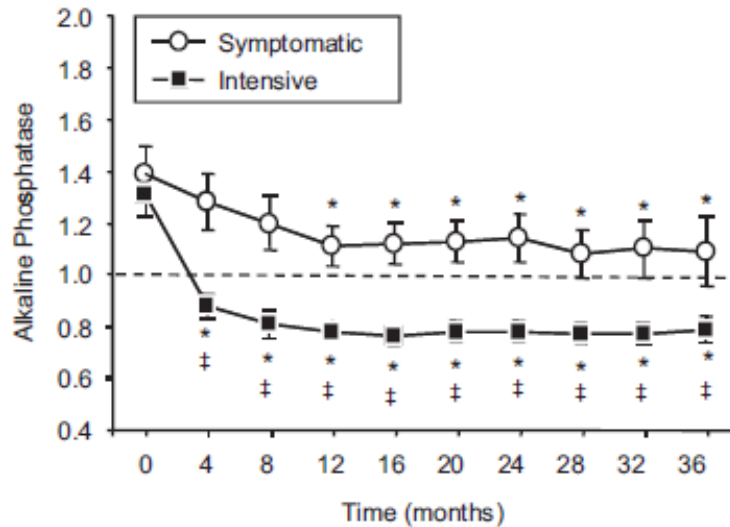
- **2x2 factorial C-RCT**
- **Fissure sealants on children's teeth**
- **Fees worked (+10%)**
- **Education did not**



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Randomized Trial of Intensive Bisphosphonate Treatment Versus Symptomatic Management in Paget's Disease of Bone

Anne L Langston,^{1,2} Marion K Campbell,³ William D Fraser,⁴ Graeme S MacLennan,³ Peter L Selby,⁵ and Stuart H Ralston^{1,2} for the PRISM Trial Group



- **No effect on fracture**
- **Or any other outcome**

	Silver alloy catheter	Nitrofur catheter	PTFE catheter control
Symptomatic antibiotic-treated UTI within 6 weeks of randomisation (primary outcome)			
Incidence	263/2097 (12.5%)	228/2153 (10.6%)	271/2144 (12.6%)
Absolute risk difference (95% CI) vs control	-0.1% (-2.4 to 2.2)	-2.1% (-4.2 to 0.1)	..
Unadjusted odds ratio (95% CI)	0.99 (0.81 to 1.22; p=0.92)	0.82 (0.66 to 1.01; p=0.037)	..
Adjusted odds ratio (95% CI)	0.96 (0.78 to 1.19; p=0.69)	0.81 (0.65 to 1.01; p=0.031)	..

Symptomatic antibiotic-treated UTI up to 6 weeks after randomisation associated with positive urine culture ($\geq 10^5$ cfu per ml)

Antimicrobial catheters for reduction of symptomatic urinary tract infection in adults requiring short-term catheterisation in hospital: a multicentre randomised controlled trial



Robert Pickard*, Thomas Lam*, Graeme MacLennan, Kath Starr, Mary Kilonzo, Gladys McPherson, Katie Gillies, Alison McDonald, Katherine Walton, Brian Buckley, Cathryn Glazener, Charles Boachie, Jennifer Burr, John Norrie, Luke Vale, Adrian Grant, James N'Dow

- **Longer catheterisation increases risk of UTI**
- **PFTE is more comfortable**
- **Patients can tolerate longer**
- **Mediation?**



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Other examples

- **Knee surgery**
- **Male infertility**
- **Sleep in children with neurodevelopmental disorders**
- **Implementation Science**



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Hashtags **#RealWorldMedStats**
#statistics
#causalmediation



@Nihrg – NIHR Statistics Group
@KimberleyGol – Kim
@KCLBHI – Kim and Richard’s Department
@gsmacLennan – Graeme
@hsru_aberdeen – Graeme’s Department
@richardaemsley – Richard