

CRE in Prevention of chronic conditions in rural and remote high risk populations 2012-15



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Today...

- Overview of the APHCRI-funded CRE
- Focus on intervention trials and methodological issues
- Examples from a CRE trial
- Dealing with sudden unpredicted changes in the policy environment
 - Change of government
 - Change of management

Chronic disease in rural and remote areas

- High rates of **diabetes, heart and renal disease, preventable complications** in remote and Indigenous communities
- Evidence for effectiveness of Primary Health Care based interventions which:
 - **Prevent progression of established disease** (reduce hospitalisations)
 - **Prevent onset of new disease**
- Different approaches in different communities (resident outreach, clinical and health promotion staff)

How do these various models of care translate into improved health outcomes for clients?

Prevention

Management

Research theme 1
Nutrition and
physical activity
opportunities

Research theme 2
Substance
misuse and
mental health

Research theme 3
PHC Management of diabetes,
renal CVD and Mental Health

PHC Model and Implementation Fidelity

Cohort studies

Economic evaluation

Policy analysis

Workforce analysis

Translating research into policy

- Through interventional and observational research **demonstrate the impact on health** and patient-important outcomes of different models of PHC and community-based prevention on chronic disease risk
- Over time, **evaluate place-based interventions** on chronic disease risk factors and avoidable hospitalisations in large cohorts utilising record linkage
- **Evaluate these models** using economic and other mixed methods approaches, including workforce implications

A systems approach to improving health outcomes in individuals with chronic conditions in rural and remote settings: lessons from a “failed” trial

Robyn McDermott
Seminar, Commonwealth DoH Canberra
December 4, 2014



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CENTRE FOR CHRONIC
DISEASE PREVENTION

Intervention trials in health services: Pragmatism and serendipity

- What's special about Health Services Research
- Methodological issues
- Example of “Getting better at chronic care” trial
- What if the trial fails?
 - Theory is wrong
 - Power is insufficient
 - Implementation failure (*type 3 error*)

What's special about health services (and much public health) research?

- Interventions are complex
- Settings are complex
- Standard control groups may not be feasible/ethical/acceptable to services and/or communities
- “Contamination” is a problem
- Unmeasured bias/confounding
- Secular behaviour and policy change over time can be strong, sudden and unpredictable
- Context is very important but often poorly described
- Example of the DCP

“Improving reporting quality” checklists

- CONSORT: RCTs with updates for cluster RCTs
- TREND: Transparent Reporting of Evaluations with Non-randomised Designs (focused on HIV studies initially)
- PRISMA: Reporting systematic reviews of RCTs
- STROBE: Reporting of observational studies
- MOOSE: Reporting systematic reviews of observations studies

Complex interventions

- Review of RCTs reported over a decade
- Less than 50% had sufficient detail of the intervention to enable replication (*Glasziou, 2008*)
- Even fewer had a theoretical framework or logic model
- Systematic reviews of complex interventions often find small if any effects, or contradictory findings. This may be due to conflating studies without taking account of the underlying theory for the intervention (eg Segal, 2012: Early childhood interventions)



CENTRE FOR CHRONIC
DISEASE PREVENTION

Getting Better at Chronic Care (GBACC) in North Queensland: a cluster RCT of community health worker care co- ordination in remote FNQ settings

Robyn McDermott, Barbara Schmidt, Cilla Preece, Vickie
Owens, Sean Taylor, Adrian Esterman, Ashim Sinha, Mark
Wenitong



Queensland
Government



Problem

- >60% life expectancy gap due to chronic diseases
- High burden of obesity, T2DM, incidence of complications especially renal, vascular disease: (T2DM Prevalence 43% adults, incidence 3% per year)
- Glycemia, albuminuria driving CVD incidence and mortality *
- Better PHC based secondary prevention is key in those with established disease

**(McDermott et al, MJA, 2011)*

Study hypotheses

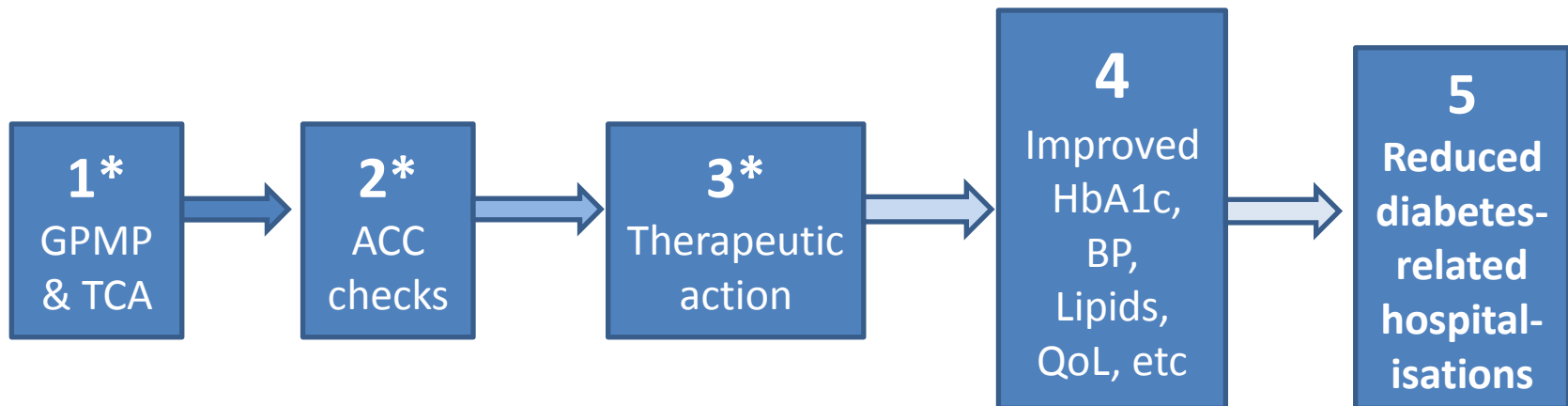
That individualised care of adults with complex poorly controlled T2DM by ***community-based IHWs*** will improve:

- Care Processes (GPMP, TCA, ACC),
- Clinical control (HbA1c, BP, Lipids);
- And reduce diabetes-related complications (hospitalisations) over 18 months

Does having IHW-led case management lead to an improvement in care processes, appropriate therapeutic action and clinical outcomes for Indigenous adults with poorly controlled diabetes over 18 months?

Baseline measures

Follow-up measures over 18 months



GBACC Program logic: IHWs will facilitate GPMP (1) which should generate a further set of activities (checks) in the annual cycle of care (ACC) (2), followed by appropriate therapeutic action (3), which should lead to improvement in clinical outcomes (4) and reduced avoidable hospitalisations (5).

*(1), (2) and (3) are brokered by the IHW, indicating better client engagement.

GBACC: mixed methods evaluation in 3 phases

Phase 1 (Intervention period: March 2012 – Sept 2013)

- **Randomised controlled trial of intensive case management by IHWs**
- **Process evaluation of model of care**

Phase 2 (Nov 2013 – Feb 2014)

- Review of lessons learned
- Implementation plan

Phase 3 (May 2014 – June 2015)

- Economic analysis
- Rollout of model

12 Participating Communities

***Intervention sites in phase 1 (randomly allocated)**

Torres and NPA HHS

- Badu*
- Bamaga
- Injinoo*
- New Mapoon
- Seisia
- Umagico*

Cape York HHS

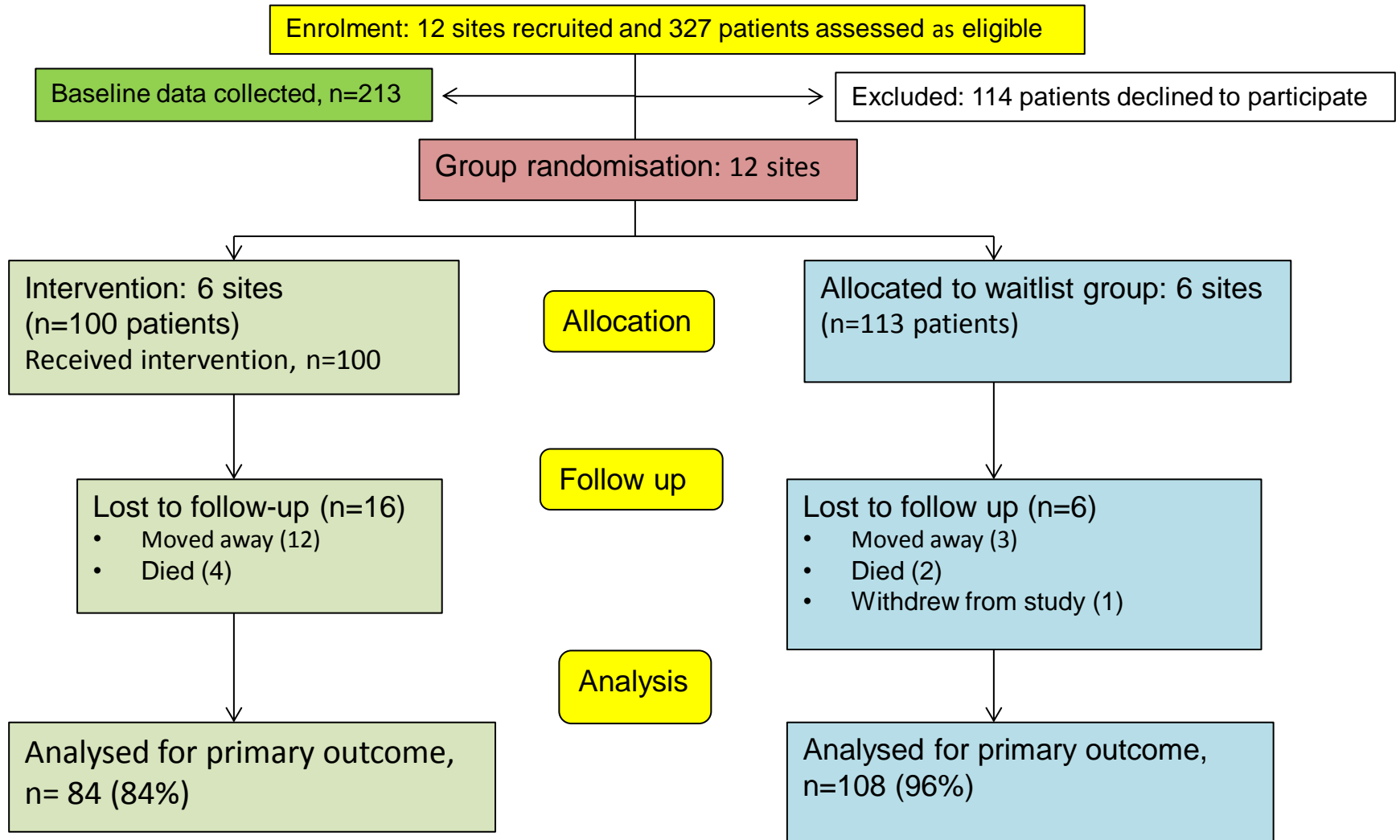
- Kowanyama*
- Mapoon*
- Mareeba (Mulungu)

Cairns and Hinterland HHS

- Mossman Gorge (ACYHC)*
- Napranum
- Yarrabah (GYHS)



CONSORT DIAGRAM: GBACC



Baseline socio-demographic characteristics of study participants (SD or %)

	Control (95% CI)	Intervention (95% CI)	All (95%CI)	p-value
Number of participants	113	100	213	
Mean age (years)	47.8 (46.2-49.5)	47.9 (45.8-50.0)	47.9 (46.6-49.2)	0.948
Number (%) women	66.4 (57.6-75.2)	58.0 (48.2-67.8)	62.4 (55.9-69.0)	0.208
Unemployed (%)	52.2 (42.9-61.5)	40.0 (30.3-49.7)	46.5 (39.7-53.2)	0.204
Did not complete 12 years education (%)	61.9 (52.9-71.0)	73.0 (64.2-81.8)	67.1 (60.8-73.5)	0.344
Median (IQR) household income	17420 (12480-33800)	20215 (13585-31200)	18200 (13000-32500)	0.598
“Not enough money for food” (%)	40.7 (31.6-49.9)	37.0 (27.4-46.6)	39.0 (32.4-45.6)	0.580
Median score (IQR) TOFLA	90.0 (81.1-94.1)	80.6 (64.9-89.0)	86.1 (71.5-92.1)	<0.001
No of people per household median (IQR)	5 (3-7)	4 (3-7)	4 (3-7)	0.608
Median AQoL mental health score (IQR) max=1	0.93 (0.89-0.98)	0.93 (0.91-0.94)	0.93 (0.89-0.95)	0.688
Current smoker (%)	37.6 (28.4-46.8)	40.2 (30.3-50.1)	38.8 (32.1-45.5)	0.231
Mean BMI (kg/m2)*	33.0 (31.2-34.9)	31.9 (29.9-33.9)	32.5 (31.1-33.8)	0.434

Did GBACC improve diabetes care processes?

Care processes (n and % with GPMP, TCA done) at T3 for intervention vs control sites in GBACC among all the participants (N=213) at T3

Care process done	Control group n=113		Intervention group n=100	
	N	% (95% CI)	N	% (95% CI)
GPMP	39	34.8 (25.9-43.7)	40	40.4 (30.6-50.2)
TCA	39	34.8 (25.9-43.7)	36	36.4 (26.8-45.9)

Intervention sites were 26% more likely to have implemented a GPMP at T3, however this did not reach statistical significance (Odds Ratio = 1.26, 95% confidence interval 0.72-2.22):

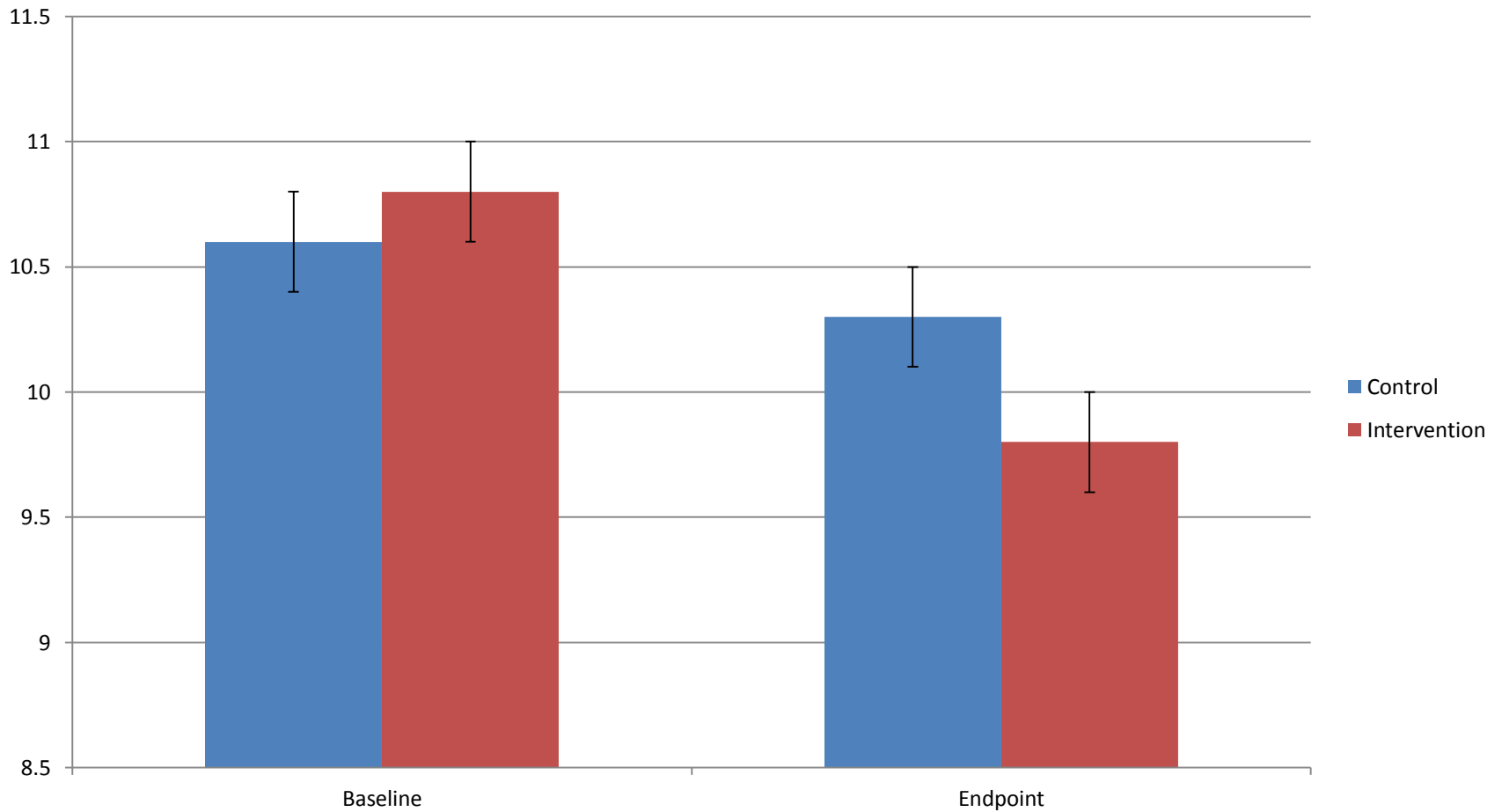
Clinical care processes at baseline and follow up (%)

	Baseline				Endpoint (excluding 22 loss of follow up)			
	Control n=113		Intervention n=100		Control n=107		intervention n=84	
	No	% (95% CI)	No	% (95% CI)	No	% (95% CI)	No	% (95% CI)
Foot check%	50	44.2 (35.0-53.5)	31	31.0 (21.8-40.2)	38	35.5 (26.3-44.7)	26	31.0 (20.9-41.0)
Seen by DM educator %	46	40.7 (31.6-49.9)	52	52.0 (42.1-61.9)	41	38.3 (29.0-47.6)	44	52.4 (41.6-63.2)
Seen by dietician %	22	19.5 (12.1-26.8)	30	30.0 (20.9-39.1)	21	19.6 (12.0-27.2)	37	44.0 (33.3-54.8)
Dentist check %	20	17.7 (10.6-24.8)	13	13.0 (6.3-19.7)	9	8.4 (3.1-13.7)	15	17.9 (9.6-26.5)
ECG check%	37	32.7 (24.0-41.5)	42	42.0 (32.2-51.8)	34	43.9 (34.4-53.4)	35	40.5 (29.8-51.1)
Eye check %	54	47.8 (38.5-57.1)	42	42.0 (32.2-51.8)	56	52.3 (42.8-61.9)	37	44.0 (33.3-54.8)
Smoker %	38	34.5 (25.6-43.5)	34	35.1 (25.5-44.7)	33	31.2 (22.4-40.4)	34	41.5 (30.7-52.2)
Blood sugar self-monitor %	45	40.9 (31.6-50.2)	46	46.0 (36.1-55.9)	63	59.4 (50.0-68.9)	44	52.4 (41.6-63.2)
Taking insulin%	55	48.7 (39.4-58.0)	40	40.0 (30.3-49.7)	47	43.9 (34.4-53.4)	40	47.6 (36.8-58.4)
Dyslipidemia %	83	73.5 (65.2-81.7)	84	84.0 (76.7-91.3)	91	85.0 (78.2-91.9)	76	90.5 (84.1-96.8)
Taking lipid lowering medicines%	5	4.4 (0.6-8.3)	3	3.0 (-0.4-6.4)	3	2.8 (-0.4-6.0)	5	6.0 (0.8-11.1)
Albuminuria and taking ACEi or ARB drugs	46	88.5 (79.6-97.3)	47	88.7 (80.0-97.4)	58	82.9 (73.9-91.8)	51	89.5 (81.4-97.6)
Adherent to all medicines	53	46.9 (37.6-56.2)	55	55.0 (45.1-64.9)	57	53.3 (43.7-62.8)	41	48.8 (38.0-59.6)
Had Fluvax	50	44.2 (35.0-53.5)	66	66.0 (56.6-75.4)	51	47.7 (38.1-57.2)	50	59.5 (48.9-70.2)

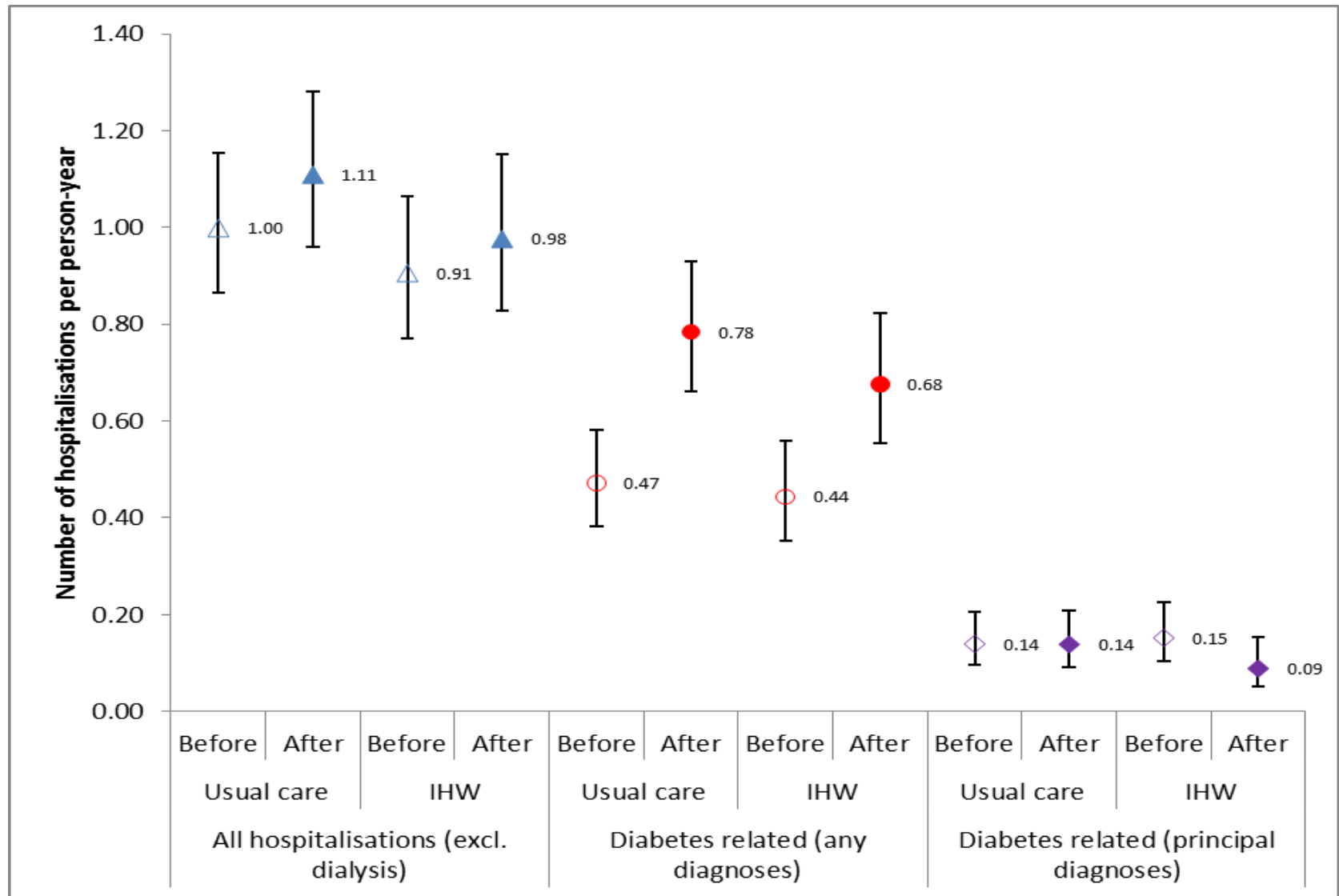
Clinical measures: 212 Indigenous adults with poorly controlled T2DM, baseline and follow-up at 18 months

Measure	Baseline						Endpoint (excluding 22 lost to follow up)					
	Control n=113			Intervention n=100			Control n=107			intervention n=84		
	No.	Mean	SD	No.	Mean	SD	No.	Mean	SD	No.	Mean	SD
HbA1c	113	10.6	1.87	99	10.8	2.0	105	10.3	2.2	84	9.8	2.3
Total Cholesterol	87	4.6	1.3	81	4.5	1.3	100	4.7	1.3	79	4.4	1.4
Trig	86	2.5	1.9	81	2.1	1.4	100	2.7	1.8	79	2.5	1.8
HDL	72	1.1	0.6	79	0.9	0.2	99	0.9	0.2	78	0.9	0.2
LDL	65	2.6	1.0	76	2.7	1.1	95	2.6	1.1	71	2.4	0.9
Weight	89	91.4	19.3	87	89.7	22.6	92	87.4	18.6	81	91.0	23.1

HbA1c measures at baseline and follow-up by group, absolute values



GBACC hospitalisations per person year for intervention and control sites (2011-2013)



Did GBACC have an impact on acute, diabetes-related hospitalisations?

Hosp category	Control T1	Control T3	Intervention T1	Intervention T3
DM complications as principal Dx	162	175	134	129
Pyelonephritis	9	7	6	5
Cellulitis	10	14	10	6
Gangrene	3	8	3	4
Subtotal DM complications & acute severe infections	184	204	153	144
% change from baseline (95% CI)		+11% (6.1 - 18.8)		-6% (-2.5 to -12.7)

Hospitalisations for acute infections and DM complications were decreased by 6% in the intervention group but increased by 11% in the control sites.

Was there evidence of Implementation Failure (type 3 error)?

Implementation fidelity was assessed from HW reports and interviews with staff

- Major issues with Doctors doing GPMPs
- Major issues with IHWs being pulled into mainstream acute work
- Major issues with IHWs getting access to clients' electronic records
- ACC could have been improved if IHWs could initiate pathology testing
- Around half clients in the intervention group were “difficult to engage” according to IHW reports

Effectiveness will vary by Context

Context elements can include

- Host organization and staff
- System effects (eg funding model, use of IT, chronic care model for service delivery)
- Target population
- Policy environment eg major perturbations caused by change of government

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