Type 2 diabetes remission in Australian primary care: Protocol for an implementation study of the DiRECT-Aus trial

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Background and objective
Type 2 diabetes is one of the most common chronic conditions managed in Australian general practice. DiRECT-Aus is replicating the UK Diabetes Remission Clinical Trial (DiRECT) in general practices across NSW. The aim of the study will be to explore the implementation of DiRECT-Aus to inform future scale-up and sustainability.

Methods
This is a cross-sectional qualitative study using semi-structured interviews to explore the experiences of patients, clinicians and stakeholders in the DiRECT-Aus trial. The Consolidated Framework for Implementation Research (CFIR) will be used to guide the exploration of the implementation factors, and the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework to report on implementation outcomes. Interviews will be conducted with patients and key stakeholders. Initial coding will be based on the CFIR, with inductive coding used to develop the themes.

Discussion
This implementation study will identify factors to be considered and addressed so that future scale-up and national delivery will be equitable and sustainable.

THE UK DIABETES REMISSION CLINICAL TRIAL (DIRECT) showed remission of type 2 diabetes at 12 months after trial commencement in nearly half (n = 68; 46%) of participants,[1] with a third (n = 53; 36%) maintaining remission at two years.[2] Remission was defined as not requiring diabetes medications for two months and glycated haemoglobin (HbA1c) of <48 mmol/mol (<6.5%).[1,2] DiRECT was set in the UK within community general practice and involved a very low energy diet (VLED), intensively monitored by a dietitian alongside the usual primary care team. After the initial 12 weeks of the VLED, participants progressed to a usual diet and were monitored for 12 months.[1]

Little is known about the transferability of this intervention into Australian primary care settings. This knowledge is important to understand whether DiRECT is feasible, actionable and acceptable to patients, clinicians and primary care settings given the original trial was developed overseas. As such, Diabetes NSW & ACT, in partnership with five Australian Primary Health Networks (PHNs), are conducting DiRECT-Aus: An efficacy trial (ACTRN12620001129976) replicating DiRECT UK led by researchers at the University of Sydney. Participating PHNs include: Sydney North PHN, South Western Sydney PHN, Western Sydney PHN, Western NSW PHN and North Coast PHN.

Our team has been separately commissioned by Diabetes NSW & ACT to lead an implementation study to focus on the scale-up and sustainability potential of DiRECT-Aus within the existing primary care system. The implementation study aim is to explore the implementation of the DiRECT-Aus intervention in Australian general practice to inform future scale-up and sustainability.

The objectives of this study are to:

- explore patient experiences of DiRECT-Aus, including perspectives on what factors affected outcomes
- identify the perceived barriers and facilitators for scaling up DiRECT-Aus, including acceptability, reach, adoption, fidelity and sustainability.

Specific questions have been developed with the input of Diabetes NSW & ACT to explore these topics, including dietitian and key stakeholder experiences, cost, telehealth and delivery mode.

Methods

Study design

This is a cross-sectional qualitative study of patients, clinicians and stakeholders in the DiRECT-Aus trial. The Consolidated Framework for Implementation Research (CFIR) will be used to guide the exploration of the implementation factors[3] and the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework to guide our implementation outcomes.[4]

CFIR is commonly used to inform the development and/or analysis of studies that focus on implementation

questions about new innovations in healthcare.[5–7] CFIR was developed in 2009 through a process that linked 19 existing implementation theories available at the time.[3] The benefit of CFIR is that it helps the research to consider factors across different levels of the system (eg external to the intervention, within the setting, within the participants) that may be influencing the implementation of an innovation. The five domains of CFIR (Box 1) can be useful to better understand how and why different elements are influencing implementation, which may then allow consideration of solutions for implementation problems.[3]

Our team includes experienced primary care researchers (ES, JA, LB, NG, TH, CW) with clinical expertise in general practice (ES) and dietetics (LB, TLC). No one in this team has been involved in either of the Australian or UK trials.

Study setting

DiRECT-Aus is currently underway in 25 general practices across NSW.

Box 1. The Consolidated Framework for Implementation Research: The five domains and potential relevance to DiRECT-Aus

- Outer context – the economic, political and social contexts relevant to the intervention, including Medicare Benefits Schedule billing, Primary Health Networks (PHNs) and other policies
- Inner setting – the general practice setting, including communication, intra-practice networks and culture
- Intervention characteristics – all factors relating to implementation, including the very low energy diet, the role of the dietitian, communication in the practice and appointments
- Individual characteristics – features of the individuals involved in the intervention, including GPs, practice nurses, dietitians, patients, and Diabetes NSW & ACT and PHN staff
- Process – elements that are related to the implementation process including planning, logistics, and change agents
- Each of these five domains have multiple constructs that make up the domain. A full description of these can be found online (https://cfirguide.org/constructs)

Intervention

DiRECT-Aus is a 12-month structured weight management program. It includes: VLED meal replacements (eg shakes and bars), support from a dietitian (fortnightly for 18 weeks, then monthly), group consultations and ongoing monitoring by the regular GP. The effectiveness of DiRECT-Aus in inducing type 2 diabetes remission will be reported by the clinical trial team from the University of Sydney.

To be eligible, GPs must have data linkage capabilities within NSW, capacity to recruit eligible patients, a room for the dietitian, a GP willing to work with the dietitian and a nominated 'practice champion'. Adults aged 20–65 years with type 2 diabetes and a body mass index >27 kg/m^2 are eligible for recruitment by their GPs. The following exclusion criteria apply: current insulin use, recent routine HbA1c ≥10% (≥86 mmol/mol) or <6% (<42 mmol/mol), weight loss of >5 kg within the past six months, recent estimated glomerular filtration rate <45 ml/min/1.73^2, substance abuse, known cancer, myocardial infarction within previous six months, learning difficulties, current treatment with anti-obesity drugs, diagnosis of eating disorder or purging, allergy to Optifast or any of its ingredients, pregnant/considering pregnancy, unstable mental illness, current participation in another clinical research trial, and severe or unstable heart failure.

Ethical issues

Ethics approval gained from the Monash University Human Research Ethics Committee (31243). We do not anticipate that the interviews will cause any distress to patients and providers, but we will provide contact details should they require extra support or have complaints.

Outcomes

Implementation outcomes, informed by RE-AIM,[4] include:

- reach – reasons for patients, practices and clinicians taking part in DiRECT-Aus; why some patients discontinued the program; PHN perspective on which practices chose to be involved
- acceptability – to patients, clinicians, practice staff and PHN staff
- implementation – adoption within each practice and within the PHN processes
- maintenance – sustainability as perceived by practice staff, clinicians and PHN staff.

We will seek to identify any effects the COVID-19 pandemic had on DiRECT-Aus implementation and consider how it may affect future scale-up and sustainability.

Participants

We anticipate interviewing approximately 20 patients, including approximately five patients who have dropped out from the program. We will seek to include a diverse range of patients: gender, age, cultural background, intervention stage, current weight loss and intervention site.

We will also interview approximately 20 key stakeholders from the general practices, dietitians, PHNs and Diabetes NSW & ACT. We will ensure these interviewees are recruited from both urban and rural settings.

Recruitment

Trial participants will be invited to participate in an interview via email from the Diabetes NSW & ACT Project Officer. Diabetes NSW & ACT will also email an invitation to participating GPs to forward to other patients who declined to participate. The DiRECT-Aus trial contact person for each participating PHN will also be invited. The research team will not have direct access to any identifying information.

Once recruited, participants will be emailed a link to an online survey requesting:

- confirmation of consent to be contacted by the research team to organise an interview
- basic demographic details: age range, gender, place of residence, cultural background, self-reported income status
- confirmation of their status in the DiRECT-Aus trial both patients (ie completed or withdrawn) and providers.

Patients only will also be asked:

- information about weight loss during the program (yes, no, prefer not to answer)

- if any sessions were conducted by telehealth (phone or video)
- if they attended any group sessions during the program.

These questions will allow us to purposefully sample a diverse range of participants, seeking maximum variation in self-reported low-income, gender, age, telehealth use, group participation and self-reported weight loss.

Patients will be offered a $50 gift card in recognition of their time, and non-salaried stakeholder participants will be offered $150 for their time, in line with published reports on honorariums in primary care.[8]

Consent

Participants will be asked to provide a scanned, signed consent form. For those who are unable to do this, verbal consent will be recorded at the start of the interview.

Data collection methods

All interviews will be conducted either over the phone or Zoom (secure teleconference platform) depending on participant preference. The CFIR interview guides will inform the interviews, tailored for each participant group (Appendix 1; available online only).[3]

Patient interviews

The focus will be on feedback about the acceptability of the intervention. Interviews will focus on the acceptability of the intervention, the patients' relationships with their dietitians and GPs, suggested improvements, telehealth versus face to face, group versus individual sessions, and any unintended consequences.

Dietitian interviews

The focus will be on the feasibility of the intervention in daily practice, suggested improvements and sustainability of the intervention.

General practice champion and clinician interviews

The focus will be on the feasibility of the intervention in daily practice, including the embedded dietitian, suggested improvements and sustainability of the intervention.

PHN interviews

The research team will focus on the CFIR 'outer setting'[3] to better understand how the broader policy environment has influenced the implementation process.

The research team will continue the interviews until there is a clear understanding of a range of patient and clinician perspectives of the DiRECT-Aus program.[9] The aim of this project is to develop a rich and full understanding of the implementation process of DiRECT-Aus.[9] As the interviews progress, the team of interviewers will meet to discuss and compare participant insights and reflections. Interviews will cease when these discussions result in a joint understanding of DiRECT-Aus's implementation and a sense of its potential sustainability and scalability.

Data analysis

The interview guides will be based on CFIR, and we will organise the initial codes on the basis of the overall structure of CFIR (outer context, inner setting, intervention characteristics, individual characteristics, process). Audio files of interviews will be de-identified and professionally transcribed. Inductive thematic coding will be used to ensure findings are grounded in the data.[10] Our research approach is guided by the post-positivist paradigm of critical realism, which recognises the mind-independent nature of reality and can be useful for research questions that consider why and how things occur.[11]

Interview transcripts will be coded by a team of four researchers with varying experience across general practice, dietetics and health promotion (ES, NG, TLC, MB). JA will oversee the coding process as she has had recent experience with the CFIR framework. At least half of the interviews will be coded by two researchers, and each researcher will code interviews from all four participant groups. Analyses will be conducted using NVivo (version 10 or higher). Summarised findings and early interpretations will be discussed with the research team in regular small team meetings. The authors will also meet on a minimum of two occasions with the entire investigator team to finalise the themes from the data.

Discussion

DiRECT has the potential to herald a paradigm shift in the way type 2 diabetes is managed in Australian general practice. The promising clinical results from the UK trial show the potential for patients with type 2 diabetes to enter remission.

This implementation study is important to ensure DiRECT is feasible for delivery within Australian primary care settings and to identify any systemic changes that may improve access for all Australians to this potentially remarkable treatment.

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Competing interests: ES and LB are supported by National Health and Medical Research Council Investigator Grants. LB is a member of the *Australian Journal of General Practice* Editorial Advisory Committee. TLC reports personal fees from Peter MacCallum Cancer Centre, outside the submitted work.

Funding: This implementation study is supported by funding from Diabetes NSW & ACT, who were involved in formulating the research questions and interview guides and reviewed the protocol. They will not be involved in data collection or analyses.

Provenance and peer review: Not commissioned, externally peer reviewed.

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Acknowledgements

The authors would like to thank KG and NS for their input into the specific research questions and overview of the interview guides.

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