

SWIFT Driving Change In Participant and Centre Diversity and Inclusivity

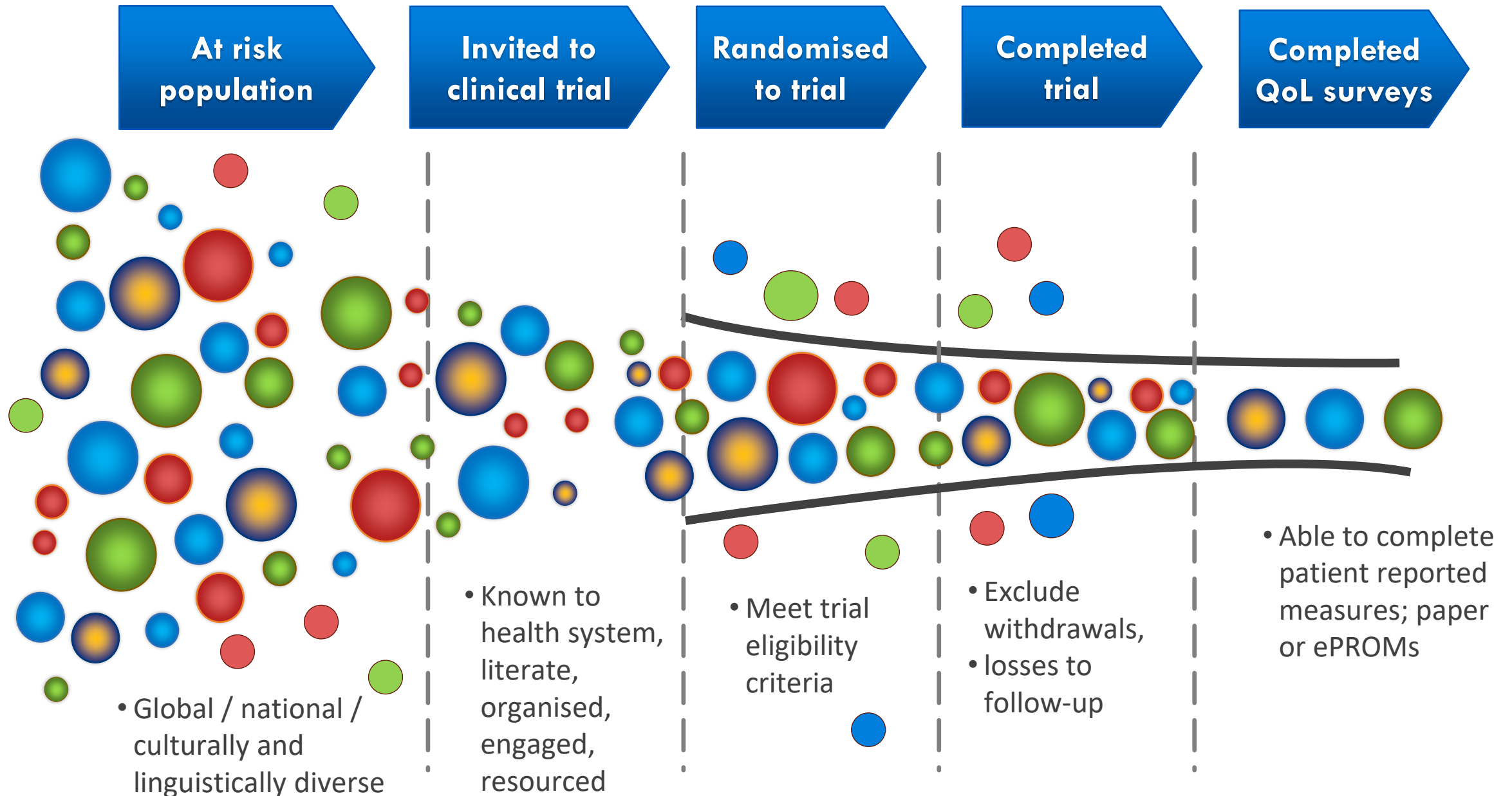
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18 November 2025, ACTA, Melbourne



Background: Selection bias in traditional clinical trials



Pragmatic registry-based randomised trials

Karanatsios *et al. Trials* (2020) 21:552
<https://doi.org/10.1186/s13063-020-04459-z>

Trials

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D.,
and Janet Woodcock, M.D., *Editors*

Pragmatic Trials

Ian Ford, Ph.D., and John Norrie, M.Sc.


PRAGMATISM IN CLINICAL TRIALS AROSE FROM CONCERNS THAT MANY trials did not adequately inform practice because they were optimized to determine efficacy.¹ Because such trials were performed with relatively small samples at sites with experienced investigators and highly selected participants, they could be overestimating benefits and underestimating harm. This led to the belief that more pragmatic trials, designed to show the real-world effectiveness of the intervention in broad patient groups, were required. Medical researchers, both

REVIEW

Open Access

Defining key design elements of registry-based randomised controlled trials: a scoping review



Bill Karanatsios^{1,2*} , Khic-Houy Prang^{3†}, Ebony Verbunt³, Justin M. Yeung^{1,2}, Margaret Kelaher³ and Peter Gibbs^{4,5,6}

Abstract

Background: Traditional randomised controlled trials remain the gold standard for improving clinical care but they do have their limitations, including their associated high costs, high failure rate and limited external validity. An alternative methodology is the newly defined, prospective, registry-based randomised controlled trial (RRCT), where treatment and outcome data is collected in an existing registry. This scoping review explores the current literature

Improving trial delivery for under-served groups

Groups by Demographic Factors

Age extremes (< 18 and > 75)

- Different ethnic minority groups
- Male/female sex
- LGBTQ+ / sexual orientation
- Educational disadvantage

Groups by Social/Economic Factors

- People in full time employment
- Socio-economically disadvantaged / unemployed
- War veterans

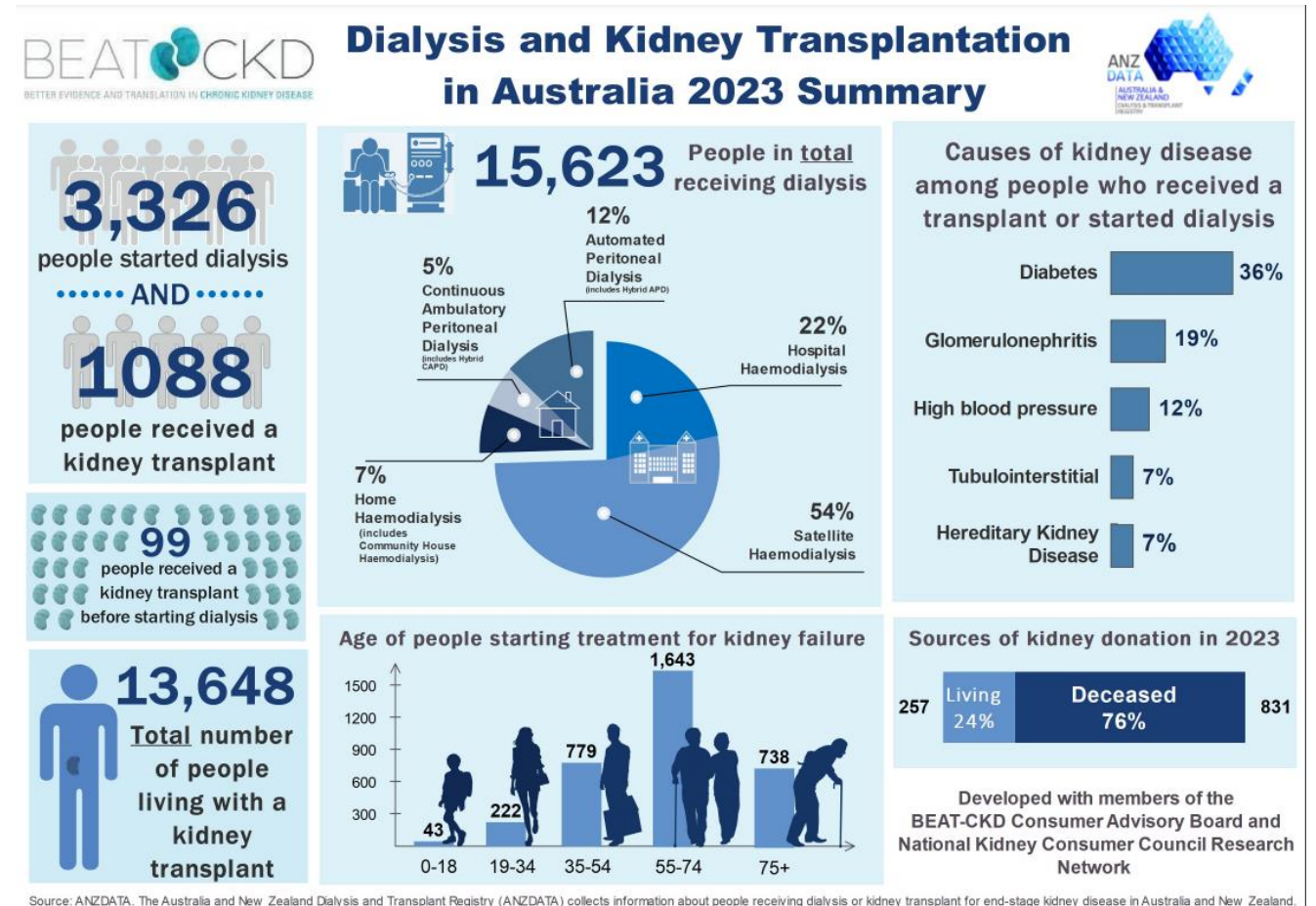
- Asylum seekers, care homes, prison populations, homeless
- People living in remote areas
- Religious minorities
- Language barriers
- Digital exclusion
- People who do not attend regular medical appointments
- People in multiple excluded categories
- Socially marginalized / stigmatised people

Aim

To determine the extent to which participants and centres randomised in the Symptom monitoring With Feedback Trial (SWIFT) represented the national population at risk

Data source for national population at risk - ANZDATA

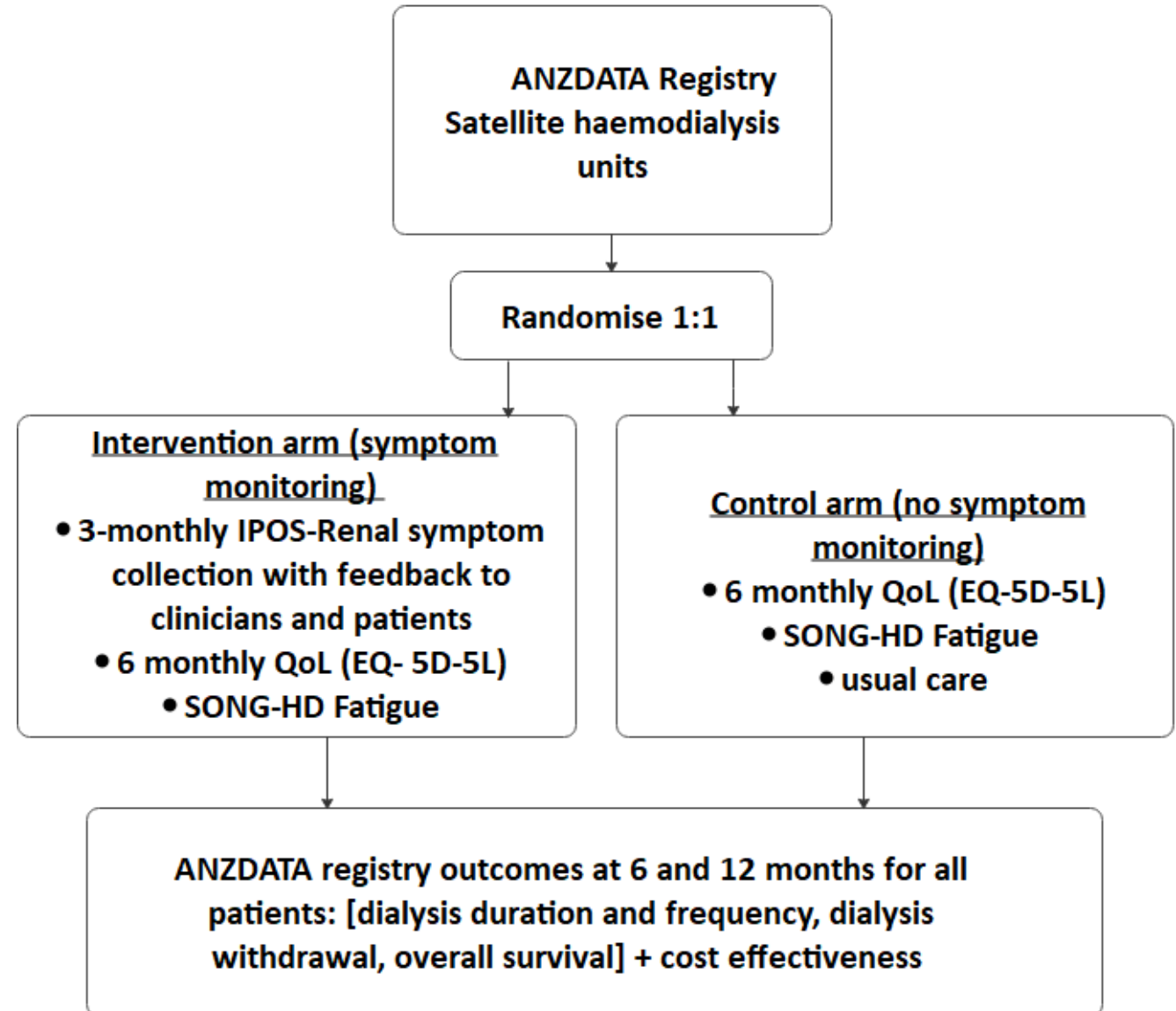
- Clinical Quality Registry
- Coverage of long term dialysis and kidney transplantation
 - All renal units in Australia and New Zealand participate
- Data collected via
 - Real time key events and yearly census
- Core data
 - Socio-demographic and clinical characteristics, treatment type, dialysis dose, clinical outcomes, treating centre characteristics, treating nephrologist
- Not routinely collected
 - PROMs (e.g. QoL, symptoms), PREMs, PAMs
- Output
 - Quality indicators, Health Service planning, Research



Data source: the Trial



- Symptom monitoring With Feedback Trial (SWIFT), a cluster-randomized registry clinical trial (ACTRN 12620001061921) among kidney dialysis patients, designed to test the effect of a systematic symptom monitoring intervention on health-related quality of life; cost-effectiveness; registry-based PROMs collection



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- People living in remote areas
- Private clinics
- Language barriers
- Digital exclusion
- People who do not attend regular medical appointments
- People in multiple excluded categories
- First Nations

Methods

Trial strategies to facilitate representative recruitment included:

- consumer co-design
- few exclusion criteria
- encouragement of >90% of eligible patients in each haemodialysis unit participating
- support for smaller research-naïve centres (CTC)
- Australian teletrials program (QLD, SA)
- translation of trial documents in 7 languages
- finger-sign consent on tablets
- on-site research support for electronic patient-reported outcomes data collection



أنت مدعو للمشاركة في دراسة بحثية باسم "تجربة مراقبة"

Quý vị được mời tham gia vào một nghiên cứu có tên 'Thử nghiệm theo dõi triệu chứng kèm phản hồi'



Methods

- Trial participant characteristics including age, sex, indigenous status, country of birth, use of language translations, social disadvantage, and comorbid conditions (coronary artery, peripheral vascular disease, cerebrovascular disease, T2 diabetes)
- Participating dialysis centre characteristics
- Reported using descriptive statistics, frequencies, means (SD)
- Comparison with available ANZDATA Registry characteristics for all Australians receiving facility haemodialysis
- Between group hypothesis tests conducted using *t*-tests, or chi-squared tests

Results – Trial and registry comparison

*92 clusters [centres]
4 states: QLD, NSW, VIC, SA

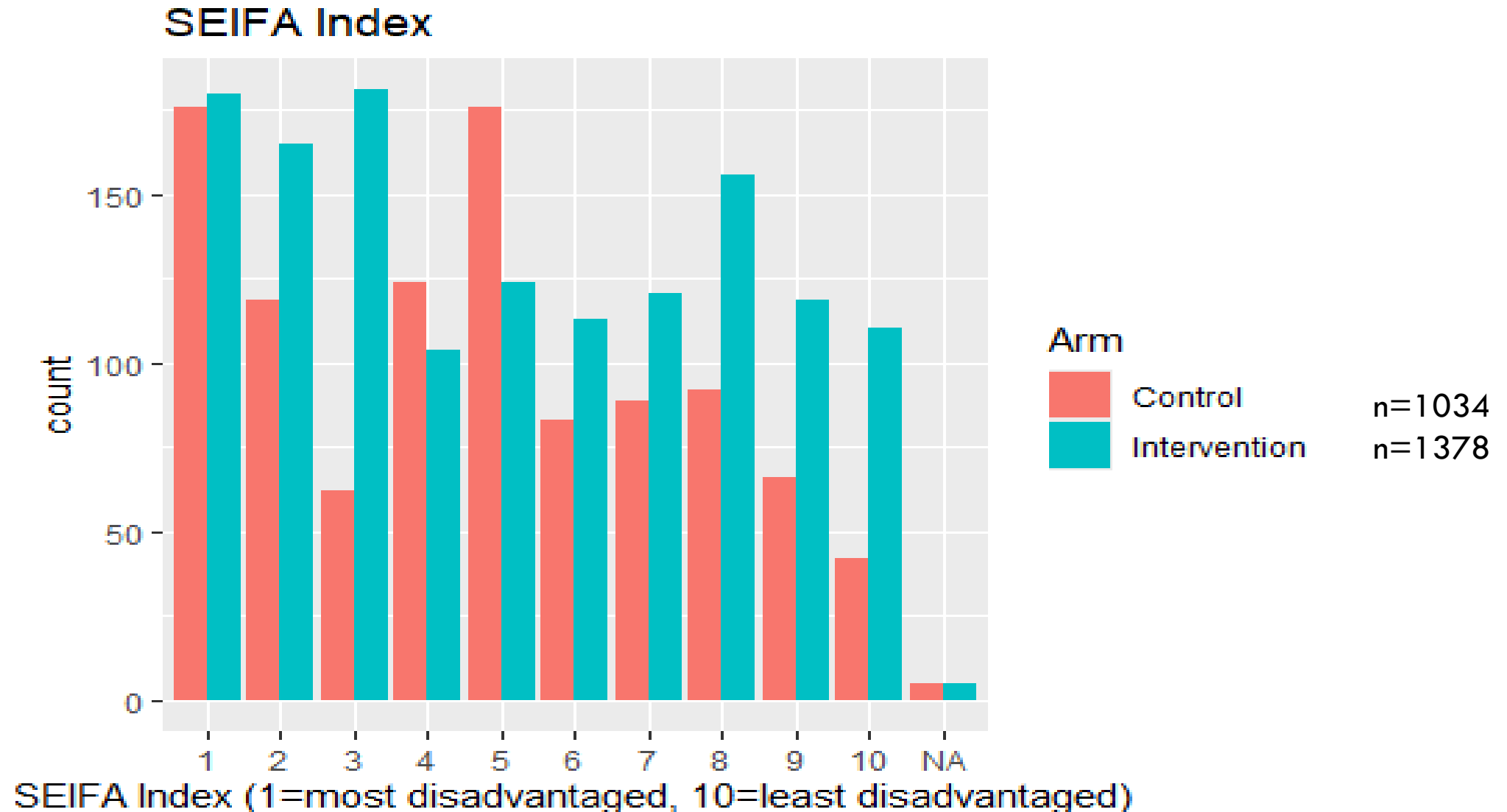
	SWIFT (n=2412)* May 2021–Jul 2025		ANZDATA (n=9633) Dec 2024		Difference (SWIFT- ANZDATA)	p-value
Characteristic	n	(%)	n	(%)		
Age, median (min, max)	68	17-99	67	18-97	+1 year	0.002
Sex, females	905	38	3688	38	0%	1.00
First Nations	186	8	881	9	-1%	0.12
Country of birth, Australia	1557	65	5886	61	+4%	0.0003
Others (S&E Europe, Oceania, S.E Asia)	855	35	3747	39	-4%	
SES, Lowest 2 deciles	640	27	2688	28	-1%	0.33
Highest 2 deciles	337	14	1306	14	0%	1.00
Comorbidities:						
CAD (yes + suspected)	1120	46	4360	45	+1%	0.38
PVD and/or CVD (yes + suspected)	962	40	3916	41	-1%	0.37
T2 Diabetes (yes + suspected)	1296	54	4771	50	+4%	0.0004

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Socio-economic status of SWIFT participants



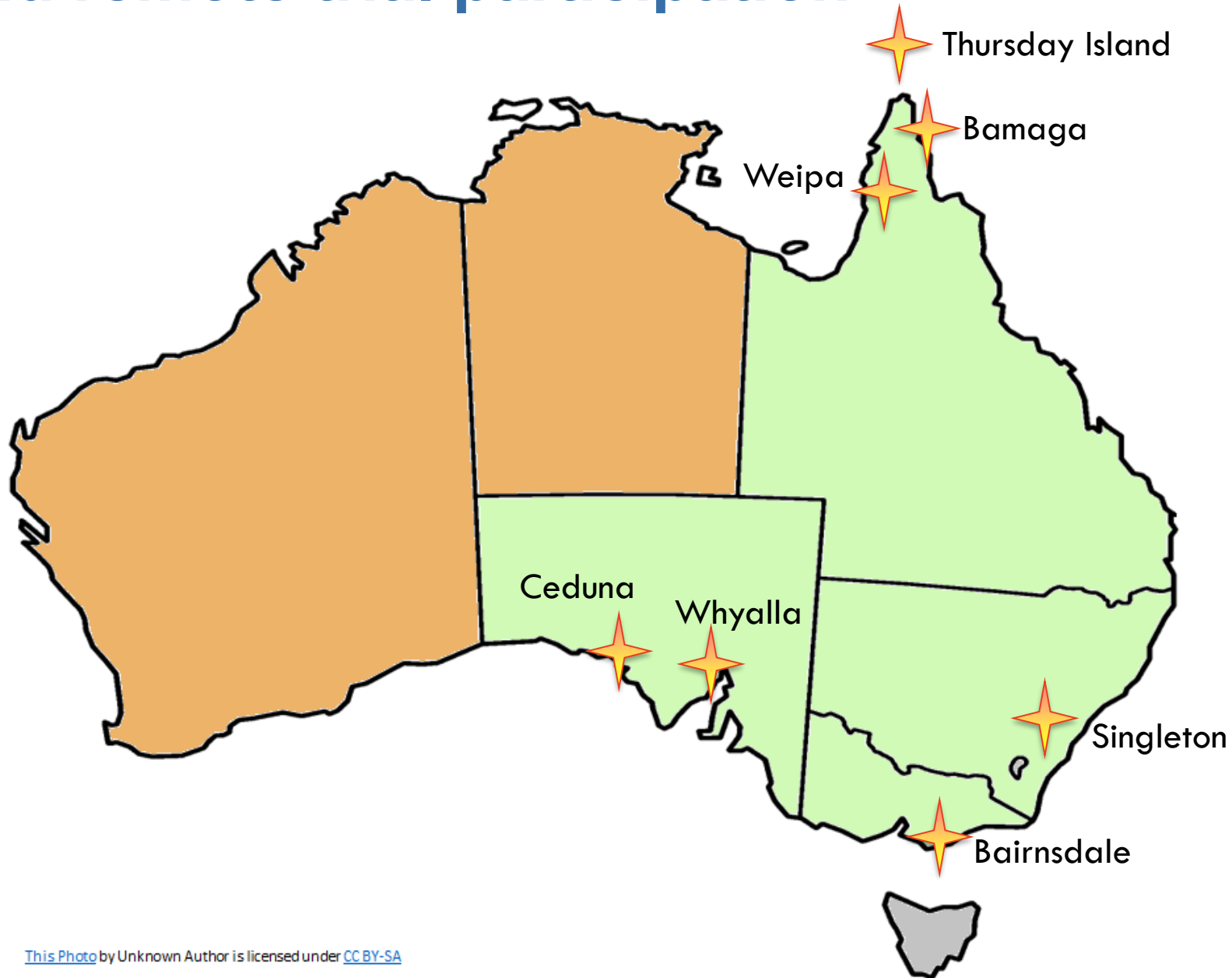
Participating dialysis centre characteristics

*92 clusters [centres]
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^ >10 pts per centre

	SWIFT (n=92)* May 2021–Jul 2025		ANZDATA (n=236)^ Dec 2024		Difference (SWIFT- ANZDATA)	p-value
Characteristic	n	(%)	n	(%)		
State: NSW	20	22	82	36	-14%	0.014
QLD	25	27	65	27	0%	1.00
VIC	31	34	67	28	+6%	0.28
SA	16	17	22	9	+8%	0.03
Rural	42	46	126	46	0%	1.00
Metropolitan	50	54	145	54	0%	1.00
Size (large >100 dx patients)	5	5	8	3	+2%	0.43
Public	56	61	233	86	-25%	<0.001
Private	36	39	38	14	+25%	<0.001

First RCT; ATP supported

Rural and remote trial participation



Discussion & Conclusions

- The SWIFT is the largest haemodialysis trial in Australia, with participants nationally representative for age, sex, First Nations, comorbid conditions
- Ethnicity
- *If only we had more time & money (5 years, 2x no-cost extensions, \$1.7M)*
- These data demonstrate pragmatic registry-based trials, with deliberate planning can maximise diversity in participant recruitment
- Generalisability
- Trial follow-up will be completed in July 2026

Acknowledgements & Contact details

- Patients participating in the trial
- The SWIFT and ANZDATA Investigator team members, CTC operations staff
- Nursing and medical staff supporting recruitment and trial conduct
- Funders: NHMRC, Kidney Health Australia, University of Sydney

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