Received: 9 March 2020 | Accepted: 25 August 2020

DOI: 10.1111/dme.14394

DIABETIC Medicine

REVIEW ARTICLE

Evidence generated from a realist synthesis of trials on educational weight loss interventions in type 2 diabetes mellitus

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Funding information
A.M. is funded by a National Institute for Health Research (NIHR) In Practice Fellowship. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Abstract

Background: Obesity and diabetes are major public health problems. Current approaches to weight loss show varying success. Complex community-based interventions work through several interconnected stages. An individual's actions in response to an intervention depend on many known and unknown factors, which vary among individuals.

Aim: To conduct a realist synthesis to identify in which context, for whom, in what circumstances, and how weight loss interventions work in obese or overweight individuals with type 2 diabetes.

Methods: A total of 49 trials identified during a systematic review were subsequently analysed using realist methodology. This iterative process involved hypothesis generation about how participants within a particular context respond to an intervention's resources producing the outcomes. We used established behaviour change theory to look for repeating themes. Theory and 'mechanisms' were tested against the literature on what is shown to be effective. Where established theory was lacking, we discussed issues during discussion groups with individuals living with the condition to generate our own programme theories.

Results: Mechanisms that were repeatedly identified included high-frequency contact with those delivering the intervention, social support, education increasing awareness of diabetes-related modifiable risk factors, motivational interviewing and counselling, goal-setting, self-monitoring and feedback and meal replacements. The central theme underlying successful mechanisms was personalising each intervention component to the participants' gender, culture and family setting.

Conclusion: This is the first comprehensive realist synthesis in this field. Our findings suggest that, for weight loss interventions to be successful in those with diabetes, they must be personalized to the individual and their specific context.

1 | INTRODUCTION

Worldwide, 1.9 billion adults were classified as overweight and 650 million as obese in 2016,[1] with this number increasing and predisposing to the development and rise of type 2 diabetes and its complications.[2–6] Worldwide, by 2030, managing type 2 diabetes is expected to cost US$2.5 tn or 2.2% of global gross domestic product.[7] Higher prevalence in black and minority ethnic (BME) populations is a particular concern as BME groups also experience the poorest outcomes from type 2 diabetes[8,9] compared to white populations. This may be attributable to cultural differences, language and

literacy issues, ignorance of available services or physical locations of services away from BME residential areas.[10] There are no published educational weight loss trials in BME individuals who are overweight or obese with type 2 diabetes in the UK, and limited trials worldwide.[11]

Weight loss is important to improve metabolic control, with large weight losses reversing type 2 diabetes[4] and smaller losses of 2.25 to 4.5 kg leading to improvements in glycaemic control and risk factor reduction.[12] Weight loss is more difficult for individuals with type 2 diabetes, who lose approximately half the amount of weight as those without diabetes undergoing the same intervention,[13] with some antidiabetes medications causing weight gain.[14]

For obese and overweight individuals with type 2 diabetes, education on weight loss is important but is often not enough to affect behaviour change. Intervention techniques to achieve behaviour change often involve face-to-face meetings, with advice on diet and physical activity.[15,16] However, community-based educational weight loss interventions show varying success in achieving significant weight loss,[11] and we do not have a comprehensive understanding as to why.

Realist methodology is increasingly being used in healthcare to review and synthesize evidence on complex social interventions,[17–19] where the underlying mechanisms interacting between the context and resources provided in an intervention are unravelled and identified. These context–mechanism–outcome configurations are treated as hypotheses that can be tested and refined by collecting evidence through an interpretive and iterative process.[20] Complex interventions may work through several interconnected mechanisms and each intervention is designed based on one or several theories. Individuals determine how they react to what is provided within an intervention through their actions, which are not uniform and depend on many factors, some unknown.

In the present study we sought to identify the underlying causal mechanisms operating within different contexts to develop a better understanding of what determines intervention success or failure and under what conditions. We sought to explain *how* interventions achieve effect rather than perform an assessment of effect, or 'what works', as provided by a systematic review, following on from our previously published work.[11] We undertook a realist synthesis to identify in which context, for 'whom', in 'what' circumstances and 'how' weight loss interventions in individuals who are obese or overweight with type 2 diabetes work.

What's new?

- Community-based interventions to achieve weight loss in people with type 2 diabetes show varying success, but less is known about why this may occur.
- This realist review of 49 trials helps provide understanding of context-specific causal mechanisms that produce weight loss. The successful mechanisms and programme theories identified involve personalising each component within the intervention to the individual. This addresses social, emotional, physical and psychological needs for participant self-actualization.
- A single uniform intervention will not meet the needs of every individual. Personalizing weight loss interventions to individuals' demographic, social and cultural contexts is vital for success.

2 | METHODS

2.1 | Rationale for using realist synthesis

We initially conducted a systematic review and meta-analysis to identify which community-based educational weight loss interventions in type 2 diabetes were successful. We found multi-component trials providing education and low-calorie, low-carbohydrate or low-fat meal replacements or diets appeared the most effective.[11]

Although, many trials achieved weight loss and other positive effects on health and well-being, they varied in the type and duration of the intervention being delivered and in the skills of the interventionists, and were delivered in varying social contexts and healthcare systems. Some interventions appeared well designed but did not result in expected significant weight loss. Trial authors provided limited or no explanations of why they felt interventions were effective or not, or why some trials achieved larger weight losses. This variation suggested intervention mechanisms may not always work in the same way. To understand this variation, we undertook a realist review following the RAMESES guidelines.[20]

2.2 | Scoping the literature

During our initial review, we searched five electronic databases, with additional hand searches. Study selection consisted of randomized controlled trials of community-based educational weight loss interventions compared to usual care which recruited individuals aged 18 to 75 years of any ethnicity, with type 2 diabetes and a BMI >25 kg/m^2, and measured weight loss as a primary or secondary outcome. Exclusion criteria included factors limiting an individual's ability to take part in a weight loss intervention or where the main intervention was weight loss surgery or medication.[11]

Two independent reviewers (A.M. and A.W.) screened 7383 records and reviewed 228 full texts. This identified 49

trials which we included in our review (Figure 1). Full details are provided in the published systematic review.[11]

2.3 | Data extraction, analysis and synthesis processes

In order to identify programme theories (hypotheses describing underlying causal mechanisms of how an intervention or intervention component is working, in what circumstances or context), one author (A.M.) reviewed the introduction, methods and discussion section of each of the 49 trials identified in our systematic review twice[20] and extracted data, which were then reviewed by a second author (F.G.). Data were extracted into Microsoft Word tables relating to context (country, ethnicity of participants, age ranges, education and income levels, where available), mechanism (participant reactions triggered by the resources provided within the intervention), outcomes (both intended and unintended), explicit programme theories (theories or mechanisms suggested by

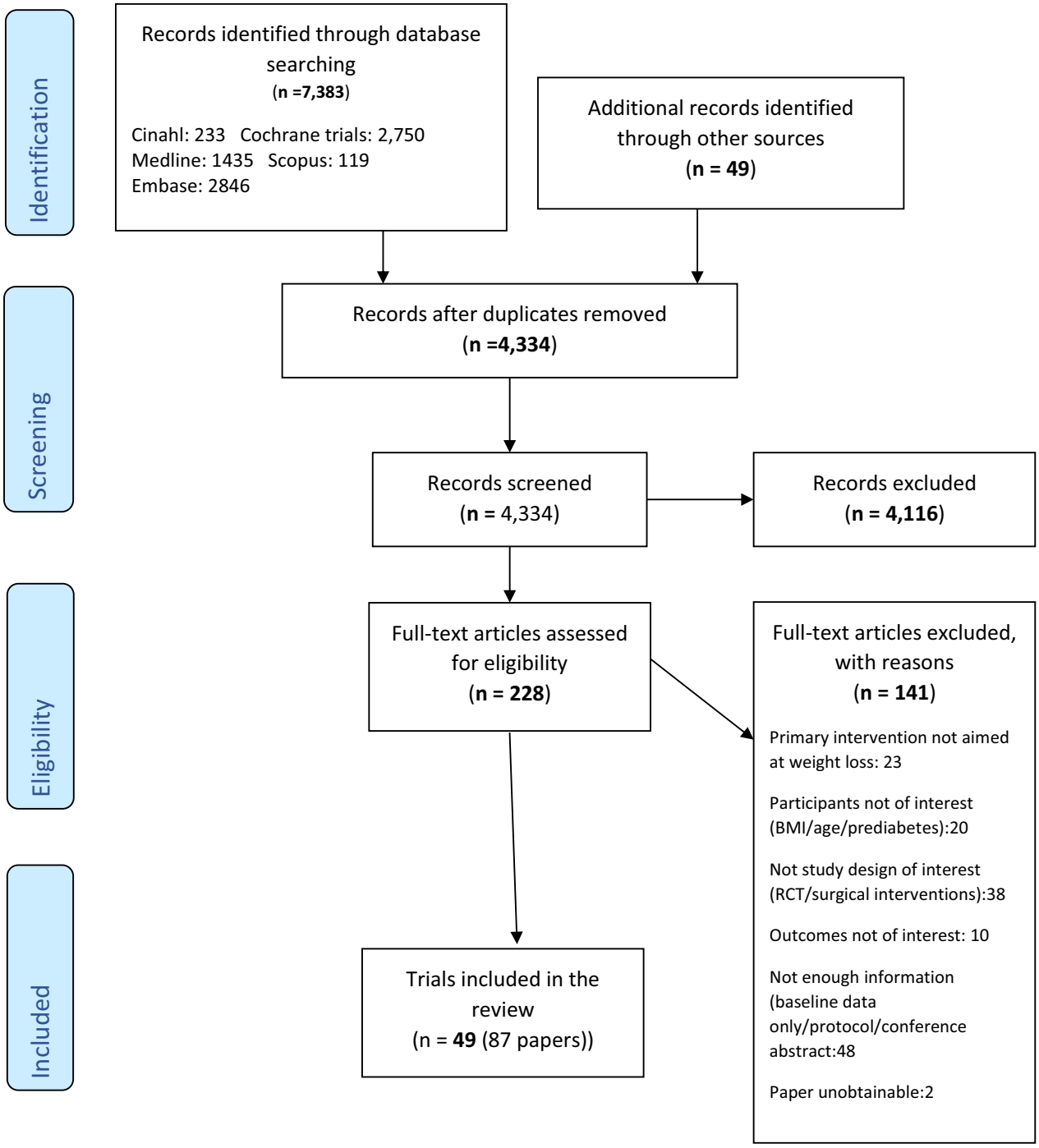

FIGURE 1 Selection of studies for inclusion into the review. RCT, randomized controlled trial

the trial authors on why they felt the intervention worked or did not work), implicit programme theories (theories or hypotheses not explicitly stated by the author but identified by us within the published paper), programme theories through retroduction (theories or hypotheses inspired by the information provided, an explanation of the underlying causal forces, not just the evidence presented) and middle-range theories (existing established generic theories available within the literature, which may help to explain the mechanism of how the intervention works, generalisable across different contexts).

Initially, we considered data collated from each trial separately for context, mechanism and outcome. We then grouped trials by similarities in context and outcome (whether trials were successful or unsuccessful at achieving weight loss), to assess if there were repeating patterns within mechanisms. We proceeded by constructing our own programme theories (hypotheses) for unsuccessful trials, based on the interaction between the mechanism and the context. The explicit programme theories we extracted were categorized according to similar mechanisms to identify thematic patterns of why intervention designers felt the intervention worked or did not work for weight loss.

We coded the methods section of all trials using behaviour change theories (BCTs) v.1,[21] and grouped trials according to whether they were successful at achieving statistically significant between-group change from baseline or not, to look for BCT patterns.

2.4 | Testing against the literature

Our main mechanisms and BCTs identified were compared to the published literature. Following the iterative process of the realist review, we identified and focused on an area lacking explicit and middle-range theory, by examining trials containing personalisation. A.M. and F.G. developed their own programme theories to understand the interaction of context and mechanism for three outcomes: losing the most, some, or no weight within trials containing personalisation. We structured these theories using BCT taxonomy. After rewriting into lay language, we tested these theories by presenting them to people with type 2 diabetes, who were asked to comment on them during facilitated discussion groups, with a scribe present. We recruited seven participants from an inner-city general practice in Leicester to attend two discussion groups. Participants were aged 18 to 75 years, had a BMI >25 kg/m^2, and were living independently in the community. All attendees received a £10 voucher and lunch.

We analysed data from the first discussion group for influence of social context on intervention impact[18,16] and generated themes.[22] We then searched the peer-reviewed literature for middle-range explanatory theories, which were lacking for the themes: role of gender and food; food in the family; and 'cheat' days. We explored these themes during the second discussion group. These were then tested against the literature to generate our new programme theories, using a combination of what participants discussed and the available literature.

3 | RESULTS

3.1 | Study characteristics

There were 12 461 participants across 49 trials. Twenty-four trials were conducted in the USA,[23–46] four each in Australia[47–50] and Germany [S51–S54] (for references >S50 see Table S1), three each in Sweden [S55–S57] and the UK[4] [S58,S59], two each in Finland [S60,S61], Belgium [S62, S63] and Canada [S64, S65], and one each in Spain [S66], India [S67], Kazakhstan [S68], Italy [S69], and New Zealand [S70]. In trials providing ethnicity data, the percentage of ethnic minority participants ranged from 2%[4] to 100%[25,41] in two trials containing Hispanic or African-American participants.

Overall, 29 trials were successful at achieving statistically significant weight change between groups from baseline. Weight loss interventions ranged in duration from 2[23] to 24 months[44,50] [S56,S70]. Nine interventions contained education alone, the remaining 40 trials were multicomponent. Intervention contacts with participants were described in 46 trials, ranging from 1 over 6 months[43] to 107 over 12 months.[33] Duration of each contact was provided in 30 trials ranging from 5[36] to 150 min[30,32] [S57]. There was pre-selection in four trials,[26,27,31,34] during which participants had to prove commitment by completing self-monitoring activities lasting 3 to 28 days prior to randomisation. In 11 trials a single educator had direct contact with participants, in 37 trials a team of educators with varying professional backgrounds were involved and in one trial it was unclear. Individual education was provided in 21 trials, group education in 10 trials and a mixture in 17 trials, with one not specifying.

Only 11 trials (24%) explicitly stated the theoretical underpinning of their interventions. These included experiential, social and cognitive learning theories as well as the cognitive theory of multimedia learning. The quality of reporting of the methods and interventions varied among trials, resulting in different amounts of detail being available for analysis. Key characteristics of each trial are reported within the original review.[11]

3.2 | Context–mechanism–outcomes

We categorised the trials (Table 1, Table S2) into 10 contexts, according to similarities in access to healthcare, high- or middle-income country [S71], and ethnicity. Within seven

TABLE 1 Mechanisms operating within different trial contexts achieving significant weight loss or not

Mechanisms	Contexts of trials achieving significant weight loss	Contexts of trials not achieving significant weight loss
High-frequency contact/ high familiarity with interventionist	A B D F	H I J
Group social support	A B D E F	H I
Coaching	A	H
Motivational interviewing	A B F	H
Counselling	A B E	H
Self-monitoring and feedback	A B C D F G	H I J
Goal-setting	A B C D F G	H I J
Diabetes-specific education	A B C D E F G	H I J
Meditation		H
Meal replacements: calorie control/ modified fasting	A B D	H
Incentivisation	E	
Incorrect targeting of intensity of physical activity		I

Note: Contexts: A, majority white >80%, access to free or paid healthcare, high-income countries; B, mainly white 52–79%, access to high-quality paid healthcare in USA (high income country); C, majority black and minority ethnic (BME) ≥ 85%, 65–82% female in intervention group, medically underserved communities in USA (high income country); D, 54–63% BME, access to high-quality paid healthcare in USA (high-income country); E, 100% black, access to high-quality paid healthcare in USA (high-income country); F, 38% black, females only, majority middle-aged and well educated, access to high-quality paid healthcare in USA (high-income country); G, Indian or Kazakhstani, access to paid healthcare (middle-income country); H, majority white ≥80%, access to paid or free healthcare (high-income country); I, 47–65% BME, access to paid or free healthcare (high-income country); J, 80–100% BME, reduced access to healthcare either uninsured or living below poverty line in USA (high-income country).

of these 10 contexts, all the included trials demonstrated statistically significant weight change between groups from baseline. The remaining three contexts were not statistically significant.

Mechanisms present in both successful and unsuccessful trials included high-frequency contact with interventionist, group social support, coaching, motivational interviewing, counselling, self-monitoring and feedback, goal-setting, diabetes-specific education, and meal replacements. This illustrated that these mechanisms were working in some contexts and not in others. Incentivisation was only identified in successful, whilst meditation and incorrect targeting of intensity of physical activity were only present in unsuccessful trials.

Within the largest context (context A, 18 trials) of successful trials there were one to six mechanisms. Self-monitoring and feedback were the most common (78% of trials), followed by goal-setting (50%), diabetes-specific education (33%) and counselling (28%).

Within the largest unsuccessful context (context H, 13 trials), there were one to five mechanisms. Goal-setting was the most common in 80% of trials, followed by self-monitoring and feedback (70%), group social support (50%), diabetes-specific education (40%) and high-frequency contact (40%).

3.3 | Programme theories for trials not achieving significant weight loss

Programme theories developed (Table S3) by A.M. and F.G. for unsuccessful trials, were grouped by mechanisms. Underlying themes included incorrect identification of barriers and not meeting the cultural, ethnic or gender needs of participants. The interventions did not provide adequate emotional, physical or social support. When applied to BME populations, individuals are more likely to face prejudice and barriers to healthcare, and even when access is available they are likely to experience poorer-quality and reduced access[10] [S72,S73]. Infrequent contact with the interventionist affected rapport, trust development and accountability [S73]. In addition, those delivering the intervention may have felt inadequately trained or supported, affecting intervention delivery. Due to failure to identify and address barriers to participant engagement, participant self-efficacy was not achieved, and health optimisation was not prioritized.

3.4 | Trials coded by behaviour change theories

The majority of trials contained four distinct BCTs: goal-setting (behaviour; 72% successful vs 90% unsuccessful); self-monitoring of behaviour (59% vs 65%); social support (unspecified; 83% vs 90%); and adding objects to the environment (55% vs 55%). Problem-solving was present in 11 of 29 successful trials (38%) and eight of 20 unsuccessful trials (40%; Table S4).

The lack of a noticeable difference in BCT frequency between successful and unsuccessful trials (Figure 2a,b) suggests that specific BCTs alone do not represent a defining feature of a successful trial. It may be the interaction

between the BCTs rather than a single BCT that supports weight loss.

Behaviour change theory feedback on behaviour, was identified in 13 of 29 successful trials (49%) but in only two of 20 unsuccessful trials (10%), with increased frequency in trials achieving 5–10kg weight loss (Figure 2c). When present, it was nearly always identified in conjunction with goal-setting, social support, and usually with action planning and self-monitoring of behaviours. This suggests that an individual BCT is unlikely to result in a successful outcome unless combined with appropriate support and feedback mechanisms. Self-monitoring of behaviours was not seen in trials reporting >10kg weight loss, but was present in most trials achieving <10kg weight loss.

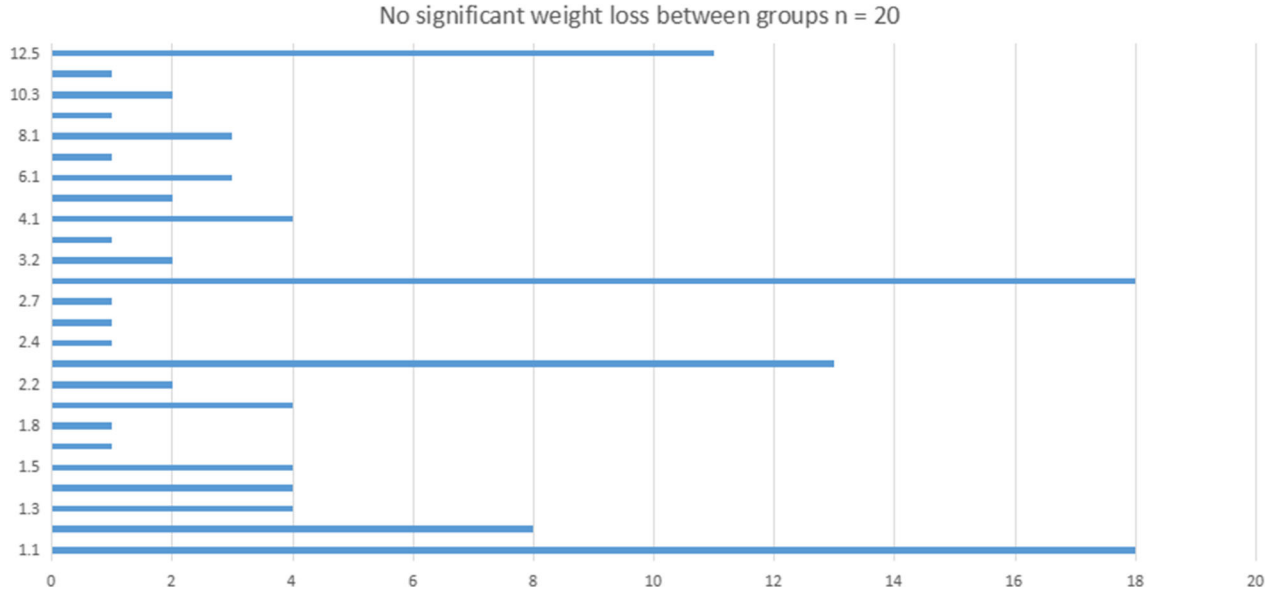

FIGURE 2 (a) Behaviour change theory (BCT) frequency in unsuccessful trials. Key: BCT ref 1.1 Goal setting (behaviour), BCT ref 1.2 Problem solving, BCT ref 1.3 goal setting (outcome), BCT ref 1.4 Action planning, BCT ref 1.5 Review behaviour goal(s), BCT ref 1.7 review outcome goal(s), BCT ref 1.8 behavioural contracts, BCT ref 2.1 monitoring of behaviour, BCT ref 2.2 feedback on behaviour, BCT ref 2.3 Self-monitoring of behaviour, BCT ref 2.4 self-monitoring of outcome(s) of behaviour, BCT ref 2.6 Biofeedback, BCT ref 2.7 feedback on outcome of behaviour, BCT ref 3.1 Social support (unspecified), BCT ref 3.2 social support (practical), BCT ref 3.3 social support (emotional), BCT ref 4.1 instruction on how to perform the behaviour, BCT ref 5.1 information about health consequences, BCT ref 6.1 demonstration of the behaviour, BCT ref 6.2 social comparison, BCT ref 8.1 behavioural practice/rehearsal, BCT ref 9.1 credible source, BCT ref 10.3 non-specific reward material reward (behaviour), BCT ref 12.3 Avoidance/reducing exposure to cues for the behaviour, BCT ref 12.5 Adding objects to the environment. (b) BCT frequency in successful trials. Key: BCT ref 1.1 Goal setting (behaviour), BCT ref 1.2 Problem solving, BCT ref 1.3 goal setting (outcome), BCT ref 1.4 Action planning, BCT ref 1.5 Review behaviour goal(s), BCT 1.6 discrepancy between current behaviour and goal, BCT ref 1.7 review outcome goal(s), BCT ref 1.8 behavioural contracts, BCT ref 2.1 monitoring of behaviour, BCT ref 2.2 feedback on behaviour, BCT ref 2.3 Self-monitoring of behaviour, BCT ref 2.4 self-monitoring of outcome(s) of behaviour, BCT 2.5Monitoring of outcome(s) of behavior without feedbackMonitoring of outcome(s) of behavior without feedback, BCT ref 2.6 Biofeedback, BCT ref 2.7 feedback on outcome of behaviour, BCT ref 3.1 Social support (unspecified), BCT ref 3.2 social support (practical), BCT ref 3.3 social support (emotional), BCT ref 4.1 instruction on how to perform the behaviour, BCT ref 5.1 information about health consequences, BCT ref 6.1 demonstration of the behaviour, BCT ref 6.2 social comparison, BCT ref 8.1 behavioural practice/rehearsal, BCT ref 10.1 Material incentive (behaviour), BCT ref 10.2 Material reward (behaviour), BCT ref 10.3 non-specific reward material reward (behaviour), BCT ref 10.4 social reward, BCT ref 10.6 non - specific incentive, BCT ref 11.1 Pharmacological support, BCT ref 11.2 Reduce negative emotions, BCT 12.1restructuring the physical environment, BCT ref 12.5 Adding objects to the environment. (c) BCT by significant weight change from baseline between groups. BCT ref 1.1 Goal setting (behaviour), BCT ref 1.2 Problem solving, BCT ref 1.3 goal setting (outcome), BCT ref 1.4 Action planning, BCT ref 1.5 Review behaviour goal(s), BCT ref 1.6 discrepancy between current behaviour and goal, BCT ref 1.7 review outcome goal(s), BCT ref 1.8 behavioural contracts, BCT ref 2.1 monitoring of behaviour, BCT ref 2.2 feedback on behaviour, BCT ref 2.3 Self-monitoring of behaviour, BCT ref 2.4 self-monitoring of outcome(s) of behaviour, BCT ref 2.6 Biofeedback, BCT ref 2.7 feedback on outcome of behaviour, BCT ref 3.1 Social support (unspecified), BCT ref 3.2 social support (practical), BCT ref 3.3 social support (emotional), BCT ref 4.1 instruction on how to perform the behaviour, BCT ref 5.1 information about health consequences, BCT ref 6.1 demonstration of the behaviour, BCT ref 6.2 social comparison, BCT ref 8.1 behavioural practice/rehearsal, BCT ref 9.1 credible source, BCT ref 10.1 Material incentive (behaviour), BCT ref 10.2 Material reward (behaviour), BCT ref 10.3 non-specific reward material reward (behaviour), BCT ref 10.4 social reward, BCT ref 10.6 non - specific incentive, BCT ref 11.1 Pharmacological support, BCT ref 11.2 Reduce negative emotions, BCT ref 12.3 Avoidance/reducing exposure to cues for the behaviour, BCT ref 12.5 Adding objects to the environment

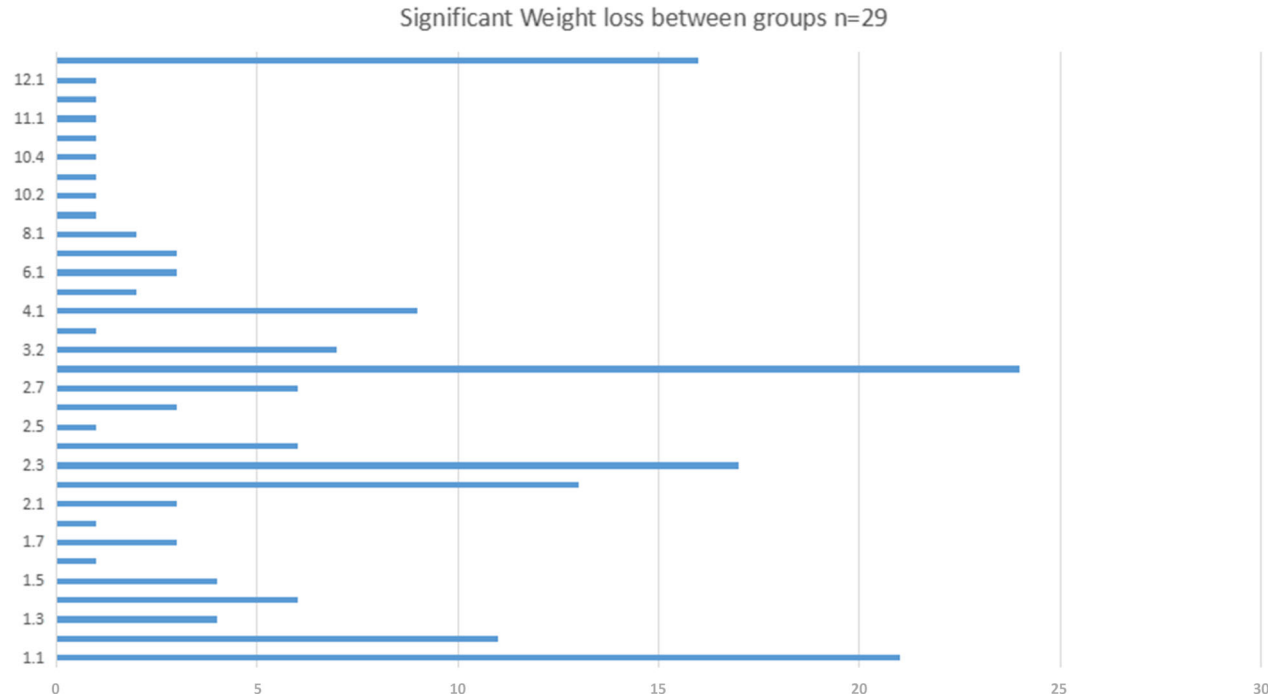

FIGURE 2 Continued

3.5 | Explicit programme theories

Our thematic analysis of the explicit programme theories provided by the original authors in 36 trials showed recurrent themes in trials achieving successful weight loss (Table S5).

- Greatest weight loss was achieved during most frequent contact with interventionists, with weight regain or plateau once contacts stop or reduce in frequency.
- Level of participant education may affect receptiveness and response to the intervention, with more specialised and specific education being less useful than education that can be applied in a variety of situations. Contact time alone cannot determine how much education is successfully received and retained.
- Pre-selection of more motivated individuals with higher locus of self-control may result in better outcomes, although their characteristics may vary from a normal population.
- A visual record of feedback helps with self-regulatory behaviours and increased self-efficacy to continue correcting health behaviours.
- Social support from peers in group situations or family members undertaking an intervention with participants supported compliance, social networking and competition. For long-term maintenance, individuals must believe meaningful improvement in their health and well-being has occurred. Weight loss and improvements in metabolic control lead to hormonal changes, resulting in decreased hunger, increased satiety, better sleep and improvements in mood.
- Meal replacements provide pre-packaged foods with a known number of calories, mitigating individual responsibility for choosing correct calorie foods.
- Personalising the intervention through identification of individual barriers helps support weight loss.

In those trials not achieving successful weight loss possible explanations included: self-selection of goals, no direct contact with healthcare providers, intensive programmes requiring larger commitment from participants, failure from intervention deliverers to give instruction on how to perform a behaviour and increases in calorie intake secondary to increases in physical activity.

3.6 | Repeated mechanisms observed in successful interventions

Repeated mechanisms were observed through hypothesis generating, coding for BCTs and reviewing explicit programme theories, and were tested against the published literature.

3.6.1 | High-frequency contact with those delivering the intervention

We found participants were motivated through continual monitoring by a 'credible source' [S74]. High-frequency contact provided emotional, psychological and social support,

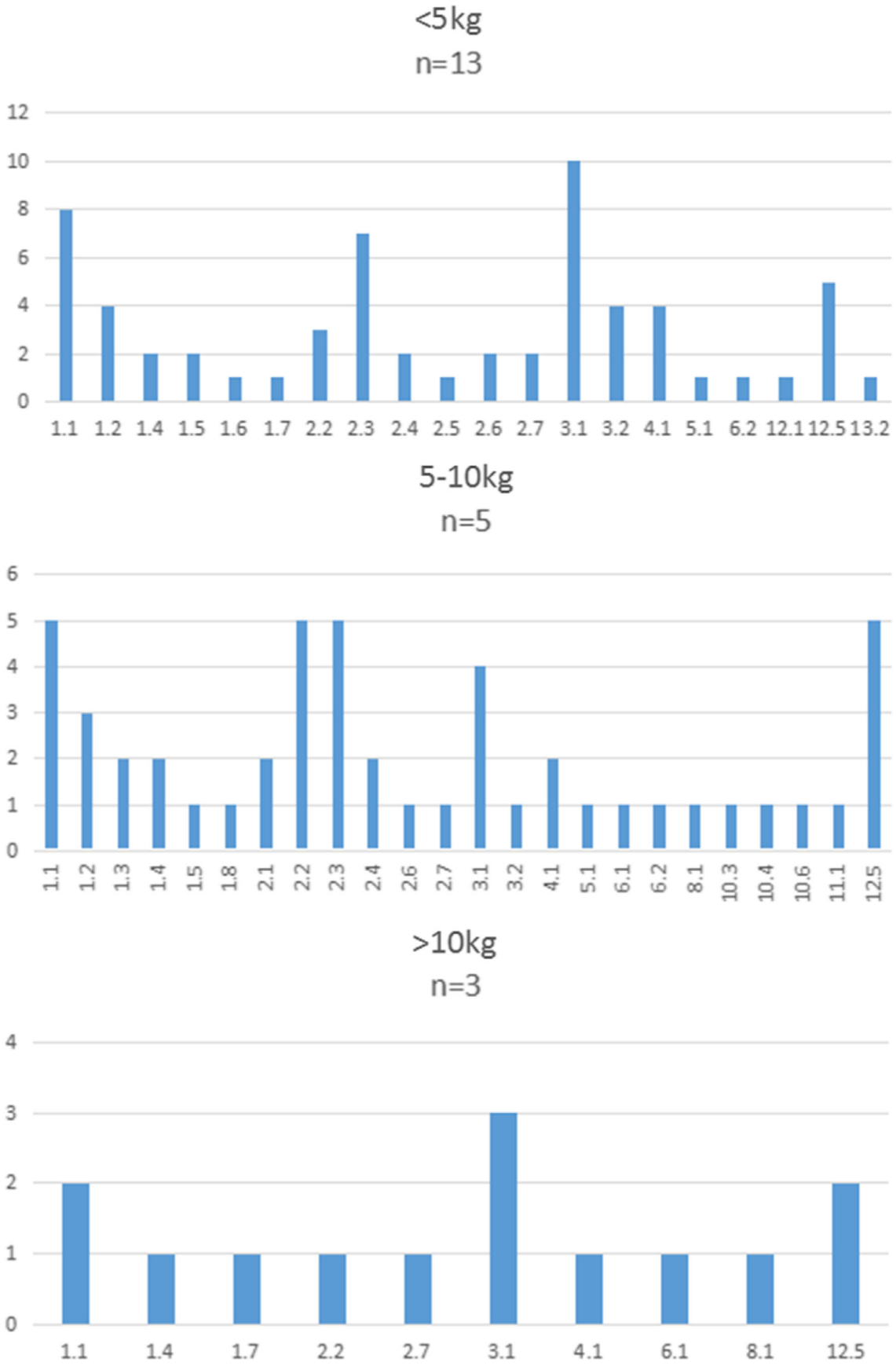

FIGURE 2 Continued

promoting trust development, increased engagement and a feeling of accountability to intervention providers, increasing compliance. High intensity or frequency of contact in those with diabetes has been associated with weight loss [S75], and HbA_{1c} reductions [S76]. There is a lack of literature analysing high-frequency contact with weight loss in type 2 diabetes.

High-frequency contact enhances weight loss in individuals who are obese [S77]. In participants who are obese and overweight, brief weight loss counselling by a health professional tripled the odds of wanting to weigh less (odds ratio 3.71) and trying to lose weight (odds ratio 3.53) [S78]. High-frequency contact may support weight loss through operant conditioning [S79], where positive behaviours are rewarded and re-enforced, through social support, recognition from staff, peers and increased quality of life from observable weight loss [S80].

3.6.2 | Social support

We found social support from family, friends, interventionists and peers increased learning and motivation for weight loss behaviours. Entering an intervention with a family member resulted in positive interdependence.[41] In type 2 diabetes, peer support and sharing of knowledge helps master new skills [S81], family support predicts treatment adherence [S82,S83], and family and friends joining in physical activity predicts weight loss [S84].

Practical and emotional social support can double medical adherence; social support is felt to help with weight management through modulating stress management [S85–S87]. Obesity has been associated with absence of close friends [S88].

3.6.3 | Education

Diabetes education increased participants' awareness of their positive and negative health behaviours, supporting self-empowerment and increased self-efficacy. Explicit theory discussed difficulties of meeting individual needs based on pre-existing knowledge levels and translating instructions to change in health behaviours.

Improvements in HbA_{1c} have been found secondary to type 2 diabetes self-management education [S89], enabled by technology [S90], where communication, participant-generated health data, tailored education and personalised feedback are key. There is extensive literature available on learning and education theory and discussion of behaviour change seen in weight loss [S91], but without specific comment on the underlying mechanism or weight loss in type 2 diabetes. Optimal learning occurs when it is relevant and useful to the individual [S92,S93]. Tailoring education to existing knowledge and actively involving individuals through identification and suggestion of solutions to problems increases learning [S94].

Group learning provided an opportunity to learn from others' questions and to reflect on learning and achievements, with a sense of competition after hearing how others are coping [S95]. It supports social networking, providing peer and professional support [S59] and increasing compliance. Praise and encouragement supports motivation [S96]. A realist review [S95] of shared medical appointments proposed that individuals developed ‘robust’ knowledge about their condition by hearing others discuss their experiences, motivation and positive feelings, increasing confidence, professional relationships and rapport [S95].

3.6.4 | Counselling/motivational interviewing

Counselling and motivational interviewing facilitated identification of personal goals, barriers and values through a supportive and collaborative partnership; improving self-efficacy, body image, stimulus control and self-esteem, encouraging weight loss.

Motivational interviewing appears most effective when tailored to the individual’s level of self-efficacy and readiness to change. Individualised motivational interviewing has led to improved self-management, self-efficacy, quality of life and HbA_{1c} levels in type 2 diabetes, increasing transition from the contemplation to preparation or action stages [S97,S98]. Motivational interviewing in type 2 diabetes has been found to be most effective in changing dietary behaviour, with the largest impact being on weight reduction [S99]. Most studies lack explanation of the mechanism by which motivational interviewing works, but acknowledge an individualized approach is most effective [S100].

3.6.5 | Self-monitoring and feedback

Self-monitoring increased autonomy for diabetes management and development of habits associated with successful weight maintenance. Self-monitoring using a device (e.g. a pedometer) or diary provided positive objective feedback on progress, increasing confidence and motivation and linking glucose levels with exercise intensity, physical activity and calories used. Self-monitoring increased accountability to interventionists, increasing likelihood of maintaining goals through self-regulation and fear of negative assessment.

Technology usage has been reported to lead to significant HbA_{1c} improvements [S90]. Feedback is more impactful if given immediately after a behaviour and linked to real-world and relatable reference points, such as the exercise equal to calories in a meal [S101]. More frequent weighing in obesity

has been linked to better weight outcomes [S102], and more frequent blood sugar-measuring to better HbA_{1c} outcomes [S101]. In patients who are obese with type 2 diabetes, increased self-monitoring of blood glucose was linked to better weight loss and HbA_{1c} improvement [S103].

3.6.6 | Goal-setting

We found participants may benefit from direction, with goals chosen. Achievement of goals delivered positive psychological rewards through self-actualization [S104].

There has been some concern that setting weight loss goals too high leads to less weight loss, attrition and negative psychological outcomes [S105]; however, some studies have shown that less realistic goals are met with better weight outcomes [S106–S108]. A meta-analysis failed to show statistically significant difference in weight loss goals and weight loss achieved [S109]. Goal-setting is used commonly in type 2 diabetes management, but there is a lack of type 2 diabetes-specific research in weight loss [S110], with most of the evidence relating to performance in sports people and motivation within the workplace. It is felt goal-setting is moderated by ability, commitment, feedback, task complexity and available resources. Goal-setting may be modulated by personal social circumstances. Unless an individual views a health goal as relevant they will fail to be motivated by it [S96].

3.6.7 | Meal replacements

We found meal replacements allowed participants to adhere to calorie targets through ease of use and convenience of portion control. As meal replacements help with weight loss, they may bolster confidence and increase engagement in other aspects of the intervention. However, they remove locus of control, self-regulating behaviours and responsibility for healthier food choices and portion sizes. Previous trials have shown that calorie-reduced meal replacements can help obese and overweight individuals with type 2 diabetes to lose weight [S111].

Individuals who are obese underestimate calories, even with a daily calorie limit[29] [S112]. Meal replacements reduce calorie counting errors [S113]. Research shows intervention groups taking meal replacements compared to calorie-restricted or portion-controlled diets achieve large weight losses [S112–S115].

3.6.8 | Personalisation

Explicit theory discussed personalisation, including identification of barriers, time to allow participants to adjust to new routines, and delivery of personalised advice, increasing empowerment and well-being.

Tailoring and personalisation have been used in overweight individuals with type 2 diabetes as part of a physical activity and low-fat dietary interventions. Tailoring during an interventionincreased low-fat diet take up with no significant reduction in BMI, HbA_{1c} or lipids [S116]. In a tailored lifestyle intervention for individuals who are overweight and obese, a home-based dietary and physical activity intervention saw greater weight loss in the intervention and higher levels of physical activity during the active phase, but a loss of significance over a longer time period [S117].

3.6.9 | Context and mechanism configurations that consistently do not work

Often there are multiple mechanisms interacting within an intervention, especially when multi-component, making it difficult to identify mechanisms which are active. Possible explanations include the intervention being designed for a specific demographic and not being applicable to all participants. Failure to prioritize health, due to basic and psychological needs not being met, including: access to adequate food, water, housing, security and safety [S104], 'love and belonging', self-esteem or emotional well-being hinder self-actualisation to achieve one's full potential to optimise health [S104]. This highlights the importance of focusing on personalisation of the intervention.

3.6.10 | Trials containing tailoring or personalization of intervention

After focusing on personalisation, we found five trials contained a personalised component for individuals not achieving weight loss targets. This included exercise and cooking classes, exercise equipment, food coupons or meal replacements, and weight loss medication;[34] meal replacements, individualised dietary advice and weight loss medication;[4] extension of the weight loss phase [S66, S68]; or adjustment of calorie prescription.[42]

Other trials tailored the intervention, offering extra contact[33,35,40] [S56,S60] with the interventionist, with personalised feedback on diet,[25,27,34,37] physical activity[23,25,37] [S60], weight, BMI or waist circumference [S53,S60,S62], step count[23] [S53,S60] and glucose levels[23,40] [S60,S62]; however, most trials were pre-designed to be delivered in the same fashion to all participants.

Programme theories generated (Table S6) for interventions containing personalisation for participants losing the most weight included extra resources or incentives, such as meal replacements or weight loss medication, pre-selection

of motivated individuals, individualised counselling and motivational interviewing, social support, and increased quality of life from observed weight loss. Those participants losing some weight were supported through culturally tailored interventions and integration of physical activity alongside other commitments. Those who failed to achieve desired weight loss may have barriers or triggers which were not addressed, including cost associated with adopting healthy behaviours, other health problems taking priority, low levels of motivation and confidence and failure to develop habit or resilience.

3.6.11 | Analysis of discussion group findings within social framework

Themes emerging in discussion groups were grouped (Table S7) as described below.

- Society/cultural differences: macronutrient composition and flavours of cultural foods differ, diet foods need to better cater for ethnic palates. Cultural practices including fasting may help with weight loss. Societal and cultural roles of gender related to cooking and housework are implicated in weight loss.
- Public policy: available time, facilities, space and cost of physical activity.
- Community: messages to prioritize participant's health first.
- Organizational: education from credible sources and monitoring, general practitioners prescribing weight loss medication, incentivization for weight loss behaviours, workplace promoting healthier habits.
- Interpersonal: responsibilities such as being a carer may take priority, social support from family friends and peers.
- Individualisation: prioritization and habit development, personalisation of programmes needed to account for comorbidities and environmental restructuring to support weight loss activities.

3.6.12 | Findings and theory generation from second discussion group

Programme theories included 'cheat days' promoting demonisation of specific food groups, with participants feeling they lost self-control on cheat days. The societal and cultural role of women in food preparation which was felt to be changing as more women enter the workforce, increasing the likelihood of processed food consumption and leading to increased normality for men to prepare food. Lastly, family mealtimes supported interpersonal connection and a sense of purpose for the individual preparing the meal (Table 2).

4 | DISCUSSION

4.1 | Summary of key findings

This realist review helps identify and provide an understanding of mechanisms interacting within a specific context, which result in intended and unintended outcomes during trials to achieve weight loss in type 2 diabetes. All interventions reviewed were delivered within complex health and social systems, which are in turn, set in complex social and other contexts. There is existing literature to show that each of the mechanisms we identified has been successfully applied, but not specifically in the context of type 2 diabetes.

Successful mechanisms identified include high-frequency contact with intervention providers who participants deem credible. Effective education in diabetes for weight loss must be relevant and relatable to an outcome, supported through translation of specific instruction on behaviour to patient-recognizable and desired outcomes, thus increasing self-efficacy. Self-monitoring increases the autonomy and accountability of the individual to intervention providers, through knowledge of feedback. Guided goal-setting is supportive of weight loss. Personalising the intervention to meet the needs of the individual, and delivering it at the right time for participants to focus on health outcomes is important. This was reinforced by findings from our discussion groups, underlining the need for tailoring the intervention to the individual's social circumstances, including culture, gender and family circumstances. It is likely, however, that not one single factor accounts for weight loss, and multiple factors work synergistically to achieve weight loss in overweight and obese adults with type 2 diabetes, moderated by the physical and social environment surrounding the individual.

Central to every mechanism or theory identified in this review that contributed to success or failure of an intervention was how relevant the resource or information provided was to the individual, whether the intervention was tailored to the individual's needs or motivational constructs, and the perceived relevance of the outcome to their social, emotional, physical and psychological needs. Social connection was important as this was intrinsic to several mechanisms. We found BCTs of goal-setting, self-monitoring of behaviours, social support and adding objects to the environment in most successful and unsuccessful trials. Feedback on behaviours was seen with increased frequency in successful trials, especially those achieving 5–10-kg weight loss, however, this was nearly always present with goal-setting, social support and usually with action planning and self-monitoring of behaviours. It is likely that an interaction between multiple BCTs determines a successful trial.

There were fewer identified trials (15) in majority BME populations compared to majority white populations (34), with eight (53%) and 21 (62%) successful trials, respectively. In this limited number of trials with majority BME populations, there

TABLE 2 Evidence-informed programme theory generation

Findings of discussion group	Testing against the literature	Programme theory generated
1. 'Cheat days': Participants did not agree with cheat days, they felt it was better to have 'a little bit everyday', and better to eat junk foods in small portions regularly instead of depriving themselves and then 'binging'. They felt they needed to exercise self-control. They felt if they did not have the food in the house they would crave it and worry about losing control and binging; if they had a small amount then they would feel satisfied. However, they felt in social situations that they would want what everybody has, so there was difficulty with self-control.	Our findings contradicted theories of cheat days seen in popular literature where it is felt that cheat days aid adherence to diets. They work by allowing some failure to be acceptable within a strict diet, otherwise abandonment of the goal from a 'failure cascade' may occur. The consensus of eating 'bad food' little and often working better can be explained by Hetaherton and Vohs beliefs that if individuals try to act according to a no-tolerance belief, then internal motivation to continue is drained. However, if they allow themselves to have 'bad foods' at their will, this will help with management of self-regulatory resources, representing flexibility instead of rigidity with goal attainment [S123].	Cheat days allow demonisation of specific food groups, creating taboo around their consumption and potential association with self-destructive behaviours. If a weight loss intervention is not working then individuals are more likely to binge on these food groups. By allowing small amounts of 'bad food' in the diet, stigma is removed and therefore the need to punish oneself at times of failure. Cheat days also represent a loss of self-control, another reminder that someone is failing to achieve their weight loss goals
2. Role of gender and food: This is very culture-dependent. In South Asian culture, traditionally it is thought that 'women's place is in the kitchen' or it is a 'woman's job' to cook for her family and 'men go out to work'. But this is slowly changing as new generations are coming through and both girls and boys are taught to cook. In western culture 'teamwork' and whoeverarrives first back home does the cooking with expectations ofcertain types of cooking, e.g. barbecueing considered a manly job. In addition, more women go out to work now so the cooking has to be shared.	We found this was related to cultural beliefs. However, this can be seen to be changing worldwide, as women account for a greater proportion of the workforce. Previous studies of individuals with diabetes have shown that women are often primarily responsible for food or meal-related tasks and husbands depend on their wives for diet support [S124,S125]. In some qualitative studies, BME women with diabetes revealed they faced opposition from partners and other family members when they tried to make changes to cultural practices. This resulted in them sacrificing dietary recommendations for themselves to prevent conflict and having to prepare different meals, negatively affecting their food intake [S126,S127]. A case study in Singapore [S128] found that as women changed their role becoming part of the workforce, this has led to increased amounts of meals being consumed outside the family home. Employment brings relative time poverty, and food preparation is not prioritised and often delegated to the food industry. Cawley and Liu [S129] report that where mothers are in employment, less time is spent on cooking and shopping for groceries which would have a subsequent effect on family nutrition. There has been a cultural shift in gender roles and cooking in the western world, with it now seen as acceptable for both sexes to cook, supported through media by the majority of celebrity chefs being male, and with men now viewing cooking as a leisure activity. A US study from 2009 to 2016 linked increased cooking rates in men with at least college education, women in higher education also saw the same pattern. However women with lower education spent a greater amount cooking per day then did those with higher education, with the opposite being true for men [S130]. A similar trend was also seen in Europe with more men beginning to cook over time [S131]. Increased cooking rates among men is consistent with linking higher education levels with developed egalitarian views about gender roles and distribution of household labour [S132].	Cultural stereotypical ideology is still prevalent in many communities, with women expected to prepare food for the family. As more women enter the workforce, this reduces time for food preparation and consumption within the family home. This may lead to more unhealthy food choices of pre-prepared and takeaway foods, which are more energy dense and nutrient poor. With gender role equality development in society, it is slowly becoming more normal for men to hold some responsibility of food preparation for the family.

(Continues)

TABLE 2 (Continued)

Findings of discussion group	Testing against the literature	Programme theory generated
3. Role of food in the family: Eating together is a necessity, helping with improved communication and bringing you closer, 'increases love between each other when you eat together'. Cooking also brings enjoyment; children enjoy the food made for them so this makes the cook/parent feel good. Eating together described as 'bonding' and 'family time', helping to keep the family together. Children invite parents over for dinner and vice versa. Cooking may be associated with a carer role: cooking for parents, resulting in cooking big portions so there is plenty for everybody.	The importance of increased home cooking is not only limited to the nutritional constitution of the prepared food but also food in the family helps to provide closeness and a sense of purpose. Previous cross-sectional and longitudinal studies have found several benefits to having regular family meals, including healthier food consumption [S133–S138], reduced fast food consumption, better weight control [S139], and improved psychosocial well-being [S140,S141], including fewer depressive symptoms and better self-esteem. Eating with the family as an adolescent and subsequently an adult has been associated with healthier diet consumption and weight and psychological outcomes in comparison to those that never ate with the family [S142].	Food becomes the common mediator and focus for conversation and acts to increase social interaction and bonding within the family group, leading to beneficial psychological and physical outcomes. Therefore, it can be associated with positive family times and a sense of interpersonal connection and purpose.

were no distinguishing patterns of mechanisms between successful and unsuccessful trials. Where trials were unsuccessful, programme theories discussed that the intervention was not culturally appropriate, failure to develop a trusting relationship with those delivering the intervention or peers within a group setting, failure to identify barriers or participants basic needs and address these, and failure to modify existing health beliefs.

4.2 | Comparison with existing literature

Similar to our findings on BCTs a previous review [S118] found that 'problem-solving', 'feedback on behaviour', 'adding objects to the environment', and 'social comparison' were associated with significant HbA_{1c} reductions. Environmental modification, including providing all foods, were more than twice as effective at reducing HbA_{1c} compared to interventions using behavioural change interventions. In an intensive behaviour change community-based trial in recently diagnosed type 2 diabetes, a higher number of BCTs were found to be associated with a reduction in BMI, with goal-setting, goal review, and social support showing the strongest relationship [S119]. Similar to our findings, goal-setting and social support were seen in the majority of successful trials, with successful trials having, on average, 6.0 BCTs, compared with 5.6 in unsuccessful trials. Another systematic review of a physical activity intervention in type 2 diabetes also found a higher number of BCTs was associated with better outcomes [S120]. A process evaluation foundover the short term, better social support was associated with increased engagement in self-regulatory behaviours [S121].

A review on physical activity and diet interventions in type 2 diabetes found four BCTs, 'instruction on how to perform a behaviour', 'behavioural practice/rehearsal', 'action planning' and 'demonstration of the behaviour', were associated with significant HbA_{1c} reductions.[15] These were not seen in the majority of successful trials within the present study.

A realist review [S122] identified the key mechanisms associated with diabetes management in people with dementia. It found the requirement for personalised, family-centred care and relationship development with healthcare professionals who reprioritise care towards the family and patient instead of clinical directives. This is very similar to our findings, where the successful mechanisms and programme theories identified concentrated on an underlying theme of personalising each resource to meet the individual's demographic, social and cultural context are vital for success.

4.3 | Strengths and limitations

Few public health interventions have been reviewed using realist methodology. The present review is unique in taking this

approach to review the mechanisms associated with successful weight loss in overweight and obese adults with type 2 diabetes.

Within realist methodology, understanding context is key. We recognise that the data we extracted from the included studies was limited to what was provided by authors within the trials and protocols, where available, for our context–mechanism–outcome generation and identification of theories based on which the intervention was developed. Authors did not describe mechanisms and explicit programme theories, when provided, were brief. While we tried to identify mechanisms, we note these often do not work in isolation and often inter-relate. However, we were able to hold discussion groups to further develop our own programme theories.

We coded the trials using BCTs dominant in healthcare research, but could have also looked at educational theory when reviewing the trials. All trials provided education, but only one trial mentioned tailoring education to participants' baseline knowledge. One trial discussed varying the stimulus during teaching to appeal to learners who learn in different ways [S58].

In trials containing pre-selection, selection bias may be important. Pre-selection may have meant individuals' readiness to change or self-efficacy was higher in committing to intensive lifestyle change, which may affect outcomes. In particular, most of the available trials reviewed consisted of mainly white participants, suggesting that research to deliver culturally sensitive and relevant behaviour change interventions is lacking in minority populations. This may be because recruitment and retention has proved challenging for researchers within these groups. All data were extracted by a single author, after reviewing each paper twice. It is therefore possible that some data may have been missed.

Five (10%) of our included studies reported weight loss as a secondary outcome and failed to show a significant effect. These studies may have been underpowered to detect significant differences. Had these studies had greater power, they may have been categorised as being successful within our review. However, as this only applies to five studies, this is unlikely to have had a major impact on our findings.

4.4 | Implications for policy and practice and further research

This study underlines that single uniform interventions will not meet the needs of everyone in a socially diverse overweight or obese population with type 2 diabetes. Each individual has unique insight and experience of living with their condition, in a unique set of circumstances. Policy makers and those who deliver interventions need to focus accordingly on matching the right person to the right intervention. Our findings highlight this challenge, and support the fundamental importance of personalising any weight loss intervention to make it relevant to an individual's social and cultural context. Given the important role of interpersonal connection between family, friends or other individuals with the same condition, lifestyle change interventions should be inclusive of the family or social unit to facilitate cultural change within this context. For example, such interventions should include group education or an ability to enter the intervention with a family member or friend.

To improve outcomes, intervention designers may wish to focus on screening of participants prior to inclusion to better identify participant's motivation, expectations and perceived self-efficacy before embarking on an intensive weight loss programme in those with type 2 diabetes, in an effort to personalise the intervention. However, this may make interventions more expensive, due to the additional steps in the process required, and also less generalizable. Research focused on BME populations is required to identify their specific needs and barriers to support weight loss.

ACKNOWLEDGEMENTS

The authors would like to thank Jeanette Eldridge and Elizabeth Doney, Medical Librarians at the University of Nottingham Medical Library, who helped to finalise the search strategy across the different databases and Dr Angharad Kate Woolley, Leicester Diabetes Research Centre, University of Leicester, who was the second reviewer for the preceding systematic review and meta-analysis.

COMPETING INTERESTS

None declared.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Maula A, Kendrick D, Kai J, Griffiths F. Evidence generated from a realist synthesis of trials on educational weight loss interventions in type 2 diabetes mellitus. *Diabet. Med*. 2020;00:e14394. https://doi.org/10.1111/dme.14394