

Expression of Interest – DiRECT-Aus

Sydney North Health Network is seeking Expressions of Interest from five general practices in the Northern Sydney PHN region to take part in a translational research study to demonstrate remission in Type 2 diabetes.

Summary

DiRECT-Aus is a translational research study looking to replicate the active arm of DiRECT-UK, the Diabetes Remission Clinical Trial. [DiRECT UK demonstrated](#) that type 2 diabetes remission can be achieved by delivering a structured weight management program within the general practice setting. DiRECT-Aus is seeking to demonstrate the same, or better outcomes, within the Australian setting in general practices throughout NSW.

We are currently seeking interest from five general practices within the Northern Sydney PHN region to take part in DiRECT-Aus.

Aim

DiRECT-Aus is seeking to demonstrate that type 2 diabetes can be reversed through the delivery of a structured weight management program in a primary care setting in Australia.

General practice role

Each participating general practice will be provided with resources and training to support the practice and GPs within the practice to deliver DiRECT-Aus to eligible participants. The role of each practice is outlined below:

- You will be supported to recruit 10 eligible participants to take part in DiRECT-Aus.
- The DiRECT-Aus structured weight management program will be available to eligible participants within your general practice. The structured weight management program consists of 20 dietitian visits, a total diet replacement and stepped food reintroduction and patient education delivered via individual and group consults. Participants will receive Optifast meal replacement bars, shakes and soups, free of charge.
- A specialty trained dietitian will deliver consultations to participants at your general practice.
- Your GPs will receive specialty training on the DiRECT-Aus protocol from the research team with the University of Sydney.

What is needed from you?

As a participating GP Practice, you are asked to provide:

- A consulting room for the dietitian to use on a fortnightly and then monthly basis to see participants in the study. The dietitian may also need access to the patient's medical record to review past medical history, blood test results and make patient notes.
- The support of your practice staff, to assist with booking patients into screening consults with their GP and dietitian visits.
- Space within your waiting room to display brochures and posters, if space permits.
- A safe and secure place within the practice for the dietitian to leave the study file.
- GP training, provided by your PHN, Diabetes NSW & ACT and the research team with the University of Sydney.

- You may choose to nominate a project champion within your GP Practice. The project champion can be your liaison between the research team and your GP practice and the person to answer patient questions about the study.
- 10 eligible patients to take part. We estimate it will take approximately 100 eligible participants to recruit 10.
- Register for the Lumos - GP Data Linkage program which brings together data from a number of health agencies in NSW and general practice.

Eligibility criteria for patients

- Men and women age 20-65 years
- Type 2 diabetes for 0-6 years
- Body mass index >27 kg/m

Time frame

Patient recruitment will commence from **1 August 2020 and close on 28 February 2021**. The active intervention period is 12 months.

How this trial may lead to improved health outcomes

Type 2 diabetes has long been considered a chronic, progressive condition. But new evidence is emerging that this might not always be the case. DiRECT-UK showed that type 2 diabetes can be put into remission through substantial weight loss in a program delivered within primary care. It has been known that bariatric surgery can achieve diabetes remission in some people. But bariatric surgery is not available to all people living with type 2 diabetes and comes with the risk of complications and long-term micronutrient deficiencies. A structured weight management program delivered within a patient's own GP practice poses much less risk and is more universally available for patients living with type 2 diabetes.

Through your general practice's participation in this study, you will help to find new ways to treat type 2 diabetes in Australia and potentially change the model of care for people living with type 2 diabetes. You will provide patients with hope and motivation and new tools to treat type 2 diabetes. This study may support improvements in the health of the patients taking part, the long-term health outcomes for people living with diabetes, and the local health economy.

Your GPs will receive expert training from the University of Sydney in providing the structured weight management program and you will have access to the study dietitian. You will be supported through our team to decrease the administrative burden on your practice and general practitioners.

Study collaborators

In addition to the general practices taking part, the study is run through a partnership between:

- Sydney North Primary Health Network
- South Western Sydney Primary Health Network
- Western Sydney Primary Health Network
- North Coast Primary Health Network
- Western NSW Primary Health Network
- Diabetes NSW & ACT
- The Boden Collaboration with the University of Sydney

How can my practice get involved?

If your general practice is interested in taking part, please complete the form below and return to:

*Sandra Collins - Primary Care Advancement Coordinator - scollins@snhn.org.au
and/ or*

Deb Pallavicini – Primary Care Advancement Manager - dpallavicini@snhn.org.au

If you would like more information, please contact DiRECT-Aus at direct@diabetesnsw.com.au, or contact Sandra Collins or Deb Pallavicini using the email addresses above.

Practice name: _____

Address: _____

Contact phone: _____ **Email:** _____

Nominated contact person: _____

Contact phone: _____ **Email:** _____

Practice Champion: Your practice may choose to nominate a practice champion. This person can be provided with additional details about the study, attend the GP practice webinar for further training, may be available to answer patient questions within your practice and may contact the research team for support. The practice champion will help to facilitate patient recruitment and enrolment into the study.

Practice champion name: _____

Contact phone: _____ **Email:** _____

A member from the research team will follow up your registration of interest to provide you with further details and forms. Please indicate a best contact date: _____ and select the best time.

Morning (9:00am – 12:00pm)	Afternoon (12:00pm – 3:00pm)	Evening (3:00pm – 5:00pm)