KANYINI GAP STUDY
Guidelines Adherence with the Polypill

Kanyini Guidelines Adherence with the Polypill (Kanyini GAP)

THE GEORGE INSTITUTE for Global Health

Baker IDI HEART & DIABETES INSTITUTE

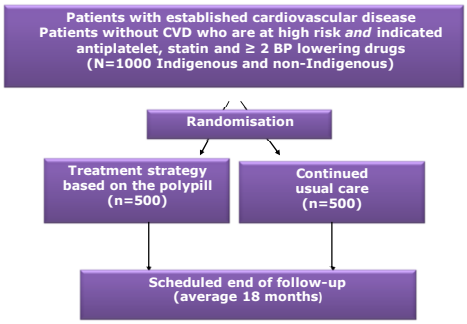
CCRE THERAPEUTICS

Primary Hypotheses

Among individuals at high risk of a cardiovascular event, a polypill-based strategy compared with usual care will result in:

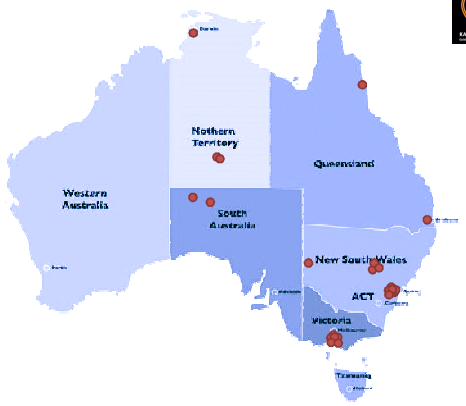
- Greater use of indicated combination treatment (use of antiplatelet, statin and at least two blood pressure lowering medications)
- Lower systolic blood pressure
- Lower total cholesterol

Study design



Polypill formulations

Version 1 (post MI)	Version 2 (post stroke)
aspirin 75mg	aspirin 75mg
simvastatin 40mg	simvastatin 40mg
lisinopril 10mg	lisinopril 10mg
atenolol 50mg	hydrochlorothiazide 12.5mg



Baseline characteristics

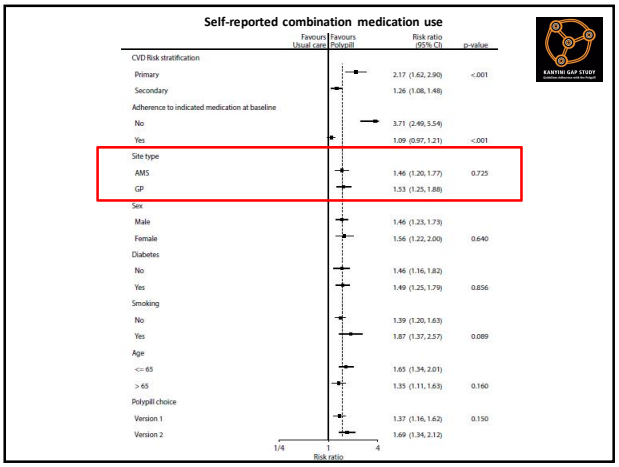
	Polypill strategy n=311	Usual care n=312
Age (years)	63.4 (12.5)	63.7 (12.7)
Male	197 (63.3%)	195 (62.7%)
Indigenous	153 (49.2%)	162 (52.1%)
Established CVD	183 (58.8%)	198 (63.4%)
SBP (mmHg)	143.4 (18.5)	142.5 (20.5)
Total cholesterol (mmol/L)	4.4 (1.1)	4.5 (1.2)
Combination treatment*	151 (48.6%)	160 (51.3%)

* Self-reported use of aspirin + a statin + at least 2 BP lowering medications

Primary outcomes

Outcome	Polypill n=311	Usual n=312	Treatment effect (95% CI)	P-value
Use of combination treatment*	70.1%	46.9%	1.49 (1.30, 1.72)	<0.001
Systolic blood pressure (mmHg)	139.0	140.5	-1.5 (-4.0, 1.0)	0.24
Total cholesterol (mmol/L)	4.39	4.31	0.08 (-0.06, 0.22)	0.26

* Self-reported use of aspirin + a statin + at least 2 BP lowering medications



Conclusions

- Polypill-based strategy significantly improves self-reported medication use
- Trial under-powered for BP and cholesterol, but use of more potent statins in the usual care group likely to have influenced the results for cholesterol

Getting polypill to market

- Funded by the National Health and Medical Research Council of Australia.
- Dr Reddy's Laboratories Ltd manufactured and supplied polypills for this trial free of charge.

- The George Institute for Global Health secured an exclusive global license in Dec 2012 for the polypills used in Kanyini GAP, following a decision by Dr Reddy's Laboratories Ltd not to proceed with taking the products to market because of existing regulatory requirements

Getting polypill to market

- Formal meetings with regulatory agencies held (including TGA and EMEA).
- Regulatory dossier (Clinical Study Report) currently being developed.
- Ongoing negotiations with potential alternate manufacturer and distributor with due diligence activities.

More research

- Combining polypill availability with strategies to help routine identification of potentially suitable patients in primary care.
- Polypill use at hospital discharge in patients with acute coronary syndromes.
- Expanding the range of polypill formulations.
- Polypill in patients with diabetes.