DiRECT Principles

Key success criteria for a DiRECT-like intervention

The Diabetes Remission Clinical Trial (DiRECT) is a research study funded by Diabetes UK testing whether a low calorie based weight management programme could put Type 2 diabetes into remission for the long term. The trial was carried out by researchers at the University of Glasgow and Newcastle University.

The second year results indicated that 36% of people receiving the intervention were in remission at 24 months[1]. Of those who were in remission at 12 months, 70% remained in remission.

These results have generated significant interest amongst people with diabetes, healthcare professionals and healthcare providers.

In order to support NHS organisations to develop and deliver effective interventions to support their patients with Type 2 diabetes to achieve remission, Diabetes UK, the University of Glasgow and Newcastle University have developed the DiRECT principles.

These principles set out the core elements of a health intervention that should be adopted in order to have the best chance of achieving the outcomes from DiRECT.

These principles will be reviewed as new evidence emerges from further research and as data and insight emerge from the roll out of pilot Type 2 remission programmes within the NHS[2,3].

The DiRECT principles have been produced in partnership between Diabetes UK, University of Glasgow and Newcastle University.

DiRECT principles

1. **An initial assessment using defined criteria for suitability of individual patients to the programme.**

There were four key inclusion criteria within the trial, as listed below:

- Age 20-65
- Diagnosed with diabetes within previous 6 years
- HbA1c of greater than 43 mmol/mol (6.0%) and, if less than 48 mmol/mol (6.5%), individuals should still be receiving anti-diabetes medication
- Body Mass Index (BMI) of 27-45 kg/m^2.

For further details including exclusion criteria, please refer to the DiRECT Lancet paper[4].

2. **An integrated programme with a focus on long-term behaviour change and strategies for relapse management, which should be introduced at the start of the programme. To include:**

I. A period of Total Diet Replacement (TDR) using a nutritionally complete diet. It should be noted that the specific calorie count may be dependent on the baseline weight of the individual, with the participants in the DiRECT study generally having less than 850kcal per day.
   a. Documentation that the proposed approach constitutes a nutritionally complete approach.
   b. Confirmation of availability of healthcare professional consultation - at least weekly for 4 weeks then monthly with on demand access to advice.

II. A period of supervised stepped food/meal reintroduction, to establish a regular and sustainable eating pattern
   a. Confirmation of at least fortnightly visit frequency plus telephone or other support on demand.

III. Supervised weight loss maintenance (supported by a trained healthcare professional and written resources) to minimise weight regain for at least 24 months
   a. Confirmation of training status of personnel.
   b. Confirmation of visit frequency of monthly, up until 24 months, and subsequently quarterly.

IV. A clear, documented relapse management protocol with the following elements:
   a. Recognition of the importance of early intervention for weight regain of >2kg;
   b. Protocol for use of either further period of low calorie liquid diet or major decrease in advised energy intake;
   c. Schedule for increased visit frequency.

3. **Protocols for management of anti-diabetes and antihypertensive medications.**

- All antihypertensive, diuretic and anti-diabetes drugs were stopped on the day TDR commenced. This is a safety measure, because blood pressure is likely to fall on the diet, and blood glucose levels fall rapidly on the diet.
- Clear protocols were established for the reintroduction of medications. For full details, refer to the appendices of the DiRECT Protocol paper[5].
- A full review of the DiRECT blood pressure data is underway and may identify clinical exceptions. Further guidance about management of antihypertensive drugs during intensive weight management will be provided as new evidence emerges.

4. Prospective data collection and audit for continuous programme improvement

- Clear description of data items to be collected which must include weight, waist circumference, HbA1c, plasma lipids and ALT + gamma GT;
- Specification of data storage;
- Specification of biannual data analysis with publication on website of the organisation.

References

1. Lean ME, Leslie WS, Barnes AC et al (2019) Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *The Lancet Diabetes and Endocrinology* *DOI: https://doi.org/10.1016/S2213-8587(19)30068-3 [Epub ahead of print]*
2. NHS England (2019) Long Term Plan https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf
3. Scottish Government (2018) A healthier future – Framework for the prevention, early detection and early intervention of type 2 diabetes https://www.gov.scot/publications/healthier-future-framework-prevention-early-detection-early-intervention-type-2/
4. Lean ME, Leslie WS, Barnes AC et al (2018). Primary care-led weight management for remission of Type 2 diabetes (DiRECT): an open-label cluster-randomised trial. *The Lancet* 391 (10120); 541-551. https://doi.org/10.1016/S0140-6736(17)33102-1.
5. Leslie WS, Ford I, Sattar N et al (2016). The Diabetes Remission Clinical Trial (DiRECT): protocol for a cluster randomized trial. *BMC Family Practice* 17:20 https://doi.org/10.1186/s12875-016-0406-2.

Version Control

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