DIRECT AUSTRALIA GP PRACTICE INFORMATION PACK





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This information is only current as of the time of printing. [Revised May 18, 2020 12:20 pm]

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What is diabetes remission? Remission of type 2 diabetes is an HbA1c of 6.5%, 48 mmol/mol, or lower while off diabetes medication for at least the preceding two months.





What is DiRECT?

Thank you for participating in DiRECT-Australia (DiRECT-Aus), which is a study being run through a partnership between the University of Sydney, Diabetes NSW & ACT and five primary health networks, including Sydney North PHN, South Western Sydney PHN, Western Sydney PHN, Western NSW PHN and North Coast PHN.

DiRECT-Aus is based on DiRECT UK, a clinical trial that demonstrated two-thirds of participants living with type 2 diabetes for less than six years could put their diabetes into remission through substantial weight loss.

How is weight loss achieved?

Participants of DiRECT-Aus will be entered into a structured weight management program. As part of the program they will receive meal replacement shakes and move through various diet phases, from total diet replacement (shakes) to a healthy, caloriecontrolled diet.

Along the way, they will be supported by individual and group consultations with a dietitian, who will employ behaviour change strategies to help support and maintain patients' healthy lifestyle choices. These consultations are designed to help with weight loss and prevent weight regain.

How long is the trial? The trial is run over one year.

Who conducts consultations for the trial? Study dietitians, recruited by the PHNs and Diabetes NSW & ACT, will deliver the structured weight management program. The study dietitians will have access to a consult room inside your practice and to your practice management software, to be able to provide your GPs with updates on patient status.

HOW ARE GP PRACTICES INVOLVED?

While the trial team will do as much as possible to reduce any burden on your practice resources, there are a few areas where we will need your support:

- 1. Recruit patients
- 2. Answer questions
- 3. Provide consult room for the study dietitian, to be agreed
- 4. Book patients in for trialrelated consultations

1. RECRUIT PATIENTS

- Each practice will recruit at least ten participants to take part in the study.
- Practices will help to identify patients meeting the selection criteria by reviewing your patient lists. We estimate that it may take as many as 100 eligible patients to achieve 10 enrolments.
- The trial team will send a letter to these patients on behalf of your practice, inviting patients to seek out more information.
- Patient information packs, and posters may be located in your waiting and consult rooms,

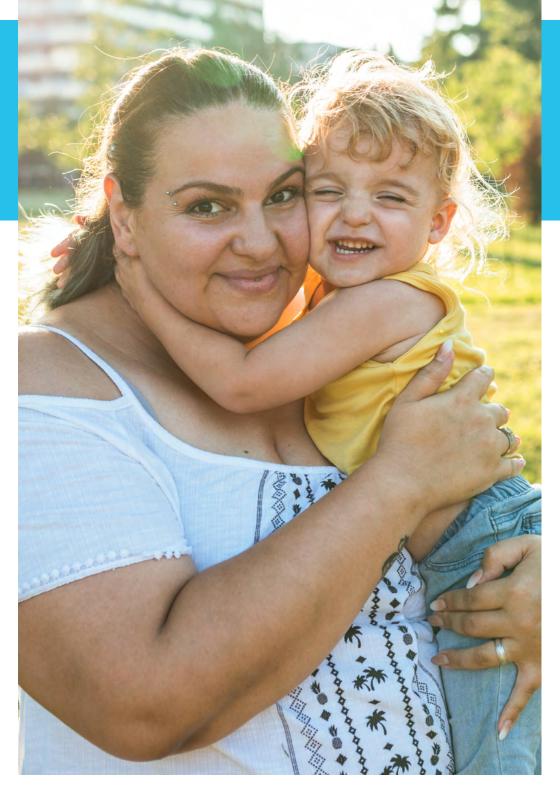
directing potential participants to trial information.

2. ANSWER QUESTIONS

- It may be helpful to nominate a practice champion - or someone from your practice who will serve as the point person for all trial related enquiries. Patients will be directed to the website, email address or 1300 234 736 number for additional information. This may be the practice nurse, GP or another person in the practice.
- We ask that practices record the name and contact details of patients expressing interest in the study in a shared document. This will be discussed in the training webinar.

3. PROVIDE A ROOM

- Most of the trial consults will take place in your practice.
- The study dietitian will use a consult room to see patients in the trial. The dietitian will need a room for about 10-12 hours for the first two weeks. This will decrease to 6 hours a fortnight and will decrease further as the trial progresses.



- They will also need to have access to your practice management software to record patient notes.
- If you have a space large enough to hold group consultations, the dietitian may use this room to run group consultations. Group consultations will be held every month. Each participant is invited to attend the group consultations with a support person. That means that up to 21 people, including the dietitian, may attend the aroup sessions. There must be enough room to comfortably hold 21 people. If the practice does not have a space large enough to support group consultations, an alternative location will be secured by trial staff.

4. BOOK PATIENTS IN

Reception staff will assist potential participants book in for consultations. There are several types of consultations that each participant will need as part of the trial:

- Screening consultation this is a consultation with the patient's GP to help determine eligibility to take part in the trial
- Study dietitian consultation this is a consultation with the study dietitian.
- Group consultation the study dietitian will lead participants in group consultations as well as individual consultations. The group consultations may take place in the GP practice or at another location, depending on room availability.
- Routine care the GPs will continue to provide routine diabetes care to their patients who are taking part in the trial.



BENEFITS

Patients enrolling in DiRECT-Aus will have the potential to put their diabetes into remission. To support this, they will have access to:

- a structured weight management program with a focus on behaviour change to promote and support healthy lifestyle modifications
- a free supply of low energy diet (VLED) meal replacement shakes and bars to assist in significant weight loss
- support from a dietitian to assist with VLED diet and food reintroduction plus meal planning for ongoing weight maintenance
- peer support through group consultations
- ongoing monitoring to prevent weight regain

WHY GET INVOLVED?

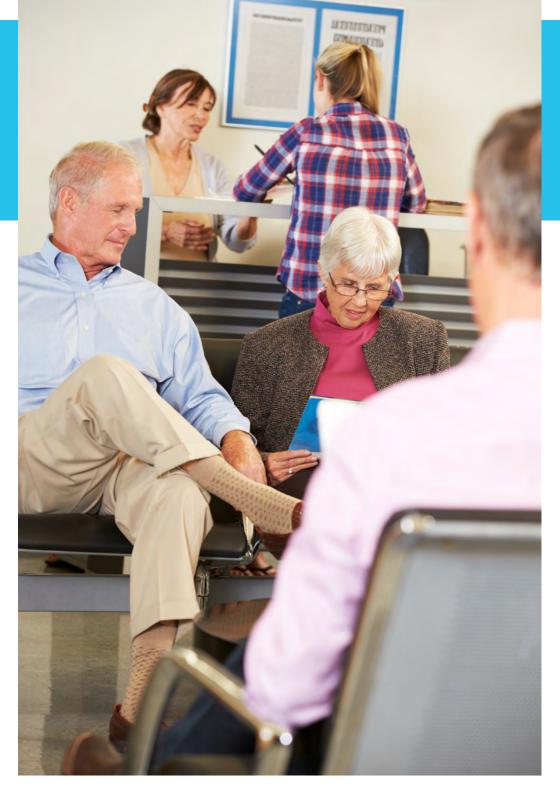
You will be a part of a clinical study that has the potential to change the way that diabetes care is delivered in Australia. Not only that, but you can change the health outcomes for your patients and reduce their long-term risk of diabetes complications. You have the potential to reduce the financial impact of diabetes on the health care system in your PHN.

PRACTICE BENEFITS

As a practice, you will be leading the way in type 2 diabetes remission. Your practice will have access to a model of care that may potentially result in type 2 diabetes remission for eligible patients. Your GPs will be expertly trained in delivering a diabetes remission program and VLED diet by the research team with the University of Sydney. You will have access to the study dietitian. who will work collaboratively with your GPs. You will take part in this exciting research that has the potential to change the future of diabetes care.

HOW DO WE SUPPORT YOU?

Your staff and GPs will be invited to attend a webinar by the University of Sydney research team and Diabetes NSW & ACT. Your practice will receive, collateral, detailed trial information and logistical support. You can contact us at 1300 234 736 or direct@diabetesnsw.com.au.









DIRECT-Australia is supported by funding from the Sydney North Health Network, Diabetes NSW & ACT, Western Sydney Primary Health Network, South Western Sydney Primary Health Network, North Coast Primary Health Network and Western NSW Primary Health Network.

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