AUSTRALIAN DIABETES
CLINICAL TRIALS NETWORK

ADCTN Trial Submission Checklist

This checklist is designed to guide investigators submitting clinical trial protocols for review by the Australian Diabetes Clinical Trials Network (ADCTN). The checklist aligns with the CONSORT 2010 guidelines. Please provide a protocol page reference for each of the checklist items (use n/a if not relevant to the clinical trial).

Trial Title:
Lead Investigator:
Submission for (please select one option):

- ☐ Expert review with feedback
- ☐ Formal endorsement (includes expert review with feedback)

Section/Topic	Item No.	Checklist Item	Reported on Page No. (include relevant comments)
Title and Summary	1a	Trial title clearly identifies the study as a clinical trial.	
	1b	Structured summary includes study design, objectives, methods, key outcomes, and anticipated impact.	
Background and Rationale	2a	Clear scientific background, including justification for the study and how it addresses a clinical need or research gap.	
	2b	Statement on how the trial aligns with current best practices and clinical guidelines.	
	2c	Discussion of how lived experience perspectives influenced the study design.	
Study Objectives and Outcomes	3a	Clearly defined objectives or hypothesis	
	3b	Pre-specified primary and secondary outcome measures, including how and when they will be assessed.	
	3c	Consideration of patient-reported outcomes where applicable.	
Trial Design and Methodology	4a	Description of trial design (e.g., parallel, factorial, crossover), including allocation ratio.	
	4b	Any planned adaptive trial features (if applicable).	
	4c	Clear eligibility criteria for participants.	
	4d	Settings and locations where participants will be recruited.	
	4e	Settings and locations where data will be collected.	

Section/Topic	Item No.	Checklist Item	Reported on Page No. (include relevant comments)
	4f	Plan for inclusion of diverse populations, including First Nations and CALD (Culturally and Linguistically Diverse) communities.	
	4g	Discussion of potential recruitment challenges and mitigation strategies.	
Sample Size and Statistical Considerations	5a	Sample size justification, including power calculations.	
	5b	Consideration of subgroup analyses based on demographics or disease characteristics.	
	5c	Strategies for handling missing data and dropouts.	
	5d	Plan for interim analysis and stopping guidelines (if applicable).	
	5e	Was a biostatistician involved in the design of the study/protocol (if yes, please specify details including unit/team)	
Intervention and Comparators	6a	Detailed description of intervention(s) and comparator(s).	
	6b	Information on how and when interventions will be administered.	
	6c	If a lifestyle or behavioural intervention, details on implementation and adherence tracking.	
Randomisation and Blinding	7a	Description of randomisation method used.	
	7b	Allocation concealment mechanism and who is responsible for implementing it.	
	7c	Blinding procedures (if applicable), including who is blinded (e.g. participants, care providers, outcome assessors) and how.	
Ethical and Regulatory Considerations	8a	Statement on ethics approval (or plans for submission).	
	8b	Informed consent process, including consideration for low-literacy participants.	
	8c	Plan for ensuring cultural safety and respect for First Nations participants.	
	8d	Risk-benefit assessment and mitigation strategies.	
Feasibility and Recruitment Plan	9a	Estimated participant recruitment timeline and feasibility justification.	
	9b	Planned recruitment strategies (e.g., community outreach, clinician referrals, digital recruitment).	
	9c	Contingency plan for slow recruitment.	
	9d	Strategies to ensure trial completion (e.g., participant retention, incentives).	
Budgeting and Funding	10a	Itemised budget with justification.	
	10b	Funding sources identified and confirmed (if applicable).	
	10c	Consideration of trial sustainability beyond initial funding.	
Data Management and Analysis	11a	Plan for data collection, storage, and security.	
	11b	Compliance with privacy laws and ethical data sharing practices.	
	11c	Statistical analysis plan, including how primary and secondary outcomes will be assessed.	
	11d	Strategy for making de-identified data publicly available where appropriate.	

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Knowledge Translation and Potential Impact	12a	How will study results be disseminated (e.g., publications, policy briefs, community reports)?	
	12b	Plans for engagement with stakeholders, clinicians, policymakers, and the diabetes community.	
	12c	Potential impact on clinical practice, health outcomes, or diabetes care.	
	12d	Statement on how the findings may improve lives of people living with diabetes (e.g. access to care, reduce health disparities).	
Additional information or comments (optional)	13	Please include comments if applicable.	

Submission Instructions:

- Complete this checklist and submit it along with your protocol.
- Email to ADCTN-info@unimelb.edu.au
- Submission deadline: [Insert Date]