

## Health Care Professional: Frequently Asked Questions

### Low Calorie Diet Programme (LCD)

#### 1. Is there any low calorie diet trial data after one year?

	Direct trial (2017)	Droplet study (2018)
Average weight loss after Total Dietary Replacement (TDR) (12 weeks)	-14.5kg	-13.3kg
Average weight loss end of programme (1 year)	-10.0kg	-10.7kg

\*Data is provider level and not NHSE data.

Some weight gain is expected once food is reintroduced (from week 13). The Direct study found that there is a close link between achieving diabetes remission and total weight lost, with 64% of those who lost more than 10kg going into remission.

Another study, the Droplet study had similar weight loss results, and demonstrated the effectiveness of a low-calorie diet programme in primary care using a trained workforce of non-HCP.

For more on the Direct trial - <https://www.directclinicaltrial.org.uk/>

For more on the Droplet study - <https://www.bmj.com/content/362/bmj.k3760>

#### 2. Does the service have any cost for patients?

No, the service is completely free for eligible patients.

#### 3. Are the diets tailored to different cultural requirements?

We adopt a patient centred approach. We do not provide specific diet plans; we empower our patients to make their own dietary decisions based on the current government EatWell guidelines which can be adapted to suit any specific cultural needs.

We provide general examples of different recipes that are culturally diverse.

The Total Diet Replacement (TDR) products are Halal certified but not suitable for vegans.

#### 4. What is the advice for physical activity for patients during the Total Dietary Replacement (TDR) Phase?

Patients are not asked to increase their activity levels during TDR. They are encouraged to maintain their usual light activity levels during this stage. Physical Activity is introduced and discussed in the weight maintenance stage of the programme.

#### 5. Can people join the programme more than once?

Patients are not recommended to repeat the programme. The programme is designed to empower patients to make sustainable lifestyle changes. Repeating the programme more than once would mean taking TDR products multiple times which would not be recommended.

## Referring

### 6. Are the patients required to receive a copy of the medication changes?

Yes. It is very important for a patient to receive their medication changes in writing so that they can begin the programme. This is to ensure they are clear on the changes they will make on the day they start their TDR.

### 7. What is the inclusion and exclusion criteria?

#### Inclusions

- Aged 18-65
- Diagnosed with Type 2 diabetes within the last 6 years
- A BMI of 27kg/m<sup>2</sup> or higher (adjusted to 25kg/m<sup>2</sup> or higher in people of Black, Asian and Minority Ethnic (BAME) ethnic origin)
- A HbA1c measurement taken within the last 12 months, with values as follows;
  - If on diabetes medication, HbA1c 43 mmol/mol or higher
  - If not on diabetes medication, HbA1c 48 mmol/mol or higher
  - In all cases, HbA1c must be 87 mmol/mol or lower
- Have attended a monitoring and diabetes review when this was last offered, including retinal screening, and commit to continue attending annual reviews, even if remission is achieved (For avoidance of doubt, if a Service User is newly diagnosed then there is no requirement to wait for a retinal screening to take place before offering referral)

#### Exclusions:

- Current insulin user
- Pregnant or planning to become pregnant within the next 6 months
- Currently breastfeeding
- Has at least one of the following significant co-morbidities;
  - active cancer, heart attack or stroke in last 6 months,
  - severe heart failure (defined as New York Heart Association grade 3 or 4),
  - severe renal impairment (most recent eGFR less than 30mls/min/1.73m<sup>2</sup>) or
  - active liver disease (not including NAFLD) (i.e. NAFLD is not an exclusion criterion)
  - active substance use disorder
  - active eating disorder (including binge eating disorder)
  - Porphyria
  - Known proliferative retinopathy that has not been treated (this does not exclude individuals who are newly diagnosed and have not yet had the opportunity for retinal screening)
- Has had bariatric surgery
- Health professional assessment that the person is unable to understand or meet the demands of the NHS LCD Programme and/or monitoring requirements (due to physical or psychological conditions or co-morbidities)
- Total diet replacement products are not suitable for milk and soya allergies and lactose intolerance

### 8. How long do patients need to be off medication before commencing the program?

Patients only stop their medication on their first day of TDR. They do not stop their medication before commencing the programme.

**9. Who provides medication reviews and potential subsequent changes?**

GPs or other nominated clinical pharmacist/ANP/PN in your practice.

**10. If a patient's HbA1c cannot be recorded due to HB D trait can they still take part in the programme?**

Yes. You would measure their fructosamine levels and it would need to be below 400.

**11. What diabetes monitoring is a practice required to do while a patient is on the LCD programme?**

The practice should arrange a review of the patient at 6 and 12 months after starting LCD programme with repeat HbA1c and further medication adjustments as necessary.

**12. Once an eligible patient has been referred, how long does it take to start the programme?**

This can vary depending on when a patient would like to start, it is important they chose a time that is most suitable for them i.e. avoiding holidays. However below outlines the typical timeframes.

- Initial contact- Provided the referral is fully complete a patient will receive a welcome text/call within 5 working days of referral.
- Initial Assessment- Provided the patient is provided with a copy of their medication changes in writing they can be offered an appointment within 30 day of referral receipt. A patient must attend their initial assessment within 90 days of referral.
- Commencement of programme- A patient can begin the programme two weeks after their initial assessment and must start the programme within six months of referral.

**13. Can the patient be referred more than once?**

Yes, if they did not previously meet the eligibility criteria ie previously their HbA1c was not within the eligible range.

**14. Can a patient be referred who has had bariatric surgery?**

No, anyone who has undergone bariatric surgery cannot participate in the programme. Bariatric surgery is a tier 4 strategy, it's an intensive treatment option, LCD is also intensive, so it wouldn't be appropriate psychologically to do both back to back. Also depending on the type of bariatric surgery, often capacity to absorb nutrients is lowered, therefore there is risk of malnutrition after bariatric surgery should someone be on a very low calorie diet.

**7. Am I able to refer patients waiting for their Retinal Screening appointments?**

Yes, as long as they have attended their last diabetes review, including a retinal screen, and are willing to continue their annual reviews.

## **Total Diet Replacement (TDR) Products**

**15. What is the patient consuming on the programme?**

During stage 1, the patient will be on a 'Total Diet Replacement', in the form of shakes or soups four times a day

- Each TDR product is 200 kcal
- Shakes: 4 flavours: Banana, Chocolate, Strawberry and Vanilla

Soups: 2 flavours: Vegetable and Chicken Soup

**16. Once TDR is complete, what are the next stages of the programme?**

In the second stage of the programme, patients will gradually reintroduce healthy balanced meals into their diet. Stage 3 is where we provide them with support (nutritional, psychological, physical) to maintain their weight loss in the long term.

**17. Can a patient have a break during TDR?**

Yes, planned breaks can include any special occasion or significant change in circumstance. However, patients are asked to avoid going on planned breaks for more than 2 consecutive days.

**18. Can patients who have specific allergies to the soups and shakes take part in the programme?**

No, if patients are lactose intolerant or are allergic to any of the ingredients, they would not be able to take part.

For full TDR nutritional information and ingredients list please click [here](#)

**19. What fibre supplementation is provided?**

The fibre is psyllium husk, a total of 9g/day (2 x servings-mixed in 250 ml water).

**20. Can patients consume alcohol while they take part in the programme?**

Yes, however not during the initial 12-week total diet replacement phase.

**21. Can the total diet replacement products used in the service also be prescribed by primary care clinicians?**

No, the total diet replacement products are not available on prescription in primary care. Eligible patients participating in the pilot will receive all products, directly from the provider.

## **Patient monitoring**

**22. How are patients monitored on the programme?**

**Possible Side Effects:** Occasionally, TDR programmes can cause side effects which in most cases are temporary and are simply caused by a lower energy intake. Common side effects can be; constipation, headaches, fatigue. Our Diabetes Practitioners are trained to support service users to manage these and fibre supplements are provided to all individuals at the start of TDR to prevent constipation. However, if symptoms persist then our MDT will discuss directly with the individual and potentially the individual's healthcare team to ensure appropriate action is taken.

**Monitoring of BP, Weight & BG:** Our Diabetes Practitioners collect weight, Blood Glucose & Blood Pressure (if required to monitor BP) measurements during their sessions. We closely

monitor these measures and any readings outside of the tolerable range are reviewed by our MDT or Medical Director as appropriate.

Area of complication	Triggers	Action
Excessive weight loss	If service users measured BMI drops below 21kg / m <sup>2</sup> (19kg / m <sup>2</sup> for service users of Black, Asian and Minority Ethnic origin)	Case reviewed by Xyla MDT and if required alert service users healthcare team  If service user is within the TDR phase; TDR stopped and individual moved to eating guidance under the weight maintenance phase of the service
Blood Glucose level outside acceptable range	If service user records blood glucose level outside of tolerable range: <ul style="list-style-type: none"> <li>• 20mmol/L or higher</li> <li>• Between 15mmol/L and 19mmol/L over 2 consecutive readings</li> </ul>	Case reviewed by appropriate Xyla MDT and if required alert service users healthcare team for appropriate action
Blood pressure outside of tolerable range	If service user records blood pressure outside of tolerable range: <ul style="list-style-type: none"> <li>• (180/120mmHg or higher, systolic and/or diastolic 89/59mmHg or lower, systolic and/or diastolic +/- postural symptoms</li> <li>• Between 160/100 and 179/119mmHg over 2 consecutive readings</li> </ul>	Case reviewed by appropriate Xyla MdT and if required alert service users healthcare team for appropriate action

### 23. Where can I find more information on the programme?

Please refer to our website: <https://xylahealthandwellbeing.com/our-services/diabetes-remission/nhs-low-calorie-diet/>