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DIABETIC Medicine

RESEARCH ARTICLE

Does the design of the NHS Low-Calorie Diet Programme have fidelity to the programme specification? A documentary review of service parameters and behaviour change content in a type 2 diabetes intervention

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Abstract

Background: NHS England commissioned four independent service providers to pilot low-calorie diet programmes to drive weight loss, improve glycaemia and potentially achieve remission of Type 2 Diabetes across 10 localities. Intervention fidelity might contribute to programme success. Previous research has illustrated a drift in fidelity in the design and delivery of other national diabetes programmes.

Aims: (1) To describe and compare the programme designs across the four service providers; (2) To assess the fidelity of programme designs to the NHS England service specification.

Methods: The NHS England service specification documents and each provider's programme design documents were double-coded for key intervention content using the Template for Intervention Description and Replication Framework and the Behaviour Change Technique (BCT) Taxonomy.

Results: The four providers demonstrated fidelity to most but not all of the service parameters stipulated in the NHS England service specification. Providers included between 74% and 87% of the 23 BCTs identified in the NHS specification. Twelve of these BCTs were included by all four providers; two BCTs were consistently absent. An additional seven to 24 BCTs were included across providers.

Conclusions: A loss of fidelity for some service parameters and BCTs was identified across the provider's designs; this may have important consequences for programme delivery and thus programme outcomes. Furthermore, there was a large degree of variation between providers in the presence and dosage of additional BCTs. How these findings relate to the fidelity of programme delivery and variation in programme outcomes and experiences across providers will be examined.

KEYWORDS
behaviour change, intervention design, intervention fidelity, low-calorie diet, total diet replacement, type 2 diabetes, weight management

1 | INTRODUCTION

Obesity and its associated comorbidities, such as Type 2 Diabetes Mellitus (T2DM), have become a global epidemic.[1,2] Recent evidence has demonstrated that low-calorie total diet replacement (TDR) approaches can be an effective dietary intervention for achieving sustained T2DM remission (HbA_{1c} <48 mmol/mol).[3,4] In line with this evidence, National Health Service England (NHSE) launched a low-calorie, TDR pilot intervention for people living with comorbid T2DM and overweight or obesity—The NHS Low-Calorie Diet (NHS-LCD) Programme.[5] Four independent service providers were commissioned by NHSE to deliver the programme across 10 socio-demographically diverse regions across England, to drive weight loss, improve glycaemia and potentially achieve remission of T2DM amongst participants. To be eligible, patients had to be aged 18–65, have received a diagnosis of T2DM within the last 6 years, be non-insulin dependent, and have a BMI of ≥27 kg/m^2 (or ≥25 kg/m^2 for Black, Asian and Minority Ethnic communities).

The 52-week NHS-LCD Programme consists of a TDR phase, such as bars, shakes and soups (estimated 900 kcal/day) for the first 12 weeks. This is followed by a 6-week structured food reintroduction phase, then a maintenance support phase for the remainder of the 1-year programme. The goals of the last two phases are to encourage healthy eating, increase physical activity and reduce sedentary behaviours following the UK government guidance.[6] This is complemented by ongoing behavioural support, via one of three delivery models: one-to-one, group (both delivered remotely during the COVID-19 pandemic) or digital (web and app-based).

How the programme aims to produce behaviour change, sustained weight loss, and improved T2DM was previously described in a logic model constructed by our group, supplemented by stakeholder input.[7] To achieve the desired outcomes, the intervention includes the use of specific behaviour change techniques (BCTs). BCTs are defined as the observable components of interventions designed to modify the cognitive and psychological processes underlying behaviour, known as 'active ingredients' (e.g., action planning, goal setting).[8] NHSE produced a service specification that stipulated the intervention contents for each of the four providers' NHS-LCD programme designs.[9] Within this, providers delivering the programme were given scope to independently design behaviour change content that is acceptable to their delivery model, available resources, and expertise, whilst aligning with the requirements outlined in the service specification. This flexibility meant the final behaviour change content within each of the providers' programme designs was unknown, including how they may differ.

Assessing intervention fidelity (whether a programme is implemented as intended)[10] is important to distinguish whether unexpected outcomes are due to a lack of intervention effectiveness or a loss of fidelity in its implementation, thus enabling accurate interpretation and scale-up of any intervention outcomes.[11–13] The National Institute of Health Behaviour Change Consortium (NIH-BCC) model[13] describes five domains of fidelity: study design (the extent to which the programme design reflects the evidence base); provider training (the extent to which deliverers are trained in a programme's components); treatment delivery (the extent to which the programme is delivered with adherence to the design); treatment receipt (the extent to which programme content is understood by participants); treatment enactment (the extent to which participants apply the programme content in their daily lives).[13] Despite the recommendation for fidelity to be

What's new?

- Assessing intervention fidelity is important, to distinguish whether unexpected outcomes are due to a lack of intervention effectiveness or a loss of fidelity in its implementation. Previous research has illustrated a loss of fidelity during the design phase in other national diabetes programmes.
- Some elements of providers' programme designs did not adhere to the service parameters stipulated in the NHS England Low-Calorie Diet service specification. Most but not all (79.5%) of the behaviour change techniques were included in providers' programme plans.
- A loss of fidelity during the design phase might have consequences for programme delivery and thus programme outcomes.

considered as multidimensional, numerous reviews report fidelity of delivery to be the most frequently examined domain across behaviour change interventions, whilst fidelity of design remains underexplored.[12,14–16] This is problematic as a loss of fidelity in delivery could be a consequence of a drift in fidelity in the domains that precede it—the design and training phases. For example, if the evidence base is not adequately translated into the design (i.e., programme protocol) and staff training, intervention delivery is likely to be suboptimal.[12]

A previous study from the NHS-LCD pilot evaluation examined a recommended component of study design—whether the programmes' 'active ingredients' are reflective of, and mapped onto, behaviour change theory.[11] We found the theoretical underpinnings of providers' programme designs to be unclear,[7] which might lead to a loss in fidelity due to the lack of a clear framework or map of how the programme is expected to work. Furthermore, the design of the NHS Diabetes Prevention Programme (NHS-DPP) (a national programme also commissioned by NHS England and delivered by external providers) was evaluated by extracting information on the service parameters and BCTs from programme protocols. Authors reported high, but not absolute, fidelity of behaviour change content in the providers' programme designs when compared to the NHS-DPP service specification.[17] The aim of this study was therefore to assess the design fidelity of the behaviour change content and service parameters in the NHS-LCD.

Objectives: (1) To describe the service parameters and behaviour change content stipulated in the NHSE pilot service specification, (2) To describe and compare the NHS-LCD programme designs across the four pilot service providers commissioned to deliver across the 10 initial pilot sites, and (3) To assess the fidelity of NHS-LCD programme designs to the NHSE service specification.

2 | METHODS

2.1 | Design

A documentary review comparing the NHS-LCD full programme specification with each of the four providers' programme designs. The following methods were informed by (a) the recommendation to evaluate whether an intervention's key components (i.e., the active ingredients) are fully operationalised, by examining programme protocols and/or manuals,[11] and (b) the methodology reported for assessing the design of the NHS-DPP.[17]

2.2 | Materials

2.2.1 | Programme specification

The following documents described what components should feature within the NHS-LCD and therefore made up the full programme specification:

- NHS England NHS Low-Calorie Diet Service Specification Version 1.[9]
- NICE PH6 public health guideline,[18] 'Behaviour change: general approaches'.
- NICE PH49 public health guideline,[19] 'Behaviour change: individual approaches'.

The National Institute for Health and Care Excellence (NICE) guidelines[18,19] were included in the analysis as they provided the most comprehensive overview of the behaviour change content to be included in the programme designs. A review of the other guidelines cited in the NHSE service specification found no new BCTs outside of these three documents (Appendix S1).

2.2.2 | Service providers' programme design

The review of the intervention design (describing what providers planned to deliver) comprised:

- Provider's programme manuals, describing the programme structure and curriculum, session plans and behaviour change components to be delivered to patients.
- STAndardised Reporting of adult behaviouraL weight management InTerventions to aid Evaluation (STARLITE)[20] survey responses from the service providers, which provided further detail on the planned programme delivery.
- Participant materials, including TDR manuals, take-home workbooks, and in-session worksheets.

2.3 | Procedures

The full programme specification and each of the service providers' programme designs were examined using two frameworks. The Template for Intervention Description and Replication (TIDieR) framework[21] was used to extract information on the service parameters, including what, who, how, where, when and how much, and tailoring. This framework aims to standardise and improve intervention reporting. The behaviour change content was coded using The Behaviour Change

Technique Taxonomy (BCTTv1),[8] a validated measure and reliable tool for identifying the 'active ingredients' of interventions,[22] consisting of 93 distinct techniques. Only core content was coded for BCTs; optional activities were excluded as these did not describe necessary 'active ingredients'.

A TIDieR data extraction sheet was developed by TE. DR and CH conducted TIDieR data extraction independently and in duplicate; TE supported discrepancy resolution through discussion. BCT coding was conducted independently and in duplicate following published guidance by the framework authors.[8] All coding researchers received training in BCT coding[23] (which sets out a number of learning principles to be adhered to when using the BCTTv1) and TE developed standardised data extraction sheets. Following familiarisation with the materials, TE and CD agreed on a set of BCT coding rules to guide the identification of BCT presence and dose (Appendix S2), which modified the coding rules set out in the evaluation of the NHS-DPP.[17] All materials were coded by TE; 2nd coding was completed by PD, CD, or CK. All discrepancies between coders were resolved via discussion with TE to achieve consensus on the final set of BCTs.

2.4 | Analysis

TIDieR components extracted from each of the providers' programme designs were tabulated and compared with the corresponding components extracted from the full NHSE service specification. The data extracted for each component was discussed by TE, CH and DR and rated as having fidelity (description meets requirements stipulated in the specification), partial fidelity (description meets some requirements stipulated) or an absence of fidelity (insufficient evidence of meeting requirements).

BCTs were labelled and the dose (frequency) of their delivery per session was reported. The numbers of different BCTs present in the providers' programme designs and the full programme specification documents were calculated and compared. This included analysis of additional BCTs identified in programme designs that were not mandated in the programme specification, as this has frequently occurred in previous studies (e.g.,[24,25]). Frequencies at which the BCTs were intended to be delivered across the programme by each of the service providers were also calculated. Cohen's kappa coefficient and Spearman's Rho analysis were conducted to report the inter-rater reliability of coding the presence of BCTs and their dose, respectively.

To maintain provider anonymity alternative service provider codes are used to present the BCT analysis to those reported for the analysis of service parameters.

3 | RESULTS

3.1 | Service parameters

Information extracted on the service parameters stipulated by NHSE[9] and providers' programme designs are described and compared in Table 1 (using the TIDieR framework).[21] A traffic light coding system was used to highlight the degree of fidelity (green—fidelity, amber—partial fidelity, red—absent). Based on the documentation describing providers' programme designs, all four providers secured high fidelity for programme materials and procedures. Instances of lost fidelity included: TDR weight loss targets, training of programme deliverers, physical activity recommendations during TDR, number of sessions during Food Reintroduction, dietary recommendations outside of general healthy eating principles during Weight Maintenance, cultural tailoring, and advice on the intake of foods outside of the TDR products for participants struggling with adherence.

Of the four service providers, three indicated developing their programme based on learnings and user feedback from existing diabetes prevention/remission programmes and other weight management services. One provider also stated that service users provided input on the design and functionality of their accompanying app in its early development.

3.2 | Behaviour change techniques

3.2.1 | Inter-rater reliability

Analysis of inter-rater reliability indicated strong agreement[26] between coders on the presence of a BCT within the full programme specification ($k = 0.775$, $p < 0.001$) and providers' A ($k = 1.000$, $p < 0.001$) C ($k = 0.774$, $p < 0.001$) and D's (k = 0.888, $p < 0.001$) programme designs. Moderate agreement[26,27] was indicated for BCT presence for provider B ($k = 0.404$, $p < 0.001$) and the dose of BCTs per session for Provider D (rs = 0.47, $p = <0.001$). Agreement on BCT dose was regarded as weak[27] for providers B (rs = 0.22, $p = <0.001$) and C (rs = 0.23, $p = <0.005$). As provider A's programme design documents did not include session plans, no information on BCT dose was available and, therefore, could not be analysed; BCT presence was coded based on provider A's

logic model, describing planned BCTs and their proposed mechanisms of action.

3.3 | Programme specification

BCT coding of the full programme specification identified 22 distinct BCTs and one group of BCTs (those targeting self-belief) (Table 2). The group targeting self-belief was coded as one BCT as no information was specified on whether one or all four BCTs in this category should be delivered, giving a total of 23 expected BCTs that should be included in providers' programme designs. Definitions of the BCTs identified in the programme specification are reported as a supplement (Appendix S3).

3.4 | Intervention design

BCT coding of service providers' programme design documents identified a total of 44, 33, 23, and 30 BCTs in the intervention designs of providers A-D, respectively. 16 BCTs were common across all providers.

3.5 | Fidelity of BCT content

Of the 23 BCTs identified in the specification, provider A included 20 (87%) in their programme design, provider B included 19 (83%), and both providers C and D included 17 (74%) in each of their design documents (Table 2). Thus, the overall mean proportion of BCTs in service providers' programme designs to the programme specification was 79.5%. This indicates variation between moderate to high fidelity across providers.[11] Twelve BCTs indicated in the full programme specification documents were included within all provider's programme plans, whilst two BCTs were absent across all providers: 'Behavioural contract'; and 'Social support (emotional)'.

3.6 | Additional BCTs

Twenty-nine BCTs were identified across the providers' designs that were not specified within the pilot service specification. The number of additional BCTs identified for each provider ranged from seven to 24. Only three of these BCTs were identified across all providers: 'Information about emotional consequences'; 'Behaviour substitution'; 'reduce negative emotions'. The variation in additional BCTs is described in Table 2.

3.7 | Dose of planned BCT content

Analysis of the intended dose of BCTs reported in providers' design documents indicated large variations in the frequency of some BCTs, and consistency in others (Table 2). The BCT with the largest degree of variability in intended dose was 'Information about health consequences', which varied from 14 to 112 occasions across the 52-week programme between the four providers. On the other hand, the most consistent intended BCT dose was for 'Feedback on outcome(s) of behaviour', which all providers generally intended to deliver by feeding back to participants their body weight at the beginning of each coaching session. A substantial degree of variation was also noted regarding BCT dose per session across the three providers reporting BCT dose. Table 3 reports the number of sessions within which each BCT was included within each provider's programme designs, in addition to the range and mean BCT dose per session across sessions where the BCT was included. The most consistent BCT dosage across providers B-D's session plans were for BCTs 'Action planning' and 'Feedback on outcome(s)'.

4 | DISCUSSION

The four providers commissioned to deliver the pilot NHS-LCD Programme demonstrated fidelity to most but not all the service parameters stipulated in the NHSE specification.[9] Providers' programme design documents included between 74% and 87% of the 23 BCTs specified by NHSE[9] and NICE,[18,19] whilst an additional 7 to 24 BCTs were included outside of the service specification. Furthermore, there was wide variation between providers in the presence and dosage of BCTs described in their design documents, both within individual sessions and across their programmes as a whole. These findings illustrate a drift in fidelity in the implementation of the NHS-LCD during the design phase, highlighting the complexity of transferring the evidence base into consistent programme plans across providers of large-scale interventions.[28]

4.1 | Relation to existing research evaluating fidelity of design

Our findings align with the NHS-DPP evaluation,[17] showing comparable (moderate to high) fidelity in planned BCT content to the NHS-DPP. Furthermore, the variation in additional BCTs across providers is similar to that reported by other studies using the BCTTv1[8] to evaluate the design of other health promotion interventions,[17,25] indicating variation in the active ingredients across providers commissioned to deliver the same programme. Our study

TABLE 1 Service parameters outlined in the NHS England programme specification in comparison with each provider's programme design (additional file).

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
3	What (Weight loss target)		Reduction in weight of Service Users and the maintenance of weight loss achieved. Service Users should be supported to set individualised weight maintenance goals or further weight loss during WM.	≥10% original body weight	Agreed between participant and programme
3	What (participant materials)	Any physical or information materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers	The clinical requirements for service providers include: Regular measurement of blood pressure, and thresholds for action. Weight measurements, and direction on when to cease weight loss. Blood glucose testing, and thresholds for action During the Food Re-introduction Phase and the Weight Maintenance Phases, the sessions must provide information and practical tools on nutrition, behaviour change and weight management based on current national guidance as set out in Section 4.1.	Paper informational booklets/hand-outs, Electronic informational booklets/hand-outs, Measuring equipment: scales BG monitor BP monitor for those on BP lowering meds. Other: Fibre sachets Shaker	Paper food/physical activity diaries, Paper informational booklets/hand-outs, electronic food/physical activity diaries, Electronic informational booklets/hand-outs Measuring equipment: Scales, glucometer, blood pressure monitor where appropriate, clinical waste disposal equipment Other: TDR products and fibre supplements
3	What (provider materials issued to staff)		No information	Programme manual	Flipcharts, Electronic training materials (DVD, computer files), Programme manual

SP2 group	SP2 digital	SP3 group	SP4 digital
Agreed between participant and programme	Agreed between participant and programme	Gold, silver, and bronze targets of 15%, 10% and 5% weight loss respectively. Participant selects the target they believe is most realistic	Yes -≥10% original body weight
Paper food/physical activity diaries, Paper informational booklets/hand-outs, electronic food/physical activity diaries, Electronic informational booklets/hand-outs Measuring equipment: Scales, glucometer, blood pressure monitor where appropriate, clinical waste disposal equipment Other: TDR products and fibre supplements	Paper food/physical activity diaries, Paper informational booklets/hand-outs, electronic food/physical activity diaries, Electronic informational booklets/hand-outs Measuring equipment: Scales, glucometer, blood pressure monitor where appropriate, clinical waste disposal equipment Other: TDR products and fibre supplements	Paper food/physical activity diaries, Paper informational booklets/hand-outs, electronic informational booklets/hand-outs Measuring equipment: Scales, glucometer, blood pressure monitor where appropriate Other: Pedometer Recipe book Wallet card (label reader) (TDR and 1 kg fibre)	Electronic food/physical activity diaries, Electronic informational booklets/hand-outs Measuring equipment: BodyTrace weight scales +/− a blood glucose monitor +/− a blood pressure monitor as required
Flipcharts, Electronic training materials (DVD, computer files), Programme manual	Programme manual	Flipcharts, Electronic training materials (DVD, computer files), Programme manual	Electronic training materials (DVD, computer files), Programme manual, Medication and monitoring protocol, Adverse events protocol, A programme brief describing service operations. A chat function to enable peer to peer support, support from senior dietitians and the service manager

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
4	What (procedures - initial contact)	Describe each of the procedures, activities and/or processes used in the intervention (excluding BCT content)	The Provider will conduct individual assessments with all Service Users who accept the invitation to participate in the Service (over the phone if necessary) The Provider will use Individual Assessments to: · verify the eligibility of the Service User;· explain in detail the rationale and requirements of the Service	Individual Assessment call contact via telephone or video. Includes eligibility check, programme rationale and requirements explained Explain rationale & requirements of service, verbal consent received Determine if SU wishes, scheduling of session 1, Send product catalogue for SU to review TDR products, Measurement equipment ordered (BP, scale, BG), confirmation of medication, post fibre supplement to SU (required for TDR phase)	Booking Call includes Medication review, Eligibility check, programme Overview of the programme, Commitments overview- our commitment to them, their commitment to us, Sample pack ordering. Initial Assessment includes Eligibility check, Medication review- Ensuring service users have a copy of required medication changes, Programme overview recap, Discussion around TDR sample pack, Full TDR product and fibre supplementation information, Commitments statement review, Motivational interviewing- assessing readiness to change, Self-monitoring tools and kit ordering discussed, and Goal setting.
4	What (procedures - TDR e.g. start date, products, no. of products per day)		This should include TDR products to replace all daily meals, consisting of 'up to' 900 calories a day for up to 12 weeks. Service Users will therefore follow a diet composed solely of nutritionally-complete TDR products, with total energy intake of up to 900 calories a day, for up to 12 weeks. TDR products can consist of soups, shakes and other suitable products but all TDR products provided on the NHS LCD programme must adhere to all legislation and standards that apply to total diet replacement products. The Provider will be responsible for procuring the TDR products that it supplies to Service Users	TDR start: week 1 Carbohydrate: 50%, Fat: 5%, Protein: 34% Soups, shakes, smoothies, porridge. Clients are instructed to consume four TDR products a day Samples not available. Delivered every 4 weeks.	TDR start: week 1 Carbohydrate: 29%, Fat: 10%, Protein: 43% Soups, shakes. Clients are instructed to consume four TDR products a day Start during first week following their first group session. Following from the booking call, service users would receive a TDR starter pack containing all the TDR flavours available to them. This is to ensure that they opt for their favourite flavours and are able to commit to 12 weeks of TDR. Service users are provided with all the TDR products they need to complete the TDR and Food Reintroduction Stages, before initiation of our programme.

SP2 group	SP2 digital	SP3 group	SP4 digital
Booking Call includes Medication review, Eligibility check, programme Overview of the programme, Commitments overview- our commitment to them, their commitment to us, Sample pack ordering. Initial Assessment includes Eligibility check, Medication review-Ensuring service users have a copy of required medication changes, Programme overview recap, Discussion around TDR sample pack, Full TDR product and fibre supplementation information, Commitments statement review, Motivational interviewing- assessing readiness to change, Self-monitoring tools and kit ordering discussed, and Goal setting.	Booking Call includes Medication review, Eligibility check, programme Overview of the programme, Commitments overview- our commitment to them, their commitment to us, Sample pack ordering. Initial Assessment includes Eligibility check, Medication review-Ensuring service users have a copy of required medication changes, Programme overview recap, Discussion around TDR sample pack, Full TDR product and fibre supplementation information, Commitments statement review, Motivational interviewing- assessing readiness to change, Self-monitoring tools and kit ordering discussed, and Goal setting.	Via video call or phone. Data from referral and participant eligibility is confirmed and verbal consent received. Individual Assessment: •Describe NHS England pilot and underpinning research •Explain programme, its' objectives, TDR products and other resources •Discuss concept of medications adjustment •Discuss potential side-effects of TDR products	Via video call or phone. Pre-assessment includes: eligibility checks, medication changes, motivation and commitment to the programme, and preferred mode of support (phone or app). The service user is given information about the programme, each phase, what devices are needed and how to set them up, and the TDR products and how to order them.
TDR start: week 1 Carbohydrate: 29%, Fat: 10%, Protein: 43% Soups, shakes. Clients are instructed to consume four TDR products a day. Start during first week following their first group session. Following from the booking call, service users would receive a TDR starter pack containing all the TDR flavours available to them. This is to ensure that they opt for their favourite flavours and are able to commit to 12 weeks of TDR. Service users are provided with all the TDR products they need to complete the TDR and Food Reintroduction Stages, before initiation of our programme.	TDR start: week 1 Carbohydrate: 29%, Fat: 10%, Protein: 43% Soups, shakes. Clients are instructed to consume four TDR products a day. Start during first week following their first group session. Following from the booking call, service users would receive a TDR starter pack containing all the TDR flavours available to them. This is to ensure that they opt for their favourite flavours and are able to commit to 12 weeks of TDR. Service users are provided with all the TDR products they need to complete the TDR and Food Reintroduction Stages, before initiation of our programme.	TDR start: week 1 Carbohydrate: 34%, Fat: 12%, Protein: 34% Soups, shakes, bars, pre-prepared meals. Clients are instructed to consume four TDR products a day	TDR start: week 2 Carbohydrate: 43%, Fat: 19.4%, Protein: 33.7% Soups, shakes, bars. Clients are instructed to consume four TDR products a day. Participants are sent 5 × TDR product samples in the Welcome Pack that goes out approx 1 week in advance of Session 1 and when they order their first products.

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
4	What (procedures - FR e.g. process of reducing TDR products, energy prescription etc.)		Service Users will gradually re-introduce food using a stepped approach. At the latest, the Service User should have ceased using TDR products provided by the Provider by the end of 18 weeks following commencement of the TDR Phase. The focus is on the transition from TDR to a balanced diet. The Provider must support the Service User to achieve the correct calorie intake and nutritional balance from real foods, with targets set according to the Service User's preference for maintaining their weight or aiming for further controlled weight loss and improved diet quality through nutritional and behaviour change support.	Participant will transition on to 'Lunch' or 'Dinner' meals whilst maintaining the other amount calories from their dietary replacement products.	1 TDR product replaced with 1 healthy balanced meal in 1-week intervals
4	What (procedures - WM e.g. dietary advice)		Following the TDR Phase or any further period of TDR, i.e. rescue packages, the design and delivery of the curriculum must be underpinned by the UK Government dietary recommendations. The current recommendations are detailed in the Eat Well Guide.	Healthy eating principles (5-a-day, Eatwell Guide)	Healthy eating principles (5-a-day, Eatwell Guide) During the Maintenance Stage we provide our SUs with a variety of options that they are able to choose from.

SP2 group	SP2 digital	SP3 group	SP4 digital
1 TDR product replaced with 1 healthy balanced meal in 1-week intervals	1 TDR product replaced with 1 healthy balanced meal in 1-week intervals	For 2 weeks 1 TDR replaced with meal and have 3 TDR products. For the following 2 weeks participant has 2 TDR products, 2 meals and 1 fruit For the final 2 weeks participant has 3 meals, 1 TDR product and 1 fruit	The standard food reintroduction model will be: o Week 1: Two shakes/day and one meal (400 kcal meal = 800 kcal/day in total) o Week 2: One shake/day and two meals (two 300–400 kcal meals = 1000–1200 kcal/day in total) o Week 3: Fully food based and working up to maintenance calories (3 meals each of 300-400 kcal = 1000-1200 kcal/day) o Week 4: Fully food based and working up to maintenance calories (3 meals each of 300-400 kcal +/− healthy snacks = 1200-1500 kcal/day) The calories per week may vary slightly from patient-to-patient. Clinical judgement used to reach their maintenance calories when setting out their four-week plan (typically 1200-1500 kcal for women and 1500-1800 kcal for men for their maintenance calories)
Healthy eating principles (5-a-day, Eatwell Guide) During the Maintenance Stage participants are offered a variety of options that they are able to choose from.	Healthy eating principles (5-a-day, Eatwell Guide) During the Maintenance Stage participants are offered a variety of options that they are able to choose from.	Healthy eating principles (5-a-day, Eatwell Guide)	Healthy eating principles (5-a-day, Eatwell Guide), Personalised meal plan Intermittent fasting Low fat diet Low-carbohydrate diet Prescribed energy deficit Patients will be advised to follow a food-based diet and will be provided with an individually tailored energy prescription to support weight stabilisation or further weight loss and prevent weight regain.

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
4	What (physical activity recommended)		During the TDR Phase it is not recommended that additional physical activity is encouraged. However, following TDR, the Provider will support Service Users to undertake regular physical activity and aim to minimise or break-up extended periods of being sedentary, ultimately working towards achieving the UK Chief Medical Officer's physical activity recommendations. WM - The Provider must support the Service User to set tailored achievable short, medium and long term dietary and physical activity goals. The Provider must support the Service User to ensure appropriate energy intake, and steady increases in appropriate physical activity to meet their individualised weight maintenance goals.	PA recommended during food reintroduction phase and maintenance phase	PA recommended during maintenance phase
4	What (physical activity offered)		No information	FR: Physical activity advice only. WM: Physical activity advice only. Signposted to another programme	WM: Non-supervised (pre-recorded) sessions, Physical activity advice only, Signposted to another programme

SP2 group	SP2 digital	SP3 group	SP4 digital
PA recommended during maintenance phase	PA recommended during maintenance phase	PA recommended during food reintroduction phase and maintenance phase	PA recommended during TDR phase, food reintroduction phase and maintenance phase
WM: Non-supervised (pre-recorded) sessions, Physical activity advice only, Signposted to another programme	WM: Non-supervised (pre-recorded) sessions, Physical activity advice only, Signposted to another programme	FR: Physical activity advice only, signposted to another programme M: Physical activity advice only, signposted to another programme	TDR: Physical activity advice only, signposted to another service: dependent on what services are available in the local area. FR: TDR: Physical activity advice only, signposted to another service: dependent on what services are available in the local area. M: TDR: Physical activity advice only, signposted to another service: dependent on what services are available in the local area.

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
5	Who provided (delivers)	State intervention providers (e.g., dietitian, psychologist), their expertise, background, any specific training given and what component they are responsible for delivering.	The Provider must ensure that all individuals involved in the delivery of the Service have sufficient and appropriate training and competencies required to deliver the actions and content of the Service	Health & Wellbeing Coaches - all qualified up to master's degree in nutrition and experience of delivering similar programmes. No information on training/supervision.	Diabetes Practitioners (DPs) with a minimum of an undergraduate degree in Nutrition or Health related science such as Sports, Exercise Science, Psychology and would have previous experience in working with people with long term medical conditions. DPs are trained/supervised and backed by a robust multi-disciplinary team composed of specialist diabetes dietitians, psychologist, exercise physiologist, consultant diabetologist and general practitioner. They receive training in Cambridge Diabetes Education Programme.
5	Who provided (develops)		The Provider must ensure that a multi-disciplinary team of health professionals or specialists relevant to the core components of the Service (i.e. Type 2 diabetes, behaviour change, weight loss, diet) is involved in development of the Service. These should include, as a minimum; for example, a registered dietitian / nutritionist and registered health professional with specialist diabetes knowledge.	Programme development team included three members with backgrounds in: nursing (registered), psychology (undergraduate degree), nutrition (master's degree), fitness instructing, and service management.	Clinical Lead Dietitian, Medical Director, Consultant Diabetologist, Clinical Psychologist, Operations Director, Service Development & Exercise Lead, Quality Assurance Lead

SP2 group	SP2 digital	SP3 group	SP4 digital
Diabetes Practitioners (DPs) with a minimum of an undergraduate degree in Nutrition or Health related science such as Sports, Exercise Science, Psychology and would have previous experience in working with people with long term medical conditions. DPs are trained/supervised and backed by a robust multi-disciplinary team composed of specialist diabetes dietitians, psychologist, exercise physiologist, consultant diabetologist and general practitioner. They receive training in Cambridge Diabetes Education Programme.	Diabetes Practitioners (DPs) with a minimum of an undergraduate degree in Nutrition or Health related science such as Sports, Exercise Science, Psychology and would have previous experience in working with people with long term medical conditions. DPs are trained/supervised and backed by a robust multi-disciplinary team composed of specialist diabetes dietitians, psychologist, exercise physiologist, consultant diabetologist and general practitioner. They receive training in Cambridge Diabetes Education Programme.	Manager, registered dietitian, certified Advisor, qualified doctor, trained overseas undergoing conversion so not yet certified in UK Medical Director, GP, certified Coach 1, registered dietitian, certified Coach 2, registered dietitian, certified Coach 3, registered nutritionist, certified Coach 4, PhD and registered nutritionist, in certification. No information on training/ supervision.	Dietitians of at least band 6 (with relevant experience in diabetes and/or weight management) and must all have at least 1 year experience working with the provider organisation. The dietitians are trained internally on the low-calorie diet programme and competency is measured prior to working on the programme as well as throughout.
Clinical Lead Dietitian, Medical Director, Consultant Diabetologist, Clinical Psychologist, Operations Director, Service Development & Exercise Lead, Quality Assurance Lead	Clinical Lead Dietitian, Medical Director, Consultant Diabetologist, Clinical Psychologist, Operations Director, Service Development & Exercise Lead, Quality Assurance Lead	Clinical & Health Psychologist, Programme Development Director (physiologist and operations specialist), Exercise Physiologist and Learning & Development and Training specialist, Registered Dietitian Plus, additional consultants e.g. copyeditor, artworker etc.	Head of Clinical and Diabetes Specialist Dietitian, Clinical Lead Psychologist, Consultant Diabetologist, Diabetes Specialist Nurse, Specialist Obesity Dietitian

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
6	How	Describe the modes of delivery (e.g. f2f, group, individual, remote, app, telephone)	NHS England is looking to test a range of different delivery models including predominantly face to face one-to-one, face to face group, and remote/digital services to understand the optimal delivery of this low-calorie diet service in the real-world setting	Remote - internet based, phone based	Remote - internet based, phone based Information accessed: Forum, Programme app, Online course/modules: New content released every two weeks. Forum with other participants and programme staff, Live sessions at specific times only: Service users select their sessions at the booking call, we offer a variety of times to suit. Their session would be on the same day and time for each session, if they are unable to attend a session they will be offered an alternative session or a catch up call with our Diabetes Practitioner Team
8	When and how much (total duration)		52 weeks	52 weeks	52 weeks
8	When and how much (if group, group size)	Describe the number of times the intervention was delivered and over what period of time including the no. of sessions, their schedule, duration, intensity or dose.	Group sessions designed to be delivered to up to 15	Not applicable	Not applicable

SP2 group	SP2 digital	SP3 group	SP4 digital
Remote - internet based Forum, Programme app, Online course/modules: New content released every two weeks, Forum with other participants and programme staff, Live sessions at specific times only: Service users select their group at the booking call, we offer a variety of times to suit. Their group would be on the same day and time for each session, if they are unable to attend a session they will be offered an alternative group session or a catch up call with our Diabetes Practitioner Team	Remote - internet based, phone based Forum, Programme app, Online course/modules: New content released every two weeks. Forum with other participants and programme staff, Live chat with programme staff (text-only), Live sessions at specific times only: Time arranged with service user for all sessions on booking- same time and day each session. If they are unable to attend a session they will be offered an alternative session or a catch up call with our Diabetes Practitioner Team	Remote - internet based, phone based Forum, Programme website, Social media group, Forum with other participants and programme staff, Live chat with programme staff (face-to-face), Live sessions at specific times only: Various Other: Face to face programmes are offered over Zoom, which can be accessed by internet or phone. We will soon have a community forum available (likely on Facebook) and some groups decide to set up their own Whatsapp groups (not part of the formal programme and opt in basis individually)	Remote - internet based, phone based Programme app, Online course/modules: Modules released throughout the year long programme at set points - initially weekly and later on a monthly basis, Live chat with programme staff (face-to-face), Live chat with programme staff (text-only) Service users can opt for either phone calls or video calls.
52 weeks	52 weeks	52 weeks	52 weeks
Minimum - 15 Maximum - 15	Not applicable	Minimum - 8 Maximum - 15	Not applicable

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
8	When and how much (duration of each phase)		The Provider must provide the following minimum sessions with a Service User during the Service, constituting an overall minimum of 20 sessions: TDR: A minimum of 8 sessions in the first 12 weeks should be provided – these should take place weekly for weeks 1–4 and fortnightly in weeks 5–12. FR: A minimum of 4 sessions in weeks 13–18 should be provided M: A minimum of 8 sessions in weeks 19–52 should be provided	TDR: 12 weeks FR: 6 weeks M: 34 weeks	TDR: 12 weeks FR: 4 weeks M: 36 weeks
8	When and how much (number of sessions for each phase)		Digital: Within the service spec for the digital model, NHS England do not refer to sessions, as above, but refer to episodes of engagement. The minimum number of episodes of engagement is the same as the minimum number of sessions; 8 episodes of engagement during TDR phase, 4 during the food re-introduction phase and 8 during the maintenance phase.	TDR: 8 sessions FR: 5 sessions M: 8 sessions	TDR: 8 sessions FR: 3 sessions M: 9 sessions and final assessment
8	When and how much (session durations for each phase)		No information	TDR: 40 min FR: 40 min M: 40 min	TDR: 45 min FR: 45 min M: 45 min

SP2 group	SP2 digital	SP3 group	SP4 digital
TDR 12 weeks FR: 4 weeks M: 36 weeks	TDR: 12 weeks FR: 4 weeks M: 36 weeks	TDR: 12 weeks FR: 6 weeks M: 34 weeks	TDR: 12 weeks FR: 4 weeks M: 36 weeks
TDR: 8 sessions FR: 3 sessions M: 9 sessions and final assessment	TDR: 7 online learning modules, 5 review calls, 7 app chat engagements 15 - 45min FR: 2 review call sessions, 2 online learning modules and 1 digital coach chat engagement Average duration of session – 30min M: 9 (8 review calls and 1 final assessment), 9 digital coach chat engagements Average duration of session—15 min per session and 45 min for the final assessment	TDR: 8 sessions FR: 4 sessions M: 9 sessions	TDR: • Service users who opt for app coaching will be app coached 3 times a week • Service users who opt for the phone pathway receive a phone call every fortnight. FR: • Service users who opts for app coaching will be app coached 3 times a week (virtual chat) • Service users who opt for the phone pathway receive a phone call every fortnight Maintenance: Monthly (8 sessions)
TDR: 60 min and pre-session 1:1 measurement call FR: 60 min and pre-session 1:1 measurement call M: 60 min and pre-session 1:1 measurement call	n/a	TDR: 80 min FR: 70 min M: 75 min	TDR: • App coaching pathway: 3 × 5 min check in a week (virtual chat) • Phone pathway: 30 min FR: • App coaching pathway: 3 × 5 min a week • Phone pathway: 30 min M: 30 min

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
8	When and how much (session schedule)		No information	TDR: 4 weekly, 4 fortnightly FR:4 weekly 1 fortnightly M: monthly	TDR: 4 weekly, 4 fortnightly FR: 2 weekly 1 fortnightly M: 2 fortnightly sessions followed by 8 monthly sessions
9	Tailoring (e.g. safety measures, extra phone calls/support, cultural/social adaptations, taking 'time off' TDR, etc.)	If personalisation or adaptation of intervention is planned, then describe what, why, when, and how.	Delivery of the Service will be tailored to the circumstances and cultural context of Service Users and will be sensitive to different culinary traditions, including where possible for the TDR products themselves. The Provider must ensure that the Service is delivered in a way which is culturally sensitive to local populations, and flexible enough to meet the needs of Service Users with diverse needs. Where reasonable and appropriate, the Provider will provide Services in languages to suit the needs of the local population. Ideally staff delivering the Service will reflect the diversity of the population accessing the Service. Where Service Users are unable to comply with full TDR and are at high risk of dropping out of the NHS LCD Programme, they may, at any point, introduce firstly a single meal of non-starchy vegetables. If they remain at high risk of disengagement, they may further substitute a single TDR meal for a nutritionally appropriate meal of no more than 300 calories. The Provider must set out the point at which Service Users start to replace TDR products with an alternative meal.	No tailoring to specific groups. Non-starchy vegetables use in TDR phase—If the participant requires more fibre intake or if the participant is struggling with feeling hungry or low energy, they can be added at the TDR stage (Pro. Pre-Q).	Ethnic minority—We are able to provide language-specific group sessions, we provide opportunities for family and friend to attend sessions, our online modules have audio translated in: Hindi (Bengali, Turkish, Farsi & Gujarati are also in development). We provide gendered-specific sessions to suit different cultures and preferences. Our TDR products are all Halal and Kosher verified, we also provide vegetarian options. Non-starchy vegetables use in TDR phase - If a service user is at risk of dropping out the programme.

SP2 group	SP2 digital	SP3 group	SP4 digital
TDR: 4 weekly, 4 fortnightly FR: 2 weekly 1 fortnightly M: 2 fortnightly sessions followed by 8 monthly sessions	TDR: Review call sessions are on week 1, 3, 5, 9 and 11 and digital coach chat via the app on weeks 2,4, 6, 7, 8, 10 and 12 FR: Sessions on week 13 and 16, 1 digital coach chat on week 14 M: Monthly	TDR: 4 weekly, 4 fortnightly FR: 1 × individual phone call followed by a group 1 week later and then fortnightly groups M: Monthly	TDR: Service users who opt for app coaching will be app coached 3 times a week. Service users who opt for the phone pathway receive a phone call every fortnight. FR: Service users who opt for app coaching will be app coached 3 times a week. Service users who opt for the phone pathway receive a phone call every fortnight. M: Monthly
Ethnic minority—We are able to provide language-specific group sessions, we provide opportunities for family and friend to attend sessions, our online modules have audio translated in: Hindi (Bengali, Turkish, Farsi & Gujarati are also in development). We provide gendered-specific sessions to suit different cultures and preferences. Our TDR products are all Halal and Kosher verified, we also provide vegetarian options. Non-starchy vegetables use in TDR phase - If a service user is at risk of dropping out the programme.	Ethnic minority—We are able to provide language-specific group sessions, we provide an opportunity for family and friend to attend sessions, our online modules have audio translated in: Hindi (Bengali, Turkish, Farsi & Gujarati are also in development). We provide gendered-specific sessions to suit different cultures and preferences. Our TDR products are all Halal and Kosher verified, we also provide vegetarian options. Non-starchy vegetables use in TDR phase - If a service user is at risk of dropping out the programme.	Momenta joker cards. Joker 1: 1 meal or for whole day - can do twice in TDR phase. Joker 2, from week 5, can add a salad, veg or 300 kcal meal during day. Check frequency. Coaches who can speak multiple community languages (e.g. actively seeking more Urdu-speaking referrals for an Urdu programme), we have Coaches who could facilitate a female-only group e.g. for a specific group e.g. Muslim women. Another coach has experience of working with a first division football club and is very comfortable with all male groups. Ramadan-specific resources offered to participants. Non-starchy vegetables use in TDR phase - Only under the extremely limited circumstances allowed for in the specification	The dietitian delivering the SP4 programme ensures tailoring to the individual patient need, e.g., of content or access requirements. Attempts are made to match participants with coaches of a similar ethnic/cultural/religious background. Non-starchy vegetables use in TDR phase - Not included as standard but can be included if participants are struggling

(Continues)

TABLE 1 (Continued)

TIDieR checklist item no.	TIDieR item name	Item description	NHS specification	SP1	SP2 1:1
9	Tailoring (rescue package procedure)		If a Service User regains 2 kg or more at any time during the Weight Maintenance Phase, the Provider will put in place a relapse management protocol, also referred to as a 'rescue package', which includes the reintroduction of TDR, as outlined below, for a period of 4 weeks. - Where regain is 2-4 kg, 2 meals replaced with TDR products should be offered for a period of 4 weeks. - Where regain is greater than 4 kg, full TDR should be offered for a period of 4 weeks. The Provider shall not put in place more than one rescue package for any Service User and shall not put in place a rescue package for any Service User after the end of week 44	This is available if participants have regained weight during the maintenance phase. 2–4 kg partial rescue package 56 sachets-2 sachets per day for 28 days. 4 + kg full rescue package 112 sachets-4 sachets per day for 28 days. Extra support sessions will need to be booked weekly if a participant is taking a rescue package	If SU experiences weight gain during stage 3 from week 16 onwards and are eligible for the Reset Plan. Weight gain of more than 2 kg (4 lb) from lowest weight: Partial Reset Plan. Replacing 2 meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 5 weeks. Weight gain of more than 4 kg (8 lb) from lowest weight: Full Reset Plan Replacing all meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 7 weeks.

Note: Degree of provider fidelity to the full programme specification is highlighted through traffic light colour coding (green = complete fidelity, amber = some fidelity, red = low fidelity).Providers 1, 2, 3 and 4 in Table 1 do not correspond to providers A, B,C and D in Table 2 to preserve anonymity for provider organisations.

Abbreviations: NHS, National Health Service; STAR-LITE, STAndardised Reporting of adult behaviouraL weight management InTerventions to aid Evaluation survey; TIDieR, Template for Intervention Description and Replication framework.

is unique in that data was collected and analysed on BCT dose, which like BCT presence, was found to vary across the providers.

Importantly, we noted how the degree of fidelity of BCTs to the full programme specification reflected the degree of explicit theory use reported in an analysis of theoretical underpinnings undertaken by the same study team.[7] The provider with the strongest theoretical underpinnings was also found to have the strongest fidelity in their BCT content, whilst the two providers with the weakest theoretical underpinnings were also identified as having the weakest fidelity in their BCT content. This supports the notion that unclear theoretical underpinnings might result in a drift in programme fidelity.[7,28,29]

Although many studies evaluating programme designs have focused on coding BCTs,[25,30] we additionally assessed fidelity to service parameters using the TIDieR[21] framework. As we found several important service parameters to not demonstrate fidelity to the service specification, this illustrates other important components of an intervention's protocol[11] outside of BCTs where fidelity might be diluted during the design phase, and not captured using the BCTTv1[8] in isolation. Evaluators of the NHS-DPP also adopted this method,[17] however, they reported stronger fidelity of service parameters than the present study.

4.2 | Relation to existing research evaluating the effectiveness of BCTs

Evidence suggests some BCTs included in the NHS-LCD design may be more effective within the context of diet,

SP2 group	SP2 digital	SP3 group	SP4 digital
If SU experiences weight gain during stage 3 from week 16 onwards and are eligible for the Reset Plan. Weight gain of more than 2 kg (4 lb) from lowest weight: Partial Reset Plan. Replacing 2 meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 5 weeks. Weight gain of more than 4 kg (8 lb) from lowest weight: Full Reset Plan Replacing all meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 7 weeks.	If SU experiences weight gain during stage 3 from week 16 onwards and are eligible for the Reset Plan. Weight gain of more than 2 kg (4 lb) from lowest weight: Partial Reset Plan. Replacing 2 meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 5 weeks. Weight gain of more than 4 kg (8 lb) from lowest weight: Full Reset Plan Replacing all meals with TDR products for 4 weeks and then repeating the Food Reintroduction Stage. Total 7 weeks.	'Joker card 3': Mini reset plan If weight has increased by 2 kg (4.5 lb) during weight maintenance a patient can play this Joker. A mini reset consists of: • 4 weeks of x2 TDR products plus a 400-calorie meal a day • Return to 'real food' This Joker can be played once in Phase 3, but only if they have not already played a full-rest Joker 'Joker card 4': Full reset plan A patient can play this Joker if their weight has increased by 4 kg (9lbs) or more during weight maintenance. A full reset plan consists of: • 4 weeks of x4 TDR products a day; then • 1 week of x2 TDR products and 1 meal a day; and then • 1 week of x1 TDR products and 2 meals a day This joker can be played once in Phase 3, but only if they have not already played a mini reset joker	During the 12-month programme, patients will have one opportunity to do the Refocus phase if weight increases by more than 2 kg. The Refocus phase protocol will vary depending on how much weight the patient has gained. - Where regain is 2–4 kg, two meals should be replaced with TDR products over a period of 4 weeks (i.e, a partial meal replacement plan) - Where regain is greater than 4 kg, full TDR should be completed over a period of 4 weeks.

physical activity and/or T2DM management. A meta-analysis identified four BCTs in diet and physical activity interventions to be associated with clinically significant reductions in HbA_{1c}.[31] These included 'Action planning' and 'Instruction on how to perform the behaviour' (both of which were included in the full programme specification and all four of the providers' programme designs), in addition to 'Demonstration of the behaviour' and 'Behavioural practice/rehearsal' (neither of which were included in the service specification but were specified in two and three of the providers' programme plans, respectively). This suggests that some of the additional non-prescribed BCTs included in providers' programme designs may be beneficial to achieving programme outcomes. Evidence also supports the effectiveness of self-regulatory BCTs (e.g., goal setting, self-monitoring) for weight loss in participants at risk of or diagnosed with T2DM,[32–34] a variation of which was identified in the full programme specification[9] and each of the four providers' designs. Self-regulatory BCTs were also identified in the NHS-DPP specification documents.[17]

Nevertheless, it is important to note that the inclusion of these BCTs within providers' programme plans does not denote the actual delivery of these BCTs. For example, NHS-DPP providers planned to deliver 74% of the 19 BCTs in the NHS programme specification, whilst the research team observed only 7 of those 19 specified BCTs in all eight observation sites,[24] indicating difficulty in translating programme design into programme delivery. Ongoing research will examine programme delivery as part of the evaluation of the NHS-LCD Programme [NIHR132075].

TABLE 2 BCTs specified in the NHS-LCD full programme specification compared with BCT presence and dose of BCTs specified in providers' programme design documents.

Behaviour change techniques (BCTTv1)[8]	NHS-LCD specification documents	SPA[a]	SPB	SPB (x)	SPC	SPC (x)	SPD	SPD (x)
Goal setting (behaviour) [1.1]	✓	✓	✓	16	✓	10	✓	3
Problem-solving [1.2]	✓	✓	✓	33	✓	5	✓	8
Goal setting (outcome) [1.3]	✓	✓	✓	1	✓	13	✓	16
Action planning [1.4]	✓	✓	✓	28	✓	33	✓	23
Review outcome goal(s) [1.7]	✓	✓	✗		✓	2	✗	
Behavioural contract [1.8]	✓	✗	✗		✗		✗	
Feedback on behaviour [2.2]	✓	✓	✓	9	✗		✗	
Self-monitoring of behaviour [2.3]	✓	✓	✓	29	✓	6	✓	1
Self-monitoring of outcome(s) of behaviour [2.4]	✓	✓	✓	3	✗		✓	1
Feedback on outcome(s) of behaviour [2.7]	✓	✗	✓	20	✓	22	✓	19
Social support (unspecified) [3.1]	✓	✓	✓	10	✓	4	✓	4
Social support (practical) [3.2]	✓	✓	✓	1	✓	2	✓	1
Social support (emotional) [3.3]	✓	✗	✗		✗		✗	
Instruction on how to perform the behaviour [4.1]	✓	✓	✓	38	✓	11	✓	35
Information about antecedents [4.2]	✓	✓	✓	7	✓	4	✓	7
Information about health consequences [5.1]	✓	✓	✓	112	✓	14	✓	56
Information about social and environmental consequences [5.3]	✓	✓	✓	2	✓	5	✓	19
Social comparison [6.2]	✓	✓	✓	10	✗		✓	1
Habit formation [8.3]	✓	✓	✗		✓	1	✗	
Graded tasks [8.7]	✓	✓	✓	1	✗		✓	2
Social reward [10.4]	✓	✓	✓	10	✓	3	✓	2
Restructuring the physical environment [12.1]		✓	✓	5	✗		✓	2
BCTs targeting self-belief [15]	✓							
Verbal persuasion about capability [15.1]		✓	✓	2	✗		✗	
Mental rehearsal of successful performance [15.2]		✗	✓	1	✗		✓	3
Focus on past success [15.3]		✓	✓	9	✓	4	✓	19
Self-talk [15.4]		✗	✓	2	✓	3	✓	1
Review behaviour goal(s) [1.5]		✓	✗		✗		✗	
Discrepancy between current behaviour and goal [1.6]		✓	✗		✗		✗	
Commitment [1.9]		✓	✗		✗		✗	
Monitoring of outcome(s) of behaviour without feedback [2.5]		✓	✗		✗		✗	
Biofeedback [2.6]		✓	✗		✗		✗	
Information about emotional consequences [5.6]		✓	✓	2	✓	1	✓	3
Demonstration of the behaviour [6.1]		✓	✗		✗		✓	2
Information about others' approval [6.3]		✓	✗		✗		✗	
Prompts/cues- [7.1]		✓	✗		✗		✓	2
Behavioural practice/rehearsal [8.1]		✓	✓	3	✗		✓	2
Behaviour substitution [8.2]		✓	✓	5	✓	2	✓	1
Credible source [9.1]		✓	✓	2	✗		✗	
Pros and cons [9.2]		✓	✗		✓	1	✓	1

TABLE 2 (Continued)

Behaviour change techniques (BCTTv1)[8]	NHS-LCD specification documents	SPA[a]	SPB	SPB (x)	SPC	SPC (x)	SPD	SPD (x)
Comparative imagining of future outcomes [9.3]		✓	✗		✗		✗	
Social incentive [10.5]		✗	✓	2	✗		✗	
Self-incentive [10.7]		✓					✓	3
Self-reward [10.9]		✗	✓	4	✗		✓	1
Pharmacological support [11.1]								
Reduce negative emotions [11.2]		✓	✓	3	✓	7	✓	3
Conserving mental resources [11.3]		✓	✗		✗		✗	
Restructuring the social environment [12.2]		✓	✓	2	✗		✗	
Avoidance/reducing exposure to cues for the behaviour [12.3]		✓	✓	2	✗		✗	
Distraction [12.4]		✗	✓	2	✓	2	✗	
Adding objects to the environment [12.5]		✓	✗		✗		✗	
Identification of self as role model [13.1]		✓	✗		✗		✗	
Framing/reframing [13.2]		✓	✓	9	✗		✓	1
Valued self-identity [13.4]		✗	✗		✓	1	✗	
Identity associated with changed behaviour [13.5]		✓	✗		✗		✗	
Total BCTs (*n*)	23	44	33		23		30	

Note: Providers 1, 2, 3 and 4 in Table 1 do not correspond to providers A, B, C and D in this table to preserve anonymity for provider organisations.Numbers in square brackets are corresponding number in BCTTv1.

Fidelity to the full programme specification is highlighted through traffic light colour coding (green = present, red = absent). Additional BCTs not specified in the specification are not colour coded.

BCTs targeting self-belief were coded as one behaviour change technique in the NHS-LCD service specification as NICE guidelines did not specify which or how many of this BCT group should be included.

Abbreviations: BCT, Behaviour Change Technique; SP, Service Provider; x BCT dose.

[a]No information on BCT dose was reported in SPA's programme design.

4.3 | Strengths and limitations

By building positive stakeholder relationships, all documentation describing the service parameters and behaviour change content of providers' programme designs were obtained. All providers additionally completed the STARLITE survey[20] as a supplement to their design documents, to ensure all intervention components were captured. Our methodological approach was informed by that set out by NHS-DPP evaluators,[17] including the use of a validated tool for coding BCTs,[8,22] ensuring clear programme comparisons can be made by researchers and stakeholders.

Another strength of the present study is that by collecting and analysing data on the dose (frequency) of BCTs within NHS-LCD programme designs, the present research reports on and compares the intended BCT dose across providers. Whilst it was interesting to report and compare how dose varied across the different providers, it is important to note: (a) the limitations in terms of a lack of unifying definition for dose, and (b) that the service specification did not specify dose, therefore, the objective was not to examine fidelity to dose. However, by reporting on this we have provided the basis for the variation in dose across providers to be considered when comparing participant outcomes in the future.

High agreement between coders was indicated for BCT presence, but less so for BCT dose. One of the challenges of external evaluation is that BCTs are not always clearly described in the documentation from service providers, making identification difficult when the research team was not involved in the intervention design. For example, 100% agreement was calculated for the coding of SP4, where the intervention description used the labels and definitions outlined in the BCTTv1.[8] This limitation was acknowledged and mitigated through a rigorous approach by double coding all documentation and discussing all discrepancies until consensus was achieved. Furthermore, a limitation of using the BCTTv1[8] is that it is not an exhaustive list of behaviour change strategies. For example, it was noted that many providers drew upon Third-Wave Cognitive Behavioural techniques (e.g., mindfulness), whilst SP1 included many elements of 'Positive

TABLE 3 Dose of BCTs per session as specified in providers' programme design documents.

Behaviour change techniques (BCTTv1)[8] included in the full programme specification	SPC no. of sessions	SPC dose range	SPC mean dose	SPD no. of sessions	SPD dose range	SPD mean dose	SPB no. of sessions	SPB dose range	SPB mean dose
Goal setting (behaviour) [1.1]	9	1–2	1.1	3	1	1	11	1–3	1.45
Problem solving [1.2]	5	1	1	8	1	1	16	1–4	2.06
Goal setting (outcome) [1.3]	13	1	1	19	1–2	1.21	1	1	1
Action planning [1.4]	21	1–2	1.1	19	1–2	1.21	21	1–3	1.33
Review outcome goal(s) [1.7]	2	1	1	0	0	0	0	0	0
Behavioural contract [1.8]	0	0	0	0	0	0	0	0	0
Feedback on behaviour [2.2]	0	0	0	0	0	0	9	1	1
Self-monitoring of behaviour [2.3]	4	1–3	1.5	1	1	1	17	1–3	1.71
Self-monitoring of outcome(s) of behaviour [2.4]	0	0	0	1	1	1	2	1–2	1.5
Feedback on outcome(s) of behaviour [2.7]	22	1	1	19	1	1	19	1–2	1.05
Social support (unspecified) [3.1]	4	1	1	4	1	1	6	1–3	1.67
Social support (practical) [3.2]	2	1	1	1	1	1	1	1	1
Social support (emotional) [3.3]	0	0	0	0	0	0	0	0	0
Instruction on how to perform the behaviour [4.1]	6	1–3	1.83	10	1–12	3.5	13	1–5	2.92
Information about antecedents [4.2]	4	1	1	5	1–2	1.4	6	1–2	1.17
Information about health consequences [5.1]	8	1–4	1.75	11	1–15	5.09	16	1–17	6.59
Information about social and environmental consequences [5.3]	0	0	0	2	1	1	2	1	1
Social comparison [6.2]	0	0	0	1	1	1	10	1	1
Habit formation [8.3]	1	1	1						
Graded tasks [8.7]				2	1	1	1	1	1
Social reward [10.4]	3	1	1	2	1	1	7	1–2	1.43
Restructuring the physical environment [12.1]	0	0	0	2	1	1	4	1–2	1.25
BCTs targeting self-belief [15]									

TABLE 3 (Continued)

Behaviour change techniques (BCTTv1)[8] included in the full programme specification	SPC no. of sessions	SPC dose range	SPC mean dose	SPD no. of sessions	SPD dose range	SPD mean dose	SPB no. of sessions	SPB dose range	SPB mean dose
Verbal persuasion about capability [15.1]	0	0	0	0	0	0	2	1	1
Mental rehearsal of successful performance [15.2]	0	0	0	3	1	1	1	1	1
Focus on past success [15.3]	4	1	1	18	1–2	1.05	7	1–2	1.29
Self-talk [15.4]	3	1	1	1	1	1	1	2	2
Additional BCTs									
Commitment [1.9]	2	1	1	0	0	0	0	0	0
Information about emotional consequences [5.6]	1	1	1	1	3	3	1	2	2
Demonstration of the behaviour [6.1]	0	0	0	2	1	1	0	0	0
Prompts/cues- [7.1]	0	0	0	2	1	1	0	0	0
Behavioural practice/rehearsal [8.1]	0	0	0	2	1	1	2	1	1
Behaviour substitution [8.2]	2	1	1	1	1	1	5	1	1
Credible source [9.1]							2	1	1
Pros and cons [9.2]	1	1	1	1	1	1			
Social incentive [10.5]							2	1	1
Self-incentive [10.7]	0	0	0	3	1	1			
Self-reward [10.9]				1	1	1	3	1–2	1.33
Reduce negative emotions [11.2]	6	1–2	1.17	3	1	1	2	1–2	1.5
Restructuring the social environment [12.2]	0	0	0	0	0	0	2	1	1
Avoidance/reducing exposure to cues for the behaviour [12.3]	0	0	0	0	0	0	2	1	1
Distraction [12.4]	2	1	1	0	0	0	1	2	2
Framing/reframing [13.2]				1	1	1	7	1–2	1.29
Valued self-identity [13.4]	1	1	1	0	0	0	0	0	0

Note: Providers 1, 2, 3 and 4 in Table 1 do not correspond to providers A, B, C and D in this table to preserve anonymity for provider organisations.No information on BCT dose was reported in SPA's programme design.

Numbers in square brackets are corresponding number in BCTTv1.

Abbreviations: BCT Behaviour Change Technique; SP Service Provider.

Psychology' (e.g., gratitude, resilience) within their TDR session plans that were not captured by the BCT coding. Positive Psychology techniques focus on fostering well-being and positive affect as opposed to decreasing negative symptomatology.[35] The absence of this in our coding might help explain why SP1 is reported as including the smallest number of BCTs in their design. 'Increase positive emotions' has been suggested as a BCT for inclusion in future versions of the taxonomy[8]; based on our findings we would recommend inclusion to ensure BCT coding captures all active ingredients of any intervention.

4.4 | Implications for practice

Although providers generally reported good fidelity to the service parameters stipulated by NHSE, the lack of fidelity to some of the service parameters could compromise programme delivery and consequently programme outcomes. For example, one provider's inclusion of physical activity recommendations during the TDR phase might have implications for the safety of participants, as changes to physical activity are not recommended when consuming a low-calorie diet (800–1200 kcal/d) (e.g.[36]). Furthermore, another provider's lack of reporting on staff training may result in a dilution of training fidelity (i.e., the degree to which delivers are trained in the essential components of the intervention),[13] which may compromise delivery fidelity. Other aspects where fidelity was variable across providers, such as a lack of cultural adaptation, could have consequences for the success of minority group members on the programme. To improve this, the Patient Public Involvement Group for this evaluation have recommended adopting minimum standards for cultural adaptation to strengthen the NHS-LCD Programme specification.

As our findings illustrate the difficulty in translating NICE guidelines into BCTs implemented in programme designs, we have recommended to the NHSE that (a) necessitated BCTs be explicitly described in the service specification and (b) that providers be required to have a member of the programme development team with expertise in behaviour change (e.g., a health psychologist). Although three out of four pilot providers included a Clinical Psychologist in their programme development team (Table 1), this profession does not denote expertise in BCTs. If implemented, this could strengthen providers' fidelity to the BCTs specified in the NICE guidance referenced in the NHS-LCD specification.

By extracting and disseminating information on the NHS-LCD Programme design, those interested in implementing a similar programme will have a clear understanding of the service parameters and programme content. The Medical Research Council framework[37] recommends that intervention developers and evaluators clearly articulate an intervention's key components so they can be retained during programme adaptation or scale-up. Readers will have an understanding of the 'active ingredients' necessitated by NHSE[9] and NICE[18,19] and how additional techniques differ between service providers. Moreover, this study is unique in that planned BCT dose—both per session and across programme designs—was analysed and reported in addition to BCT presence. This will provide useful insights when comparing participant outcomes across the four providers, as these can be interpreted within the context of their differences in design and planned content. This may also further the evidence base for BCTs in diabetes programmes, as more research is needed on 'how much' of a BCT is necessary to improve T2DM management[31] and whether more BCTs are associated with superior outcomes. Advancements in this area will be supported by a systematic review and meta-analysis of common and effective BCTs in low-calorie diet interventions.[33] Furthermore, we recommend that service providers developing behavioural weight management programmes use a taxonomy to report their active ingredients in their design documents (e.g., the BCTTv1[8]) to ensure transparency and minimise the need for interpretation by independent evaluation teams.

4.5 | Implications for research

Although fidelity of design is key, equally important is what is subsequentially delivered, and how participants receive and enact the BCTs (i.e., the degree to which BCTs are understood and used by participants in their daily lives). A loss of fidelity at each stage could impact programme outcomes.[33] For example, BCT enactment was associated with improved effectiveness of a diabetes weight management programme (ADDITION-Plus trial); participants using all 16 programme BCTs lost significantly more weight than those using 10 or fewer.[34] However, evidence on the role of BCT delivery and/or enactment is limited, warranting investigation in future evaluations.[33] By reporting each of the providers' key intervention components and active ingredients, the current study provides the basis for assessing these in the later stages of the NIH-BCC model.[13]

Importantly, future research should link the data reported by the present study with the clinical outcomes of programme participants to examine whether the degree of fidelity and/or variation in delivery is associated with the degree of weight loss and T2DM remission.

5 | CONCLUSION

Although the four providers commissioned to deliver the pilot NHS-LCD Programme were identified as having fidelity to most of the service parameters outlined in the NHSE service specification, this study identified some important elements of lost fidelity. This may have consequences for programme delivery and thus programme outcomes, which will be assessed as part of the ongoing evaluation. Furthermore, most but not all (79.5%) of the BCTs specified by NHSE[9] and NICE[18,19] were included in providers' programme plans, in addition to a large number of further, non-prescribed, BCTs. Programmes featured large variations in the use of specific BCTs, as well as variations in their intended dose. We recommend that participant outcomes and experiences are compared across providers to understand how the variation in intervention techniques influences programme engagement and success.

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CONFLICTS OF INTEREST

All authors confirm that they have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

I confirm that my Data Availability Statement (pasted below) complies with the Expects Data Policy. The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study did not include human participants and therefore did not require ethical approval.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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