

Is the NHS low calorie diet programme delivered as planned? An observational study examining adherence of intervention delivery to service specification

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1 **Abbreviations**

2 T2DM – Type 2 Diabetes Mellitus

3 TDR – Total diet replacement

4 NHSE – National Health Service England

5 NHS-LCD – NHS Low-Calorie Diet Programme

6 LCD – Low-calorie diet

7 T2DR - NHS Type 2 Diabetes Path to Remission Programme

8 BCT – Behaviour change technique

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Title: Is the NHS low calorie diet programme delivered as planned? An observational study examining adherence of intervention delivery to service specification

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What is already known about this subject?

- Low calorie diets can have a positive impact on Type 2 Diabetes Mellitus and obesity.
- NHS England has commissioned a Low-Calorie Diet programme to aid in diabetes remission.
- Previous research from our group identified a drift in fidelity from the translation of service specification to provider service design.

What this study adds

- This study provides a synthesis of session observations of the delivery of the NHS Low-Calorie Diet programme.
- This is crucial for commissioners of similar services as it provides insight into the often unobserved interaction between coach and service user, and the way in which service specifications are translated into delivery.

Abstract

Aims: Obesity and Type 2 Diabetes Mellitus (T2DM) are chronic conditions with significant personal, societal, and economic impacts. Expanding on existing trial evidence, the NHS piloted a 52-week low calorie diet programme for T2DM, delivered by private providers using total diet replacement products and behaviour change support. This study aimed to determine the extent to which providers and coaches adhered to the service specification outlined by NHS England.

Methods: An observational qualitative study was conducted to examine the delivery of both one-to-one and group-based delivery of programme sessions.

Results: Observations of 122 sessions across eight programme delivery samples and two service providers were completed. Adherence to the service specification was stronger for those outcomes that were easily measurable, such as weight and blood glucose, while less tangible elements of the specification, such as empowering service users, and person-centred delivery were less consistently observed. One-to-one sessions were more successful in their person-centred delivery, and the skills of the coaches delivering the sessions had a strong impact on adherence to the specification.

Conclusions: Overall, the results show that there was variability by provider and delivery mode in the extent to which sessions of the NHS Low-Calorie Diet Programme reflected the intended service specification. In subsequent programmes it is recommended that one-to-one sessions are used, with accompanying peer support, and that providers improve standardised training and quality assurance to ensure specification adherence.

Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic condition with an increasing global prevalence (1), often associated with increased rates of obesity (2). The personal (3) and financial (4) cost of T2DM is high, and there is an urgent need to develop effective and equitable interventions. Recent trials have suggested that low-calorie diet interventions incorporating total diet replacement (TDR) may be an effective treatment for weight reduction and improved blood glucose control (5, 6). Building on this evidence, the National Health Service England (NHSE) launched a pilot programme of a low-calorie diet, TDR-based intervention for people living with T2DM and overweight or obesity, in September 2020 ('NHS Low Calorie Diet Programme' (NHS-LCD) now known as the NHS Type 2 Diabetes Path to Remission Programme (T2DR)). The NHS-LCD was a 52-week long programme, delivered by four independent providers via digital, group or one-to-one coaching sessions. The programme included a 12-week TDR phase followed by approximately 6-weeks of gradual food reintroduction, then a weight maintenance phase, alongside dietary and physical activity guidance, supported by behaviour change techniques (BCTs). A full description of the intervention can be found in Evans et al. (7).

The commissioned providers' programme designs, including the content and delivery of the coaching sessions, were derived from the NHSE service specification (8), which mandated use of BCTs and other service parameters such as empowering service users, promoting inclusion and tailoring to cultural context. Both the service parameters and the delivery of BCTs were important elements of the pilot; the delivery of BCTs was crucial to support efficacy and adherence to the lifestyle components of the programme, while the service parameters were established to ensure consistency and equity of provision.

Previous studies have evaluated the underpinning behavioural science theory (7) and the intended BCTs and service parameters (9) across the different service providers. This work highlighted a drift in fidelity when comparing the provider specifications to that stipulated by NHSE (9), and demonstrated that fidelity of BCT delivery in comparison to the service specification was low to moderate, with variation across providers and delivery models (10). This suggests a drift in fidelity from NHSE service specification at design stage, and an incomplete adherence to the delivery of BCTs within the sessions, which could have implications for the outcomes of the programme.

The current study provides a supporting narrative to Evans et al (10) by qualitatively exploring whether the sessions were delivered in accordance with the service parameters stipulated by NHSE: providing insight into the consistency and equity of the programme, and whether it was delivered in alignment with the service specification commissioned by NHSE. The study therefore addresses the following two research questions: 1) Based on qualitative observation of sessions, did the delivery of sessions reflect the stipulated parameters of the NHSE service specification? 2) Were there differences in delivery across providers, delivery modes and programme stages?

Methods

Design, setting and participants

An observational study was conducted to examine the delivery of both one-to-one and group-based delivery of programme sessions, employing a qualitative approach (11). Full details of the methodology can be found in Table A in the supplementary material and is briefly described below.

Three providers were commissioned to deliver one-to-one or group-based online or face-to-face behavioural support across ten localities in England. However, due to a lack of engagement from one provider, sessions were sampled from two providers across five localities between January 2022 and February 2023. In response to the COVID-19 pandemic, all sessions were conducted remotely using videoconferencing software. Table 1 outlines the coverage of session observations for each sample.

[Insert Table 1]

For provider 1, two group-based courses were observed, for provider 2, two group-based courses and four one-to-one courses were observed. Due to two participant withdrawals, only one full one-to-one course across all phases and weeks of the programme was observed. In sample eight, data collection began during the middle of the programme to ensure observation of the remaining sessions (see Table 1).

Procedure

Service providers were invited to participate in this study by NHSE who acted as the gatekeeper. We asked service provider leads who are delivering the sessions to be observed, to circulate a participant information sheet and to gain consent from each group participant prior to the observations. The service provider session leads completed a consent form which confirmed the distribution of the information sheet, and gaining of consent, from each group participant. The researchers were not active participants in the group and were there to observe only. The study received ethical approval from Leeds Beckett University (107887) and data collection occurred between January 2022 and February 2023.

Two researchers observed the live sessions. One recorded the delivery of planned BCTs as described by Evans et al (10). The other researcher (JM, KK, TB, LJE, KD, SJ, or CH) used a session observation checklist to capture whether the delivery of the session aligned with the service specification (8). The checklist was developed by KD, by extracting information from the NHSE service specification and included a list of programme principles which acted as prompts for qualitative field notes for session observers (see Table B in supplementary material). The final checklist was reviewed and agreed with the rest of the research team.

Analysis

The field note observation logs were coded using NVivo 12 software against a coding framework containing the 33 service specification items spanning each phase of the programme. Initially data were coded against each item within the 33-item specification, which were then consolidated, merging 33 items to 5 core components. The merged groupings were further amended, to remove items already addressed via the BCT coding (see Evans et al (10)) resulting in a final group of 4 core components: 1) methods of delivery; 2) person-centred delivery; 3) empowering behaviour change via social and psychological support; and 4) procedural items. These components were used as a framework for summarising the qualitative observational data, see Table 2.

[Insert Table 2]

Results

Table 3 shows participant retention in the group programme. Both providers experienced attrition, with each group seeing a high rate of reduction in participants by the 52-week end of the programme (retention ranged from 42.9% - 60.0%).

[Insert Table 3]

The adherence of the sessions to the programme specification varied between and within providers. Table C in the supplementary material illustrates examples of good practice and areas for improvement by provider and delivery model, supported by extracts from observer field notes. Below is a synthesis of observations pertaining to specification adherence organised by the four core components.

1. Methods of delivery

‘Methods of delivery’ encompassed factors such as the type of information that was provided, and how this was delivered. Delivery was conducted online using PowerPoint presentations, participant handbook/modules and references to a provider app where relevant. During remote delivery, participants were able to join sessions from various locations such as their workplace or car, leading them to often refrain from using cameras, microphones, or chat functions. While this flexibility was beneficial for individuals who might not have otherwise participated, it hindered group engagement and interaction with the coach. As a result, it proved challenging for observers to determine the level of engagement in the programme. Although the service specification did not stipulate specific methods of delivery, the observations made here, such as the skill of coaches in delivering the material, underpin the adherence to other service specification items, as discussed in the following sections.

Across both providers, variations in teaching styles and levels of staff experience were observed in the delivery methods of different coaches. Although both providers demonstrated instances of strong delivery, the methods used by Provider 1 more often provided a hands-on approach to learning, promoting visual engagement and interaction with the content and between group members through methods such as flip-chart activities. These

included delivering online presentations in an informal yet structured manner and prioritising discussion over reliance on PowerPoint slides. The use of breakout rooms using the videoconferencing software enabled participants to engage in smaller group discussions, promoting active participation. In contrast, the delivery from Provider 2 often followed a lecture-style format, with emphasis on slides, and fewer opportunities for discussions. Many of these slides detailing session structure and approach were repeated during sessions throughout the programme. This demonstrates the provider adhering to the service specification content, but observations often suggested that this approach was repetitive and left less time for covering important session content and participant interaction.

There was also variability between coaches in the time allocated for questions and the use of the chat function. When coaches possessed strong facilitation skills, they were able to effectively manage the session and allocate sufficient time for participants to ask questions. This approach ensured that participants understood the topic and had opportunities to clarify their understanding and gain further insights which enhanced the person-centredness of delivery. However, across both providers some coaches appeared to lack the skills to manage time effectively meaning that content was missed, and there were missed opportunities to fully engage in issues brought up by participants. For Provider 2 group delivery, the main approach to interaction between coach and participants was through the online chat function, which resulted in a less interactive delivery.

2. Person-centred delivery

Adopting a person-centred approach was stipulated in the NHSE service specification. Effective person-centred delivery included building relationships with participants. Participants appeared to be well-engaged when coaches used friendly language, accessible

217 communication, and made efforts to establish connections. For example, coaches created an
218 inclusive atmosphere by using language such as 'us' instead of 'you', emphasising their
219 presence and support throughout the participant's journey.

220 There was evidence of a person-centred approach being delivered in all three phases and by
221 both providers, with Provider 1 demonstrating more effective implementation. In the first
222 phase (TDR), the coach empathised with potential challenges such as experiencing hunger. In
223 the second and third (food reintroduction, weight maintenance) phases, the coach used a
224 calming tone to reflect on group achievements and reinforce success and efforts.

225 During Provider 2 one-to-one sessions, tailored person-centred delivery was evident. The
226 coaches focused on the participant's personalised action plan and employed motivational
227 interviewing skills by summarising, affirming, and reflecting on positive aspects. The one-to-
228 one delivery model appeared to facilitate adherence to the service specification. Maintaining
229 focus on individual goals and discussions proved more challenging in group sessions, and
230 some participants appeared more willing to share experiences in breakout groups without
231 direct coach involvement.

232 Coach continuity influenced the relationship with participants; over time the rapport between
233 coach and participants grew stronger. In contrast, when substitute coaches led sessions,
234 participants interacted less. This was particularly important for the one-to-one delivery
235 illustrated by Provider 2, where one participant experienced poor coach continuity, making it
236 difficult to establish a relationship despite the encouraging and empathetic nature of different
237 coaches.

238 Some coaches, across both providers, demonstrated less person-centred approaches,
239 including rehearsed and rigid delivery reminiscent of reciting from a script, as well as direct

240 and unempathetic approaches, and the use of academic and non-person-centred language.

241 In one session, person-first language was not used, and participants were referred to as

242 'diabetics'. Some sessions were described by observers as prescriptive, with didactic delivery

243 and limited group interaction. There were also instances where a disconnect existed between

244 the coach and participants' lived experiences, particularly concerning socio-demographic

245 differences. For example, during a group session, one participant reported that her clothes

246 no longer fit her due to weight loss. The coach responded by saying it was a good excuse to

247 buy a new wardrobe, however, the participant responded that she could not afford it.

248 Despite some efforts to customise service delivery and address the diverse needs of the

249 population, this was not consistently achieved, particularly in group settings. For example, a

250 participant raised challenges related to work and home life, concerning the timing of using

251 TDR products. The participant worked in a nursery and found it difficult to provide food for

252 others while being on TDR. The coach was unable to offer tailored solutions or advice on how

253 to handle these challenges effectively. However, in one-to-one sessions, these needs were

254 more easily accommodated, providing a personalised and accessible approach tailored to a

255 participants' specific needs and circumstances.

256 Despite the ethnically diverse composition of the groups, there was limited cultural

257 adaptation in the programme delivery across Provider 2's sessions (both group and one-to-

258 one). Missed opportunities occurred in addressing cultural barriers to exercise and the

259 significance of culturally adapting food, which could have offered valuable insights and

260 strategies for fostering inclusivity, meeting diverse needs and improved future service

261 delivery through feedback by coaches. Provider 1 demonstrated adaptations to encompass

262 cultural diversity, such as accommodating dietary preferences, discussing culturally diverse

263 foods and signposting to the provider website which offered resources related to Easter and
264 Ramadan.

265 3. Empowering behaviour change via social and psychological support

266 Provider 1 coaches encouraged participants to seek social support from family and friends,
267 share experiences, and adopt new habits during the programme. As a result, some people
268 attended the sessions with a family member. Observers noted varying degrees of social
269 support within the group setting, with some groups showing cohesion, peer discussion, and
270 encouragement, while others had limited interaction. In one instance, a group independently
271 created a peer WhatsApp group for support and idea sharing. For some groups, peer support
272 was evident in breakout rooms, where participants discussed common challenges or tips.

273 Some coaches opted for a procedural delivery style, while others actively sought to empower,
274 verbally reward, and motivate individuals through praise, and celebrating success. When
275 coaches encouraged active participation and fostered a sense of achievability within a
276 supportive environment this was well received. An example of this was a step count activity
277 where participants tracked their weekly steps to reach a destination on a map, which service
278 users actively engaged with. However, some instances of social support may have had
279 unintended consequences; in Provider 1's final session, the coach specifically highlighted
280 individuals who had achieved weight loss and publicly recognised their accomplishments by
281 announcing their names in front of the group. As a result, the observer noted that some
282 members of the group left the session shortly after the discussion. This raised concerns about
283 potential feelings of shame for those who had not met their weight loss targets. In contrast,
284 the other Provider 1 coach reported achieving targets as a group rather than an individual
285 level. This approach appears to be more inclusive and empowering, as it acknowledged the

progress of the entire group and provides support to all participants regardless of their individual weight loss.

Although not stipulated in the specification, it was observed that a clear support gap was identified across providers on emotional eating and psychological support (see Table C 'areas for improvement'). It was unclear if this support gap arose from time constraints or insufficient coach training. This observation was important, as the ability to empower participants for long-term behaviour changes relied on the individual coach's skill set which appeared to be variable.

4. Procedural items

Providers used varying approaches to ensure adherence to the TDR phase. The NHSE specification stipulated where there was risk of disengagement, a single meal of non-starchy vegetables could be offered, with further substitution of a single TDR meal with a nutritionally appropriate meal of no more than 300 calories. Between providers, there was some discrepancy around supplementing TDR products with non-starchy vegetables. Initially, Provider 2 permitted consumption of non-starchy vegetables during the TDR phase. Provider 1 discouraged regular use but offered an alternative by allowing one-off food consumption for a day, which could be used up to three times during the TDR phase. Neither of these approaches were entirely compliant with the NHSE service specification. However, observers noted that the approach of Provider 1 was advantageous for participants who had special events to attend, providing them with the opportunity to enjoy the occasion without feeling restricted, and therefore making the programme more personalised and accommodating to individual needs.

308 Providers generally followed the specification regarding the gradual transition from TDR to
309 food reintroduction and weight maintenance stages. However, for one provider, sessions
310 appeared to lack a clear association with the relevant phase of the programme. This is
311 essential as each phase of the programme involves specific requirements and changes, and
312 therefore needs different information and support. For example, one coach failed to discuss
313 TDR in multiple sessions during the TDR phase. In addition, coaches occasionally deviated
314 from the session plan, discussing topics such as physical activity which should not be
315 discussed or advocated during TDR according to the NHSE specification (section 3.2.15).

316 Session content aligned with national dietary and physical activity recommendations (as cited
317 in section 4.1), providing information, and promoting behaviour change. Evidence-based
318 research and government guidelines were presented during food reintroduction and weight
319 maintenance, along with tools supporting the Eat Well Guide and practical resources for
320 behaviour change, such as meal planning using recommended measures/servings and online
321 tools.

322 Both providers demonstrated strong adherence to recording and monitoring outcomes that
323 were easily measurable, such as weight and blood glucose, which were collected via the
324 provider app, in the session (for 1:1 delivery), or via 1:1 phone calls with individuals taking
325 part in group delivery. Comparatively, there was less adherence to outcomes that were not
326 captured as part of programme reporting, for example there was inconsistency of messaging
327 regarding physical activity during the TDR phase, and of linking to local services. Participant
328 involvement and engagement in the design, evaluation, and improvement of the programme
329 appeared limited during sessions. Occasionally coaches signposted participants to survey links

to provide feedback on their experience of the programme as part of a provider-led evaluation.

Discussion

This study explored whether providers and coaches of the NHS LCD Programme delivered sessions which reflected the NHSE service specification, and whether there were differences in delivery across providers, observed delivery modes, and programme stages.

Overall, the study revealed generally consistent delivery of the specification across all three phases, while the primary differences observed related to delivery models and providers. However, these differences did not appear to impact the level of attrition, which was considerable over the programme, with both providers experiencing almost a 50% reduction. Although this is not uncommon in similar low calorie diet programmes (12), it may suggest that participants were not sufficiently engaged by the LCD programme, content, or delivery. Participant engagement with the content was difficult to ascertain, however the observations suggested providers and coaches did not appear to seek participant involvement in the evaluation, and improvement with the programme which was a requirement of the NHSE specification. Better enactment of this specification item by regularly seeking and acting on service user feedback within sessions may have improved attrition.

Regarding methods of delivery observed, it is important to acknowledge the effect of COVID-19 and the impact of session plans designed for face-to-face delivery being delivered remotely. While remote delivery allowed participants to fit the sessions around their existing commitments, it may have also presented barriers to group engagement that may not have been present if the programme had been delivered as planned. As the national roll-out of T2DR will include the provision of a choice of digital or in-person one-to-one delivery, this

353 could potentially enhance adherence to the service specification and improve intervention
354 delivery.

355 Coaches from both providers had heterogeneous experience and skill sets, potentially
356 impacting their methods of delivery because the providers deliver a range of weight and
357 lifestyle interventions, supporting the findings from Evans et al (10) which highlighted that
358 coaches were a source of variability in the delivery of BCTs. The use of complex and
359 academic language in some sessions was problematic and could present challenges for
360 those who have English as a second language or have lower health literacy than assumed by
361 the coaches, potentially hindering their understanding of the programme. Previous research
362 has identified that communication strategies used in public health interventions need to be
363 sensitive to language in order to be appropriate for global majority communities (13).
364 Furthermore, there is an association between lower health literacy and poor glycaemic
365 control in patients with T2DM (14), demonstrating the importance of ensuring session
366 content is clearly communicated and understood by a wide range of audiences.

367 One-to-one delivery was successful in offering a person-centred approach, while group
368 settings posed challenges in achieving the same level of personalisation. Evans et al (10)
369 found that there was greater fidelity of BCT delivery in the group-based delivery models
370 (64%) as opposed to the one-to-one models (46%), however this was largely due to
371 provider-level characteristics, rather than the delivery model itself. Evans et al (10) also
372 found that the delivery methods adopted by Provider 1 contributed more favourably to the
373 successful delivery of BCTs than the methods used by Provider 2. This complements the
374 current findings which suggest that the diverse and interactive delivery methods used by
375 Provider 1 promoted more engagement with the session content. It is critical to understand

376 service user experience of these delivery models to further inform session design, and to
377 evaluate the impact of delivery style on programme outcomes (15).

378 Friendly and accessible communication, an ability to provide positive feedback, and
379 dedicated efforts to establish connections and build relationships were all critical to person-
380 centred delivery. The impact of coach continuity on building the coach-participant
381 relationship was also crucial, as it fostered trust over time, leading to better support for
382 participants. The findings reported in this study suggest that in one-to-one delivery, the
383 coach-participant relationship allowed for better support and a deeper understanding of
384 individual needs which enabled more personalised feedback and tailored guidance. In
385 contrast, tailoring of the service was more challenging in group sessions due to limited
386 opportunities for individualised attention. However, providing tailored resources, like TDR
387 support during religious celebrations, can play an important role in enhancing commitment,
388 encouraging participation, and fostering inclusivity. Personalising the delivery of health
389 interventions has been found to have a beneficial impact on the understanding of a
390 condition in people with hypertension (16), suggesting that interventions which allow for
391 greater tailoring and person-centred delivery may be more impactful on clinical outcomes.

392 Instances of a lack of person-centred delivery are problematic and should be addressed by
393 providers. Inappropriate language such as referring to participants as 'diabetics' is
394 potentially stigmatising and contrary to Language Matters guidance (17). Additionally, a lack
395 of sensitivity to the differing socio-demographic and economic situations of participants
396 could contribute to embarrassment or ultimately disengagement from the programme, and
397 it is essential that providers ensure that coaches are trained to be mindful of these issues.

398 Coaches across both providers and delivery models sought to empower participants to
399 engage with behaviour change via social and psychological support. While some of this
400 support was provided in the sessions, this study found that additional peer support was
401 facilitated through the participant-led WhatsApp group in Provider 1. Previous research in
402 nicotine use has demonstrated that interventions that encompass WhatsApp groups are
403 more effective than Facebook groups in reducing relapse, due to the enhanced social
404 support provided (18). Utilising platforms like WhatsApp enables real-time communication,
405 group interaction, and idea exchange, promoting peer support and encouragement in a
406 convenient and accessible manner. Opportunities to integrate wider social and familial
407 support also need to be capitalised on by coaches, as previous research has demonstrated
408 the importance of familial support in the effective management of T2DM (19).

409 The identified gap in psychological support for emotional eating needs to be addressed by
410 providers. The Diabetes Prevention Programme identified a positive association between
411 emotional eating and BMI (20), and other studies have evidenced that reducing emotional
412 eating increases the odds of weight loss in adults with diabetes (21), suggesting that people
413 who report emotional eating in similar programmes may have a higher starting BMI, and may
414 experience more difficulties in managing their weight and sustaining weight loss. Additionally,
415 a significant proportion of people referred to the LCD programme report binge or emotional
416 eating (22). Other insights from the evaluation (23) suggest that providers view service users
417 with mental health issues and disordered eating to be ‘inappropriate’ referrals, therefore
418 training for coaches should cover supporting participants with emotional and disordered
419 eating behaviours (24).

Procedural items were most consistently observed when they related to programme reporting. The other elements of the specification that were observed under this component were often not delivered in adherence to the specification, such as the provision of NSV, the use of TDR products and the appropriateness of physical activity in TDR stage. This finding aligns with previous research (9) which highlighted a lack of adherence to the NHSE specification in the design phase. Having sessions aligned with the respective programme phases ensures participants receive the appropriate guidance and assistance at each stage, so this lack of discussion, or misinformation on a crucial aspect of the programme could have impacted participants' understanding and adherence to the TDR phase. It is critical that there is adequate translation of the specification into the programme design, that coaches do not deviate from the programme specification, and standardised training for all coaches is provided to ensure consistent delivery, but that this is balanced with coaches being able to adapt to participant needs.

Strengths and limitations

The study gives insight into what is often an un-observed relationship between provider and participant, therefore adding to our understanding of best practice, and where provision can be improved. Few commissioned services are observed in this way, and this study therefore provides important learning for commissioners about the translation of a service specification into practice. Reducing health inequalities was a key element of the NHSE service specification, however this was difficult to assess through observations of delivery, and needs to be assessed through analyses of programme data collected by providers, and the National Diabetes Audit (25). While it is important to include the reduction of health inequalities in the service specification, there is a need for clarity on the specific meaning and metrics attributed

to this statement. Additionally, the observation of sessions is only one element of provider content, meaning that while elements of the service specification may be missing from this delivery, they may be met using other elements of delivery such as via apps or 1:1 phone calls, that were not observed by researchers. Finally, one of the three providers did not engage with the evaluation process and therefore could not be observed, and of the two providers included in this paper one provided more data to the evaluation.

Conclusion and recommendations

Overall, there was variability by provider and delivery mode in the degree to which sessions of the NHS LCD Programme reflected the intended service specification. Elements of the Re:Mission evaluation have already informed development of the programme specification and been integrated in the national roll out of the LCD programme, including solely one-to-one delivery (either in-person or digitally), cultural competency training, and provision of peer support groups.

While both group and one-to-one delivery models can be effective, the one-to-one model allows for a more personalised and tailored delivery. Consequently, providing participants with the opportunity to choose their preferred delivery model is recommended. Providers should improve standardised training for coaches, and quality assure delivery to ensure consistency and improved outcomes, and should include specific training around supporting participants with emotional and disordered eating behaviours. Providers should also seek to improve the cultural competence of programme, learning from good practice such as incorporating tailored dietary support for different religious festivals. Finally, coaches should promote and facilitate informal peer-to-peer support among programme participants, which can foster a sense of community, empathy, and motivation among the participants.

Conflicts of Interest:

All authors confirm that they have no conflicts of interest to declare. Louisa Ells has received funding from NIHR, MRC, Leeds City Council and OHID/PHE in the last 3 years and has an honorary contract with OHID. Tamara Brown received funding from NIHR and OHID/PHE in the last 3 years and has an honorary contract with OHID.

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Tables

Table 1. Sample characteristics

Provider	Sample	Delivery model	Access to a programme specific app	Session numbers observed (n=124)
One	1	Group	No	Full course
One	2	Group	No	Full course
Two	3	Group	Yes	Full course
Two	4	Group	Yes	Full course
Two	5	One-to-one	Yes	Full course
Two	6	One-to-one	Yes	1 - 10
Two	7	One-to-one	Yes	1 - 3
Two	8	One-to-one	Yes	14 - 21

Note. locality is not reported to protect anonymity.

Table 2: Merged specification grouping

Merged grouping name	Original service specification groupings	Original service specification items added to merged grouping name
1.Methods of delivery	Methods of delivery	<ul style="list-style-type: none"> - What information has been provided? - What supporting material has been used? - What methods of communication has been used for delivery?
2.Person-centred delivery	Adopted approach	<ul style="list-style-type: none"> - Adopt a person-centred, empathy-building approach in delivering the service. This includes finding ways to help service users make changes by understanding their beliefs, needs and preferences and building their confidence. -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 - Delivery of the service will be Tailored to the circumstances and cultural context (their needs) of Service Users and will be sensitive to different culinary traditions, including where possible for the TDR products themselves. - Access to the Service will accommodate the diverse needs of the target population in terms of availability, accessibility, customs and location, as far as possible.
	Relationship	<ul style="list-style-type: none"> - All individuals must be treated with courtesy Nature of relationship between provider and service user - Does the practitioner appear to be an appropriate person to be delivering the programme? - Staff delivering the service will, ideally, reflect the diversity of the population accessing the service.
	Content	<ul style="list-style-type: none"> - Dietary advice should reflect the culinary traditions of the communities in which the Service is being provided wherever possible.
3.Empowering behaviour change via social and psychological support	Content	<ul style="list-style-type: none"> - Content must consider the social and psychological support needed to support people to implement behaviour changes in environments which promote unhealthy behaviours - The content of the sessions with Service Users should aim to empower people with Type 2 diabetes to take a leading role in instituting and maintaining long-term behaviour changes.
	Support	<ul style="list-style-type: none"> - Ensure that family or peer support is accommodated where this would be helpful to a service user. - The Provider must provide Service Users with appropriate support throughout the duration of participation in the Service.
4.Practical support for goal setting outcome focus	Content	<ul style="list-style-type: none"> - Support to set tailored achievable short, medium and long term dietary and physical activity goals. - Support to ensure appropriate energy intake, and steady increases in appropriate physical activity to meet their individualised weight maintenance goals.

<p>*Note this grouping was removed as it covers BCTs discussed in Evans (9).</p>	<p>Support</p>	<ul style="list-style-type: none"> - Provide support for engagement, retention, and achievement of intended outcomes.
<p>5.Procedural items</p>	<p>Content</p>	<ul style="list-style-type: none"> - Provide information and practical tools on nutrition, behaviour change and weight management based on current national guidance e.g., the Eat Well Guide. - The Provider must support Service Users to achieve the Government's dietary recommendations, using dietary approaches that are evidence based and sustainable in the longer term. - The Provider must support Service Users to achieve the Government's dietary recommendations, using dietary approaches that are evidence based and sustainable in the longer term. - The Provider should ensure Service User involvement and engagement in the design, evaluation, and improvement of the Service.
	<p>Checks and measures</p>	<ul style="list-style-type: none"> - Medication check at commencement of TDR specifically: sulphonylureas, meglitinides or SGLT2 inhibitors - Weight measurements must be taken objectively at every face-to-face session. - Monitoring of adverse events and appropriate actions taken - For Service Users who are prescribed medication which may lower blood pressure at the time of referral, blood pressure must be monitored by the Provider as follows. During the TDR Phase blood pressure monitoring should be undertaken at every session with the Provider. - BMI check to ensure that if below 21 kg/m² (19 kg/m² in people of South Asian or Chinese origin) service user moves to weight maintenance phase with no further weight loss supported - During the TDR Phase and during any rescue package period finger prick capillary blood glucose testing should be undertaken at every session with the Provider
	<p>Programme messaging</p>	<ul style="list-style-type: none"> - Emphasise to service users the importance of continuing to attend for annual reviews at their GP practice, regardless of the outcome achieved with the Service.
	<p>Abstract programme principles</p>	<ul style="list-style-type: none"> - The Provider must use reasonable endeavours to ensure equal access by all Service Users, reduce health inequalities and promote inclusion, tailoring the Service to support and target those with greatest need through a proportionate universalism approach and equality of access for people with protected characteristics under the Equality Act 2010.
	<p>Food reintroduction</p>	<ul style="list-style-type: none"> - Stepped and gradual approach to food reintroduction. - Focus on transition from TDR to balanced diet. - Work with service users to assess their dietary intake and support planning of sustainable dietary changes, to achieve a

		<p>healthy balanced diet as set out in the current national guidance.</p> <ul style="list-style-type: none"> - During the Food Re-introduction Phase, the sessions must provide information and practical tools on nutrition and weight management based on current national guidance.
	Support	<ul style="list-style-type: none"> - The sessions must support behaviour change, enabling compliance with the TDR during the TDR Phase. - Support to achieve 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.
	Physical activity	<ul style="list-style-type: none"> - 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. - Sessions may incorporate methods for self-monitoring and may include the provision of, or integration with, wearable devices once the TDR Phase is complete.
	Rescue Package	<ul style="list-style-type: none"> - During the TDR Phase and during any rescue package period finger prick capillary blood glucose testing should be undertaken at every session with the Provider.
	Weight maintenance	<ul style="list-style-type: none"> - Focus on service user preference for maintaining a steady weight or aiming for further controlled weight loss and ensuring changes are embedded for the longer term. - As part of the Final Session, the provider must conduct a post intervention assessment of (objective) weight and wellbeing for all service users who attend. - As part of the Final Session BMI must also be calculated. - As part of the Final Session arrangements for collection of service user's feedback / customer satisfaction survey should be agreed. - As part of the Final Session, the Provider must conduct a post intervention assessment on the achievement of individual goals for all service users who attend.
Removed	Content	<ul style="list-style-type: none"> - Appearance of engagement by service users with session content. <p>This spec item was removed as this was deemed too subjective (determining someone's level of engagement based on whether their camera was on or off during virtual session is not an appropriate approach. There could be various reasons why someone keeps their camera off such as privacy concerns or technical limitations. Engagement was assessed based on active participation, contribution to discussion if there was one)</p>

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597 Table 3: Participant retention in the group programme

	Number of participants enrolled	Number of participants retained
Provider One Group A	15	7 (41.2%)
Provider One Group B	14	6 (42.9%)
Provider Two Group A	10	6 (60.0%)
Provider Two Group B	17	9 (52.9%)

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