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Healthy Eating and Active Lifestyles for Diabetes (HEAL-D), a culturally tailored self-management education and support program for type 2 diabetes in black-British adults: a randomized controlled feasibility trial

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ABSTRACT

Introduction Black-British communities are disproportionately affected by type 2 diabetes (T2D). Structured education programs are a core component of T2D healthcare but they are less successful in people from minority ethnic groups. Culturally tailored T2D education has demonstrated greater benefits than usual care. The aim of our study was to evaluate acceptability, fidelity and trial feasibility of the Healthy Eating and Active Lifestyles for Diabetes ('HEAL-D') culturally tailored T2D self-management education and support (DSMES) program.

Research design and methods A mixed-methods randomized controlled feasibility trial in black-British adults with T2D was conducted. Participants were assigned to control (usual care) or intervention (HEAL-D; 7 sessions, 14 hours of group-based culturally tailored diet and lifestyle education, behavior change support and supervised physical activity), in a ratio of 1:1. Primary outcomes were recruitment and retention rates, intervention attendance and completion. Fidelity was assessed through observations and qualitative evaluation was undertaken with participants and educators.

Results 102 patients responded to invitation letters (n=1335); 63 were randomized but 8 were subsequently deemed ineligible due to high baseline glycosylated hemoglogin (HbA1c) requiring intensive medical management or missing baseline HbA1c measurement. Of the remaining 55 participants (27 intervention, 28 control), 69% were female, 47% were of African and 51% were of Caribbean ethnicity. 93% completed the trial, providing end point data. Intervention attendance was high; 85% completed the program (attendance at ≥5 sessions), and 74% attended ≥6 sessions. The intervention was delivered with acceptable fidelity, although the qualitative evaluations identified some areas of structure and format in need of refinement.

Conclusions We have shown it is feasible to recruit and randomize black-British adults with T2D to a trial of a culturally tailored DSMES program. We have shown the intervention is highly acceptable for both patients and healthcare providers. A future trial should assess clinical and cost-effectiveness of HEAL-D.

Trial registration number NCT03531177.

SIGNIFICANCE OF THIS STUDY

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT?

⇒ Black-British communities are disproportionately affected by type 2 diabetes.
⇒ Diabetes structured education programs are less successful in people from minority ethnic groups.
⇒ Culturally tailored diabetes education has demonstrated greater improvements in diabetes control and knowledge than usual care, and the benefits are maintained long-term but there are no such programs for black-British adults.

WHAT ARE THE NEW FINDINGS?

⇒ We have shown that it is feasible to recruit and randomize black-British adults with type 2 diabetes to a trial of a culturally tailored diabetes self-management education and support program.
⇒ We have shown a culturally tailored diabetes self-management education and support program to be highly acceptable for both patients and healthcare providers.

HOW MIGHT THESE RESULTS CHANGE THE FOCUS OF RESEARCH OR CLINICAL PRACTICE?

⇒ Improving the cultural sensitivity of diabetes self-management education is an important means by which to improve the management of type 2 diabetes in minority ethnic groups.
⇒ The evaluation of the real-world delivery of the Healthy Eating and Active Lifestyles for Diabetes culturally tailored diabetes self-management education and support program has shown it to be highly acceptable to both black-British adults living with type 2 diabetes and healthcare professionals involved in their management.

INTRODUCTION

In the UK, as in other upper-middle-income and high-income countries, minority ethnic

groups are disproportionately affected by type 2 diabetes (T2D).[1] In black-British communities, T2D is three times more prevalent than among white-Europeans[2] and poorer outcomes are evident.[3 4]

Supporting people living with T2D to make healthy diet and lifestyle changes forms the cornerstone of management.[5 6] Black-British adults are recognised to participate in relatively low levels of physical activity[7] and consume diets high in carbohydrate and salt.[8] Self-management and lifestyle change is challenging, adherence is a major issue, with only a minority of patients achieving their treatment goals.[9] Several factors influence adherence, including knowledge gaps, personal and cultural beliefs as well as barriers between patients and healthcare practitioners relating to communication and access to, and quality of, care and education.[10]

Diabetes self-management education and support (DSMES) has been shown to enhance self-management.[11] Management guidelines (eg, UK National Institute for Health and Care Excellence) recommend provision of structured education programs to support the development of self-management skills.[12] These programs are effective at improving clinical outcomes and well-being. However, they are mostly based on generic advice that is not sensitive diverse cultures and there is evidence that they are less successful in people from minority ethnic groups.[13 14] This is often attributed to healthcare practitioners lacking cultural knowledge and awareness, and a failure to account for cultural beliefs and practices in generic education programs.[15] Culturally tailored DSMES programs that are responsive to the health beliefs and cultural practices of minority ethnic groups have demonstrated greater improvements in T2D control and knowledge than usual care.[15] However, to date, culturally tailored DSMES interventions for communities of black-African ancestry have largely been based in the USA, and may not translate to UK healthcare structures or black-British communities, whose cultural needs may be different.[16] To address this gap, we developed an evidence-based, culturally tailored DSMES program for black-British communities, called Healthy Eating and Active Lifestyles for Diabetes (HEAL-D).[17]

Prior to a definitive evaluation, we undertook a mixed methods feasibility trial to evaluate key considerations, namely intervention acceptability, fidelity and trial feasibility. Specific objectives were to determine:

- the proportion and characteristics of black-British adults living with T2D who are willing to participate in a randomized controlled trial (RCT) of a culturally tailored DSMES program (ie, recruitment and retention rates);
- feasibility of data collection for potential primary and secondary outcomes;
- estimates of SD for potential primary outcomes, to enable trial sample size calculations;
- estimates of the change in glycosylated hemoglogin (HbA1c) to provide a signal of efficacy;
- the rates of attendance and intervention acceptability;
- if a culturally tailored DSMES program can be delivered with fidelity.

PARTICIPANTS AND METHODS

Trial design

A single-center, parallel-group, RCT design was conducted, the protocol has been published previously.[18]

Participants

Recruitment was open April–October 2018. In the London Boroughs of Lambeth and Southwark, primary care database searches identified potential participants and letters of invitation were sent. Additionally, primary and intermediate care practitioners referred participants that they identified through their practice, and posters/flyers were distributed in practices for self-referral. Participants from the preceding intervention development project were invited to participate but, due to their prior involvement, they were allocated to receive HEAL-D and were not included in the randomization process.

Eligible participants were of self-declared black-British, African or Caribbean ethnicity; aged ≥18 years; had a clinical diagnosis of T2D; able to communicate in English and suitable for general diet and lifestyle advice, and group-based education (ie, no complex diet needs such as chronic kidney disease, or complex learning needs; suitability judged by the referring healthcare practitioner). Exclusion criteria included pregnancy and complex clinical needs. Following recruitment, an additional criterion was added (October 2018), HbA1c <86 mmol/mol, after a proportion of participants were found to have high baseline values that needed intensive medical management.

Randomization

Individual participants were randomized (1:1 ratio, without blocking) to intervention (culturally tailored DSMES program plus usual care) or control (usual care alone), using sealed envelopes. The research assistant performed randomization at the baseline visit after gaining consent before data collection. The research assistant was aware of allocation but the nurses conducting the biomedical assessments were not. Participants from the intervention development study were recruited but not randomized or included in the main outcome data due to issues of contamination; they were included in the qualitative evaluation of intervention acceptability.

Sample size

A pragmatic sample of 60 randomized participants, 30 in each arm, was anticipated to be sufficient to evaluate the program, allowing for 10% drop-out/non-completion. Delays in research governance approval processes and restrictions preventing extension of the study end, required a sample size reduction from that of the published protocol to n=60; this amendment was approved prior to trial commencement.

The intervention

The intervention was developed through a co-design project;[17] HEAL-D, consisted of 14 hours of face-to-face, group-based culturally tailored education, behavior change support and participatory physical activity. Seven sessions, each 2 hours, were delivered by a lay educator of black-British ethnicity and a diabetes specialist registered dietitian (no specific ethnicity). Physical activity classes, delivered by exercise instructors trained in rehabilitation exercise, were included in five sessions; these included resistance (eg, circuit training and resistance band training) and cardiorespiratory (eg, walking group, dance aerobics and Zumba) exercises. Sessions were scheduled for daytime, evening and weekend delivery, using a weekly or fortnightly schedule, with participants choosing the program location and timing that best suited their needs. 'Flexible attendance' allowed participants to switch between programs where needed/desired, for example, missed sessions. The sessions were delivered in community venues such as church halls or community centres, aiming for group sizes of 8–12 participants. The sessions followed an evidence-based curriculum, focusing on four specific diet and lifestyle goals:

I. Carbohydrates: limit portion sizes.
II. Physical activity: participate in 30 min of moderate to vigorous physical activity daily and strength training twice a week.
III. Body weight: lose 5%–10% body weight if overweight/obese or maintain a healthy weight.
IV. Cardiovascular risk: limit saturated fat and salt intake.

Culturally tailored materials, including information booklets, games and videos were developed. A range of behavior change techniques (BCTs) were used (online supplemental table S1), selected from analysis of the qualitative data collected in the co-design study, which identified key barriers relating to the behavioral goals of the intervention (full details of the intervention[17] and choice of BCTs[19] have been published).

An educator delivery manual was developed, which detailed the structure and delivery of the sessions. Delivery of specific sections of the sessions were designated to the different educator roles, whereby the dietitian mainly led on education/information and discussion-based sections and the lay educator led on interactive games and tasks.

The educators received 8 hours of formal training, delivered by the lead researcher (LMG); both educator roles received training on the learning objectives of the sessions, how to deliver the different components of the sessions and the theory and delivery of the BCTs. In addition, the lay educators received training on T2D and principles of self-management while the dietitian educators received training on important cultural beliefs and practices relevant to the intervention.

Lay educators were recruited via a range of channels, including the Diabetes UK 'Community Champion' initiative, which trains members of ethnic minority communities to raise T2D awareness among their communities (eg, risk screening roadshows), and through the research teams' networks. Lay educators were considered eligible if they were of black-British ethnicity, with good command of written and spoken English, an interest in health and/or T2D, effective presentation skills, confident at communicating and working with the public and having rights to work in the UK. Dietitian educators were recruited from clinical service provision in south London.

Usual care was determined by the participants' medical team, typically in primary care, and was not actively influenced by the research team. Both arms received usual care; there was no other intervention provided to the control arm. Medical management of diabetes, blood pressure and lipids were undertaken by the participants' primary care physician throughout the study.

Outcome measures

Measures were taken at baseline (randomization) and 6–8 months postrandomization; the majority started the intervention within 2–4 weeks of randomization, however, for a small number this was delayed by 2–4 weeks due to program scheduling and locations. In all cases, follow-up was scheduled for 6 months after starting the intervention. All outcome data, other than intervention acceptability and fidelity, were collected in a 2-hour study visit at the Clinical Research Facility at Guy's and St Thomas' NHS Foundation Trust, London, UK.

Biomedical measures

HbA1c, blood lipids, blood pressure, weight, height, body mass index and waist circumference were measured with the participant fasting and wearing light clothing (shoes removed). Standard operating procedures ensured quality and consistency. Samples were drawn from a venous sample and assayed locally in the accredited hospital laboratory.

Patient report outcome measures

The following questionnaire measures were completed: Perceived Diabetes & Dietary Competence[20] (*dietary competence*) and International Physical Activity Questionnaire-short form[21] (*physical activity*) to assess lifestyle changes; Short Diabetes Knowledge Instrument[22] (*diabetes knowledge*), Diabetes Empowerment Scale Short Form[23] (*empowerment*) and Multidimensional Scale of Perceived Social Support[24] (*social support*) to assess potential intervention mechanisms and EuroQol EQ5D-3L visual analog scale[25] (*quality of life*) and 5-item Problem Areas In Diabetes scale[26] (*diabetes distress*) as potential intervention outcomes.

Acceptability and fidelity of the intervention

Intervention participants participated in focus groups, conducted after completion of the program, to evaluate overall intervention acceptability as well as key components of format, structure and content. A sample of sessions were observed using a bespoke checklist to assess fidelity of delivery and to identify any refinements

that were needed. Selection of sessions for fidelity observations aimed to ensure each session within the course was observed, to determine adherence to the delivery manual and at least half of the course sessions were observed more than once and with different educator pairings, to determine variability in adherence to the delivery manual.

Adherence to intervention elements was scored as: occurrence (2 points), attempted occurrence (1 point) or non-occurrence (0 points); means were calculated. Adherence to scheduled times was calculated as per cent actual/recommended time. Educators were interviewed after delivering the intervention to evaluate acceptability from an educator perspective and to identify any refinements that were needed. All focus groups and interviews were digitally recorded and transcribed verbatim. The transcripts data were analysed by one member of the research team (CR) for descriptive themes using thematic content analysis with data managed using NVivo V.10 (QSR International, 2021) and with themes discussed by the team. As themes were descriptive process considerations, extensive double coding was deemed unnecessary. However, all extracts for each theme were read by a team member (LMG) against each theme name, for validation.

Statistical analysis

Descriptive analyses are presented. Recruitment rates were calculated in two ways: the number randomized as a percentage of people who were sent letters of invitation and the number randomized as a percentage of people who expressed an interest in participation. Intervention adherence was assessed using attendance records; completion of HEAL-D was defined as attendance at ≥5 out of 7 sessions. Retention was calculated as the number of participants who attended the end point visit as a percentage of those recruited. Data completion was calculated as the proportion of participants who had paired baseline and end point data. These rates were evaluated by sex, ethnicity, age group and employment status. Rates are expressed as number (%), and clinical and patient-reported data are presented as mean (SD), with 95% CIs.

For variables that may form primary and secondary outcomes in a definitive trial, the mean at baseline and follow-up has been calculated, as well as the mean of the change from baseline to follow-up (change score). To account for regression to the mean effects, the difference in change scores between treatment groups was adjusted for the baseline values. The adjusted mean difference in change score has been presented with 95% CI, providing signal of efficacy estimates. In line with the Consolidated Standards of Reporting Trials extension for pilot studies and because we were not formally powered to detect between-group differences in outcomes, differences have not been tested for significance. Analyses were conducted using Stata V.15 (StataCorp, 2017).

RESULTS

Participants and characteristics

A total of 102 black-British adults with T2D expressed an interest in participating in response to invitation letters sent from database searches of 11 primary and intermediate care practices (1335 letters sent). Of these, 63 consented and were randomized. A further 14 participants from the intervention development study participated and were allocated (non-randomized) to the intervention. Following baseline assessment of HbA1c, 5 randomized participants (n=3 intervention, n=2 control) were found to have HbA1c levels ≥86 mmol/mol (10%), requiring referral for intensive medical management; these participants were considered ineligible and excluded from data analysis, although they continued to receive the intervention and, due to the group-based nature of the intervention acceptability evaluations, were included in the qualitative data collection (figure 1). A further 3 participants did not have HbA1c measured at baseline, leaving 55 randomized participants in the main quantitative analyses.

Of the 55 participants, 69% were female, there was an equal mix of participants of direct African versus Caribbean ethnicity, 73% were first-generation migrants (born outside UK), 42% were in receipt of welfare benefits and 38% were in paid work (table 1).

Six HEAL-D courses were delivered between April and December 2018 in five different community venues in the London Boroughs of Lambeth and Southwark. Four dietitian (two of black-British and two of white-British ethnicity) and four lay educators (all black-British ethnicity) delivered the courses, with all sessions within a course delivered by the same educator pairing. The group sizes ranged from 2 to 10, with an average of six participants per course.

Trial recruitment and retention

The recruitment rate was calculated based on the number of eligible randomized participants (n=55) in relation to the number of invitation letters sent (n=1335) (4% (95% CI 3 to 5)) and in relation to the number who expressed interest in response to the invitation letters (n=102) (54% (95% CI 44 to 64)).

Fifty-one of the 55 randomized participants completed the trial, giving a retention rate of 93% (95% CI 82 to 98); retention rates were equal across intervention and control arms (online supplemental table S2) and there were no appreciable differences seen by sex, ethnicity, age group and employment status (online supplemental table S2). Most withdrawals were due to missing the end point visits, in which two participants were sick or travelling and two participants could not be contacted.

Intervention attendance

Attendance at the intervention was high: 85% (23/27) completed the program (attendance at ≥5 sessions), and 74% (20/27) attended ≥6 sessions. No appreciable differences in attendance were seen in relation to sex, ethnicity,

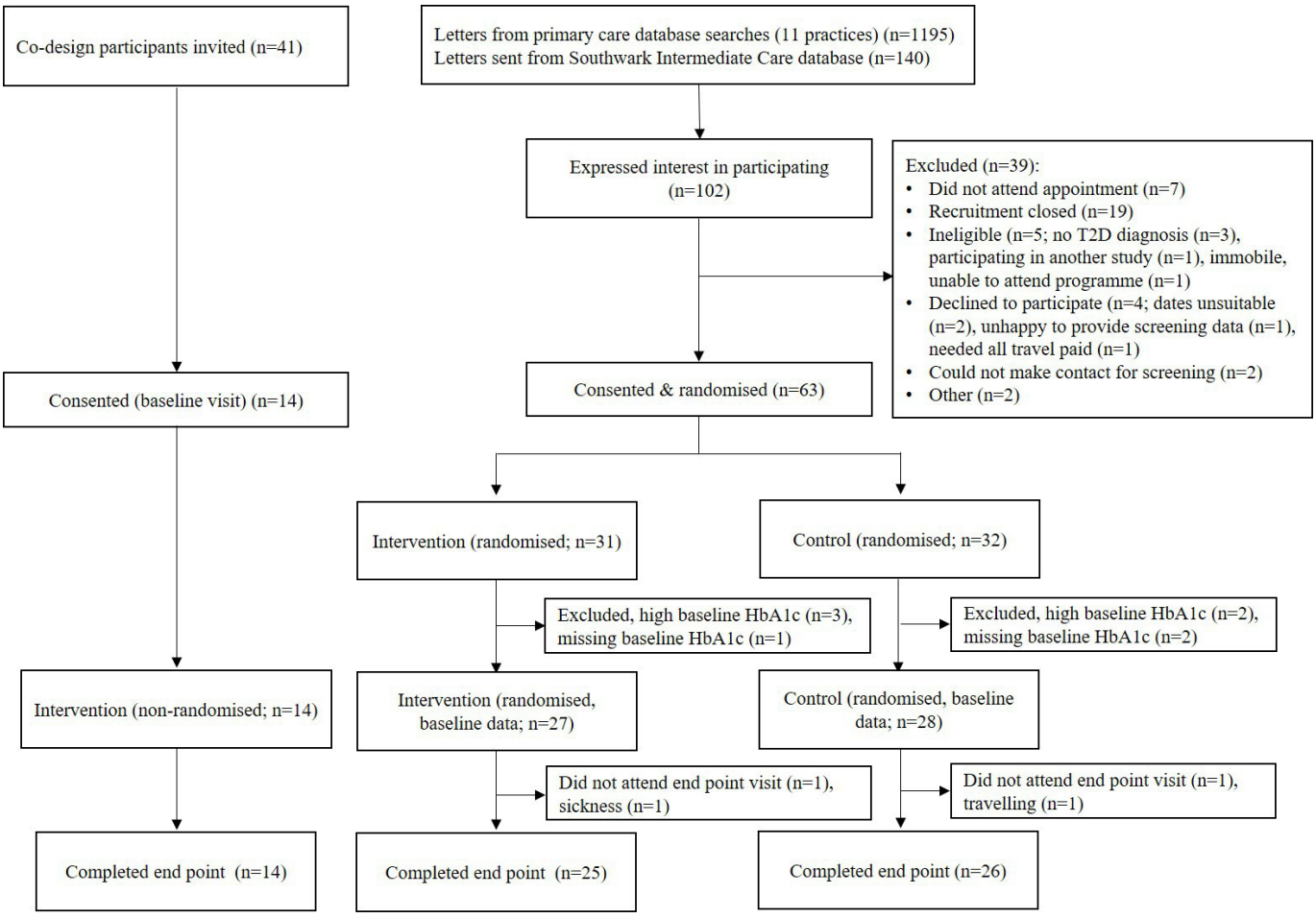

Figure 1 Consolidated Standards of Reporting Trials diagram. Flow of participants through the Healthy Eating and Active Lifestyles for Diabetes feasibility trial. HbA1c, glycosylated hemoglogin; T2D, type 2 diabetes.

age group and employment status (online supplemental table S3). A third of participants (10/27) used 'flexible attendance', switching between courses, thus enabling them to attend more sessions/complete the program.

Trial outcome data and estimates of sample size

Of the 55 participants who entered the trial, 93% (n=51) had complete outcome data for HbA1c, weight and lipids. Each patient-reported outcome variable was complete for at least 85% (n=47) of participants (online supplemental table S4 and S5).

Table 2 shows the clinical and patient report outcome measures, by arm and timepoint. Mean baseline HbA1c was 60.6 (SD 11.4) and 59.1 (SD 11.2) mmol/mol in the intervention and control groups, respectively. Adjusted mean difference in HbA1c change scores between intervention and control was −2.8 (95% CI −9.5 to 3.9) mmol/mol. The primary outcome in a future definitive trial would be HbA1c, as the main clinical measure used to assess overall glycemic control and a predictor of long-term complications. To inform the sample size calculation for a future definitive trial, we analyzed the Pearson's correlation coefficient between baseline and end point HbA1c, which is estimated to be 0.672, as well as the SD of HbA1c values by treatment group (table 2).

Self-reported physical activity is shown in table 3. At baseline, 48% and 43% of participants in the intervention arm and 40% and 52% of participants in the control arm rated their physical activity as low and moderate, respectively. At end point, the proportion of intervention participants who rated their physical activity as low decreased by 17 percentage points and moderate increased by 25 percentage points, while in the control group low physical activity dropped by 4 percentage points and moderate increased by 4 percentage points.

Fidelity and acceptability

Thirteen sessions were observed, no session was observed by more than one person (online supplemental table S5). Focus groups were conducted with participants from four (out of six) courses, and interviews were conducted with all educators, to understand the extent to which components of the program were operationalized as intended, how acceptable and effective they were and what refinements were needed. Online supplemental table S6 provides a summary of the findings, with illustrative quotes from participants and educators.

Table 1 Sociodemographic characteristics of study participants

	Overall (n=55)	Intervention group (n=27)	Control group (n=28)
Sex, n (%)			
Female	38 (69)	18 (67)	20 (71)
Male	17 (31)	9 (33)	8 (29)
Ethnicity, n (%)			
African	26 (47)	10 (37)	16 (57)
Caribbean	28 (51)	16 (59)	12 (43)
Mixed white and black African	1 (2)	1 (4)	0 (0)
Age (years), n (%)			
<45	3 (5)	1 (4)	2 (7)
45–55	16 (29)	9 (33)	7 (25)
55–64	20 (36)	8 (30)	12 (43)
65–74	12 (22)	6 (22)	6 (21)
≥75	4 (7)	3 (11)	1 (4)
Employment status, n (%)			
Paid/Self-employed	21 (38)	11 (41)	10 (36)
Voluntary	2 (4)	0 (0)	2 (7)
Unemployed	10 (18)	4 (15)	6 (21)
Student	0 (0)	0 (0)	0 (0)
Housewife/ Husband	3 (5)	2 (7)	1 (4)
Retired	19 (35)	10 (37)	9 (32)
Generational status, n (%)			
First generation	40 (73)	21 (78)	19 (68)
Second generation	13 (24)	5 (19)	8 (29)
Missing	2 (4)	1 (4)	1 (4)
Educational attainment, n (%)			
Primary	0 (0)	0 (0)	0 (0)
Secondary 16	10 (18)	7 (26)	3 (11)
Secondary 18	14 (25)	8 (30)	6 (21)
Tertiary	28 (51)	12 (44)	16 (57)
Missing	3 (5)	0 (0)	3 (11)
In receipt of benefits, n (%)			
Yes	23 (42)	10 (37)	13 (46)
No	27 (49)	16 (59)	11 (39)
Missing	5 (9)	1 (4)	4 (14)

Intervention fidelity

Overall, content (mean 1.65) and time adherence (mean 108% of the scheduled time) were satisfactory but with inconsistencies. Content adherence was poorest for session 2 ('get moving'; 1.42) and session 4 ('shape up'; 1.08), which were the two sessions in which new interactive tasks were introduced. Session 5 ('drop the pressure') had the greatest content adherence score (1.92) but was delivered more quickly than planned (72% of scheduled time). In session 7, the time spent on the education content was double that of the scheduled time (online supplemental table S7).

The educator interviews illuminated some fidelity issues:

- While session 1 was designed to adhere to pedagogic practice in providing scaffolding for the remaining sessions (eg, identifying objectives, goal setting), educators concurred this did not suit the participants, was not easily delivered and the session felt rushed, with corners often cut in content or interactivity: "*we probably stuck to the taught curriculum very well and the practical tasks very well, but probably not the goal setting, problem-solving, the tasks for them.…The first session was, the time, we just didn't deliver anywhere near the whole session". Group 1—Lead Educator.* This had a knock-on effect on session 2: as one assessor noted elements could not be done because '*probably hadn't had time to give out the task cards [in Session 1]'.*
- Educators all agreed that the educational/discussion part of the sessions, was too packed, resulting in some tasks being dropped/covered less well: "*The overall programme was excellent. I think my only issue was timing. It was cutting it a bit fine for a lot of them.…if we're trying to encourage them to engage and to give that kind of feedback as to how they've done, or any issues that they might have". Group 4/5—Lead educator.*
- Most educators felt they were '*breaking the rules*' by dropping or changing aspects but perceived this as necessary to accommodate participant needs: "*Some of the educators really went by the book. I guess that's what they're meant to do, but with X, they really allowed people to ask questions which are not part of the session. They would spend a lot of time going over those type of things, so it made the class quite interesting, even if we didn't really cover everything". Group 5—Lay educator.*
- Practical issues, like equipment availability, also prevented fidelity: "*the scales were too heavy to carry around, so they didn't come to the session, so we basically, in this programme, the weight thing got completely left. It just didn't get delivered". Group 1—Lead educator.*

Acceptability of the intervention—patient and educator

Overall, the educator and participant data showed that HEAL-D was acceptable and successfully implemented (online supplemental table S6). Numerous statements illustrated that participants had taken on board the advice and information and made real changes in their life. Concerning the structure and content, participants and educators provided examples of good operationalization and effectiveness in practice. Some delivery had to be matched to individual groups for optimal engagement, such as: the use of videos and PowerPoints versus activities; demonstrating and discussion; the relative inputs of the lay and professional educators.

The acceptability and usefulness of the chosen BCTs were evaluated. Those BCTs focused particularly at improving knowledge and skills were seen to be highly

Table 2 Summary of clinical and patient report measures by arm and timepoint, and signal of efficacy estimates

	Intervention				Control					
	N*	Mean baseline (SD)	Mean end point (SD)	Mean change (SD)	N*	Mean baseline (SD)	Mean end point (SD)	Mean change (SD)	Unadjusted mean difference† (95% CI)	Baseline-adjusted mean difference† (95% CI)
Clinical outcomes										
HbA1c (mmol/mol)	25	60.6 (11.4)	58.2 (13.2)	−2.4 (8.7)	26	59.1 (11.2)	59.6 (18.4)	0.5 (14.1)	−2.8 (−9.4 to 3.8)	−2.8 (−9.5 to 3.9)
HbA1c (%)	25	7.68 (1.06)	7.48 (1.20)	−0.20 (0.79)	26	7.56 (1.04)	7.60 (1.68)	0.05 (1.30)	−0.25 (−0.86 to 0.36)	−0.24 (−0.86 to 0.37)
Waist circumference (cm)	25	104.8 (13.9)	105.8 (14.2)	1.0 (5.8)	25	109.5 (14.5)	111.2 (13.4)	1.7 (8.3)	−0.7 (−4.8 to 3.3)	−1.5 (−5.5 to 2.5)
Weight (kg)	25	88.0 (18.5)	87.6 (18.8)	−0.4 (2.9)	26	95.6 (18.2)	94.9 (18.6)	−0.7 (3.7)	0.3 (−1.6 to 2.2)	0.3 (−1.6 to 2.3)
BMI (kg/m^2)	25	32.7 (6.0)	32.6 (6.3)	−0.1 (1.1)	26	34.9 (6.5)	34.6 (6.5)	−0.3 (1.3)	0.1 (−0.6 to 0.8)	0.1 (−0.6 to 0.9)
SBP (mm Hg)	24	135.6 (13.2)	132.3 (15.5)	−3.3 (11.7)	26	134.1 (16.6)	131.2 (13.5)	−2.8 (14.6)	−0.4 (−8.0 to 7.2)	0.2 (−6.5 to 6.9)
DBP (mm Hg)	24	74.8 (9.1)	73.8 (12.6)	−1.0 (9.5)	26	75.2 (5.7)	76.2 (7.1)	1.0 (8.0)	−2.1 (−7.0 to 2.9)	−2.2 (−7.1 to 2.7)
Total cholesterol (mmol/L)	25	4.25 (1.10)	4.18 (1.09)	−0.07 (0.59)	26	4.32 (0.87)	4.13 (0.92)	−0.19 (0.60)	0.12 (−0.22 to 0.45)	0.11 (−0.22 to 0.43)
HDL (mmol/L)	25	1.30 (0.43)	1.42 (0.53)	0.11 (0.21)	26	1.31 (0.36)	1.30 (0.34)	−0.01 (0.18)	0.12 (0.01 to 0.23)	0.12 (0.01 to 0.23)
LDL (mmol/L)	25	2.36 (0.76)	2.26 (0.74)	−0.09 (0.48)	26	2.50 (0.69)	2.37 (0.71)	−0.13 (0.51)	0.04 (−0.24 to 0.32)	0.00 (−0.26 to 0.27)
Triglycerides (mmol/L)	25	1.51 (1.00)	1.11 (0.41)	−0.40 (0.91)	26	1.10 (0.49)	1.00 (0.45)	−0.10 (0.38)	−0.30 (−0.69 to 0.09)	0.00 (−0.22 to 0.23)
Patient-reported outcomes										
Diabetes knowledge	24	6.50 (2.28)	7.17 (2.53)	0.67 (1.95)	25	6.92 (2.74)	7.80 (2.43)	0.88 (2.28)	−0.21 (−1.43 to 1.01)	−0.37 (−1.48 to 0.74)
Dietary competence	23	7.80 (0.78)	8.29 (1.08)	0.49 (0.94)	26	7.93 (0.82)	8.21 (0.99)	0.28 (0.87)	0.21 (−0.31 to 0.73)	0.17 (−0.34 to 0.67)
Empowerment	23	3.77 (0.48)	3.88 (0.65)	0.10 (0.58)	24	3.75 (0.43)	3.78 (0.37)	0.03 (0.43)	0.07 (−0.23 to 0.37)	0.08 (−0.19 to 0.36)
Quality of life	24	63.8 (20.3)	74.6 (16.6)	10.8 (19.5)	26	64.0 (15.2)	74.0 (14.0)	10.0 (12.9)	0.8 (−8.6 to 10.1)	0.7 (−6.8 to 8.2)
Diabetes distress	24	6.33 (6.45)	5.29 (4.89)	−1.04 (5.40)	26	7.35 (5.86)	6.38 (5.57)	−0.96 (5.81)	−0.08 (−3.28 to 3.12)	−0.64 (−3.22 to 1.94)
Social support	24	62.2 (16.9)	61.3 (19.9)	−0.9 (13.9)	25	61.1 (16.6)	66.0 (14.5)	4.9 (9.2)	−5.8 (−12.6 to 1.0)	−5.6 (−12.1 to 1.0)

Measurement tools for patient-reported outcomes: quality of life, EuroQol EQ5D-3L visual analog scale; diabetes distress, using the 5-item Problem Areas In Diabetes (PAID-5) scale; diabetes knowledge, using the Short Diabetes Knowledge Instrument; empowerment, using the Diabetes Empowerment Scale Short Form; dietary competence, using the Perceived Diabetes & Dietary Competence measure and social support, using the Multidimensional Scale of Perceived Social Support.
*Number with complete baseline and end point data.
†Intervention minus control.
BMI, body mass index; DBP, diastolic blood pressure; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

Table 3 Summary of self-reported physical activity levels using the IPAQ questionnaire, by arm and timepoint

	Intervention (n*=23)			Control (n*=25)		
	Baseline	End point	Change	Baseline	End point	Change
IPAQ activity, n (%)						
Low	11 (48)	6 (26)	−5 (−22)	10 (40)	9 (36)	−1 (−4)
Moderate	10 (43)	16 (70)	+6 (+27)	13 (52)	14 (56)	+1 (+4)
High	2 (9)	1 (4)	−1 (−5)	2 (8)	2 (8)	0 (0)

*Number with complete baseline and end point data.
IPAQ, International Physical Activity Questionnaire.

effective. The balance between theoretical and practical components of *demonstrating the behavior* were valued (eg, participatory physical activity and cook and taste sessions alongside verbal and visual information). The participatory physical activity sessions and cooking demonstrations seemed to increase both capability and self-efficacy, empowering participants to repeat the activities outside of the sessions. Components designed to achieve *social support* (eg, group sessions facilitated for interaction and support) and *social comparison* (eg, sharing experiences) were well received. The group interaction was key as individuals motivated each other and learned from each other, which gave the information credibility and salience that they may not have previously experienced. These components supported the learning by raising self-efficacy, making it acceptable to challenge traditions and created confidence to resist social pressures. The use of *credible sources* (eg, culturally concordant lay educators and videos with tips from faith leaders and other community members), reinforced the social acceptability of the new behaviors. BCTs aimed at supporting behavior regulation and self-efficacy (eg, self-monitoring, goal-setting, action planning, problem-solving) were less frequently mentioned in the evaluations and appeared to be less effective in supporting behavior change.

Overall, the observations and evaluations identified the need for the following refinements:

- Restructuring of session 1 to focus more on education to provide a foundation for goal-setting. Move goal-setting to session 3, 4 or 5.
- Restructuring of session 7 to allow more time for 'question and answer' so participants conclude the course with needs addressed.
- Ensure availability of equipment storage at venues to enable BCT delivery as planned.
- Modify/Expand educator training to provide more BCT training and ensure that key components of delivery are prioritised and delivered as intended.
- Modify educator training to ensure measurable competence and attainment of required skills set.

DISCUSSION

Using mixed methods, we have evaluated the acceptability of HEAL-D, an evidence-based, culturally tailored DSMES program for black-British adults, alongside assessing intervention fidelity and trial feasibility. Importantly, we have shown that it is feasible to recruit, randomize and retain black-British adults with T2D in an RCT, and to implement a culturally tailored DSMES program in primary care, training healthcare professionals and lay educators to deliver a curriculum of evidence-based BCTs. Our attendance data demonstrate, overall, a high degree of acceptability among participants. Our in-depth evaluation methods have enabled us to understand the operationalization of HEAL-D, particularly understanding what elements worked and what components need refinement. This is important in allowing us to refine the delivery to enhance effectiveness and uptake.[27–29]

We engaged key stakeholders, particularly people living with T2D, healthcare professionals and community leaders, in developing HEAL-D to ensure its sensitivity to service users while also being implementable and having adoption potential by the health service. Intervention co-development is time-consuming, requiring a multidisciplinary collaborative approach and is therefore expensive to conduct.[30] Co-development of HEAL-D was conducted over an 18-month period and involved three phases of qualitative research.[17 31] This enabled us to identify priorities, from both a patient and service provider perspective, for the intervention and where there were competing priorities to resolve these with our stakeholders. The HEAL-D program reflects this input, with specific elements that would otherwise not have been chosen if we had used a researcher-driven, 'top down' approach. An example is the flexible attendance schedule, identified as a priority by patients and subsequently used by a third of participants, resulting in near maximal attendance.

The development and evaluation of complex behavioral interventions should include assessment of intervention fidelity, focusing on transferring principles and processes based around theorized mechanisms of change.[32] While fidelity is a multidimensional construct and there is little consensus about its key elements, recently it has been proposed to consist of five domains: study design; training; intervention delivery; intervention receipt by participants and intervention enactment,

defined as the extent to which participants apply the skills learned.[32–34] In the evaluation of HEAL-D, we focused on the complexity of intervention delivery, receipt and enactment, using observations of delivery alongside participant focus groups and educator interviews. The effectiveness of complex interventions is often dependent on the skills of those delivering them. Due to time and resource limitations, we were not able to focus in detail on developing educator training modules and processes for evaluating educator competencies. Our delivery was largely manualized, and our fidelity observations focused on assessing 'adherence', defined as the extent to which the educators delivered the essential content prescribed in the manual. 'Competence' is a related construct, which includes the ability of educators to responsively tailor intervention content and develop a collaborative and trusting relationship with participants as well as accurately pacing delivery and content.[35–37] We did not systematically assess competence, but our data confirm the need for further training of educators, particularly around the BCTs and appropriate pacing of delivery.

A major strength of our work is our use of mixed methods, enabling a much greater understanding of the delivery and acceptability of our intervention than would be the case from purely quantitative assessments and is increasingly recognised as an area of 'best practice' in feasibility trials.[38] The sociodemographic profile of our participants shows that we engaged a diverse range of participants. We did not see any clear differences in attendance or acceptability based on gender, socioeconomic status or age. However, we do acknowledge that this trial largely recruited from two South London boroughs in which people of black-British ethnicity form a 'majority-minority' ethnic group, therefore, it was highly relevant to both the local communities and healthcare practitioners. It will be important that a future trial evaluates HEAL-D in different areas/regions and considers issues of implementation where people of black-British ethnicity are not so well represented. We principally focused on two methods of recruitment, primary care database screening with invitation letters and clinic referrals from healthcare practitioners; our recruitment rates are calculated from only the database screening letters of invitation and show a low response rate. While we were not able to formally quantify the response rate to practitioner referrals, anecdotally we observed that this was more effective. This is important for a future trial, in which focusing on recruitment through referral pathways rather than invitation letters is recommended. This feasibility trial employed broad eligibility criteria, avoiding the need for additional screening visits. However, a small number of randomized participants were subsequently found to have high HbA1c, deemed in need of intensive medical management, thus these participants were excluded from the data analysis. A trial will need to have eligibility criteria and screening procedures that ensures the suitability of participants prior to randomization. Our focus group evaluations of intervention acceptability included participants from our co-design study as it was not feasible to run separate groups; these participants may have viewed the intervention differently due to their prior involvement and may have introduced a source of bias in the data. Additionally, our study did not evaluate the feasibility of generating economic data; an evaluation of the cost-effectiveness of the intervention would be an important aspect of a future trial.

In conclusion, culturally appropriate T2D education has been shown to bring about significantly greater benefits for people from minority ethnic backgrounds compared with standard education.[15] To be effective it is important that interventions are sensitive to the needs of patients, while also being implementable within the healthcare system. We have shown that it is possible to recruit and retain black-British adults with T2D in a trial of a culturally tailored DSMES program, and train healthcare professionals to deliver the intervention in primary care with good fidelity. It will be important to take the HEAL-D intervention forward to a fully powered trial to evaluate its clinical and cost-effectiveness. It is important that we use our qualitative data to recognise and address any potential implementation issues before HEAL-D is rolled out at larger scale.

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