

# **DiRECT AUSTRALIA** GENERAL PRACTITIONER INFORMATION PACK



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A healthcare professional, a man with dark hair wearing a light blue button-down shirt and a blue lanyard, is sitting at a desk. He is holding a tablet and looking towards a pregnant woman with blonde hair wearing a black and white striped shirt. They are in a clinical setting with a printer, a computer monitor, and a window in the background. The scene is framed by blue vertical bars on the left and right sides.

## 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?

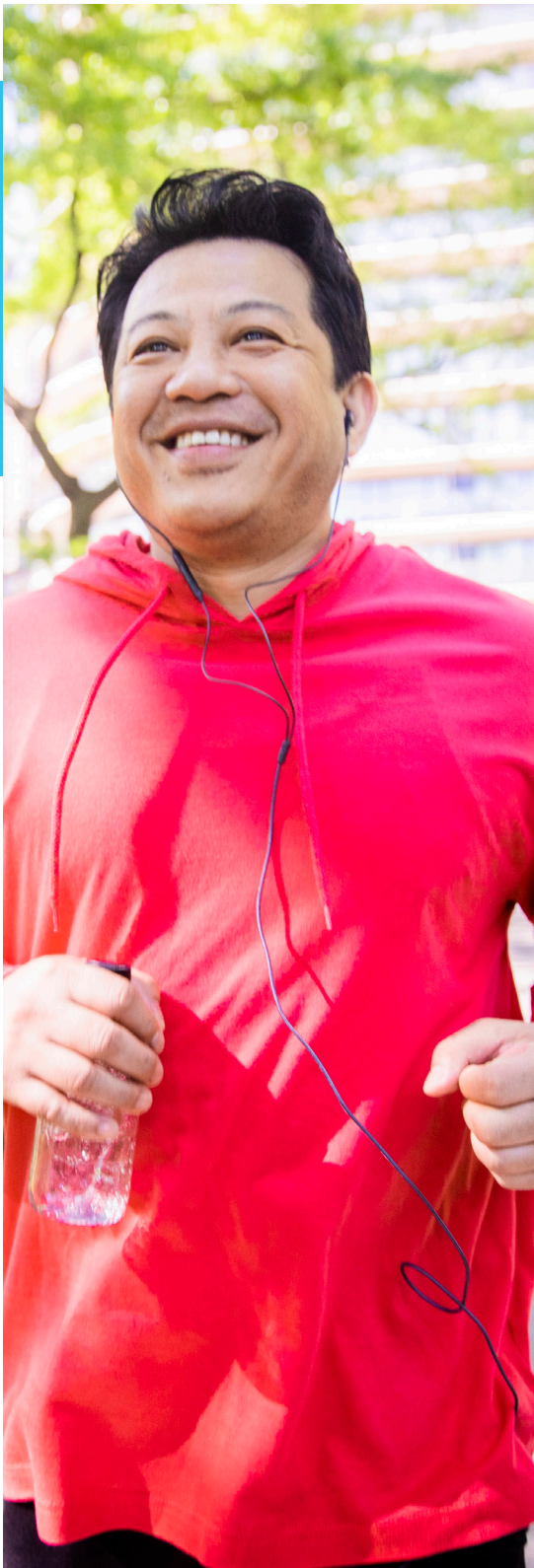
Thank you for taking part in DiRECT-Australia (DiRECT-Aus) as a GP. Your practice is participating in this translational study seeking to demonstrate remission of type 2 diabetes through substantial weight loss. DiRECT-Aus is replicating the active arm of DiRECT UK, which demonstrated that type 2 diabetes remission was achieved in 66% of participants with weight loss greater than 10kg.

The trial is being run through a partnership between 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. The trial protocol and evaluation are being conducted by the University of Sydney.

## How is diabetes remission achieved?

DiRECT UK showed that people living with type 2 diabetes for less than six years can put diabetes into remission through weight loss in a program delivered in primary care.

Results from DiRECT demonstrated that patients could lose enough weight through a structured weight management program delivered at their own doctor's office to achieve diabetes remission. DiRECT-Aus is seeking to replicate the same results but in the primary care in Australia.



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 supply of very low energy diet (VLED) meal replacement shakes and bars to assist in significant weight loss
- support from a dietitian to assist with the diet phases plus meal planning and support for ongoing weight maintenance
- peer support through group consultations
- ongoing monitoring and evaluation to prevent weight regain

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## BENEFITS OF TAKING PART

### Why get involved?

You can potentially change the health outcomes for your patients and reduce their long-term risk of diabetes complications. By entering patients in this study, you will be providing them with hope and motivation to put their diabetes into remission.

You will also be a part of a clinical study that has the potential to change the way diabetes care is delivered in Australia and therefore reduce the financial impact of diabetes on the health care system.

While not everyone will be able to achieve diabetes remission, the benefits of participating go beyond diabetes remission. Your patients may be able to lose weight, improve food and lifestyle choices, improve blood glucose levels, reduce cholesterol and blood pressure and reduce diabetes medication.

### How do we support you?

As a GP participating in DiRECT-Aus, you will be leading the way in type 2 diabetes remission. You will have access to a diabetes remission program, delivered in your own practice. You will receive education and support through the research team with the University of Sydney and Diabetes NSW & ACT.

If you would like to access additional posters, info packs or brochures, you can download these via the website [diabetesnsw.com.au/directaus](http://diabetesnsw.com.au/directaus) or you can request additional copies via [direct@diabetesnsw.com.au](mailto:direct@diabetesnsw.com.au) or 1300 234 736.



A photograph of a woman with dark hair pulled back, wearing a white top, smiling warmly. She is holding a young child with blonde hair, who is also smiling and looking towards the camera. The background is a bright, outdoor setting with greenery and a building, suggesting a park or residential area. The image is framed by blue vertical bars on the left and right sides.

## Eligibility

As part of the study, you, the GP, play an important role in determining whether patients are eligible to take part. You may review your patient's eligibility based on the following inclusion and exclusion criteria.

### INCLUSION CRITERIA

- men and women age 20-65 years
- type 2 diabetes for 0-6 years, based on Australian diagnostic criteria
- HbA1c  $\geq$  48 mmol/mol ( $\geq$  6.5%) at study entry
- Or, if HbA1c 6% - 6.5%, subjects needs to be on glucose lowering medication
- BMI  $>$ 27 kg/m<sup>2</sup>





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## PATIENT CRITERIA

### EXCLUSION CRITERIA

- current insulin use
- recent routine HbA1c  $\geq 10\%$  or  $< 6\%$
- weight loss of  $> 5\text{kg}$  within the last 6 months
- recent eGFR  $< 30\text{ml/min}/1.73^2$
- substance abuse
- known cancer
- myocardial infarction within previous 6 months
- learning difficulties
- current treatment with anti-obesity drugs
- diagnosed with eating disorder or purging
- allergy to Optifast or any of its ingredients
- pregnant/considering pregnancy
- patients with unstable mental illness
- people currently participating in another clinical research trial
- severe or unstable heart failure defined as equivalent to the New York Heart Association (NYHA):
  - Grade 3 – marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation or breathlessness and
  - Grade 4 – unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

A photograph of a person's hands holding a blue lid over a white shaker cup in a kitchen. The background shows a kitchen counter with various items, including a large white container and a window. The scene is brightly lit, suggesting a clean and organized environment.

## How is weight loss achieved?

Participants of DiRECT-Aus will be entered into a 12-month structured weight management program. As part of the program they will receive meal replacement shakes and will move through various diet phases, from total diet replacement (shakes) to a healthy, calorie-controlled 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.

## TOTAL DIET REPLACEMENT (TDR) | 1-12 WEEKS



The study dietitian will provide participants with enough meal replacement shakes to replace three meals every day for at least 12 weeks. Participants will see the study dietitian fortnightly plus group consultations.

## FOOD REINTRODUCTION (FR) | 13-18 WEEKS



Participants will gradually add meals, one at a time, until they are eating three calorie-controlled meals each day. The study dietitian will assist in reintroducing food, to prevent weight regain by prescribing a calorie-controlled diet. Participants will continue to have group consultations and fortnightly visits with the dietitian.

## WEIGHT MAINTENANCE | 19-52 WEEKS




During weight maintenance, participants will continue to eat three calorie-controlled meals each day and will see the dietitian monthly.

## RESCUE PACKAGE | ANYTIME FROM WEEK 19-52 WEEKS



If participants begin to regain weight, the dietitian will provide participants with meal replacement shakes, either to replace one or all meals each day, depending on weight gain. Participants will also have more frequent reviews with the dietitian.





## What will be required of your GP practice?

Whilst 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** – we will use your practice lists to identify and reach out to eligible patients.
2. **Answer questions** – a point-person at your practice may be available to answer study-related questions.
3. **Provide consult room for study dietitian consultations** – ideally the study dietitian will use a consult room in your practice to hold individual and/or group consultations.
4. **Book patients in for trial-related consultations** – reception staff will book patients into trial-related consultations.





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## GP ROLE

### What role do you, the GP, play?

As the GP, you play an integral role in working with patients taking part in the trial. You will continue to provide routine diabetes care while also ensuring the safety of your patients taking part. You may do this through:

- determining patient's eligibility based on the inclusion and exclusion criteria
- reviewing, and if necessary modifying, patient's medication while taking part in the study
- engaging in ongoing monitoring and support to avoid adverse events
- providing routine medical appointments and blood work, per clinical practice guidelines

A photograph of an elderly woman with short white hair and glasses, wearing a light blue jacket and dark blue jeans, standing in a pharmacy aisle. She is looking at a product on a shelf. She has a large brown leather shoulder bag. The aisle is filled with shelves of various medications and products. The lighting is bright and even.

## Medication guidelines

When participants commence the VLED phase, they will come off their diabetes medication and potentially antihypertensive medication. Antihypertensive medications will be reduced or ceased only if blood pressure is  $<110/60$ . Blood pressure will be monitored by the study dietitian throughout and if it is abnormal ( $<110/60$  or  $>140/90$ ) then they will be referred to you. If the patient is symptomatic at the appointment time, they will be referred to you urgently.



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## CONSULTATIONS

The consultations you deliver as part of DiRECT-Aus are outlined below:

### **SCREENING CONSULTATION**

Patients who are interested in taking part in DiRECT-Aus will make a screening consultation with you to discuss the trial in more detail. At this appointment, their eligibility to take part will be assessed by you, the GP, based on the inclusion and exclusion criteria, found on page 6 and 7 of this booklet.

### **ROUTINE CARE**

Patients taking part in DiRECT-Aus will continue to receive routine diabetes care which includes ordering routine blood work and screening for diabetes complications.

### **GLUCOSE LOWERING MEDICATION**

It is anticipated that all patients that reduce their weight will have better glycaemic control. Their HbA1c will be checked 3 monthly. You may choose to recommence glucose lowering treatment if necessary.



## Who is the Study Dietitian?

Specialty trained dietitians will deliver the diet and lifestyle components of the trial and will work with the research team to collect data. The dietitians will be selected by Diabetes NSW & ACT and the Primary Health Network and will be trained by Diabetes NSW & ACT and Sydney University to deliver the DiRECT-Aus protocol. They will work collaboratively with you, the GP, to ensure your patients' safety and achieve the best possible outcomes. The dietitians will deliver a total of 20 consults across the 12-month intervention period and they will see your patients within your own GP Practice.





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## FAQ'S

**Q: What if a patient complains of dizziness, tiredness, headaches or lack of motivation after starting the total diet replacement phase?**

**A:** Check blood pressure and adjust blood pressure medication, as needed. It's also important to remember that a VLED may lead to feelings of tiredness, headache and lack of motivation, particularly in the first few days of total diet replacement. These symptoms generally improve with time.

**Q: What if a patient complains of hunger after starting total diet replacement.**

**A:** Feeling hungry is normal after starting a VLED. It usually takes a few days up to a week for the body to convert to using ketones for

energy (ketosis). This occurs as a result of the body using fat as a fuel source instead of carbohydrates. Ketosis will help suppress the appetite. To help maintain ketosis, it is essential that the patient's carbohydrate intake is kept to a minimum. Encourage patients to drink plenty of water or allowed fluids and consume the allowed non-starchy vegetables to help manage hunger. Also, encourage patients to speak with the dietitian, who will be able to help and provide suggestions.

**Q: What if a patient complains of diarrhoea, after starting the total diet replacement phase?**

**A:** This may happen for some patients. If it continues for longer than a week, explore options and encourage patients to speak with the

study dietitian. S/he may be able to suggest alternative Optifast products that may be better tolerated.

**Q: What if a patient is experiencing constipation after starting the total diet replacement phase?**

**A:** Going to the toilet less often may happen as patients are consuming less food. Encourage patients to eat plenty of fibre from the allowed non-starchy vegetables and drink plenty of water or other allowed fluids. The study dietitian will be able to provide suggestions to improve constipation.

**Q: What if a patient wants to stop the meal replacement shakes before the end of the total diet replacement phase?**

**A:** Encourage patients to review with the study dietitian. S/he will be able to trouble shoot problems and identify reasons for wanting to stop the total diet replacement phase early. If you identify major concerns, use best practice to assist patients.

**Q: What if a patient is not losing weight as planned?**

**A:** Weight loss will vary from patient to patient. Assess the patient's current routine in line with the protocol and encourage patients to speak to the study dietitian. The dietitian will be able to assess weight loss and address concerns around weight loss.

**Q: What if a patient tells you that they are not following the protocol as prescribed?**

**A:** Following the protocol as prescribed will give patients the best possibility of achieving the desired weight loss and metabolic outcomes. Encourage patients to stick to the protocol and also speak with the study dietitian, who can help explore reasons for not following the protocol and find solutions.

**Q: Are there any other side effects a patient may experience during total diet replacement?**

**A:** Weight loss is a risk factor for cholecystitis and this may occur with a VLED.

While Optifast contains a small amount of fat, to try to prevent this, we also encourage the patients to include 1 teaspoon of olive oil (or vegetable oil, if preferred) per day to stimulate emptying of the gall bladder.

Patients may experience bad breath, due to ketosis. The study dietitian will be able to provide ideas to manage bad breath.

**Q: How long will a patient stay on the total diet replacement?**

**A:** Most patients will stay on the VLED for 12 weeks, but this may be adjusted due to individual circumstances. It is important that the study dietitian move patients from one diet phase to the next.

**Q: What happens if a patient regains weight?**

**A:** It is important that patients see the study dietitian for all of their sessions. The study dietitian will evaluate weight and be able to provide a rescue package, or meal replacement plus further instructions, for patients regaining weight.

**Q: What if a patient is losing weight too quickly?**

**A:** Patients may lose weight quite rapidly after starting the VLED. The study dietitian will be able to assess weight loss and stop the total diet replacement if the BMI drops too low. Encourage patients to attend all of their sessions with the study dietitian. It has been shown that rapid weight loss can improve motivation and studies show that the faster the weight is lost the more durable it is.







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## DETAILED TRIAL INFORMATION

### What is DiRECT?

The diabetes remission clinical study (DiRECT) was conducted in the United Kingdom through funding from Diabetes UK with results published in Lancet in 2017 and 12 month follow up results published in Lancet Diabetes & Endocrinology in 2019. Results from DiRECT UK demonstrated that nearly half (46%) of people with type 2 diabetes (T2DM), diagnosed for less than 6 years, could achieve remission at 12 months through following a structured weight management program. For participants achieving a weight loss of 15kg or more, 86% achieved remission.

It was previously known that bariatric surgery could put diabetes into remission for about 70-80% of patients (Guidone, 2006). The results from DiRECT UK demonstrated that remission of diabetes could also

be achieved through intensive lifestyle interventions in the primary care setting. This not only decreases the burden on the hospital system for costly surgery with long wait times, but it improves access to a diabetes remission program for most people living with diabetes.

### DiRECT-Australia

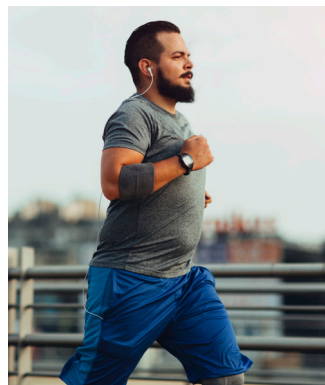
DiRECT-Australia (DiRECT-Aus) is a study designed to replicate the active arm of DiRECT UK and potentially demonstrate the same, or better, results. Results from DiRECT-Aus will add to the existing body of evidence supporting diabetes remission through structured weight management programs. Outcomes may result in change to standard practice for people living with T2DM and the development of a sustainable model of care..



Diabetes remission not only provides hope and motivation for people living with type 2 diabetes, but it may have a significant impact on health care costs in Australia. The total annual cost of diabetes in Australia is estimated at \$14.6 billion (Lee, 2013). Additionally, the complications of diabetes can be quite devastating, including blindness, amputations, heart disease and kidney failure. Putting diabetes into remission can potentially reduce the financial impact of diabetes on the health care system as well as reduce rates of long-term complications.

### PRIMARY OBJECTIVES

1. To determine whether a program designed to achieve remission of T2DM to normal glucose tolerance by substantial weight loss using a very low energy diet can be effectively delivered within the routine primary care setting in Australia where most people with T2DM are managed.
2. Evaluate the attitudes of participants to the VLED program including acceptability, ease of use and perceived value.
3. Develop a sustainable delivery model that can be incorporated into general practice through the Medicare Benefits Schedule.



## OUTCOME MEASURES

- Primary endpoint
  - reversal of diabetes at 1 year (HbA1c <6.5% and off treatment for at least 2 months)
- Secondary endpoint
  - weight change
  - quality of life
  - physical activity
  - serum lipids
  - attitudes to the VLED
  - effect of VLED on eating behaviour
  - durability of diabetes remission

## REFERENCES

Lean, M. (2017). Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. *The Lancet*, 33102 - 33110.

Guidone, C. M.-M. (2006). Mechanisms of recovery from type 2 diabetes after malabsorptive bariatric surgery. *Diabetes*, 2025-2031.

Lee, C. C. (2013). The cost of diabetes in adults in Australia. *Diabetes Research and Clinical Practice*, 385-390.

## FOR MORE INFORMATION

If you would like more information about DiRECT-Aus, visit the DiRECT-Aus website at [diabetesnsw.com.au/directaus](http://diabetesnsw.com.au/directaus), email [direct@diabetesnsw.com.au](mailto:direct@diabetesnsw.com.au) or ring 1300 234 736.

We recognise the significant contribution you are making through your participation in this trial, the potential improvements to the health outcomes of your patients, to people living with diabetes and to the health care system. Thank you for this contribution!

# Notes

A series of horizontal dotted lines for taking notes.



Handwriting practice area consisting of 20 horizontal dotted lines.

18 horizontal dotted lines for writing.





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.

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X20/0060



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[diabetesnsw.com.au/directaus](http://diabetesnsw.com.au/directaus)