**LCD HCP: Frequently Asked Questions (FAQs)**

**Low Calorie Diet Programme**

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

The Direct Study does have data on follow-up after 1 year - <https://www.directclinicaltrial.org.uk/>

1. **What is the estimated drop-out rate from the service?**

The DIRECT and DROPLET clinical trials recorded dropout rates of 25% and 27%, respectively.

1. **Does the service have any cost for patients?**

No, the service is completely free for eligible patients.

1. **Can non-English speaking patients take part in the programme?**

Service delivery is available in Hindi and Urdu with additional languages supported through in-app audio in Hindi, Bengali, Turkish, Farsi and Gujarati. We will continue to review the language needs of the patients in the area and review if additional languages should be provided.

1. **Are the diets tailored to different cultural requirements?**

We adapt 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.

However, our TDR products are not suitable for vegans.

1. **What is the advice for physical activity for patients during the TDR Phase?**

Patients are not asked to increase their activity levels during TDR. They are asked to maintain their usual light activity levels during this stage. Physical Activity is introduced in the following stages of the programme.

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

Our Diabetes Practitioners collect measurements during their sessions. Our reporting system is able to pick up on any health triggers, inconsistencies, etc. which then trigger an action from the Multi-disciplinary Team.

The patients are given an email address to send any concerns to and this is monitored by the Multi-disciplinary Team.

The patients are encouraged to call 999 or seek medical advice if there are any medical emergencies.

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

*Response from NHSE:*

The eligibility criteria states “Have attended for monitoring and diabetes review when this was last offered, including retinal screening, and commits to continue attending reviews, even if remission is achieved.” Therefore, if the referring GP is content that this criteria is met and the individual will attend when offered, they can be referred.

**Referring**

1. **Can patients with Fatty Liver participate in the programme?**

Patients with fatty liver can take part in the programme… details: <https://www.diabetes.org.uk/research/research-round-up/research-spotlight/research-spotlight-low-calorie-liquid-diet>

1. **Is there a contra indication to join the programme if the patient has advanced CKD?**

Yes. Severe renal impairment (most recent eGFR < 30mls/min/1.73m2 persisting (i.e not due to AKI) within the last 12 months)) is part of the exclusion criteria.

1. **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.

1. **Are the patients required to receive a copy of the medication changes?**

Yes. If a patient does not receive a copy of their medication changes (electronic or paper) they will not be able to progress to the next stage. They will be redirected back to the practice to gain a copy of their medication changes if they do not have it.

1. **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.

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

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

1. **Who provides blood glucose and blood pressure monitoring kits?**

Xyla Health & Wellbeing provide all equipment and TDR products needed for the programme.

1. **Is there a drug re-introduction guideline, if indicated by regular monitoring of blood glucose/blood pressure?**

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.

1. **Once a patient has been referred, if suitable, how long does it take to start the programme?**

The service provider will contact the patient within 5 working days. The patient must have their Initial Assessment within 90 days of being referred. The patient will begin the programme within 2-6 weeks from their Initial Assessment; this allows time to order self-monitoring kits and TDR products. If patient doesn’t attend the first session within 6 months of referral they are discharged.  Our aim is to have patients begin the programme as quickly as possible but also offer flexibility to make sure it is the right time.

1. **Can people do the programme more than once?**

Patients are not recommended to repeat the programme. The programme is designed to empower patients to lose weight and maintain their weight loss in the long term.  Repeating the programme more than once, would mean going through TDR multiple times and we would like to avoid weight cycling and reliance on the shakes.

The service provider has put in place a system whereby they are able to reject more than 1 referral per patient.

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

The patient can be referred more than once if they did not previously meet the criteria and their situation has now changed to meet the criteria.

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

Since the type of bariatric surgery performed and outcomes are unique for each patient, the local referring clinician and clinical lead for the site will need to come to a decision on the appropriateness of referral of these individuals based on the eligibility and individual circumstances (for example has the individual had successful bariatric surgery or has the surgery failed or been reversed). In any case, you will need to ensure these referrals have been made consciously following full consideration of all the eligibility criteria.

1. **Can primary care clinicians have access to the app to help support conversations with patients about what the service will look like/offer?**

Yes. We will soon be providing a trial login for practices but there is also lots of information available on our website and the marketing and engagement websites.

**Total Diet Replacement (TDR) Products**

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

During the Total Diet Replacement stage, the patient will consume specially designed products in the form of shakes or soups, instead of the patient’s usual meals for 12 weeks. Shakes are available in 4 flavours: banana, chocolate, strawberry and vanilla. Two soup flavours are provided: vegetable and chicken. All products are gluten-free. The TDR products are nutritionally complete and each product provides approximate 200 kcal. If patients struggle during the TDR stage, they may also include non-starchy vegetables at any time of the day, in any amount. All beverages must be calorie free, i.e. no sugar containing drinks, no milk in tea or coffee, and no alcohol. Full nutritional information on the TDR products is available at: <https://nualtra.com/media/wy5n1a0p/altralifeallproducts.pdf>

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

If patients are lactose intolerant or are allergic to any of the ingredients, unfortunately they would not be able to take the products and would be excluded. We don't yet have alternatives to the current products but will continue to explore other options.

1. **Are the TDR products suitable for vegetarians and vegans?**

The products are suitable for vegetarians but not for vegans

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

The fibre is psyllium husk. Service Users are advised to have a total of 9g/day. 2 x servings of 4.5g sachets mixed in 250 ml water.

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

During the 12-week total diet replacement phase, patients should not consume alcohol; during this period, patients should only be consuming the 4 total diet replacement products provided.

1. **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.

1. **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/>