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How is the NHS Low-Calorie Diet Programme expected to produce behavioural change to support diabetes remission: An examination of underpinning theory

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Abstract

Background: In 2020, the National Health Service Low-Calorie Diet Programme (NHS-LCD) was launched, piloting a total diet (TDR) replacement intervention with behaviour change support for people living with Type 2 Diabetes (T2D) and excess weight. Four independent service providers were commissioned to design and deliver theoretically grounded programmes in localities across England.

Aims: (1) to develop a logic model detailing how the NHS-LCD programme is expected to produce changes in health behaviour, and (2) to analyse and evaluate the use of behaviour change theory in providers' NHS-LCD Programme designs.

Methods: A documentary review was conducted. Information was extracted from the NHS-LCD service specification documents on how the programme expected to produce outcomes. The Theory Coding Scheme (TCS) was used to analyse theory use in providers' programme design documents.

Results: The NHS-LCD logic model included techniques aimed at enhancing positive outcome expectations of programme participation and beliefs about social approval of behaviour change, to facilitate programme uptake and behaviour change intentions. This was followed by techniques aimed at shaping knowledge and enhancing the ability of participants

to self-regulate their health behaviours, alongside a supportive social environment and person-centred approach.

Application and type of behaviour change theory within service providers' programme designs varied. One provider explicitly linked theory to programme content; two providers linked 63% and 70% of intervention techniques to theory; and there was limited underpinning theory identified in the programme design documents for one of the providers.

Conclusion: The nature and extent of theory use underpinning the NHS-LCD varied greatly amongst service providers, with some but not all intervention techniques explicitly linked to theory. How this relates to outcomes across providers should be evaluated. It is recommended that explicit theory use in programme design and evidence of its implementation becomes a requirement of future NHS commissioning processes.

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Key words: theory, intervention design, logic model, behaviour change, type 2 diabetes, diabetes remission, low-calorie diet, total diet replacement.

Background

It is considered best practice for complex interventions to be theoretically grounded throughout the process of design, evaluation and implementation.¹⁻³ Programme theory is a theory or model that explicitly describes how an intervention's components expect to produce change and achieve intended outcomes.⁴ There are numerous benefits of theory use, including informing what psychosocial constructs should be targeted, selecting appropriate intervention techniques (sometimes referred to as an intervention's active ingredients) to target these constructs, and deciding which research questions and measures are appropriate as part of a process evaluation.⁵ Through this, mechanisms of action can be understood (that is, how a programme is expected to achieve the desired outcomes), and intervention theory and design can be refined in light of findings. This has further benefits for intervention adaptation and scale-up, as in the absence of programme theory it is difficult to decipher which key mechanisms and techniques of interventions are necessary to retain for outcomes to be produced in other settings.^{1,6}

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Theory, therefore, facilitates the intervention development process from early conceptualisation and planning through to scale-up and adaptation through a structured framework. Health promotion interventions across a range of behaviours are argued to be more effective when a theory or theoretical constructs have been explicitly described.⁷ Since behaviour change is central to diabetes care, explicit use of underpinning behavioural science theory is argued to guide intervention developers and healthcare professionals in delivering evidence-based behaviour change support to optimise diabetes self-management.⁸

Despite these benefits, there is often a lack of explicit application of theory to intervention design and evaluation.⁵ There is often a misconception that an intervention is theory-based, leading to a growing concern that intervention developers are not using theory throughout the intervention development process. For example, one review of theory use in health promotion interventions found 69% of studies described an underpinning theoretical framework. However only 18% evidenced application, few (44%) tested changes in theoretical constructs, and 9% refined theory following evaluation.^{7,9} A meta-review found that 56% of physical activity and healthy eating interventions reported a theoretical basis, whilst only 10% of these reported links between all behaviour change techniques (BCTs) and theoretical constructs.¹⁰ Similar findings have been reported within the context of diabetes self-management programmes.⁸ This suggests that although the majority of intervention developers report theory use initially, evidence of theory being 'an integral part of a rigorous scientific process' is limited.⁵

One way in which intervention developers can articulate programme theory is through the construction of a logic model. Logic models provide a visual representation that maps out the theorised mechanisms of action and change, and can be a useful way of illustrating aspects of multiple theories that have informed an intervention's design. In other words, a logic model is a process which represents the theory of how an intervention produces its outcomes, and typically considers: the intervention's purpose (what motivates the need for change?); context (what is the climate in which change will take place?); inputs (what raw materials will be used to conduct the effort or initiative?); activities (what will the intervention do with its resources to direct the course of change?); outputs (what evidence is there that the activities were performed as planned?); and outcomes (what kinds of changes came about as a direct or indirect effect of the activities?).

A logic model creates a shared understanding of the programme assumptions and relationships between intervention components amongst the stakeholders and multidisciplinary teams involved in its development or implementation.¹¹ Logic models are a useful guide for intervention design and evaluation as they outline the necessary techniques (e.g. BCTs) and the constructs that require assessment as part of a process evaluation. This is particularly useful for teams who were not involved in an intervention's development who subsequently evaluate or adapt an intervention. Without a clear underpinning programme theory, consequences might include a loss in fidelity (i.e. the extent to which a programme is implemented as intended).¹² Logic modelling has been used as a helpful tool across diabetes services; for example foot care,¹³ retinal

screening,¹⁴ and the national diabetes prevention programme evaluation.¹²

In 2020, the National Health Service Low-Calorie Diet Programme (NHS-LCD) was launched.¹⁵ This is a weight loss intervention for patients living with comorbid T2D and overweight or obesity. Four independent weight management service providers were commissioned by NHS England (NHSE) to deliver theoretically grounded behaviour change support to achieve weight loss and improve T2D through a total diet replacement (TDR) approach. Patients were prescribed soups, bars and shakes providing ≤ 900 kcal/d followed by a period of food reintroduction and weight maintenance support. The 52-week programme was initially piloted across 10 socioculturally diverse areas of England and expanded to a further 11 areas in 2022.

NHSE produced a service specification detailing the intervention contents that should be included in the NHS-LCD programme. This was based on new knowledge about the pathophysiology of T2D,¹⁶⁻¹⁸ and evidence demonstrating low-calorie TDR approaches to be the most effective dietary intervention for achieving T2D remission ($\text{HbA}_{1c} < 48 \text{ mmol/mol}$), followed by weight maintenance support to sustain outcomes.¹⁹⁻²¹ Within the service specification, commissioners stipulated that the programme must be theoretically grounded in behaviour change support.²² Previous research has evaluated the service delivery fidelity of the NHS Diabetes Prevention Programme (NHS-DPP), another behaviour change programme commissioned by NHSE and delivered by independent service providers that was aimed at adults in England who are at risk of developing T2D.¹² Evaluators of this programme found explicit theory use in providers' programme designs to be lacking. Importantly, none of the NHS-DPP providers had included a logic model in their programme designs to describe how their interventions were expected to work.^{12,23}

The recently updated Medical Research Council (MRC) framework recommends that those identifying an intervention (i.e. those evaluating an intervention who were not involved in programme development) should uncover the underpinning programme theory where one has not been previously established, and should refine it during successive evaluation phases even if roll-out has begun.¹ Furthermore, evaluators of the NHS-LCD have been commissioned to conduct a realist-informed evaluation to identify what works for whom, in what contexts and why [NIHR132075]. Without a logic model detailing how an intervention expects to produce behavioural changes and health outcomes, evaluators cannot identify the underpinning mechanisms and constructs that need to be evaluated in a process evaluation, thus inhibiting a theory-based approach. Logic models have been highlighted as useful for guiding other realist-informed evaluations and successive development of realist matrices by identifying tentative contexts, mechanisms and outcomes.^{11,24} By understanding what a programme intends to do, realist evaluators can assess whether this is achieved, but also why or why not.²⁵ As NHSE did not provide a logic model in their programme specification, the present study authors aimed to devise a model to articulate programme logic and inform the realist evaluation approach.

The NHS-LCD Service Specification v1 required that service providers delivering the programme to patients "must be explicit regarding the behaviour change theory and techniques that are being

used, and the expected mechanism of action of their intervention".²² Considering the previous evidence suggesting that providers commissioned to deliver NHSE programmes are not sufficiently theory-driven,¹² study authors deemed it necessary to assess whether providers' programme designs have fidelity to this expectation.

Objectives

This study aimed: (1) to develop a logic model detailing how the NHS-LCD was expected to produce behavioural changes and health outcomes, and (2) to analyse and evaluate the use and application of behaviour change theory in providers' NHS-LCD programme designs.

Methods

Design

Documentary analysis of the NHS-LCD Programme specification documents and the four service providers' programme manuals, staff training materials and participant materials was conducted. The study was based on the providers of the original 10 pilot areas. The methodological approach reported by NHS-DPP evaluators was adapted;¹² amendments included the absence of staff training observations and an additional extraction sheet to report the extent to which BCTs are linked to theory in providers' design. These are described further below.

Aim 1: development of a logic model underpinning the NHS-LCD

Materials

The following programme specification documents included in the analysis were selected by authors TE and LE as they provided the basis for the NHS-LCD:

- NHS England NHS LCD Service Specification v1:²² This document was provided to service providers as part of the commissioning process, providing a comprehensive overview of the expected programme design and delivery.
- The DiRECT trial,¹⁹ and its accompanying protocol,²⁶ referenced in the NHS-LCD service spec as providing evidence for programme efficacy.
- National Institute for Health and Care Excellence (NICE) PH6 and PH49 public health guidelines to general and individual approaches, respectively, to behavioural change.^{27,28} These guidelines were referenced in the NHS-LCD service specification alongside other guidelines that were set out as requiring adherence from service providers. The two guidelines were selected for inclusion as they provided the most comprehensive information on the behaviour change content recommended for inclusion in the programme.

Procedures

Information was extracted from the NHS-LCD service specification,²² and the DiRECT study^{19,22,26} detailing: the expected outcomes for patients participating in the programme; assumptions underpinning the NHS-LCD; programme structure; and behaviour change content. Information was extracted for each document separately. Further information on the BCTs specified

for inclusion and the constructs targeted were extracted from NICE guidance PH6 and PH49.^{27,28}

The information extracted from all service specification documents was firstly formulated into separate 'If-Then' tables for each document. Tables were then merged to form overall 'If-Then' statements underpinning the programme logic (Table 1). For clarity, If-Then statements were separated into two tables. The first included statements about what the service aims to achieve, whilst the second included the psychological mechanisms underpinning how the service is expected to produce change. This was followed by the formulation of a psychobehavioural logic model depicting these underlying assumptions and the psychological mechanisms linking programme structure and content to the expected short- and long-term behavioural changes and outcomes. The model was refined through team discussions and consultation with NHSE, as stakeholder input in logic model development is recommended to ensure the model accurately reflects the intervention.^{11,29} This process took an iterative approach, conducted over many months to refine the 'If-Then' table and logic model to ensure it accurately reflected the programme specification.

Aim 2: application and use of behaviour change theory in NHS-LCD providers' programme designs

Materials

The following documentation for each service provider were examined:

- Providers' programme manuals describing the programme structure and curriculum, session plans, and the theoretical underpinnings and behaviour change components to be delivered to patients.
- Staff training materials, including training session slides and distance learning workbooks (during the COVID-19 pandemic). Delivery of training sessions could not be observed since they took place before this evaluation.

Procedures

To identify the theoretical underpinnings of providers' programme designs, programme content was examined using the Theory Coding Scheme (TCS).⁵ The TCS is a tool for assessing and reporting whether interventions are theory-based, with good inter-rater reliability evidenced by its authors.⁵ Documentation was sourced through liaison with the management staff of each of the four service providers. Theory coding was conducted individually and in duplicate by authors TE and CK, following author published guidance, with discrepancies resolved through discussion. Inter-rater reliability was determined using Cohen's kappa coefficient.³⁰ Staff training materials were sourced from the service providers. Any information on theoretical principles delivered to trainees was coded using the TCS.⁵

A data extraction sheet (as shown in Table 2) was developed based on the items specified in the TCS,⁵ including additional items proposed by NHS-DPP evaluators (items 1b, 7b, 8b and 9b). This was justified as ensuring all relevant theoretical content in programme designs are captured.¹² As the service providers are not conducting the NHS-LCD evaluation, items 14-19 of the TCS were

Table 1 'If-Then' table to Inform the BCT logic model of the NHS Low-Calorie Diet Programme

"If" statements are colour coded with their corresponding "then" statements.

IF	<ul style="list-style-type: none"> - Participants are supported in developing an accurate knowledge about the short, medium and longer-term consequences of their health-related behaviours, for themselves and others - The personal salience of weight reduction and avoidance of regain is emphasised
	<ul style="list-style-type: none"> - The visibility of positive health behaviours amongst similar or aspirational others are promoted - Significant others are encouraged to provide social approval for health behaviours
	<ul style="list-style-type: none"> - Family or peer support is accommodated where this would be helpful to a service user - If appropriate advice is given on, and arranged for, friends, relatives, colleagues or 'buddies' to provide practical help, emotional support, praise or reward
	<ul style="list-style-type: none"> - The provider supports the service user to set tailored achievable short-, medium- and long-term dietary and physical activity goals - Participants set and record goals to undertake clearly defined behaviours, in particular contexts, over a specified time and the resulting outcomes - Participants plan their changes in terms of easy steps over time - Participants share their behaviour change goals with others - Support is tailored to a service user's needs, goals and capabilities, including setting achievable goals in being active
	<ul style="list-style-type: none"> - Participants are supported in recognising how their social contexts and relationships may affect their behaviour - Participants are supported in identifying and planning for situations that might undermine the changes they are trying to make - Participants plan explicit 'if then' coping strategies - Participants who regain 2kg or more are offered a relapse management protocol, including reintroduction of 4-week TDR and problem solving
	<ul style="list-style-type: none"> - Food-based tailored energy prescription is provided during the weight maintenance phase
	<ul style="list-style-type: none"> - Outcome goals are reviewed - Feedback on outcomes is provided - Self-monitoring tools are provided - Dietary intake is assessed during food reintroduction
	<ul style="list-style-type: none"> - A person-centred, empathy-building approach is adopted - Behaviour change support is tailored to participants levels of motivation - The content of the sessions with service users empowers them to take a leading role in instituting and maintaining long-term behaviour changes
THEN	<ul style="list-style-type: none"> - Participants will have positive outcome expectancies regarding the behavioural changes - They will perceive the consequences of behavioural changes as personally relevant - Positive feelings towards the outcomes of behaviour change will be promoted
	<ul style="list-style-type: none"> - Subjective norms will be enhanced
	<ul style="list-style-type: none"> - Participants will have a supportive social environment in which to make the behavioural changes
	<ul style="list-style-type: none"> - Personal and moral commitments to behaviour change will be promoted - Participants will develop routines that support the behavioural changes / embed health-promoting behavioural changes into their existing routines - Goals will meet the participants' circumstances, cultural context and preferences, making them better able to adopt the changes and embed these into their lifestyle long term - Self-efficacy will be enhanced – enhancing their belief in their ability to change
	<ul style="list-style-type: none"> - Participants will develop skills to cope with difficult situations and conflicting goals
	<ul style="list-style-type: none"> - Participants will be aware of their caloric and nutritional needs for weight maintenance
	<ul style="list-style-type: none"> - Individuals will consider achievement of outcomes and set further goals and plans in light of achievement - Participants and the provider will be able to identify discrepancies between behaviour and behavioural/outcomes goals - Participants will be able to use feedback to inform their behaviour - Providers can support planning of sustainable changes, to achieve a healthy balanced diet as set out in the current national guidance
	<ul style="list-style-type: none"> - Participants' beliefs, needs and preferences will be understood, and their confidence enhanced - Self-efficacy will be enhanced – enhancing their belief in their ability to change
SO THAT	<ul style="list-style-type: none"> - Completion rates of service users are maximised, including across groups that share a protected characteristic - Reduction in weight of service users and the maintenance of weight loss is achieved through adherence to the TDR and achievement of a healthy balanced diet and active lifestyle, as set out in the current national guidance - Reduction in glycaemic parameters in service users and resulting remission of T2D is achieved - Reduction in medication usage among service users in line with the intervention is achieved
THEREFORE	<ul style="list-style-type: none"> - The future risk of T2D complications is reduced - The associated impacts of complications on wellbeing and healthcare costs are reduced

tracted information on which and how many BCTs were explicitly linked. A second data extraction sheet (Figure 1) was developed to extend upon TCS items 7a, 7b, 8a and 8b (referring to whether at least one or all BCTs have been linked to theory, a construct and/or a predictor). Once coded, data were converted into percentages to report numerically the extent to which BCTs were explicitly linked.

Results

The logic model describing how the NHS-LCD is expected to produce the primary outcomes of weight loss/maintenance to improve HbA_{1c}, achieve diabetes remission and reduce medication use is shown in Figure 2.

removed, as these refer to the measurement of theoretical constructs in a process evaluation - these items were also previously justified for removal by NHS-DPP evaluators.¹²

To assess the extent to which BCTs in providers' programme designs were linked to theory, constructs or predictors, coders ex-

The flowchart illustrates a person-centred and empathy building approach for T2DM, structured into three phases: Phase 1, Phase 2 & 3, and Phase 4. The approach is tailored to individual needs, capabilities, cultural contexts, and levels of motivation.

Phase 1: Initial Assessment and Planning

- Referral:** Social approval, benefits of lifestyle change.
- Phase 1:** Benefits of lifestyle change, behavioural antecedents.
- Phase 2 & 3:** Behavioural instruction.
- Information provision:** Personal commitment made, environmental restructuring.
- Knowledge:** Feedback on outcomes, Review goals.
- Subjective norms:** Positive outcome expectancies.
- Action self-efficacy:** Intention Programme uptake.

Phase 2 & 3: Goal Setting and Action Planning

- Goal setting (weight loss):** Action planning, Problem solving.
- Action:** adherence to TDR.
- Outcomes:** weight loss, reduction in HbA_{1c} and medication use.
- Maintenance self-efficacy:** Outcomes: weight loss, reduction in HbA_{1c} and medication use.
- Goal setting (diet, physical activity):** Action planning, Problem solving.
- Action:** physical activity, healthy eating.
- Outcomes:** improved diet, increased PA, maintenance of weight loss / reduced HbA_{1c}.

Phase 4: Relapse and Recovery

- Relapse:** weight regain of $\geq 2\text{kg}$.
- Rescue package:** 4-week TDR, problem solving, coping planning.
- Recovery self-efficacy:** Rescue package: 4-week TDR, problem solving, coping planning.

Supportive social environment: family and/or peer support is accommodated and encouraged, provision of social rewards.

resulting in programme uptake and intention to initiate behaviour change.

This section also depicts how the type of information provision changes throughout the phases of the programme: phase one focuses on the benefits of weight loss without sudden increase in exercise and on enhancing understanding of behavioural antecedents (i.e. internal and external cues of eating behaviours); phases two and three focus on behavioural instruction for both dietary and physical activity behaviours to maintain weight loss.

Section two of the model describes how participants move through a self-regulatory cycle (i.e. the ability to control their own behaviour) once phase one goals are set and TDR is initiated, including reviewing progress, receiving feedback, developing coping strategies and modifying goals in light of achievement. This facilitates self-efficacy (confidence in one's ability to initiate and maintain behaviour change) and TDR adherence.

As participants move into phases two and three (section 3), new achievable behavioural goals are set, leading to incremental improvements in physical activity and healthy eating behaviours. Participants move into a second self-regulatory cycle that replicates the phase one cycle whilst additionally being provided with self-monitoring tools to identify and resolve discrepancies between behaviours and goals. This cycle is expected to ensure routines that support behavioural changes are developed and self-efficacy maintained.

Table 2 Use of theory in providers' programme designs

TCS Items	SP1	SP2	SP3	SP4
Theory mentioned (1a)	✓	✓	✓	✓
Construct mentioned (1b) *	✓	✓	✓	✓
Target construct mentioned as predictor of behaviour (2)	✓	✓	✓	✓
Intervention based on a single theory (3)				
Theory/predictors used to select recipients for the intervention (4)				
Theory/predictors used to select/develop intervention techniques (5)		✓	✓	✓
Theory/predictors used to tailor intervention techniques to recipients (6)				
All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor (7a)				✓
All intervention techniques are explicitly linked to an overall theory/model but not a specific construct (7b) *				
At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor (8a)		✓	✓	
At least one, but not all, of the intervention techniques are explicitly linked to an overall theory/model but not a specific construct (8b) *		✓		
Group of techniques are linked to a group of constructs/predictors (9a)	✓	✓		
Group of techniques are linked to an overall theory/model but not a specific construct (9b) *		✓		
All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique (10)			✓	
At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique (11)		✓		✓

TCS, Theory Coding Scheme; SP, Service Provider

* Additional items added by NHS-DPP evaluators (11) and retained by authors for this analysis

Section four of the model describes how participants who regain 2kg or more during the weight maintenance phase return to the TDR for 4 weeks and are encouraged to problem-solve and form coping plans, ensuring that they develop self-efficacy in managing future relapses. Shaping knowledge is targeted throughout the programme through information provision, in line with UK Government guidance to support self-efficacy.^{31,32} A person-centred and empathy-building approach is adopted throughout, and supportive social environments are facilitated. The processes outlined were identified as mapping onto constructs proposed by three unique but overlapping models of behaviour change: the Theory of Planned Behaviour (TPB),³³ the Health Action Process Approach model (HAPA)³⁴ and Self-Regulation Theory (SRT).³⁵

Theory described in providers' programme plans and staff training

The theory coding analysis revealed that the application of behaviour change theory to programme designs varied across providers, summarised in Table 2. One provider explicitly linked theory to programme content by including a logic model. Two providers described the theoretical basis of their interventions in detail; however, some but not all BCTs were linked to the theories proposed. One provider had limited evidence of theory use as theory was only described on a single training slide to guide coaches' approach to session delivery and was not linked to any programme content.

Table 3 Theory and constructs mentioned in each provider's programme plans and staff training

	SP1	SP2	SP3	SP4
Models of behaviour mentioned				
ABC model of behaviour change			✓	
Cognitive Behavioural Model		✓	✓	
COM-B		✓		✓
Health Beliefs Model		✓		
Stages of Change / Transtheoretical Model	✓	✓		
Social-Cognitive Theory				✓
Constructs mentioned				
Antecedents			✓	
Capability		✓		✓
Consequences			✓	
External triggers			✓	
Feelings		✓	✓	
Internal triggers			✓	
Motivation		✓		✓
Observational learning				✓
Opportunity		✓		✓
Reinforcement				✓
Self-control/regulation				✓
Self-efficacy				✓
Pre-contemplation, contemplation, preparation, action, maintenance	✓	✓		
Thoughts		✓	✓	

SP, Service Provider

The behaviour change theories and constructs selected varied amongst providers (Table 3). Service Provider 1 included the Transtheoretical Model (Stages of Change) within their training content.³⁶ Service Provider 2 described multiple theories as underpinning their programme design, including COM-B,³⁷ the Health Beliefs Model,³⁸ the Transtheoretical Model,³⁶ and the Cognitive Behavioural Model.^{39,40} Service Provider 3 also included the Cognitive Behavioural model,^{39,40} in addition to the Antecedents-Behaviour-Consequence model.⁴¹ Finally, Service Provider 4 included COM-B and Social-Cognitive Theory in their programme logic model.^{37,42}

Analysis of the extent to which BCTs in providers' programme designs were linked to theory, constructs or predictors revealed that Service Provider 1 linked no (0%) BCTs, Service Provider 2 linked 20 (63%) of BCTs, Service Provider 3 linked 23 (70%) of BCTs, and Service Provider 4 linked all (100%) BCTs.

Across the four providers, analysis of Cohen's kappa revealed substantial agreement between the two researcher's judgements when using the TCS ($\kappa = .701$, $p < .001$) and moderate agreement when coding linkage to BCTs ($\kappa = .424$, $p < .001$) prior to resolving discrepancies.⁴³

Discussion

The first aim of this study was to develop a logic model describing how the NHS-LCD programme expected to produce change. By extracting information on programme assumptions, structure and content from the NHS-LCD service specification documents, authors devised a behaviour change logic model demonstrating the active ingredients (BCTs) and the psychological mechanisms targeted throughout the three phases of the 52-week programme. Programme logic included positive outcome expectancies and subjective norms resulting from information provision, facilitating uptake and behaviour change intentions. This was followed by BCTs targeting shaping knowledge and self-regulation, alongside a supportive social environment and person-centred approach throughout the programme.

The second aim of this study was to analyse and evaluate the use and application of theory by service providers in their programme designs. Although NHSE commissioned independent service providers to design programmes that are explicit in their theory use, TCS coding revealed that although all four providers mentioned theory at least once within their designs or staff training documents, only one provider evidenced all BCTs being linked to theory and/or constructs (through construction of a logic model). Two providers linked some but not all BCTs to theory, and one provided no evidence of theory use in their programme design, aside from inclusion in a staff training slide. By additionally coding which and how many BCTs were linked to theory, constructs or a predictor, we were able to establish that the two providers evidencing some but not complete use of theory in BCT selection linked 63% and 70% of BCTs respectively, demonstrating a similar degree of theory application between them. Furthermore, six different behaviour change theories were described across all four programme designs, whilst providers appear to have utilised aspects from more than one theory to inform their programmes. Finally, no provider included details about their theory selection process, therefore if and how models were selected

based on their evidence of effectiveness for dietary change and T2D management is unclear. Together this evidence demonstrates some but not complete justification for the behaviour change theories and techniques selected. The behaviour change content and fidelity of providers' programme designs to the intervention components described in the logic model presented here will be reported in a separate paper.

Strengths and limitations

It is important to recognise that logic model construction involves an interpretative approach informed by authors' knowledge and expertise in the health psychology domain. There may be other models or theoretical constructs that map onto the programme logic, and the logic model might have differed if constructed from outside a psychological perspective. This limitation was acknowledged and mitigated through repeated reflection throughout the logic modelling process, triangulating with co-authors' interpretations, and an iterative process to continuously refine if-then statements and the model diagram, facilitating a robust methodology. Furthermore, as this was an independent evaluation of a national pilot programme, the research team were not involved in the programme development. Thus, the authors were in regular contact with the NHSE LCD programme management team, who confirmed this was an accurate reflection of the programme and what it set out to achieve.

All documentation describing the theoretical basis and behaviour change content of service providers' programme designs was obtained by building successful stakeholder relationships. Providers were given the opportunity over many months to provide all documentation, including any existing logic model. Our methodological approach was informed by that set out by NHS-DPP evaluators,¹¹ including the use of a validated tool for coding theory use,⁵ ensuring clear programme comparisons can be made by researchers and stakeholders. However, it was not possible to analyse staff training in a way comparable to the NHS-DPP evaluation, as staff training courses had already taken place prior to the commissioning of this evaluation and thus could not be observed. Therefore, the extent to which staff were trained in the theoretical principles underpinning their programme could not be fully assessed.

Relation to existing research

Evaluators of the NHS-DPP found a lack of explicit theory use in the behaviour change content across providers delivering the programme.¹² Our findings are similar in that most providers did not evidence explicit use and application of theory. One provider did include a logic model to describe how their intervention expected to achieve the desired programme outcomes; however, no justification was documented for the theories and constructs selected for the purposes of the NHS-LCD programme. This is an important omission as the appropriateness of a behaviour change model for any given target behaviour or population cannot be assumed; selection must be based on evidence demonstrating effectiveness for improving dietary behaviours and T2D management. These findings demonstrate that improvements are still needed for ensuring that large-scale behaviour change pro-

grammes are clear in their theoretical underpinnings and what constructs they are targeting, and why.

Additional similarities exist between the NHS-DPP¹² and NHS-LCD logic models, with both having elements that map onto the HAPA model³⁴ and include a self-regulatory cycle.³⁵ This is not surprising considering they are both national NHS programmes that have taken a similar approach in their commissioning model, and are based on similar behaviour change evidence for similar behaviours and populations. However, in contrast to the NHS-DPP model,¹² initial information provision in the NHS-LCD targets positive outcome expectancies (for example, the belief that behaviour change will reduce reliance on medications) as opposed to risk perception (for example, the belief that one is at risk of future reliance on medication if behaviours remain unchanged). This is in line with evidence suggesting that targeting intrinsic motivation (the person's own desire or intention to perform a behaviour) is related to better diabetes self-care, whilst fear appeals may lead to avoidance or denial for people living with diabetes.⁴⁴ Furthermore, unlike the NHS-DPP, the NHS-LCD implements multiple programme phases, across which the target behaviours and outcomes change to facilitate maintenance of treatment outcomes.

Implications and recommendations

The findings of this study add to the growing body of research demonstrating that theory is not always explicitly and effectively applied throughout the entirety of the intervention development process, including the design of diabetes programmes specifically.^{5,7-10,12} This is in line with findings of the NHS-DPP evaluation, in that they support the notion that health promotion interventions are often 'evidence-inspired' rather than a rigorous scientific process.^{5,12} Michie and Prestwich argued that although theory is included in numerous frameworks, a detailed guide to its use during the design process is lacking and would benefit those without expertise in theory use.⁵ The MRC has addressed this in its recently updated framework for designing and evaluating complex interventions,¹ which guides developers through the iterative process of applying programme theory throughout all development phases.

More needs to be done to achieve the rigorous application of theory in national programmes: future research and consultancy work should seek to understand and address the barriers to explicit theory use in programme design. For example, it is important to consider the time and resource constraints that are likely experienced by intervention developers, especially within the context of health services, which may act as a barrier to a meticulous theoretically driven process. Providers often have previously established intervention components found to be effective in other programmes; providers may adapt these components instead of using a theoretically informed approach, thus reducing staff training and resource development needs. However, it is best practice to ensure that theory guides intervention development, identification of target constructs and selection of appropriate BCTs to target these mechanisms, and not to source theory to justify pre-designed intervention components.¹

Similar to conclusions reached by NHS-DPP evaluators,¹² NHSE



Key messages

- The NHS-LCD aims to improve T2D self-management and reliance on medication use by providing behavioural support that facilitates TDR adherence, healthy lifestyle behaviours and resulting weight loss/maintenance.
- NHS England commissioned four independent service providers to design behaviour change interventions explicit in their theoretical underpinnings and mechanisms of action.
- Only one of the four providers evidenced a detailed description of how their intervention was expected to achieve the desired outcomes.
- Without a clear underpinning programme theory, justification for the behavioural change techniques selected in the NHS-LCD is unclear and may result in a loss of programme fidelity and effectiveness.
- Service providers should be required to state their underpinning programme theory explicitly during the NHS commissioning process.

guidance on theory use in the programme specification was vague, with only the instruction to be explicit in theory application and to use the Public Health England Behaviour Change Guide.⁴⁵ No specific guidance on the target constructs of the programme was provided, and although study authors were able to unpick these through a meticulous logic model construction process, this would be time-consuming for service providers to achieve. The lack of guidance may explain the variation in behaviour change theories and constructs selected by providers, and will likely result in variation of behaviour change content across their designs – a finding observed in the NHS-DPP.¹² However, it was the intention of NHSE to ensure providers had scope to design their own programmes based on their own behaviour change expertise. It is therefore recommended that outcomes across providers are compared to evaluate whether differences in the theoretical approaches adopted are associated with better outcomes.

Without a clear underpinning theory, providers do not have a clear justification of the intervention techniques they plan to use in their programme designs. This variation and lack of clear underpinnings may result in a loss of fidelity in behaviour change content and its delivery,¹² and may result in variation in what is received by programme recipients and thus variation in programme outcomes. This may be problematic considering that interventions requiring high personal agency, such as weight management programmes, are argued potentially to exacerbate existing health inequalities. Inclusion of the logic model constructed in the NHSE specification may improve theory use amongst providers and fidelity to the programme specification. Alternatively, future NHSE commissioning processes should require providers to demonstrate a) explicit theory use (i.e., by providing a logic model), and b) the process in which

appropriate theory for the target group and health behaviours were selected. Alongside this, more detailed guidance or training in theory application should be included, to support them in achieving this.

Finally, programme theory, explicitly communicating how an intervention expects to produce change, is essential for conducting a thorough realist evaluation. By developing a logic model, evaluators of the NHS-LCD programme can identify the proposed mechanisms underpinning why or why not the programme works and assess the impact of contexts on these mechanisms.⁴

Conclusions

The NHS-LCD aims to improve T2D self-management and reliance on medication use by providing behavioural support that facilitates TDR adherence, healthy lifestyle behaviours and resulting weight loss/maintenance. Despite NHSE commissioning providers to design behaviour change interventions explicit in their theoretical underpinnings and mechanisms of action, only one of the four providers evidenced a detailed description of how their intervention was expected to achieve the desired outcomes through the construction of a logic model. Without a clear underpinning programme theory describing how providers programmes expect to produce behavioural changes and health outcomes, justification for the BCTs selected is unclear and may result in a drift in the fidelity of programme delivery.¹² To prevent this drift, it is recommended that programme commissioners adopt the logic model presented in this manuscript or require service providers to state their underpinning programme theory explicitly during the commissioning process to ensure a rigorous, theoretically-driven approach to developing and implementing national programmes.

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Authors' contributions TE lead the conceptualisation, design, analysis, interpretation of data, and drafted the report for this study. RH made substantial contributions to the interpretation of data and revision of the report. CK made substantial contributions to the data analysis for this study. LN made substantial contributions to the interpretation of data and revision of the report. DR made substantial contributions to data collection and revision of the report. AH and JM made substantial contributions to the revision of the report. LE made substantial contributions to the design of this study and revision of the report and supervised TE. All authors read and approved the final manuscript.

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