PROTOCOL INFORMATION

FULL/LONG TITLE OF THE TRIAL

HEAL-D (Healthy Eating & Active Lifestyles for Diabetes): a multicentre, pragmatic randomised controlled trial comparing effectiveness and cost-effectiveness of culturally tailored versus standard diabetes self-management programmes in Black-African and Black-Caribbean adults with type 2 diabetes.

SHORT TRIAL TITLE / ACRONYM

The Healthy Eating & Active Lifestyles for Diabetes trial ('HEAL-D')

PROTOCOL VERSION NUMBER AND DATE

V1.1 09/05/2024

IRAS NUMBER: 326064

SPONSOR: University of Leicester

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TRIAL REGISTRATION: ISRCTN 45319

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Declaration of HRA protocol template use

This protocol has regard for the Health Research Authority (HRA) guidance and order of content, in line with Version 1.1 (March 2016) of the HRA Protocol Development Tool.

Confidentiality Statement:

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research (2017), GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given. Any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

SPONSOR	
Signature:	Date:
Name (please print):	
Position:	
CHIEF INVESTIGATOR	
Signature:	Date:
Name (please print): Louise Goff	
PRINCIPAL INVESTIGATOR	
Signature:	Date:
Name (please print):	

Statistician's Agreement

The study as detailed within this research protocol will be conducted in accordance with the current UK Policy Framework for Health and Social Care Research (2017), the World Medical Association Declaration of Helsinki (1996), Principles of ICH E6-GCP, ICH E9 - Statistical principles for Clinical Trials and ICH E10 - Choice of Control Groups.

I take responsibility for the statistical work in this protocol is accurate and take responsibility for statistical analysis and oversight in this trial.

STATISTICIAN	
Signature:	Date:
Name (please print):	

KEY STUDY CONTACTS

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Funder(s)	NIHR Health Technology Assessment (HTA) programme NIHR-151372 netspostawardsetup@nihr.ac.uk
Funder start and end date(s)	01/08/2023 - 31/7/2027 (48 months)
NIHR Portfolio adopted	Yes

PROTOCOL CONTRIBUTORS

NAME	POSITION	ROLE ON STUDY	ORGANISATION
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Mr Tony Kelly	Person with lived experience	Grant co-applicant PPIE representative	PPIE

CONTENTS

LIST OF ABBREVIATIONS

AE	Adverse Event
AD-SUS	Adapted Adult Service Use Schedule
AHSN	Academic Health Science Network
AR	Adverse Reaction
ARC	Applied Research Collaboration
BABC	Black African and black Caribbean
BCTs	Behaviour change techniques
BRAG	Black, Asian minority ethnic Research Advisory Group
BRC	Biomedical Research Centre
CAHN	Caribbean and African Health Network
CI	Chief Investigator
COM-B	Capability Opportunity Motivation-Behaviour
COMET	Core Outcome Measures in Effectiveness Trials
CRF	Case report form
CRN	Clinical Research Network
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSMES	Diabetes self-management education and support
F2F	Face-to-face
DMSES-UK	Diabetes Management Self-Efficacy Scale
GDPR	General Data Protection Regulation
GM	Greater Manchester
GP	General practice/practitioner
GSTT	Guy's & St Thomas' Trust
HbA1c	Glycated haemoglobin
HEAL-D	Healthy Eating & Active Lifestyles for Diabetes
HDL	High-density lipoprotein
HRA	Health Research Authority
HTA	Human Tissue Act
ICB	Integrated Care Board
ICC	Intracluster correlation coefficient
ICER	Incremental cost-effectiveness ratio
GCP	Good clinical practice
IMD	Index of multiple deprivation
INB	Incremental net benefit
IPAQ	International Physical Activity Questionnaire
IRAS	Integrated Research Application System
ITT	Intention to treat
KCL	King's College London
LDL	Low-density lipoprotein
LDN	London

LTC	Long-term condition
MET	Metabolic equivalent
MLTC	Multiple long-term conditions (multimorbidity)
MTBQ	Multimorbidity Treatment Burden Questionnaire
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
PAID	Problem Areas in Diabetes
PHQ-9	Patient Health Questionnaire
PI	Principal Investigator
PPIE	Patient and public involvement and engagement
PDDC	Perceived Diabetes & Dietary Competence
QALY	Quality-adjusted life year
QMUL	Queen Mary University London
QOF	Quality and Outcomes Framework
QoL	Quality of life
RCT	Randomised controlled trial
REC	Research ethics committee
SAE	Serious adverse event
SAR	Serious adverse reaction
SD	Standard deviation
SDKI	Short Diabetes Knowledge Instrument
SGUL	St George's University of London
SOP	Standard operating procedure
SUSAR	Suspected unexpected serious adverse reaction
SWAP	Study Within a Project
UCL	University College London
UoL	University of Leicester
T2D	Type 2 diabetes
TDF	Theoretical Domains Framework
TFA	Theoretical Framework of Acceptability
TMF	Trial master file
TMG	Trial management group
TSC	Trial steering committee
EQ VAS	EQ visual analogue scale
WHO	World Health Organization
WM	West Midlands
WP	Work package

TERMINOLOGY

Throughout this protocol and relevant study documentation, reference is made to both 'ethnicity' and 'heritage'. Ethnicity, as defined by census classification, is used as a key inclusion criterion for this trial. However, our patient and public involvement and engagement (PPIE) feedback has highlighted that use of the term 'heritage' is often preferred to 'ethnicity' by patients. Therefore, 'heritage' and 'ethnicity' are used interchangeably. Similarly, PPIE feedback highlighted that 'study' was preferrable to 'trial', such that these terms are also used interchangeably. 'Heritage' and 'study' are used on all participant-facing documentation.

KEY WORDS

Type 2 diabetes, self-management, education, randomised controlled trial, culture, African-Caribbean ethnicity.

TRIAL SUMMARY

Trial Title	HEAL-D (Healthy Eating & Active Lifestyles for Diabetes): a multicentre, pragmatic randomised controlled trial comparing effectiveness and cost-effectiveness of culturally tailored versus standard diabetes self-management programmes in Black-African and Black-Caribbean adults with type 2 diabetes	
Short Title	The Healthy Eating & Active Lifestyles for Diabetes ('HEAL-D') Trial.	
Trial acronym	HEAL-D	
Trial Design	Multi-centre, 2-arm, parallel group, individually randomised group treatment trial, evaluating clinical and cost effectiveness of HEAL-D (culturally tailored DSMES programme) compared with standard DSMES programmes (those that are commissioned in the trial locations). An internal pilot study, a mixed methods process evaluation, and study within a project are embedded within the trial.	
Trial Participants	Adults (≥ 18 years) of African or Caribbean heritage who have been diagnosed with type 2 diabetes	
Planned Sample Size	Main trial (WP1/WP2): 300 participants (150 in the intervention arm and 150 in the control arm). Process evaluation and SWAP (WP3/WP4): 48 participants from the intervention arm (including ≥8 with multiple long-term conditions for the SWAP) and 27 intervention delivery staff.	
Follow up duration	104 weeks Primary endpoint at 52 weeks	
Planned Trial Period	37 months	
	Objectives	**End Points / Outcome Measures**
Primary	To compare the effect of HEAL-D with standard DSMES programmes for improving HbA1c at 52 weeks.	Change in HbA1c at 52 weeks.
Secondary	To compare the effect of HEAL-D with standard DSMES programmes for improving HbA1c at 26 and 104 weeks. To compare the effect of HEAL-D with standard DSMES programmes on cardiovascular risk factors at 26, 52 and 104 weeks. To compare the effect of HEAL-D with standard DSMES programmes on psychological wellbeing and quality of life at 26, 52 and 104 weeks. To compare the effect of HEAL-D with standard DSMES programmes on knowledge and self-efficacy at 26, 52 and 104 weeks. To compare the effect of HEAL-D with standard DSMES programmes on lifestyle behaviours at 26, 52 and 104 weeks. To assess the cost-effectiveness of HEAL-D.	At 26, 52 and 104 weeks, change in: HbA1c Blood pressure Blood lipids Weight, waist circumference, body fat Health-related quality of life Diabetes-related distress Depressive symptoms Diabetes knowledge Self-efficacy Physical activity Diet Quality Health service resource utilisation

	To assess delivery, implementation, and fidelity of HEAL-D in an embedded mixed-methods process evaluation. To assess the impact of multiple long-term conditions - multimorbidity (MLTC) on recruitment, engagement with the HEAL-D intervention and the impact of the intervention on MLTC, in an embedded mixed-methods *study within a project* (SWAP).	

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR Health Technology Assessment, NIHR-151372 Tel: Email: netspostawardsetup@nihr.ac.uk	As detailed in the award letter. The funder will be responsible for funding the study but will not be part of the study conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

ROLE OF TRIAL SPONSOR

The Sponsor of this research is the University of Leicester (UoL). UoL is registered as a research sponsor with the Department of Health and routinely takes responsibility as sponsor for research activities within the NHS. The Sponsor will not be part of the study conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

ROLE OF COLLABORATOR(S)

The collaborators will work collectively with the trial Chief Investigator (CI) throughout the scientific development and/or delivery of the proposed work.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

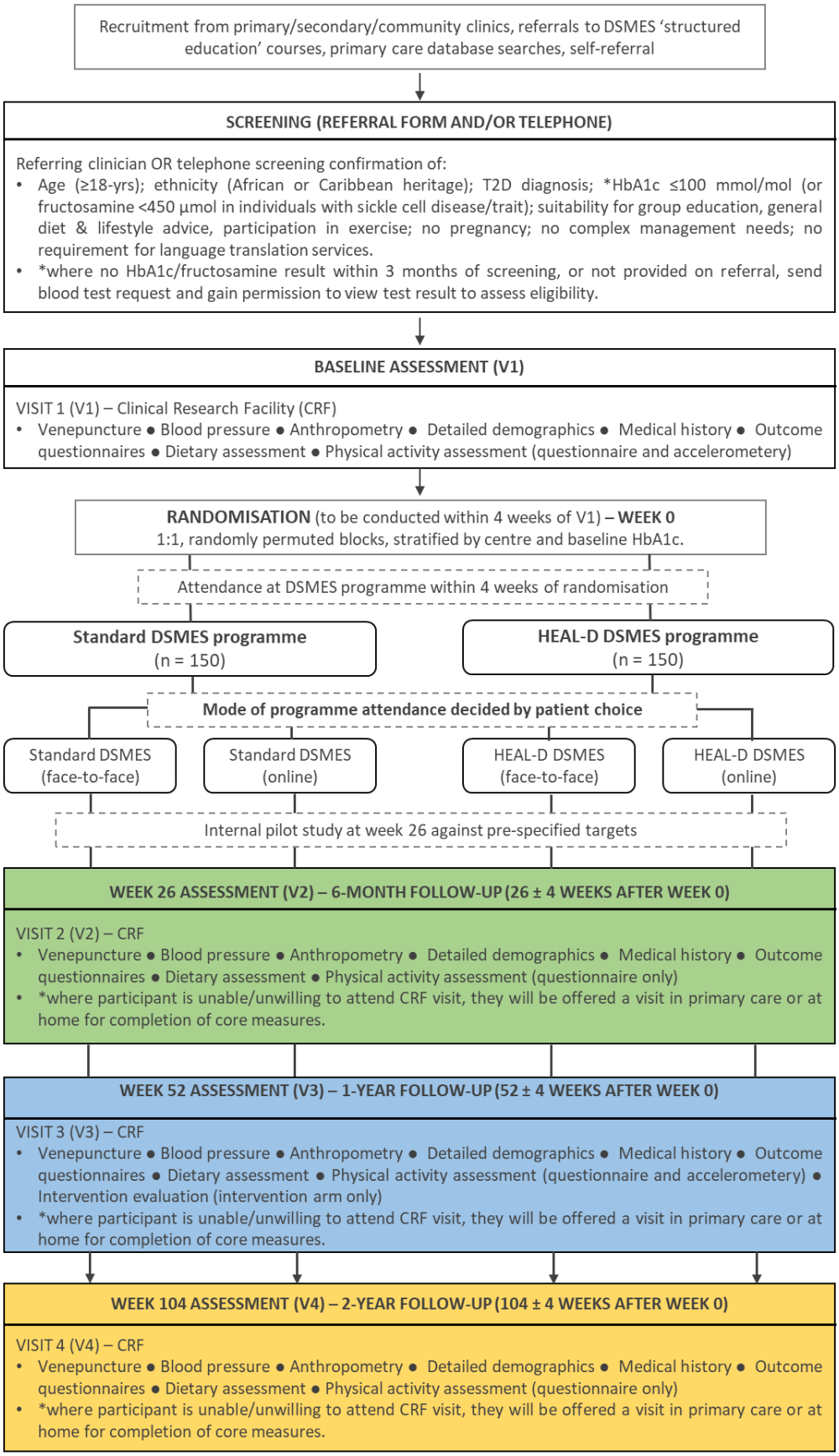
Trial Steering Committee

A Trial Steering Committee (TSC) has been convened. The TSC consists of two independent clinical academics (one who acts as chair), an independent statistician, an independent health economist, and an independent person with lived experience (Patient and Public Involvement/engagement, PPI/E, representative). The TSC meet regularly (at least annually) along with the CI and select members of the research team as required. The TSC will offer independent strategic oversight throughout the duration of this randomised controlled trial (RCT). More information on the TSC can be found in section 24.

Trial Management Group

A trial management group (TMG) consisting of the CI, site leads, core delivery staff (including trial statistician) and other co-investigators and collaborators where required will meet regularly (approximately bimonthly or more regularly as required) to oversee and coordinate delivery of the trial. More information on the TMG can be found in section 25.

TRIAL FLOW CHART



BACKGROUND

In the UK, around 3.4 million people, and one in ten adults over 40, have type 2 diabetes (T2D) [1]. If trends continue, by 2030 there will be 5.5 million people living with the condition [1]. T2D is a chronic, progressive condition that causes several disabling and life-threatening complications [2, 3] and is a significant driver of premature mortality [4]. In a significant proportion of people, microvascular and macrovascular complications have developed by the time of diagnosis [5] or early in the condition [6], and risk increases in line with poorer glycaemic control (indicated by higher haemoglobin A1c (HbA1c)) [7]. Alongside effects on physical health, individuals with T2D have a poorer quality of life (QoL) [8] and a two-fold increased risk for depression [9], which hinders treatment [10]. Overall, T2D and its physical and mental health comorbidities have a substantial cost to individuals, society, and the healthcare system. The NHS spends over £10 billion a year on diabetes, which is about 10% of its budget, with around 80% spent on treating complications [11].

People of Black African and Black Caribbean (BABC) ethnicity are 2-4 times more likely to develop T2D than people of White ethnicity [1, 12]; furthermore, it occurs, on average, 10 years earlier, and more commonly in people of working age [13]. Further inequalities include higher HbA1c; greater medicating needed to achieve HbA1c targets, and poorer outcomes compared with people of White ethnicity [14-16]. One cause is a lack of access to T2D healthcare [17], made clear in the Department of Health report 'No patient left behind' [18]. First-line T2D management is situated in primary care, and aims to promote patient involvement and self-management as integral to T2D care [19].

In self-management, individuals take an active role in the day-to-day management of their diet, physical activity, medications and ongoing medical care. Diabetes self-management education and support (DSMES) programmes are provided routinely within NHS care. National T2D management guidelines recommend that all patients attend a DSMES programme at the time of diagnosis and annually thereafter [19], with referral of newly-diagnosed patients incentivised through primary care Quality and Outcomes Framework (QOF) standards [20]. DSMES programmes aim to empower and provide knowledge, skills and motivation to support long-term behaviour change towards a healthy lifestyle [21, 22]. DSMES programmes are effective, improving HbA1c and cardiovascular outcomes, and providing a range of behavioural and psychological benefits [23-27]. However, they are considerably less successful in minority ethnicities, with lower participation, higher attrition rates and worse outcomes [16, 28, 29]. Particularly for BABC populations, DSMES programmes have provided limited benefit to HbA1c [16]. This is often attributed to a lack of cultural knowledge and awareness amongst healthcare practitioners, and to generic programmes not being sensitive to the cultural beliefs and practices of people of BABC ethnicity [30-32], despite recommendations for programmes to meet the needs of cultural groups [19]. Culturally tailored DSMES that is respectful of, and responsive to, the health beliefs, practices, and linguistic needs of diverse patients is shown to result in greater improvements in HbA1c, knowledge and QoL than standard training, with benefits maintained long-term [32-34]. However, to date, culturally tailored interventions for communities of BABC ethnicity have largely been USA-based, with no such programmes evaluated in the UK [32, 35].

DSMES programmes must adhere to quality standards, requiring an evidence-based curriculum and delivery by trained, competent educators [19]. Several programmes are accredited and commissioned in the UK [36, 37], mainly using a group-based format and face-to-face (F2F) delivery; digital programmes and online adaptations of F2F programmes [38] have been recently evaluated or implemented in response to COVID-19 [39]. Healthy Eating & Active Lifestyles for Diabetes ('HEAL-D') was codesigned with BABC people living with T2D, healthcare practitioners, commissioners and community leaders, in a previous NIHR-funded study [40, 41] and is the only UK programme tailored to the cultural needs of people of BABC. HEAL-D is theoretically underpinned and uses Behaviour Change Techniques (BCTs) supported by co-development findings [40] and described in a logic model [41]. The multistakeholder co-development process ensured an intervention that would be acceptable to, and meet the needs of, BABC people living with T2D, whilst also aligning with, and being feasible to implement within, current NHS pathways. HEAL-D is a group-

based DSMES programme which delivers a curriculum of culturally tailored, evidence-based education, behaviour change support and participatory physical activity in a series of F2F or virtual online sessions. Extensive proof-of-concept testing of HEAL-D has been conducted, to ensure it is sensitive to the needs of both BABC adults and NHS service pathways. Acceptability of F2F delivery has been evaluated in a feasibility trial and virtual delivery has been evaluated in a pilot service evaluation in south London.

This trial evaluation of HEAL-D addresses recognised current needs within the NHS. It aligns with the 2017 James Lind Alliance Priority Setting Partnership for T2D's top five research priorities. This included the need to understand more about how to encourage all people living with T2D to self-manage their condition and support healthful lifestyle change [42]. Importantly also, the NHS has an explicit duty to reduce inequalities in healthcare outcomes [43], of which ethnicity-driven inequalities are central, as recognised in the Core20PLUS5 framework from NHS England and NHS Innovation [44]. The trial also meets the needs of the NHS Long Term Plan which identifies tackling health inequalities and better care for major health conditions as two priorities, including expansion of T2D self-management provision, particularly digital options [45].

1. RATIONALE

This trial will address the following research question: In adults of Black-African and Black-Caribbean (BABC) ethnicity living with type 2 diabetes (T2D), is a culturally tailored DSMES programme provided in person or online effective and cost-effective, in comparison with standard DSMES, at improving glycaemic control (HbA1c) at 12-month follow-up?

Rationale: Around 4% (1.9 million people) of the UK population identify as of BABC ethnicity, forming the second largest and fastest growing UK minority ethnic group[46]. People of BABC ethnicity develop T2D at a significantly younger age, with around 25% of cases in people aged under 40. The significant health inequalities already experienced by people of BABC ethnicity, particularly within T2D, have been spotlighted during the COVID-19 pandemic[47], with a much higher risk of severe COVID-19 and death than in White ethnic groups, linked with higher rates of T2D[48].

Diabetes self-management education and support (DSMES) programmes (commonly referred to as 'structured education'), are provided routinely within NHS care and are the first line of management for all people diagnosed with T2D. However, they are considerably less successful in minority ethnicities, with lower participation, higher attrition rates and worse outcomes[16, 28, 29]. Particularly for BABC populations, DSMES programmes have provided limited benefit to HbA1c[16]. This is often attributed to a lack of cultural knowledge and awareness amongst healthcare practitioners, and to generic programmes not being sensitive to the cultural beliefs and practices of people of BABC ethnicity[30-32], despite recommendations for programmes to meet the needs of cultural groups[19]. Culturally tailored DSMES that is respectful of, and responsive to, the health beliefs, practices, and linguistic needs of diverse patients is shown to result in greater improvements in HbA1c, knowledge and QoL than standard training, with benefits maintained long-term[32-34]. However, to date, culturally tailored interventions for communities of BABC ethnicity have largely been USA-based, with no such programmes evaluated in the UK[32, 35]. The proposed trial will undertake the first evaluation of a UK culturally tailored DSMES programme for adults of BABC ethnicity.

Healthy Eating & Active Lifestyles for Diabetes ('HEAL-D') is a culturally tailored DSMES programme for adults of BABC heritage. It was codesigned with BABC people living with T2D, healthcare practitioners, commissioners and community leaders, in a previous NIHR-funded study[40, 41]. HEAL-D has been developed in both a F2F and online format, thus maximising its pragmatic use in healthcare. Health interventions utilising digital technologies are recognised for their potential to improve the quality of health services and have the potential to reach individuals who may not be able to access F2F interventions[49], which may have particular relevance for minority groups[39]; for example, digital options can bring together minority groups where there may not be the population density to make in-person groups viable. Digital interventions are potentially also more

cost effective[50] and have been spotlighted during the COVID-19 pandemic as a safe way to provide DSMES to vulnerable groups[51]. To date, a range of digital DSMES interventions have been evaluated worldwide[52] but only one culturally tailored digital DSMES programme specifically for BABC communities - in the USA[53]. By offering HEAL-D in an online or a F2F format, we are increasing its usefulness and accessibility to suit different needs. We have successfully tested the F2F and online formats for acceptability. The proposed trial of HEAL-D, a culturally tailored intervention available in both F2F and online formats, therefore adds new knowledge in the UK context.

Most trials of culturally tailored DSMES worldwide have been conducted with relatively short-term follow-up and without cost-effectiveness evaluation[54]. Therefore, our proposed research will address several important evidence gaps, relating to UK cultural tailoring, online delivery for BABC communities and effectiveness and cost-effectiveness by evaluating longer-term effectiveness and cost-effectiveness of HEAL-D. Our trial team includes two public/service user co-applicants of African and Caribbean heritage with lived experience of T2D (TK and ST), who have actively participated in the development of this proposal and been instrumental in decision making regarding trial design and conduct. Alongside their input we have developed a network of people with lived experience, community leaders and organisations who work with people of African and Caribbean heritage, such as the Caribbean African Health Network and West Bromwich African Caribbean Resource Centre. This has provided us the opportunity to discuss the importance and relevance of this research, creating initial interest, as well as anticipating any areas that are important to the design, engagement of potential participants, as well as dissemination and impact. Our public contributors have told us that HEAL-D is "much needed" for their communities; they place importance on "the NHS" funding work with historically "ignored" and "neglected" communities, viewing it as an important opportunity to address issues of "structural racism" within healthcare.

When sensitive to the needs of service users, DSMES programmes are highly cost-effective, bringing about significant HbA1c improvements and ultimately reducing the health and economic burden of T2D[7, 55]. If effective, this intervention has the potential to offer the NHS equitable DSMES services, which meet the needs of some of its most vulnerable service users.

2. RESEARCH QUESTION/OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The HEAL-D trial will answer the following research question:

- In adults of BABC ethnicity living with T2D, is a culturally tailored DSMES programme provided in person or online effective and cost-effective, in comparison with standard DSMES programmes, at improving glycaemic control (HbA1c) at 12-month follow-up?

In doing so, it will contribute robust evidence to inform future delivery of care for this under-represented, under-researched population, and address several UK healthcare priorities recognised by the 2017 James Lind Alliance Priority Setting Partnership for T2D[42]. Importantly also, the NHS has an explicit duty to reduce inequalities in healthcare outcomes[43], of which ethnicity-driven inequalities are central, as recognised in the Core20PLUS5 framework from NHS England and NHS Innovation[44]. This trial also meets the needs of the NHS Long Term Plan which identifies tackling health inequalities and better care for major health conditions as two priorities, including expansion of T2D self-management provision, particularly digital options[45].

3.1 Primary objective

To test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on diabetes management (assessed via HbA1c) at 52 weeks in adults of BABC ethnicity living with T2D.

3.2 Secondary objectives

1) To run an internal pilot study with clear stop/go criteria, primarily to test recruitment systems and intervention engagement.

In adults of BABC ethnicity living with T2D:

2) Test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on diabetes management (HbA1c) at 26 and 104 weeks.
3) Test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on cardiovascular risk factors at 26, 52 and 104 weeks.
4) Test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on psychological wellbeing and quality of life at 26, 52 and 104 weeks.
5) Test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on knowledge and self-efficacy at 26, 52 and 104 weeks.
6) Test the effectiveness of the HEAL-D programme, compared to standard DSMES programmes, on lifestyle behaviours at 26, 52 and 104 weeks.
7) Test the cost-effectiveness of the HEAL-D programme, compared to standard DSMES programmes.
8) To assess delivery, implementation, and fidelity of HEAL-D in an embedded mixed-methods process evaluation.
9) To assess the impact of multiple long-term conditions - multimorbidity (MLTC) on recruitment, engagement with the HEAL-D intervention and the impact of the intervention on MLTC, in an embedded mixed-methods *study within a project* (SWAP).

3.3 Outcome measures/endpoints

3.3.1 Primary endpoint/outcome

- The difference between groups in the change in HbA1c (glycated haemoglobin) from baseline to 52 weeks (primary endpoint), 26 and 104 weeks (both secondary endpoints).

HbA1c has been chosen because:

i. it is the principal clinical measure of diabetes status and glycaemic level;
ii. it is a valuable surrogate measure of holistic engagement with diabetes management and self-care;
iii. HbA1c at a target of 6.0% (42mmol/mol) is associated with lower risk of micro- and macro-vascular complications and, in some cases, all-cause mortality[56];
iv. it is a prominent component of the COMET initiative core outcomes set for T2D[57].

A 12-month primary endpoint has been chosen to examine the effectiveness of the HEAL-D intervention as this is a duration long enough to observe a clinically important difference in HbA1c (5 mmol/mol). Follow-up at 24-months allows exploration of the impact of HEAL-D on HbA1c (as well as secondary outcomes, trial engagement and retention) over a longer period. Intermediate follow-up at 6-months allows exploration of the time-course of any observed changes.

3.3.2 Secondary endpoints/outcomes

The effectiveness of the HEAL-D intervention in adults of BABC ethnicity living with T2D, compared to standard DSMES programmes, will be tested at 26, 52 and 104 weeks, on the following secondary outcomes, grouped into holistic health domains:

Cardiovascular risk factors

- Total cholesterol
- HDL-cholesterol
- Systolic blood pressure
- Diastolic blood pressure
- Body weight
- Body mass index

- Waist circumference
- Body fat mass
- Body lean mass

Psychological wellbeing and self-management support

- Quality of life (EQ5D-5L)
- Diabetes-related distress (Problem Areas In Diabetes-5, PAID-5)
- Depressive symptoms (Patient Health Questionnaire, PHQ-9)
- Diabetes knowledge (Short Diabetes Knowledge Instrument, SDKI)
- Diabetes self-efficacy (Diabetes Management Self-Efficacy Scale, DMSES-UK)
- Diabetes dietary competence (Perceived Diabetes & Dietary Competence, PDDC)
- Multimorbidity treatment burden (Multimorbidity Treatment Burden Questionnaire, MTBQ)

Lifestyle behaviours

- Physical activity (short International Physical Activity Questionnaire, IPAQ) and 10-day accelerometer (accelerometer assessment at baseline and 52 weeks, only)
- Diet quality (Diet Quality Questionnaire, DQQ)

Health economics

- Health service resource utilisation (adapted Adult Service Use Schedule, AD-SUS)
- EQ-5D-5L

3.3.3 Exploratory endpoints/outcomes

The effectiveness of the HEAL-D intervention in adults of BABC ethnicity living with T2D, compared to standard DSMES programmes, will be tested at 26, 52 and 104 weeks, on the following exploratory outcomes:

- LDL-cholesterol
- Triglycerides
- Body fat percentage
- Changes to glucose-lowering therapies (including addition, removal or dose adjustment)
- Changes to anti-hypertensive therapies (including addition, removal or dose adjustment)
- Change in multimorbidity status (including additional diagnoses, remission, or changes in severity)
- Self-report sleep duration and chronotype

3.4 Table of endpoints/outcomes

Objective	Outcome Measure	Timepoint of outcome measure			
		Baseline	26-wks	52-wks	104-wks
Primary Objective To test the effectiveness of HEAL-D, compared to standard DSMES, on HbA1c.	HbA1c (mmol/mol)	√	√	√	√
Secondary Objectives To test the effectiveness of HEAL-D, compared to standard DSMES, on cardiovascular risk markers.	Total cholesterol (mol/l)	√	√	√	√
	HDL-cholesterol (mmol/l)	√	√	√	√
	Systolic blood pressure (mmHg)	√	√	√	√
	Diastolic blood pressure (mmHg)	√	√	√	√
	Body weight (kg)	√	√	√	√
	Body mass index (kgm^{-2}	√	√	√	√
	Waist circumference (cm)	√	√	√	√
	Body fat mass (kg)	√	√	√	√
	Body lean mass (kg)	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on psychological wellbeing and quality of life.	EQ-5D-5L quality of life questionnaire	√	√	√	√
	PAID-5 Diabetes-related distress questionnaire	√	√	√	√
	PHQ-9 Patient Health Questionnaire	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on knowledge and self-efficacy.	SDKI Diabetes knowledge questionnaire	√	√	√	√
	DMSES-UK Diabetes self-efficacy questionnaire	√	√	√	√
	PDDC Diabetes dietary competence questionnaire	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on lifestyle behaviours.	Short IPAQ Physical activity questionnaire	√	√	√	√
	Wrist-worn accelerometer device	√		√	
	Diet Quality Questionnaire (DQQ)	√	√	√	√
To test the cost effectiveness of HEAL-D, compared to standard DSMES.	AD-SUS (adapted) health service receipt log (self-report)	√	√	√	√

To assess participant acceptability of HEAL-D.	Quantitative evaluation questionnaire			√	
To assess delivery, implementation, and fidelity of HEAL-D.	Qualitative interview and/or workshop			√	
Tertiary Objectives To test the effectiveness of HEAL-D, compared to standard DSMES, on blood lipid concentrations.	LDL-Cholesterol (mmol/l)	√	√	√	√
	Triglyceride (mmol/l)	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on body composition.	Body fat (%)	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on changes in pharmacological therapies.	Glucose-lowering therapies usage.	√	√	√	√
	Blood pressure-lowering therapies usage.	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on multimorbidity status	Diagnoses/remission/changes in severity of medical conditions.	√	√	√	√
	MTBQ Multimorbidity treatment burden questionnaire.	√	√	√	√
To test the effectiveness of HEAL-D, compared to standard DSMES, on lifestyle behaviours.	Self-reported sleep duration and chronotype	√	√	√	√

3. TRIAL DESIGN

This is a 104-week, multi-centre, open-label, 2-arm, parallel-group, individually randomised group treatment trial, with primary endpoint assessment at 52 weeks, and with embedded internal pilot study, cost-effectiveness analysis, mixed-methods process evaluation and study within a project. The trial flow chart on page 17 provides an overview of the trial design and core trial visits.

Adults, aged 18 years or older, of African or Caribbean heritage with diagnosed T2D will be allocated equally to one of two groups:

- HEAL-D DSMES programme (intervention)
- Standard DSMES programme (control)

Participants will be allocated using stratification with the following factors: trial centre, baseline HbA1c.

Participants will be recruited at 3-5 trial centres. Participants will be approached through: screening of referrals to structured education services from primary, intermediate/community, and secondary care clinics; primary care database searches; and self-referral in response to advertising. Eligibility will initially be assessed through screening of referrals; potentially eligible participants will be telephoned to invite to participate, confirm full eligibility and to indicate, verbally, their intention to participate. They will then attend their local trial centre on four occasions to undertake in-person trial assessments:

- Visit 1 (week -4) – Informed Consent & Baseline Assessments
- Visit 2 (week 26) – Intermediate Follow-Up Assessments
- Visit 3 (week 52) – Primary Follow-Up Assessments (including Primary Endpoint)
- Visit 4 (week 104) – Extended Follow-Up Assessments

Internal pilot study

The feasibility of recruitment, allocation and engagement will be assessed against pre-specified targets at 6 months after the start of recruitment at the lead site (see 7.6 Internal Feasibility Assessment). Information from the internal pilot will be used to inform subsequent action planning to ensure the trial meets key milestones.

Cost-effectiveness analyses

To assess the cost effectiveness of the HEAL-D intervention, using a cost-utility analysis conducted from a health and social care perspective with participant health impacts expressed as quality-adjusted life years (QALYs) gained.

Mixed methods process evaluation

An embedded mixed methods process evaluation, combining relevant data gathered within the trial with qualitative interview data will provide a formative evaluation of the intervention's delivery, fidelity and implementation, including:

- an assessment of whether *intervention engagement* is achieved, and how well.
- generating an understanding of the intervention's key mechanisms of action.
- identification of the contextual factors that influence its implementation and adoption.

Study within a project

A Study Within A Project (SWAP) is embedded within the trial to assess the impact of multiple long-term conditions (MLTC) on the uptake of and engagement with HEAL-D, and the impact of the intervention on MLTC.

4. TRIAL SETTING

This is a multi-centre trial that will be conducted across 3-5 trial centres in the UK. Centre eligibility criteria will include the ability to recruit adults of BABC ethnicity, and to deliver a culturally tailored DSMES programme (i.e. appropriately qualified staff, namely diabetes specialist dietitians, exercise trainers). Three centres serving large BABC communities (London, West Midlands and Greater Manchester) are prepared for trial recruitment: (south-east and south-west London, lead centre, 20-30% of population are of BABC ethnicity; West Midlands (Birmingham, Sandwell & Wolverhampton), 7-10% BABC ethnicity; and Greater Manchester, 9% BABC ethnicity). The trial will be centrally coordinated from the Leicester Diabetes Research Centre (UoL) which is situated at the Leicester General Hospital. The study will also be supported by the infrastructure provided through the NIHR CRN.

Participants will be recruited through several means: referrals to diabetes structured education services from primary, secondary, and intermediate care clinics; primary care database searches; and self-referral in response to advertising (e.g. social media, community organisations). Referral to a diabetes structured education course within 9 months of diagnosis is a Quality Outcome Framework standard. The research team in each centre will work with their local DSMES service providers to establish recruitment processes that fit with the local T2D care management pathways and we anticipate a slightly different approach to recruitment will be needed in each area. For example, in London we will primarily focus on south-east and south-west London where there are large BABC communities and where we have ongoing partnerships with commissioners and service providers. The south-east and south-west London ICBs jointly commission a central booking portal, called Diabetes Book & Learn, for managing referrals to structured education/DSMES programmes; all referrals for people living or registered with a GP in the 12 boroughs are managed through this single booking portal. The portal receives 400-650 referrals per month and 27% (~140) are for BABC adults.

5. PARTICIPANT ELIGIBILITY CRITERIA

5.1 Inclusion criteria

- Adult, ≥18 years of age.
- BABC ethnicity: we will record ethnicity according to the Census classification, which is used within NHS services; people of Black African, Black Caribbean, Black British, Black other, and Mixed race with either African or Caribbean ancestry, will be eligible to participate.
- Type 2 diabetes, confirmed by medical history.
- HbA1c ≤100 mmol/mol (or fructosamine <450 µmol for individuals with sickle cell trait/disease) recorded in medical records within 3 months of screening for trial participation.
- Suitable for group-based training (suitability confirmed by GP or referring healthcare practitioner).
- Suitable for participation in physical activity (suitability confirmed by GP or referring healthcare practitioner).
- Willing to undergo randomisation.
- Able to provide informed consent.

5.2 Exclusion criteria

- Current pregnancy.
- Complex medical or lifestyle needs that require personalised advice or for which group-based training is unsuitable e.g. advanced chronic kidney disease (suitability confirmed by GP or referring healthcare practitioner).
- Complex learning needs that require personalised advice or for which group-based training is unsuitable e.g. people with learning disabilities (suitability confirmed by GP or referring healthcare practitioner).
- Need for language translation services (spoken or written).
- Unable or unwilling to provided informed consent.

- Current participation in competing clinical trial (as determined by trial investigator).

6. TRIAL PROCEDURES

This section provides a clear and concise timeline of the HEAL-D trial visits, enrolment process, interventions, and assessments that participants will undertake. These are also summarised in the schedule of procedures outlined below.

Schedule of Procedures

	Invitation	Pre-screening	Baseline (V1)	Week 0	Week 4	Week 13	Week 26* (V2)	Week 39	Week 52* (V3)	Week 65	Week 78	Week 91	Week 104* (V4)
Visit number			1				2		3				4
Eligibility screening[a]		X											
Telephone invitation	X												
Telephone screening[b]		X											
Consent[c]			X										
Review of consent			X		X	X	X	X	X	X	X	X	X
Demographics and medical history[d]			X										
Outcome questionnaires[e]			X				X		X				X
Venepuncture[f]			X				X		X				X
Anthropometric measures[g]			X				X		X				X
Blood pressure measurement[h]			X				X		X				X
Accelerometery[i]			X						X				
Health economics questionnaires[j]			X				X		X				X
Randomisation[k]				X									
Commence participation in intervention/control programme[l]					X								

	Invitation	Pre-screening	Baseline (V1)	Week 0	Week 4	Week 13	Week 26* (V2)	Week 39	Week 52* (V3)	Week 65	Week 78	Week 91	Week 104* (V4)
Visit number			**1**				**2**		**3**				**4**
Adverse event recording						**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Interviews & workshops[m]									**X**				

***assessment visits will be conducted ± 4 weeks of the timepoint; where the participant is unable/unwilling to attend the research site within this timeframe, a home visit or primary care based visit will be offered for data collection.

Grey shading denotes timepoint of primary endpoint measurement.

[a] Eligibility screening will include screening of structured education referral form for: age, ethnicity, HbA1c, suitability for group-based education.

[b] Telephone screening will include confirmation of ethnicity and English speaking. Where no current HbA1c result provided on referral, instruction to have HbA1c measurement.

[c] Consent will be taken in writing when attending baseline assessment visit.

[d] Demographic and medical history includes: sex, date of birth, ethnicity, birthplace and generational status, employment, education, marital status, socio-economic status, and a detailed past medical history including previous or current diseases.

[e] Outcome questionnaires include: PAID-5, DMSES, PDDC, SDKI, PHQ-9, IPAQ, MTBQ, DQQ, and self-reported sleep duration and chronotype.

[f] Venepuncture includes: HbA1c, lipid profile (total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides).

[g] Anthropometric measures include: body weight, height, body mass index, waist circumference, body fat percentage, body fat mass, body lean mass; all measured without shoes and removal of heavy clothing.

[h] Blood pressure measurement includes: seated systolic and diastolic blood pressure; three measurements will be taken and the mean value of the last two measurements recorded.

[i] Accelerometery includes: wearing a wrist-worn accelerometer for 10 days (24 hr per day) to measure physical activity, as well as sleep duration.

[j] Health economics questionnaires include: EQ-5D-5L and adapted version of the Adult Service Use Schedule.

[k] Randomisation: will be conducted up to 4 weeks after the baseline assessment visit and communicated to the participant by telephone; this is to reduce/standardise the time between randomisation and commencing the intervention.

[l] Commencement of intervention/control programme will occur up to 4 weeks after randomisation and date of attendance recorded.

[m] Interviews and workshops will be conducted for the process evaluation and SWAP work packages; these will be scheduled following the 52-week follow-up visit.

7.1 Recruitment

The PI at each site will ensure that all regulatory approvals, confirmation of capacity and capability from NHS sites and sponsor green light are in place before participants are identified and approached. The number of potential participants identified will be collated for Consolidated Standards of Reporting Trials (CONSORT).

7.1.1 Participant identification

The recruitment phase will commence as soon as all necessary approvals have been received. Potential participants may be identified and/or contacted in the following ways:

7.1.1.1 Recruitment from DSMES referral pathways

Centres will work closely with their local commissioners and structured education/DSMES providers to support recruitment from structured education/DSMES referral pathways. Attendance at a structured education/DSMES course is a core management recommendation for T2D, with referral to a structured education/DSMES course within 9 months of T2D diagnosis incentivised in primary care through the Quality Outcomes Framework (QOF) standards. A majority of referrals for DSMES services come from primary care for people with newly diagnosed T2D, but referrals are also initiated by community, intermediate and secondary care services, and for people with long-standing/established T2D. Referral processes normally require the referring clinician to provide information on patient ethnicity and HbA1c, and to confirm that the individual is suitable for a group-based DSMES course, in terms of learning and language needs. Potential participants will be identified through screening of referrals for DSMES courses; the research team in each centre will work with their local DSMES service providers to establish recruitment processes that fit with the local T2D care management pathways and we anticipate a slightly different approach to recruitment will be needed in each area.

Our recruitment processes are shown in the flow chart on page 31. GP's, practice nurses and/or the DSMES service management team will screen referrals for DSMES services to identify potential participants, based on ethnicity and HbA1c*. GP's, practice nurses and/or the DSMES service management team will telephone potential participants and provide a brief overview of the trial. Participants will be asked if they are interested in receiving further information about the trial and what their participation would entail; those who agree will be sent either a trial participant information video via text/WhatsApp/email (see rationale below) and/or a written participant information leaflet according to their preference. These materials will include a QR code with a link to the trial website where further details will be provided; on the website, participants will be able to register their interest in participating and provide their contact details for the research team to contact them. If after 24 hours of receiving trial information potential participants have not registered interest in participating, they will be telephoned by a research nurse/DSMES service provider to gauge their interest in participation; those who are interested in participation will be asked to consent to their contact details and HbA1c test result (to aid eligibility screening) being passed to their local trial team (local trial teams are based at higher education institutions; one trial team corresponds to each individual recruitment centre, University of Leicester for London, Warwick University for the West Midlands, and The University of Manchester for Greater Manchester). Those who are not interested will be managed within usual care service pathways e.g. appointment for a structured education/DSMES course.

*Where HbA1c is not provided on the referral, participants will still be contacted and invited to participate, with additional screening procedures to ensure eligibility.

7.1.1.2 Recruitment from primary care database searches

Primary care database searches will be used to identify potential participants. The database search, conducted by GP's and/or practice nurses, will initially screen for eligible participants based on the criteria outlined in section 6. A study invitation text message, including a link to the trial information video and/or letter, both with accompanying QR code or text message reply instructions will be sent

to potentially eligible participants. If willing, GP practices will add notes or reminders to medical records within Electronic Health Records to aid recruitment. The trial teams will work with GP practices to add notes and/or set-up reminders on eligible medical records for a GP, Diabetes Specialist Nurse or other health care provider will inform potential participants about the trial during routine appointments. In addition, where willing, individual clinicians, GPs and other healthcare professionals may engage in opportunistic identification of potentially eligible participants using study materials and the participant information leaflet.

After receipt of verbal consent to do so, contact details and HbA1c test result (to aid eligibility screening) of interested people identified by healthcare practitioners from primary care will be shared with their local trial team, who will then contact the potential participants and share trial materials (e.g., link to the trial information video), if they have not already received these materials. Members of the research team and clinical staff not involved in the person's usual care, will not identify participants or access medical records before consent has been obtained. Researchers may however visit clinical sites to promote the trial to clinical teams.

7.1.1.3 Recruitment from primary, intermediate/community or secondary care clinics

The trial teams at each centre will coordinate with local primary, intermediate/community and secondary care T2D clinics/services to attend relevant clinics and discuss the trial with potential participants who have expressed an interest after being told about the trial by their healthcare providers, and share trial recruitment materials. Healthcare providers will screen their clinic lists for potentially eligible participants and approach potentially interested individuals.

Healthcare providers will be encouraged to discuss the trial with their clinic patients, even if the trial team are not in attendance. After receipt of verbal consent to do so, contact details and HbA1c test result (to aid eligibility screening) of interested people identified by healthcare practitioners from either primary, intermediate/community or secondary care will be shared with their local trial team, who will then contact the potential participants and share study materials. Whether approached in primary, intermediate/community or secondary care, non-clinical members of the research team, or clinical members not involved in the person's usual care, will not identify participants or access medical records before participant consent to do so has been obtained from the clinical team.

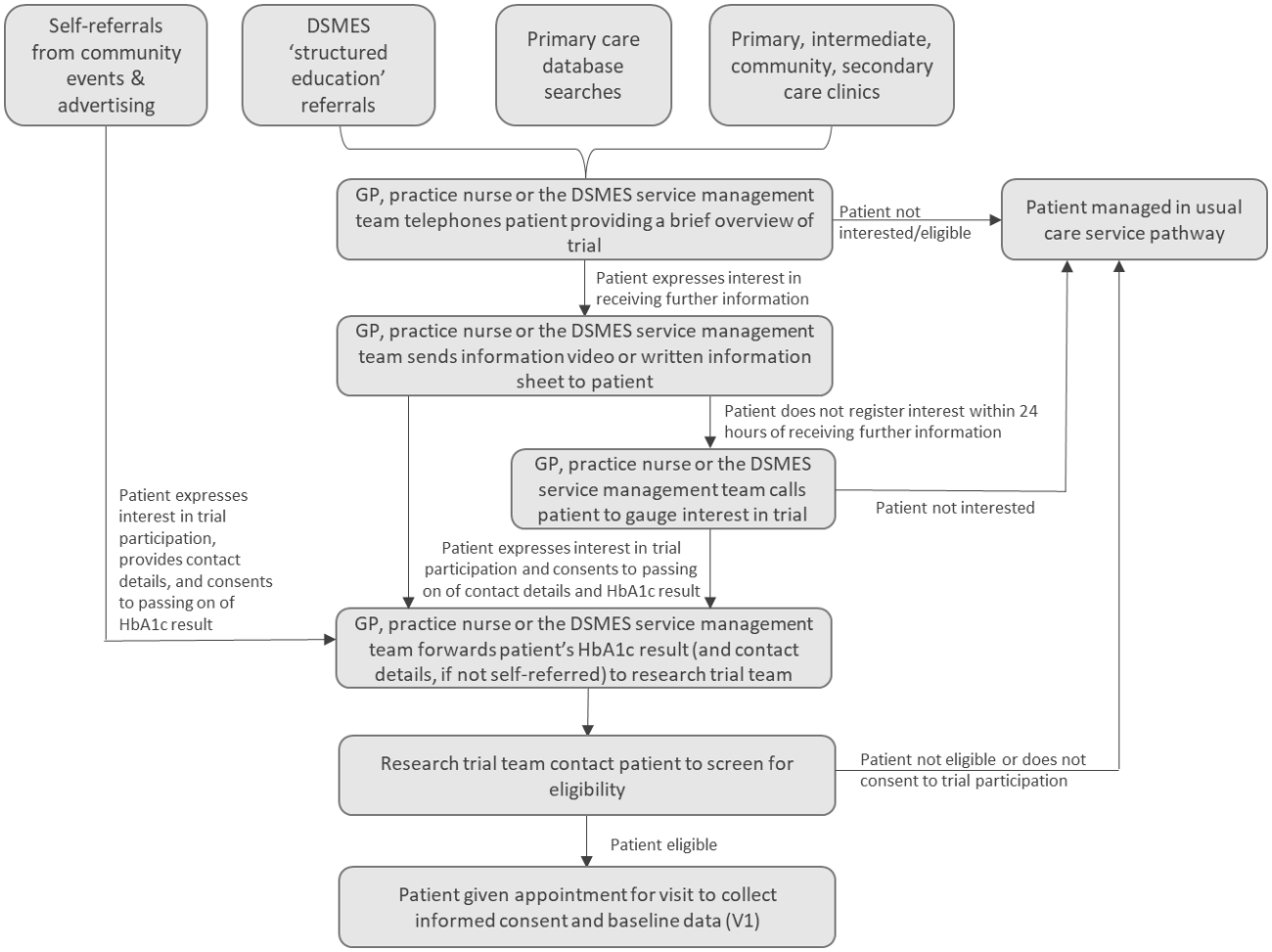
7.1.1.4 Recruitment through self-referral and other methods

The trial will be promoted and advertised via several formats including, but not limited to, social media, local radio, press releases, and advertising via a range of community organisations. Participant case studies (with media consent in line with the research sites' Trust policies), will be used to promote the trial on social media, websites and press releases. Trial information, including a brief video or leaflet about the trial, will be distributed by text/WhatsApp message or email to various mailing lists held by the research sites, included but not limited to PPI groups, and local intranets and internal mailing lists.

A range of media may be used to promote the trial, including (but not limited to) animations, videos, and QR codes enabling people to access more information. The trial team at each centre will also distribute posters and information to publicise the study across both clinical (e.g., GP practices, local hospitals, pharmacies) and non-clinical environments (e.g., faith institutions and community centres). All methods of advertisement will contain the trial acronym and logo (excluding radio due to the visual nature), a description of the trial and contact details of the trial team.

Rationale for trial information video: from our extensive experience of recruiting BABC people into research studies, we are aware that formal letters and lengthy written documents are off-putting; verbal communication is much preferred and visual information is more welcoming and easily understood. We have worked with our PPI group to identify the most appropriate methods for informing participants of the trial and explaining what is involved; the importance of 'jargon-free' communication (i.e. no medical terminology or acronyms) was highlighted, with suggestion of a short video with visual information and community figureheads describing the process rather than written

documents. This video will also support people who have limited understanding of written English but are confident in spoken English.



Flow chart of participant identification and recruitment

7.1.2 Screening

Initial screening checks will be conducted prior to consent and the participants first visit (V1). Site specific and centralised trial screening logs will be kept by local trial teams; the recruiting and trial teams (i.e. research nurses and trial coordinators) will log all patients who are screened for trial participation.

Potential participants identified via structured education/DSMES referral pathways, primary care database searches, primary/intermediate/community/secondary care clinic referrals, or those who self-refer in response to local advertising/community engagement will go through a two-stage screening process:

Stage 1:

All potential participants will be sent a text/WhatsApp/email including a trial participant information video and/or a written participant information leaflet and the research team's contact details. They then have two options for expressing interest with the local trial team contacting them to discuss participation.

They can either:

- Text, email or call to consent to being contacted by their local trial team and having their HbA1c test result shared with the research team.

Or

- Scan a QR code which will take them to further information about the trial online. A trial website containing information about the trial and a top line pre-screening questionnaire will be used to enable potential participants to express an interest in taking part in the trial. The website has functionality for potential participants to leave their contact information and provide consent for their local trial team to contact them and having their HbA1c test result shared with the research team.

All individuals who are sent trial information by DSMES teams, and who have not expressed an interest in taking part (via QR code), or texted or called to consent to being contacted by their local trial team, will receive a follow-up telephone call from the research nurse/service provider, a minimum of 24 hours later, to determine if the individual is interested in trial participation or, for those not interested in participating, is to be managed through the usual care pathway. Those interested in trial participation will be asked to consent to their contact details and HbA1c test result from their referral being shared with their local trial team.

Stage 2:

Via either route, participants who consent to being contacted by the local trial team will be telephoned by their local trial team and taken through a screening questionnaire to assess eligibility. The questionnaire will confirm the following eligibility criteria:

- Age
- Ethnicity
- Type 2 diabetes diagnosis
- Presence of any chronic conditions affecting suitability for group-based, general diet and lifestyle self-management advice
- Suitable for group-based attendance based on learning and language needs
- Safe to participate in exercise
- Pregnancy
- *HbA1c ≤ 100 mmol/mol (or fructosamine <450 µmol for individuals with sickle cell trait/disease), measured within preceding 3 months and documented in medical records.

*HbA1c is usually required on referral for DSMES courses. Where this is not available, participants will be asked to consent to the research team contacting their healthcare provider to obtain their HbA1c result. If there is no result on record in the permitted timeframe (3 months prior to screening date), individuals will be sent a blood test request to have performed in primary care and asked to provide consent to the result being shared by their healthcare team with the trial team. Participants will be eligible if *either* HbA1c (or fructosamine where the individual has sickle cell disease/trait) within the medical records over the past 3 months prior to screening date *or* HbA1c (or fructosamine where applicable) analysed from trial-specific screening falls within eligible range.

During the screening, the individual will also be encouraged to ask any questions they might have about the trial and their participation.

Any adverse findings that come to light throughout screening (or at follow-up assessments) will be reported to the participant's GP. Anonymised information on participants who do not progress beyond each stage of the recruitment and randomisation process will be recorded for CONSORT reporting, including:

- age

- sex
- whether the person is registered or not registered
- reason for ineligibility or decline trial participation.

7.1.3 Payment

Participant travel (and parking) for all visits associated with the trial (outside of those received for usual care) can be reimbursed up to the value of £10 (plus parking) per visit provided that receipts can be provided as evidence. The amount will be reviewed on a case-by-case basis, depending on circumstance. In addition to travel reimbursements, participants may receive up to £200 for their participation in the trial in recognition of their time commitment, and to reflect potential need for time away from work and the current cost of living costs. Payment will be provided by each centre at £50 per visit for visits at baseline, 26, 52 and 104 weeks. Additionally, £25 will be offered to participants who complete an interview, or £40 for participation in a workshop, as part of the process evaluation sub-study. Participants will also be provided with refreshments as required and preferred during the visits.

7.2 Consent

Participant information leaflets, consent forms and any amendments will be in compliance with GCP, local regulatory requirements and legal requirements and will have been approved by Research Ethics Committee (REC), Health Research Authority (HRA), Study Sponsor and the local trust R&I department prior to implementation.

The screening telephone call, or possibly a follow-up call, will allow for individual discussion between the participant and a member of the research team, checking that the participant has had sufficient time and opportunity to consider the trial information video/written leaflet previously sent, confer with other parties (e.g. family members), and ask any questions related to the trial. During this telephone call, the individual will be asked to indicate, verbally, their intention regarding participation; where the individual indicates a willingness to participate, they will be made an in-person appointment (V1), where informed written consent will be collected as well as baseline measurements. When the participant attends in person for their baseline assessment (V1), informed written consent will be collected.

The person obtaining informed consent will be a suitably trained and competent person who, in the opinion of the Principal Investigator (PI) at each site, will be able to give a full and unbiased explanation of the study (including benefits and risk) to the potential participant. As part of the process, they will make an informed judgement on the capacity to provide informed consent, by checking the participant understands:

- the purpose and nature of the research.
- what the research involves, including its potential benefits risks and burdens.
- the alternatives to taking part.

and that they can:

- retain the information long enough to make an effective decision.
- make a free choice.
- make this decision at the time it needs to be made.

The person obtaining consent will also have been named in the delegation log of staff as undertaking this duty and approved as study personnel by the relevant governance procedures. Written and verbal versions of the participant information leaflet and informed consent will be presented to the participants detailing no less than: the exact nature of the trial; the implications and constraints of the protocol; the known potential risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the trial at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

Each participant will be provided with a copy of their consent form and participant information leaflet, including a contact point in case they have further questions about the trial. A copy of their consent form will be placed in their medical records and the original copy held in the site master file. A screening log will be designed to identify trends and capture numbers of people screened, eligible, approached, randomised, and numbers accepting their randomised allocation.

The PI will retain overall responsibility for the conduct of research at their site, including the receipt of informed consent of participants. Where a participant is required to re-consent or new information is required to be provided to a participant it will be the responsibility of the PI to ensure this is done in a timely manner.

7.3 Baseline data (V1)

Prior to randomisation, participants will attend a baseline assessment visit (V1), where written consent will be obtained and several measures and questionnaires will be completed, detailed in Section 7.9.2. As part of the informed written consent process, participants will be asked to consent to access their medical records and to link their research data to routine health data. Participants will consent to their data from participating sites being securely transferred to the PCTU for data management. Permission will also be sought to inform the participant's GP of their participation in the trial.

Baseline assessments may be undertaken in any order, although to facilitate complete data collection, a preferred assessment order will be established and outlined through the visit case report form. In addition to the measures outlined in section 3.3, demographics will be collected via bespoke questionnaire/case report form (CRF) completion. These will include:

- sex
- age
- ethnicity
- generational status/place of birth
- employment
- education
- marital status
- socio-economic status will be determined using participant postcode to calculate the index of multiple deprivation (IMD) score
- A detailed past medical history including previous or current diseases and surgical interventions will be recorded by the site PI or study clinician (individual who is providing clinical oversight for the site) on the CRF. A full medication history will also be collected.

The baseline visit will occur within 90 days of screening. Baseline assessments will be conducted on a single day as standard but may be conducted across multiple visits where required (e.g., due to participant preference, staff or equipment availability), provided they are completed within a maximum of a 14-day window.

7.4 Randomisation

Randomisation will occur up to 4 weeks after the baseline assessments. The date of randomisation will mark timepoint 0 weeks, it will be from this timepoint that follow-up assessments are scheduled.

Eligible participants will be randomly assigned in a 1:1 ratio to one of two arms:

- Intervention group: the HEAL-D intervention

OR

- Control group: standard DSMES ('structured education') course that is commissioned locally

Allocation will use randomly permuted blocks of variable block length and be stratified by centre, accounting for provision of different standard DSMES programmes between centres, and baseline HbA1c (<53, 53-76, 77-100 mmol/mol).

7.4.1 Method of implementing the randomisation/allocation sequence

Allocation will be performed by an appropriate delegated member of staff using a validated web-based system. Eligible participants will be assigned in a 1:1 ratio to one of the two study arms, using stratification, as detailed above. A letter will be sent to the participant's GP, notifying them of their patient's participation in the trial and confirming randomisation assignment.

Each participant will be given a unique participant identification (ID) number after providing consent. This participant ID number will be used to identify the individual participant throughout the study and will not be reassigned to any other participant. Due to the nature of the intervention, blinding of participants and the trial team to allocation is not possible.

Core members of the team at each centre (e.g. centre lead, trial manager) will receive new participant/randomisation alerts at their respective centre, provided by the lead centre. Core members of the team at the lead centre (e.g. CI, trial manager) will receive alerts for all randomisation at all centres. The allocation will be documented within the site and trial master files and participant medical notes.

Allocation will be communicated to participants via telephone at which point participants will be asked to choose which mode of attendance of their allocated DSMES they wish to receive, F2F or online. Aligned with usual clinical service provision, participants will be offered both modes of attendance and be made aware of the days/times for the programmes to aid them in the decision-making. Information on the factors that drove the choice of attendance mode will be collected using a standardised questionnaire. Wherever possible, after randomisation, participants will commence the intervention within 4 weeks and time from randomisation to attendance will be recorded. Deviations from these timeframes will be recorded in the protocol deviation log.

A centralised randomisation database, managed by the PCTU and accessible to all the research team, will be used to log all trial enrolment; the trial coordinator at each site will log all patients who are randomised.

7.5 Blinding

This is an open trial where it is not possible to blind participants and intervention providers to allocation, due to the nature of the intervention. Outcome assessors will be blinded to the primary outcome of HbA1c, which will be analysed and reported via the clinical pathology services at each centre.

The trial statisticians will remain blind to treatment allocation until the analysis plan has been signed off. Any analysis or report production required that involves knowledge of treatment allocation will be carried out, under the instruction of the trial statistician, by a suitably qualified statistician independent to the trial team.

Research nurses/assistants involved in data collection will receive training and standard operating procedures will be followed to ensure standardisation and minimisation of bias in methods between staff and centres. Training will be provided by the lead centre, who will provide oversight of all centres, and quality assurance visits will be conducted at regular intervals, particularly upon commencement of each new phase of data collection visits to ensure consistency in the procedures. We will attempt to minimise bias in the subjective measures e.g. questionnaires, patient reported outcome measures, by instructing participants not to disclose their allocation to the research nurses/assistants during data collection visits.

7.6 Internal Feasibility Assessment

A feasibility assessment will be conducted in the first 6 months of the trial to establish the feasibility of completing the trial within desired timelines. Given the relatively short duration of the recruitment period (11 months), this will occur 6 months from the host centre receiving the green light, to allow subsequent changes to be implemented if required.

The assessment will use the following three criteria:

- Identification of eligible participants.
- Consent and randomisation of 20% of eligible participants.
- Engagement with treatment allocation of 80% of randomised participants.

Data from the first four months of recruitment (target: 84 randomised participants) and intervention engagement (months 4-6), measured as having attended one or more intervention sessions, will be reviewed by the TSC with predefined criteria and a 'traffic light system' used to determine progression to full trial:

		Red 60%	**Amber 80%**	**Green 100%**
Progression criteria		Number per month - LDN/GM/WM		
1.	Eligible referrals, invited to participate	36/18/18	48/24/24	60/30/30
2.	Consented & randomised	7/4/4	10/5/5	12/6/6
3.	Engaged with treatment allocation	6/3/3	8/4/4	10/5/5
4.	Total participants recruited (month 1-4)	51	66	84

Possible actions are as follows:

- Proceed (green) – if all criteria, or criteria 3 & 4, are met the trial will continue as planned.
- Amend (amber) - if two or three criteria met. In this instance, root causes of failure to meet criteria will be assessed on a centre-by-centre basis, and action plans will be created and implemented. Decisions will be made in the context of wider trial performance and reported to the funder.
- Refer to funder (red) - if <2 criteria are met. In this instance, the same actions as above will be taken, but with immediate involvement of the funder guiding decision-making in relation to trial continuation/action-planning.

7.7 Trial intervention

Participants allocated to the intervention arm (HEAL-D) will be offered the choice of attending face-to-face or online virtual delivery; participants will be made aware of the days/times for the programmes to aid them in the decision-making. Information on the factors that drove the choice of attendance mode will be collected. Following randomisation, participants will attend the HEAL-D programme within 4 weeks where possible and time from randomisation to attendance will be recorded.

HEAL-D culturally tailored DSMES programme (F2F and online): HEAL-D is a multistakeholder co-designed DSMES programme. It is underpinned by an evidence-based diet and lifestyle curriculum [58] and aligns with quality standards [19]. It uses evidence-based education and BCTs, informed by the Behaviour Change Wheel, including the Capability Opportunity Motivation-Behaviour (COM-B) model [59], with full consideration of context-specific needs of BABC adults, elicited through our co-design work with patients, healthcare practitioners and community leaders.
HEAL-D consists of 16 hours of group-based education and support (eight 2-hr sessions) delivered using F2F or online delivery modes. It is designed to support adoption and long-term maintenance of the following evidence-based diet and lifestyle goals [58]:

1. Achieve 5-10% weight loss or weight maintenance in those of healthy weight;

2. Undertake 150 minutes/week of moderate-to-vigorous intensity aerobic physical activity plus 2 sessions/week of strength training;
3. Balance carbohydrate intakes through portion control and promotion of low glycaemic index and wholegrain sources;
4. Limit saturated fat intake (<10% of energy intake), replace with mono-unsaturated fats;
5. Limit salt intake (<6g per day);
6. Consume oily fish at least twice per week.

Culturally tailored resources have been developed and are used to deliver the curriculum, including diet booklets, portion size guides and interactive games focusing on cultural foods and dishes, and videos including health and motivational messages. HEAL-D is delivered by a diabetes specialist dietitian (no specified ethnicity), a community trainer of BABC ethnicity and exercise instructors (no specified ethnicity). Sessions are scheduled for daytime, evening, and weekend delivery; sessions 1-7 use a weekly or fortnightly schedule and session 8 is delivered 6 months after the start of the programme. Participants are invited to bring a 'significant other' (not compulsory), and a 'flexible attendance' schedule allows participants to switch between programmes where needed/desired e.g., missed sessions, but not between online and F2F programmes due to room size restrictions. HEAL-D F2F is delivered in community settings, such as church halls and community centres, aiming for 8-12 patients in each group. HEAL-D online is delivered via a video-conferencing platform, aiming for 6-8 patients in a group. Online group sizes are slightly smaller than F2F to facilitate the development of a supportive group dynamic whilst using a virtual platform. HEAL-D online will be delivered by either a central delivery team, whereby participants from all centres will be grouped together and receive the programme from a central team, or by delivery teams at each centre whereby participants from all centres can be allocated to courses delivered by any centre. In both cases, online courses will not be comprised of participants from a single recruiting centre but can comprise of participants from all recruiting centres.

7.8 Control arm – standard DSMES course

Participants allocated to the control arm will receive the standard DSMES course that is commissioned by their local ICB and which meets the QOF standard for 'diabetes structured education'. They will be offered the choice of attending face-to-face or online virtual delivery; participants will be made aware of the days/times for the programmes to aid them in the decision-making. Information on the factors that drove the choice of attendance mode will be collected. Following randomisation, participants will attend the DSMES course within 4 weeks where possible and time from randomisation to attendance will be recorded.

7.9 Trial assessments

7.9.1 Trial visit schedule

Visits 2 (Week 26), 3 (Week 52) and 4 (Week 104) will occur 182 (± 28) days, 365 (± 42) days, and 730 (± 56) days after the date of randomisation. As per the baseline assessment (V1), it is intended that all assessments at each follow-up time point will be completed on a single day but may occur across multiple visits provided they are completed within a maximum 14-day window. This might include completion of questionnaires via telephone or video call, and/or primary care or home visits for anthropometric or questionnaire measures. At each time point, willingness to continue will be confirmed and documented on the CRF, and participants will be asked to undertake all the measures outlined in Section 3.3. Relevant assessments will be performed at each visit, except for accelerometery measurements (which will be conducted after visits at baseline and week 52), as described in Section 7.1 Schedule of Procedures.

An unscheduled visit can be used when a participant misses their appointment or is outside of their visit window due to unforeseen circumstances, but this will be logged accordingly as being outside of intended trial timelines (e.g. protocol deviation).

Participants will receive brief study review contacts (via telephone or video calls) from a trained member of the research team at three-monthly intervals (±14 days) where assessment visits are not scheduled (i.e., Weeks 16 39, 65, 78 and 91), to review ongoing willingness to continue and report events.

7.9.2 Methods to assess trial outcomes

All objective tests will have standardised standard operating procedures (SOPs) to ensure consistency of measurement between participating centres.

Questionnaire-based measures will be completed either interviewer-led or self-complete, according to participant preference and/or literacy skills.

7.9.2.1 Blood testing

At all visits, venous blood samples (non-fasting) for the measurement of circulating biomarkers (including HbA1c; primary outcome) will be taken using venepuncture, performed by trained staff according to local standardised SOPs.

All biochemical samples will be analysed by the pathology department at the corresponding hospital site. Results for these measures will be reviewed against normal ranges. Clinically significant results will be actioned by the study clinician and sent to a participant's GP, with a copy also placed in the participant's medical records.

7.9.2.2 Blood pressure

At all visits, arterial blood pressure will be measured in the seated position using an automated sphygmomanometer after participants have been resting for ~5 minutes. Three measurements will be obtained and the average of the last two measurements will be used.

7.9.2.3 Anthropometry and body composition

At all visits **body weight** will be measured using digital scales, with the patient wearing light clothing (without shoes), to the nearest 0.1 kg. **Height** will be measured to the nearest 0.5cm, using a stadiometer, without shoes. Body mass index will be calculated using the following equation: weight, kg/(height, m x height, m). **Waist circumference** will be measured using a flexible tape, with the patient wearing only light clothing, using the WHO methodology, which defines the 'waist' as the mid-point between the lowest rib and the iliac crest. **Body composition** will be measured using Tanita DC-430-MA P bioelectrical impedance scales. Body fat (%) and lean mass (kg) will be recorded.

7.9.2.4 Psychological wellbeing and self-management support

At all visits, several questionnaires will be completed to assess psychological wellbeing and self-management support.

- **Diabetes-related distress**: the Problem Areas In Diabetes (PAID) questionnaire is a reliable and widely used measure of diabetes distress. It consists of 20 questions rated on a 5-point scale (not a problem, minor problem, moderate problem, somewhat a serious problem, serious problem) scoring 0 (not a problem) to 4 (serious problem). Total score is calculated, with a higher score indicating higher levels of diabetes distress (lower diabetes-specific quality of life). The PAID-5 is an abbreviated version of the PAID, whereby presence of diabetes distress determined using 5 core questions from the 20-item PAID (Q3, 6, 12, 16 & 19): score of ≥8 = is distressed; score of 1 = has diabetes related stress; score of 0 = does not have diabetes related stress (range 0-20).
- **Depression**: the Patient Health Questionnaire-9 (PHQ-9) provides a reliable and valid measure of depression severity. It consists of nine questions rated on a 4-point scale (0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day). Total score is calculated, range

0-27, with depression severity rated as: 0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe.

- **Diabetes knowledge**: the Short Diabetes Knowledge Instrument (SDKI) questionnaire will be used to assess diabetes knowledge. The Short Diabetes Knowledge Instrument (SDKI) contains 13 questions; for this trial we will omit Q9 relating to insulin usage as it is not relevant to our participant group. Correct responses for the 12 included questions are as follows: Q1, 4; Q2,1; Q3, 1; Q4, 2; Q5, 3; Q6, 2; Q7, 2; Q8,3; Q9, 1; Q10, 2; Q11, 1; Q12, 1. Each correct response receives 1 point, and the score is the sum of those points. Score range: 0-12, with higher scores indicating greater knowledge.[60]
- **Self-efficacy**: the Diabetes Management Self-Efficacy Scale (DMSES-UK) questionnaire will be used to assess self-efficacy. The questionnaire contains 15 questions rated on a 10-point scale where 0 = cannot do at all, 5 = maybe yes/maybe no, and 10 = certain can do. Scores are totalled, range 0 – 150. For missing data: if more than 4 items are missing, the total score for the individual is marked as missing; if up to 4 scores are missing, then substitute missing scores with mean score for that person from items that were completed and then calculate the total score. Total score 0-50 = low self-efficacy; 51-100 = moderate self-efficacy; 101-150 = high self-efficacy.
- **Dietary competence**: the Perceived Diabetes & Dietary Competence (PDDC) questionnaire will be used to assess diabetes related dietary knowledge and competence. The PDDC questionnaire contains 20 questions rated on a 4-point Likert scale. Questions 1-9 measure positive competence, questions 10-15 measure negative dietary competence, and questions 16-20 measure negative control. Questions 1-9 are scored: strongly agree = 4, agree = 3, disagree = 2, strongly disagree = 1, with a higher total score indicating more competence. Questions 10-20 are scored: strongly agree = 1, agree = 2, disagree = 3, strongly disagree = 4, with higher overall score indicating less competence and control.[61]
- **Multimorbidity treatment burden:** the Multimorbidity Treatment Burden Questionnaire (MTBQ) will be used to assess the treatment burden of multimorbidity. The MTBQ consists of 10 questions rated on a 5-point Likert scale. Scores are totalled (range 0-40), an average score for the questions answered calculated, which is then multiplied by 25 to give a global score between 0 and 100. Categorisation of scores is as follows: no burden (score 0), low burden (score <10), medium burden (10-22), high burden (≥22). Due to the skewness of global MTBQ scores, researchers should report the median or interquartile range rather than the mean and SD, and report the proportion of patients with high, medium, low or no treatment burden (global MTBQ scores ≥22, 10-22, <10, 0).

7.9.2.5 Self-reported quality of life

At all visits, self-reported quality of life will be assessed via the EQ-5D-5L questionnaire. The EQ-5D-5L is used as a standardised measure of self-reported health status and quality of life and is considered to have a good discriminatory power and validity. EQ-5D-5L consists of two sections, the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system has 5 dimensions, each dimension has 5 levels (no problems, slight problems, moderate problems, severe problems, and extreme problems); the respondent is asked to select their health state for each of the 5 dimensions. The EQ VAS records the respondent's self-rated health on a visual analogue scale from 'best imaginable health' to 'worst imaginable health'. EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension. The index can be calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). To present all aspects of the EQ VAS data, a measure of the central tendency and a measure of dispersion should be presented. This could be the mean values and the standard deviation or, if the data is skewed, the median values and the 25th and 75th percentiles. A higher VAS score indicates better quality of life. The EQ-5D-5L will be used to determine health state descriptions for five components combined with preference-weighted health-related quality of life index scores (as

approved by NICE) to generate Quality Adjusted Life Year (QALY) profiles for the cost-effectiveness analysis.

7.9.2.6 Lifestyle behaviours – diet quality, physical activity and sleep

- **Diet quality:** the Diet Quality Questionnaire (DQQ) will be used to derive the following indicators: Diet Diversity Score (DDS; 0-10), Consumption of all five recommended food groups (ALL-5), NCD-Protect score (0-9), NCD-Risk score (0-9), and Global Dietary Recommendations (GDR) Score (-9-9 or transformed to 0-18). The DQQ gathers information on consumption of 29 food groups, each defined as a set of foods that share similar nutritional properties or biological or culinary characteristics. Food groups are represented by frequently consumed foods within a given food group. For each food group, a participant will answer 'yes' or 'no' when asked whether they consumed any of the frequently consumed foods yesterday.
- **Physical activity:** will be measured using the International Physical Activity Questionnaire (IPAQ) and a wrist-worn accelerometer watch. The IPAQ questionnaire has 7 questions about the amount of time spent in different levels of physical activity (vigorous, moderate, low intensity) over the previous 7 days. Physical activity is categorised as 'low' if no moderate or vigorous activity; 'moderate' where (a) 3 or more days of vigorous-intensity activity of at least 20 minutes per day, or (b) 5 or more days of moderate-intensity activity and/or walking of at least 30 mins per day, or (c) 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum T=total physical activity of at least 600 MET-minutes/week; 'high' where (a) Vigorous-intensity activity on at least 3 days (20min minimum), achieving a minimum Total physical activity of at least 1500 MET-minutes/week, or (b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes/week.

  The accelerometer will measure 24-hour physical activity, including sleep duration. The wrist worn device will be worn for 10 continuous days on the non-dominant arm.

- **Sleep:** The accelerometer will measure 24-hour physical activity, including sleep duration. The wrist worn device will be worn for 10 continuous days on the non-dominant arm. Participants will also report perceived sleep duration and chronotype.

7.9.2.7 Health service resource utilisation

At all visits, a modified version of the Adult Service Receipt Schedule (AD-SUS) questionnaire will be used to assess health services use.[62]

Trial assessment schedule with methods for maximising compliance

MEASURE	PURPOSE	SOURCE	STANDARDISED TOOL	DATA FORMAT	COLLECTED BY	TIMEPOINT COLLECTION				METHODS FOR MAXMISING COMPLIANCE
						V1	V2	V3	V4	
HbA1c	Primary outcome	Blood test at research visit	Venepuncture procedure with standard laboratory assay	Continuous (numeric)	Research nurse	X	X	X	X	Participants will be asked to consent to the trial team contacting their GP in the event of them not being able to attend their follow-up research visits – three attempts will be made to book a research visit, after this the GP will be contacted and asked to carry out a HbA1c & lipids assessment. If the participant fails to attend for a blood test with the GP, the GP will be asked to provide their most recent results with the date.
Blood lipids	Secondary outcome	Blood test at research visit	Venepuncture procedure with standard laboratory assay	Continuous (numeric)	Research nurse	X	X	X	X	
Blood pressure	Secondary outcome	Measurement at research visit	Procedure using digital blood pressure monitor	Continuous (numeric)	Research nurse	X	X	X	X	If a participant is not able to attend their follow-up

			– mean of 3 measures recorded							research visits, they will be offered either a home or GP visit where measurement of blood pressure, weight and waist circumference can be taken.
Body weight	Secondary outcome	Measurement at research visit	Procedure using digital scales, with the patient wearing light clothing (without shoes), to the nearest 0.1 kg	Continuous (numeric)	Research nurse	X	X	X	X	
Height	Secondary outcome	Measurement at research visit	Procedure using wall-mounted stadiometer, measured to the nearest 0.5cm, without shoes	Continuous (numeric)	Research nurse	X	X	X	X	
Body mass index	Secondary outcome	Measurement at research visit	Calculated using the following equation: weight, kg/(height, m x height, m)	Continuous (numeric)	Research nurse	X	X	X	X	
Waist circumference	Secondary outcome	Measurement at research visit	Procedure using a flexible measuring tape, with the patient wearing only light clothing, using the WHO methodology, which defines the 'waist' as the mid-point between the lowest rib and	Continuous (numeric)	Research nurse	X	X	X	X	

			the iliac crest. The mean of three measurements will be recorded							
Body composition	Secondary outcome	Measurement at research visit	Procedure using Tanita DC-430-MA P bioelectrical impedance scales. Body fat (%) and lean mass (kg) will be recorded	Continuous (numeric)	Research nurse	X	X	X	X	None.
Quality of life	Secondary outcome	Patient questionnaire at research visit	EuroQol (EQ-5D-5L) questionnaire	Categorical & continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	During the baseline research visit, the participant will be assessed for their ability and preference for interviewer-led or self-completion of the questionnaires. Self-completion will be offered at either the research visit or online. The mode of completion will be based on their literacy, confidence and preference. Where
Diabetes distress	Secondary outcome	Patient questionnaire at research visit	Problem Areas In Diabetes (PAID-5) questionnaire	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	
Depression severity	Secondary outcome	Patient questionnaire at research visit	Patient Health Questionnaire-9 (PHQ-9)	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	
Diabetes knowledge	Secondary outcome	Patient questionnaire at research visit	Short Diabetes Knowledge Instrument (SDKI) questionnaire	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	

Self-efficacy	Secondary outcome	Patient questionnaire at research visit	Diabetes Management Self-Efficacy Scale (DMSES) questionnaire	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	participants are not able to attend their research visits, they will be offered a telephone appointment for completion of the questionnaires.
Dietary competence	Secondary outcome	Patient questionnaire at research visit	Perceived Diabetes & Dietary Competence (PDDC) questionnaire	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	
Multimorbidity treatment burden	Secondary outcome	Patient questionnaire at research visit	Multimorbidity Treatment Burden Questionnaire (MTBQ)	Continuous & categorical (numeric)	Research nurse or self-complete by participant	X	X	X	X	
Physical activity	Secondary outcome	Patient questionnaire at research visit	International Physical Activity Questionnaire (IPAQ)	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	
Physical activity	Secondary outcome	Wrist worn device, fitted at research visit and returned via postal services	Research grade wrist-worn accelerometer	Continuous (numeric)	Research nurse/ self-complete by participant	X		X		If a participant is not able to attend their follow-up research visits, they will be offered either a home or GP visit where accelerometer can be fitted.
Sleep	Explanatory variable	Wrist worn device, fitted at research visit and returned via	Research grade wrist-worn accelerometer	Continuous (numeric)	Research nurse or self-complete by participant	X		X		

		postal services								
Diet Quality	Explanatory variable	Patient questionnaire at research visit	The Diet Quality Questionnaire (DQQ)	Continuous (numeric)	Research nurse or self-complete by participant	X	X	X	X	Where participants are not able to attend their research visits, they will be offered a telephone appointment for completion of the interview.
Sleep	Explanatory variable	Patient questionnaire at research visit	Self-reported sleep duration and chronotype	Continuous & categorical (numeric)	Research nurse or self-complete by participant	X	X	X	X	Where participants are not able to attend their research visits, they will be offered a telephone appointment for completion of the interview.
Service use	Health economics	Patient log throughout trial	Modified version of the Adult Service Use Schedule (AD-SUS) questionnaire	Qualitative	Self-complete by participant	X	X	X	X	Participants will keep the log throughout their trial participation and asked to bring the log to their research visits. Where research visits are missed, participants will be provided with a postage

										envelope for returning of the log to the trial team.
Programme attendance	Explanatory variable	Programme attendance log (completed by programme facilitators)	Session registers completed by programme facilitators	Continuous (numeric)	Programme facilitators		X			N/A
Programme evaluation	Process evaluation	Quantitative evaluation questionnaire	Questionnaire with Likert scale.	Continuous & categorical (numerical)	Self-complete by participant			X		Where participants are not able to attend their research visits, they will be offered a telephone appointment for completion of the questionnaire.
Process evaluation	Process evaluation	Interviews with trial participants, observation of intervention and staff training sessions, staff logbook entries & stakeholder workshops	NVivo software to assist analysis of qualitative data	Qualitative data from interviews and workshops, logbooks, and observations. Quantitative data from observations.	Researcher			X		During trial recruitment, participants will be asked to consent to be contacted about an interview and a workshop. Interviews and workshops will be delayed until completion of primary outcome. The interview can

										take place within one month of this. Interviews will be conducted via telephone, workshops will be conducted in person. Participants will receive a £25 retail for their time. Workshop participants will be offered a £40 retail voucher plus travel costs.
MLTC SWAP	Process evaluation & explanatory variable	Mixed methods SWAP, including questionnaire, interviews, and co-development workshop	Semi-structured interviews and workshop participation. (Questionnaires already collected for secondary outcomes: EQ5D-5L QoL score; PHQ-9 depression screening questionnaire; MTBQ score).	Qualitative data from interviews and workshops. Continuous and categorical numeric data (questionnaires).	Researcher			X		During trial recruitment, participants will be asked to consent to be contacted about an interview and a workshop Interviews and workshops will be delayed until completion of primary outcome. The interview can take place within one month of this. Interviews will be conducted via telephone, workshops will be

										conducted in person or virtually (video conferencing). Participants will receive a £25 retail for their time. Workshop participants will be offered a £40 retail voucher plus travel costs.

7.10 Post-trial follow-up assessments

No post-trial follow-up is currently planned, but participant contact details may (with consent) be retained by the central trial management team for a period of up to six years following the end of the trial. Consent for long-term follow-up using electronic health records may be sought via contacting these participants during this period.

7.11 Economic evaluation

The primary aim of the health economic evaluation will be to assess the within-trial incremental cost-effectiveness of both versions of the HEAL-D programme compared to standard DSMES programmes. This will be undertaken though a cost-utility analysis of the programme with participant outcomes measured in quality-adjusted life years (QALYs) gained. Secondary aims include: 1. whether within-trial cost-effectiveness conclusions are affected by a consideration of long-term cost and QALY outcomes extrapolated from observed clinical end-points within the clinical trial; 2. whether the programme is likely to be cost-effective when delivered at scale in routine practice, accounting for costs of implementation and expected population reach/engagement levels.

Inferences regarding the cost-effectiveness of HEAL-D will be made with reference to the incremental cost-effectiveness ratio (ICER), applying varying cost-effectiveness thresholds (inclusive of those adopted by NICE) for identifying whether new health programmes offer the NHS sufficient value for money[63]. The resource and cost implications of HEAL-D will be evaluated from an NHS/Personal social services perspective. All analyses will be undertaken probabilistically to reflect uncertainty in key economic and clinical parameters of relevance.

The short-term costs and benefits of HEAL-D will be quantified using data collected over the period of the trial, including resource inputs allocated to programme delivery and implementation (e.g., training activity), wider service utilisation among trial participants over follow-up (using the self-report AD-SUS), and short-term health-related quality of life outcomes (based on the EQ5D-5L instrument). For secondary analysis long-term resource and QALY impacts will estimated using the UKPDS Outcomes model[64]. The UKPDS is a micro-simulation modelling tool that can be applied to make extrapolations regarding the incidence of complications (micro- and macro-vascular) and associated cost, QoL and survival trajectories.

In further secondary analysis we will draw on data and evidence from the main evaluation of programme cost-effectiveness to assess whether it would be cost-effective to deliver alternative versions of HEAL-D at scale within routine service settings within a defined locality and population (south London). We will utilise existing frameworks and toolkits[65, 66] to estimate the potential costs of implementation at scale and will evaluate the cost-effectiveness of scale-up allowing for implementation costs and population engagement/reach.

7.12 Mixed methods process evaluation

An embedded mixed methods process evaluation, combining relevant data gathered within the trial (questionnaires, monitoring data), qualitative interview data, logbook entries, workshops and observations will provide a formative evaluation of the intervention's implementation, including:

- **Implementation:**
  - fidelity (whether training was delivered as intended, whether the intervention was delivered as intended, whether healthcare professions can deliver culturally sensitive behaviour change support, and whether there are any observed barriers to this).
  - dose (the quantity of the intervention implemented) delivered (i.e. attendance and completion rates).
  - reach (whether the intended audience encounters the intervention, and how).
- **Mechanisms of action:**
  - satisfaction (satisfaction with the programme).

- experiences of the intervention among participants, those delivering the intervention and other stakeholders.
- effective and less effective components of the programme in engaging participants and producing desired results (e.g. increasing physical activity) and potential reasons.

- **Identification of the contextual factors that influence its implementation and adoption:**
  - implications for workforce capacity and for intervention integration within existing care.

7.12.1 Participant eligibility criteria for mixed methods process evaluation

Participants who are enrolled in the trial and randomised to the intervention arm will be eligible to participate in the process evaluation. Staff involved in the delivery and interested in taking part in the process evaluation, will be eligible to participate provided they meet the following criteria:

- clinical and non-clinical staff working at/in partnership with centres participating in the HEAL-D trial.
- age ≥ 18 years.
- ability to give written informed consent.

7.12.2 Sampling and sample size

Patient participants: we aim to recruit a total of 48, 16 per centre, based on sampling for diversity in relation to high *vs* low engagement, F2F *vs* online attendance, and MLTC *vs* non-MLTC:

16 interviews per site	High engagement/ MLTC	High engagement/ Non-MLTC	Low engagement/ MLTC	Low engagement/ Non-MLTC
F2F intervention	n=2	n=2	n=2	n=2
Online intervention	n=2	n=2	n=2	n=2

Maximum variation sampling of participants will be guided by age, gender, employment status and ethnicity (Black-African or Black-Caribbean). The characteristics of the sample will be continually reviewed to achieve balanced representation, inviting consecutive participants until we have achieved the target sample and data saturation.

Staff participants: we aim to recruit up to 27, that is up to 9 per centre, including delivery staff and trainers.

7.12.3 Recruitment and consent

7.12.3.1 Patient participants

Patient participants will be identified and recruited as described for the main trial (Section 7.2). A separate consent process will not be undertaken, to reduce participant burden, but participants will be made aware that they may or may not be asked to take part in the interviews and will have the opportunity to opt out of this component if they wish.

7.12.3.2 Staff participants

Observations: Both the training of HEAL-D facilitators by trial personnel and the delivery of HEAL-D sessions by facilitators will be observed for the process evaluation. All study personnel involved in training and HEAL-D delivery (facilitators) will be provided with an information leaflet and required to give written informed consent prior to taking part in training and delivery. Consent for the observation of the delivery of HEAL-D is received from participants as part of their consent to participate in the trial.

Workshops: Eligible staff will be approached by the qualitative research team and invited to take part in a workshop. Those interested in taking part will be provided with an information leaflet. When a participant has indicated willingness to participate, the researcher will take verbal consent by telephone, with written informed consent taken when attending for the workshop.

Participants will be given at least 24 hours to decide whether to take part or not. The researcher will have received appropriate training in obtaining consent and have been delegated this task by the PI. Before proceeding, they will check that the participant has understood the information and has had opportunity to ask questions. The researcher will obtain written informed consent immediately prior to the observations or workshop commencing. All consent forms will be retained at sites. The staff involvement in the process evaluation will end once the observations/workshop is complete.

7.12.4 Qualitative data collection

7.12.4.1 Interviews with trial participants

Semi-structured interviews, conducted by telephone, will be used to gather qualitative data as they offer an open and flexible method for exploring the participants' individual experiences in-depth. Interviews will occur after the 12-month visit, aiming for within one month after this, when the participants will have had sufficient experience of the HEAL-D intervention, and any burdens associated with involvement will likely have become apparent, whilst avoiding effects of the interview on participation.

Topic guides for each interview will be developed in advance of the process evaluation commencing in partnership with the TSC and PPI/E representatives. To ensure broad coverage, topics will be informed by the Theoretical Domains Framework (TDF), which defines 14 domains of determinants of behaviour change (e.g., social influences, knowledge) and by the Theoretical Framework of Acceptability (TFA)[67], which covers seven domains of acceptability (e.g., affective attitude, self-efficacy). Interviews will be conducted by an experienced qualitative researcher at an appointment separate from the other trial assessments, via telephone or video link; we have done this previously with this population and many prefer the practicality of this approach. In cases where a participant is unwilling to use telephone or video link, but would be willing to be interviewed face-to-face, we will offer a face-to-face interview.

During the interviews, the researcher will introduce the process, explaining the background, how the interview will proceed, and details of audio-recording and note-taking. Participants will be reassured about the preservation of their anonymity and confidentiality as well as being given the opportunity to ask questions before audio-recording commences. Interviews are expected to last up to 45 minutes. At the end of the interview, participants will be given another opportunity to ask questions, or seek clarification and the voluntary nature of their participation will be re-iterated. Should any participant request further information or highlight any concerns during the interview then these will be discussed with the PI at their recruiting site, for appropriate onward referral as required. All participants will be made fully aware of the contact details for the research team, should they have any concerns following the interview.

7.12.4.2 Observation of training sessions and intervention sessions

Observations of HEAL-D facilitator training sessions will be used to provide information on:

- The extent to which the facilitators are adequately trained to deliver interventions, including elements of training delivery;
- The intervention-as-planned that facilitators are trained to deliver, including content. This will help to determine external validity of HEAL-D.

Observations of HEAL-D delivery will be used to provide information on:

- Internal validity of HEAL-D (i.e., intervention effectiveness and 'active ingredients' (i.e., BCTs),
- External validity of HEAL-D (e.g., implementation, replication).

- Comparability of online versus F2F.

A researcher will conduct one observation per centre of a training session for HEAL-D staff and 48 live observations, 16 per centre, with two observations of each of the eight intervention sessions, involving various delivery staff.

Checklists of BCTs (e.g., goal setting, self-monitoring), will be used to examine intervention delivery. We will produce scores based on the BCT checklists.

Delivery staff logbooks: observations will be supplemented by delivery staff logs. Potential contamination between trial arms and protocol modifications will be assessed through examination of BCT checklists and logs, and through regular reporting by trial research teams to the trial management group. We will assess whether any identifiable modifications were planned adaptations to fit context, or unforeseen, and report our findings according to FRAME, an established framework.

7.12.4.3 Stakeholder workshops

Implementation will be explored through one F2F stakeholder workshop per centre, with around 6-9 individuals, including trainers, trial participants, and service delivery staff. Stakeholders will be invited through our networks, sent an information sheet and asked for written consent at the workshop. Topics will be informed by the TDF and NPT and will explore issues related to implementation of the intervention in routine practice. Workshops will last up to 2 hours.

7.12.5 Quantitative data collection

To complement our qualitative analyses, quantitative data will be collected from the observation checklists, and from attendance logs and questionnaires.

7.12.5.1 Questionnaires

A self-report questionnaire, containing a mix of Likert scale and free text responses, will be used to assess acceptability of trial procedures, including enrolment and randomisation. This will be completed by all trial participants at the 12-month follow-up visit.

A self-report questionnaire, containing a mix of Likert scale and free text responses, will be used to assess the acceptability of the HEAL-D intervention. The questions will be informed by the seven domains of the Theoretical Framework of Acceptability (TFA)[67]

- Affective attitude: how individuals feel about taking part in an intervention.
- Burden: the amount of effort required to engage with an intervention.
- Perceived effectiveness: whether individuals perceive an intervention as likely to achieve its purpose.
- Ethicality: the extent to which an intervention fits with individuals' values.
- Intervention coherence: whether individuals understand an intervention and how it works.
- Opportunity costs: what is given up, such as time, to take part in an intervention.
- Self-efficacy: how confident individuals are about doing the intervention.

7.13 Study Within A Project (SWAP)

7.13.1 Rationale

People with T2D often experience multiple long-term conditions – multimorbidity (MLTC). In a Scottish national study of 40 Long Term Conditions (LTC), Guthrie *et al*. found that 82.4% of patients with T2D had MLTC with a mean of 2.9 LTCs and for adults ≥65 years, a mean of 6.5 LTCs[68]. For many of these adults, the associated LTC was cardiovascular in nature. However, chronic pain (21%) and depression (19%) were also commonly associated. T2D often inhabits MLTC clusters and in one study based on a multi-ethnic community in south London, the most common cluster co-morbidities associated with T2D were osteoarthritis, cancer, chronic pain and hypertension. In communities of

BABC ethnicity, the prevalence of some of these clustered conditions is likely to be higher still, such as chronic pain and hypertension[69].
We propose a SWAP embedded within the HEAL-D trial to assess the impact of MLTC on the uptake of and engagement with HEAL-D and the impact of the intervention on the MLTC. Given that MLTC is the majority experience for adults with T2D, and particularly within our BABC participants, in whom MLTC are even less studied than in the White-British population, the HEAL-D trial provides the rare opportunity to explore the interaction between the HEAL-D intervention and MLTC in adults of BABC ethnicity. It is possible that the presence of MLTC will have a bi-directional impact. The presence of MLTC may influence uptake of the intervention, and the HEAL-D intervention may influence the management and control of the associated MLTC. We will survey patients recruited to the HEAL-D study to determine their own experience of MLTC, in terms of which LTCs and combinations of LTCs they experience, the extent to which this contributes to functional impairment, while bearing in mind the cultural context of the HEAL-D trial, focussing on BABC communities.

7.13.2 SWAP aim and objectives

Aim: To explore uptake of and engagement with HEAL-D in adults with T2D who also have MLTC.

Objectives:
1. To assess the prevalence of MLTC in adults of BABC ethnicity participating in the HEAL-D trial and identify and describe common MLTC clusters.
2. To assess the impact of MLTC on uptake, engagement with and completion of HEAL-D.
3. To assess the impact of the HEAL-D intervention on associated MLTC.
4. To co-develop knowledge exchange and dissemination outputs in a workshop with a PPIE group and other relevant stakeholders, ensuring strong representation of those with MLTC.

7.13.3 SWAP methods
A mixed methods SWAP, including questionnaires, qualitative interviews and co-development workshops will be conducted.

7.13.4 SWAP inclusion and exclusion criteria

The SWAP will be conducted in two phases: quantitative data collection, to address objective 1, and qualitative data collection to address objectives 2-4. All participants recruited to the trial will be eligible for the SWAP and have quantitative data collected (e.g. prevalence and details of MTLC); only participants randomised to the intervention arm will be eligible to participate in the qualitative data phase (i.e. semi-structured interviews and workshops).

7.13.5 Sample size calculation

Sample size for the SWAP is determined by the sample size calculation for the host HEAL-D trial and the number of participants within the intervention group. It is not powered to detect a statistically significant difference between groups.

7.13.6 Consent procedures

Participants will consent to participate in the SWAP as part of the consent procedure for the full trial. To introduce separate consent would introduce additional burden for both sites and participants.

7.13.7 Quantitative data collection

MLTC questionnaire: all trial participants (n=300) will complete a questionnaire to elicit background information on the LTCs they experience (with MLTC defined as per Guthrie *et al.*,[68]). The extent to which these LTCs affect their day-to-day living will be assessed using the Multimorbidity Treatment Burden Questionnaire (MTBQ). The questionnaire will be analysed together with participant demographic data and baseline exercise capacity, QoL, and psychological assessments, using descriptive statistics (e.g. mean, SD, %).

7.13.8 Qualitative data collection

Semi-structured interviews: a sample of participants from the intervention arm of the trial will be invited to participate in a qualitative interview as part of the main process evaluation (Section 7.12) in which the SWAP is embedded. The process evaluation will conduct 48 interviews in total, aiming for proportionate representation of people with MLTC according to their recruitment questionnaire; we anticipate this will be approximately 16 of the 48 process evaluation interviews. Purposive sampling of the 48 interviewees to ensure additional analysis for the SWAP will ensure a balance of associated LTCs with representation from patients with both cardiovascular and non-cardiovascular LTCs, physical health and mental health conditions. A topic guide for the interviews will be co-developed with our PPIE group. It will focus on experience of T2D, experience of LTCs, uptake of and engagement with the HEAL-D intervention (both F2F and online attendance), trial experience, trial completion, interaction between LTCs and intervention: how the trial intervention influenced experience and self-management of LTCs; how LTCs influenced uptake of and experience with the trial intervention.
Data analysis: Qualitative data will be analysed using methods detailed in Section 10.11.

Workshops: within our process evaluation we are conducting three workshops, one at each centre, based on themes emerging from the qualitative analysis and including other relevant stakeholders. These will be structured to encourage discussion. We will use a timeline marked out with different HEAL-D sessions to form a so-called 'journey map'. This will enable participants to consider 'the journey' through the HEAL-D trial and intervention. We will follow this with structured brainstorming, where participants are asked to suggest solutions to barriers to acceptance of HEAL-D brought up in the journey map (they can add more if they wish). To meet SWAP objectives, they will discuss additional needs of people with MLTC, the burden of MLTC, and barriers and facilitators to acceptance of HEAL-D. For the SWAP, we have added two further workshops that recognise the specific needs of patients with MLTC: (1) an online workshop to be inclusive of participants with MLTC who would find it difficult to attend the F2F process evaluation workshops, especially as we wish to ensure diversity in including the less engaged, and (2) to deliberate on whether the intervention could be optimised for MLTC and what lessons can be shared with other stakeholders going forward, we have added a fifth workshop (F2F but will pivot to online if needed to ensure MLTC involvement). This will bring together learning from the other workshops, using a participatory approach to co-develop outputs such as guidance and recommendations for the inclusion of people with MLTC in clinical trials, research and intervention roll-out. Specifically, this workshop will take the barriers, facilitators and suggestions for solutions to barriers from the previous workshops (which the research team will have edited and refined if necessary between workshops). Participants will be asked to prioritise the items in the list in terms of impact and feasibility, to provide detail for any guidance or recommendations. They will also discuss how these recommendations might be disseminated, for example the formats to be used, the audiences, and how the outputs might be disseminated or shared. We will share examples of existing guidance and recommendations designed for other purposes and sourced from the internet so that participants can make decisions about design using concrete examples. This approach builds on work successfully undertaken during the development of HEAL-D and enables our learning to be disseminated widely.

7.13.9 Proposed outcomes of SWAP:

- Enhancement of the HEAL-D intervention for adults of BABC ethnicity with T2D and MLTC
- Enhanced engagement of adults with MLTC in the HEAL-D intervention
- Enhanced self-management of MLTC in adults with T2D
- Production of learning points for broader dissemination.

7.14 Withdrawal criteria

Participants may withdraw from (a) complying with the allocated trial intervention and/or (b) providing

data to the trial, at any time for any reason without affecting their usual care. Participants in the intervention arm who wish to revert to usual care will be asked if they are willing to continue to provide outcome data, which will be included within the intention to treat (ITT) analysis but excluded from any 'per protocol' analyses (see statistics and data analysis section). Participants may withdraw from the SWAP and the process evaluation but remain within the main trial, should they wish. Participants who have withdrawn but consented to be part of the long term follow up will be given the option to remain in the long term follow up.

In addition, the PI may discontinue a participant from the study at any time if considered necessary for any reason including:

- discovered ineligibility after eligibility assessment at screening.
- major protocol deviation.
- other reasons encountered that may necessitate a withdrawal to be discussed with the CI.
- participation in another intervention research trial.
- an AE which results in inability to continue to comply with trial procedures.
- disease progression which results in inability to continue to comply with study procedures.
- prolonged or serious hospital admission (at the discretion of review by a site PI/study clinician who is providing clinical oversight).
- development of:
    - type 1 diabetes.
    - eGFR<30 mL/min per 1.73m^2 or requirement for renal replacement therapy.
    - serious illness with life-expectancy <1 year or other significant illness which, in the opinion of a site PI/study clinician who is providing clinical oversight, precludes involvement.
    - loss of capacity to provide ongoing informed consent.
    - any other reason considered necessary by site PI/study clinician or other investigators.

Withdrawals from the trial will be recorded in the CRF, database and medical records. Participants do not have to give a reason for withdrawal, however if they do provide a reason for leaving the trial, this will be documented. If the participant is withdrawn due to an AE, the investigator will arrange for safety follow-up visits or telephone calls until the adverse event has resolved or stabilised.

They will be sent a letter thanking them for their participation and informing them that the data collected up to the time point they withdrew will be included in the trial analysis and that they will not be contacted again with regards to this trial, unless they consent to withdraw from active intervention but remain enrolled for subsequent follow-up. They will not be asked to complete any further trial measures. A letter will also be sent to their GP to inform them of their withdrawal in the trial. For participants who fail to return to the centre, the trials team will make reasonable efforts to re-contact the participants (e.g., contacting participant's family or GP, reviewing available registries or health care databases) and to determine their health status, including at least their vital status. Attempts to contact such participants will be documented in the participant's records.

Each patient participant will have a copy of the consent form and participant information leaflet placed in their hospital medical records. A standard label will be used on the front of the medical notes to highlight to any reviewer that this individual is taking part in the trial and any issue regarding contra-indication of a procedure should be discussed with a site PI/study clinician. Staff participants will be provided with a copy of the documents for their records.

The recruitment target has allowed for a drop out of 15% therefore we have already anticipated the potential loss of participants into our overall recruitment target and thus will not be attempting to replace recruits for those that may withdraw.

7.15 Assessment and management of risk

There are minimal risks associated with taking part in the HEAL-D trial and process evaluation. Participants will be made fully aware of any potential risks before consenting. All research investigations are detailed in the participant information sheets and will be explained to the participant before each investigation to ensure that they are willing to undertake each one.

The proposed SWAP is also low risk. Additional potential burdens and risks associated with the study are outlined below.

7.15.1 Time commitment

Individuals with T2D often lead complex and busy lives, and participation in this trial represents the primary burden to participants. The burden may be greatest to those within the intervention group, as this group will be asked to the HEAL-D intervention, which requires 16 hours of attendance over 8 sessions, compared with typically 6 hours over 2 sessions for standard diabetes structured education courses.

Whilst the HEAL-D intervention has specifically been co-developed with people of African and Caribbean heritage with T2D to minimise the burden of treatment and its acceptability has been evaluated in a feasibility trial, we acknowledge that any burdens associated with the intervention may only come to light during or after their involvement. To understand this, participants will be asked to participate in an interview as part of the mixed methods process evaluation. The focus of these interviews will be to explore the patient experience and acceptability of the intervention.

To reduce the potential burden of this component of the trial, participants can opt out the interviews and will still be able to make an important contribution to the trial. Interviews will last up to 45 minutes maximum, arranged at the participant's convenience, and conducted using a range of options (telephone or online) to support participation.

A pragmatic approach to the collection of research outcomes will also be employed, including utilisation of devices (tablet/phone) to allow completion of appropriate measures remotely, at the participants convenience, within a specified time.

7.15.2 Interview content

Interviews will be in-depth and will follow a topic guide but also allow for the exploration of other areas that are important to or significant for the participant, in relation to the research questions. Interviews may include discussion of health issues which significantly impact upon participants physical and mental health and may mean that participants discuss emotive and distressing topics, or issues which they feel strongly about. The researcher will remain sensitive to the signs of distress and discomfort during the interviews and ask the participant if they wish to continue or would prefer to end the interview or move on to a new topic. In the case of significant distress, the participant will be referred to their care provider for further support.

7.15.3 Risks associated with the HEAL-D intervention

The HEAL-D intervention delivers evidence-based self-management education and support in a culturally tailored manner. Consequently, the risks associated with the HEAL-D intervention are minimal. In addition to education and support, attendees of the HEAL-D intervention will take part in group-based physical activity classes. To minimise any potential risks, the classes are delivered by exercise trainers specialising in rehabilitation exercise, and appropriately structured, in terms of intensity and movements, to meet the needs of people with mobility issues or comorbidities. Additionally, participants will undergo a physical activity assessment by the physical activity providers. This will assess their fitness and safety to participate in physical activity and provide them with guidance as to the amount and level of physical activity that is appropriate for them. Furthermore, in each physical activity session participants will be reminded to self-monitor their perceived exertion and to work within safe levels of exertion for their ability.

7.15.4 Risks associated with outcome tests

In addition to the potential for participant burden associated with the outcome data collected, some of the measures used may be associated with minimal additional risk.

Several of the patient reported outcome measures may bring to light conditions and concerns requiring onward referral and ongoing support. Where participants score more than or equal to 3 (indicative of diabetes-related distress) on the PAID questionnaire and more than or equal to 10 points overall or scoring on question 9 on the PHQ-9 (both indicative of a depressive disorder) their GP will be informed and advised to make the appropriate referral for investigation.

Assessment of the impact of the intervention on the participants glycaemic and lipid profile, alongside other biomarkers, will require additional venepuncture. Although these require some additional time from participants, and in the case of venepuncture, may be uncomfortable, there is no risk to health. Any clinically significant results that arise from these tests will be actioned by the study clinician and sent to a participant's GP with a copy also placed in the participant's medical records.

7.16 End of trial

End of trial will be defined as the collection of outcome data at the 24-month visit of the last participant.

8. STORAGE AND ANALYSIS OF CLINICAL SAMPLES

A full laboratory manual for collection of venous blood samples will be provided to the teams at each centre during the delivery of trial protocol training.

For outcomes being analysed by local pathology departments, local SOPs will be used for the collection of samples, transportation to the pathology laboratories, and retrieving of results, before appropriate clinical review, source data filing, and upload of data onto the trial database.

It is the responsibility of the trial site to ensure that samples are appropriately labelled in accordance with the trial procedures to comply with the Data Protection Act. Biological samples collected from participants as part of this trial will be transported, stored, accessed and processed in accordance with national legislation relating to the use and storage of human tissue for research purposes and such activities shall at least meet the requirements as set out in the 2004 Human Tissue Act and the 2006 Human Tissue (Scotland) Act.

8.1 Arrangements for sample collection

A 5ml venous blood sample will be taken for measurement of HbA1c (EDTA tube) and full lipid profile (gel-activated clotting agent tube), with exact brands/systems as locally available. Blood samples will be transferred to the local clinical pathology labs for analysis.

8.2 Arrangements for sample analysis

Samples will be tested/analysed locally, sent for analysis following collection.

8.3 Storage arrangements for samples

Samples will not be stored for future research.

8.4 The destruction arrangements for samples

Samples will be disposed of by the clinical labs, as per standard clinical sample protocols.

9. RECORDING AND REPORTING OF SAES

The HEAL-D trial is not a clinical trial of an investigational medicinal product, therefore the usual monitoring of pharmacovigilance and associated terminology is not relevant.

It is not expected that there will be any adverse reactions (ARs), serious adverse reactions (SARs) and Suspected Unexpected Serious Adverse Reaction (SUSARs) experienced within the trial and so these have not been included in the safety reporting section of the protocol.

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical investigation participants, which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study, whether or not considered related to the study.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

9.2 Reporting procedures for All Adverse Events

All AEs occurring during, and attributed to the trial, which are observed by the investigator or reported by the participant, will be recorded in the participant's medical records and an AE log from the time the participant is randomised. The following information will be recorded: description, date of onset and end date, severity, assessment of relatedness to study, and action taken. Additional follow-up information should be provided as necessary. AEs considered related to the study as judged by a medically qualified investigator or the sponsor will be followed until resolution, or the event is considered stable. All related AEs that result in a participant's withdrawal from the trial or are present at the end of the trial, should be followed up until a satisfactory resolution occurs.

It will be left to the clinical judgment of the centre's PI/lead clinician whether or not an AE is of sufficient severity to require the participant's removal from treatment. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable AE. If either of these occurs, the participant must undergo an end of trial assessment and be given appropriate care under medical supervision until symptoms cease or the condition becomes stable. The severity of events will be assessed using the following scale: 1 = mild, 2 = moderate, 3 = severe. AE's will be recorded within the participant's medical records and an AE log, and discussed periodically with the TSC as required. Any safety concerns that arise as a result of this, will be reported to the sponsor as soon as possible.

9.3 Expected Adverse Events and Serious Adverse Events

Due to the population of the study sample, the following events could be expected to occur throughout the duration of the trial and will therefore not be collected or reported to the sponsor:

- outpatient appointments or treatments for ongoing conditions that were present at the start of the study

9.4 Reporting Procedures for Serious Adverse Events

All SAEs (except from those outlined as expected) occurring from the time of randomisation until the final trial visit must be reported to the Sponsor immediately and within 24 hours of becoming aware of the event. The SAE will be reported using appropriate forms and according to the Sponsor SOP for reporting serious adverse events. Additional information will be provided if requested to the Sponsor and main Research Ethics Committee (REC). The PI or another delegated physician (as agreed by the Sponsor) is responsible for the review and sign off of the SAE and the assessment of causality (i.e., whether an event is related to a study procedure or intervention).

The Sponsor will perform an initial check of the information and ensure that the SAE line listing is reviewed by the Director of Research & Innovation. All SAE information must be recorded on an SAE form and sent to the Sponsor. Additional information received for a case (follow-up or corrections to the original case) needs to be detailed on a new SAE form and sent to the Sponsor. Copies of all documentation and correspondence relating to SAEs will be stored in the TMF and / or ISF.

For each **SAE** the following information will be collected:

- full details in medical terms and case description
- event duration (start and end dates, if applicable)
- action taken
- outcome
- seriousness criteria
- relationship to the study procedure or intervention

Any change of condition or other follow-up information should be emailed to the Sponsor immediately and within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached. In addition to the expedited reporting above, the CI shall submit once a year throughout the study or on request an Annual Report to the Ethics Committee which lists all SAEs.

9.4 Responsibilities

In accordance with the Trial Terms of Reference, it is the responsibility of the TSC, to periodically review safety data.

9.5 Reporting urgent safety measures

HEAL-D is a low risk study, so it is expected that no events should occur that would affect the benefit-risk balance significantly.

10. STATISTICS AND DATA ANALYSIS

10.1 Sample size calculation

An assumed difference in HbA1c of 5mmol/mol leads to clinically significant risk reductions for T2D complications and is the minimal clinically important difference used to evaluate intervention effectiveness in T2D (3). Power is calculated at 90%, 5% 2-sided significance level and to detect a standardised effect size of 0.45 (difference in HbA1c of 5 mmol/mol and SD (11) determined from feasibility trial and Lambeth primary care data).
To allow for correlation of outcomes among group attendees the sample size assuming no correlation (103 per arm) is inflated by a design effect (1.09) and then rounded up to ensure divisibility by group size. The F2F intervention is to be delivered in groups of up to 12, while online intervention will be delivered in groups of up to 8; for the calculations we assume an average group size of 10. Given

the objective outcome, short duration of treatment, patterns observed in the intracluster correlation coefficient (ICC) for cluster randomised trials suggest an ICC of 0.01[70].
In our feasibility trial, loss to follow-up was 7%, with 6-mth follow-up. Given our pragmatic design, whereby participants are given free choice as to their mode of attendance (F2F or online) in both the intervention and comparator arms, we do not expect substantial differences in retention between arms. However, we estimate that with a longer primary outcome follow-up of 12-mth, loss to follow-up will be higher at 15%. For the intervention arm, this is accounted for by increasing the number of clusters. Therefore, we will recruit 150 participants in the control arm and 150 participants in the intervention arm, each across 15 groups of average size 10.

10.2 Planned recruitment rate

We estimate a recruitment rate of 26-28 participants per month based upon 3 recruiting centres recruiting over an 11-month period to achieve a sample size of n=300.

10.3 Statistical analysis plan

The trial will be analysed and reported according to the CONSORT statement for RCTs. A statistical analysis plan (SAP) will be prepared by the Trial Statistician and will contain full details of all statistical analyses. The SAP will be prepared and finalised before the database lock. It will be agreed with TSC before data lock. Any changes to the original SAP will be detailed along with the reason(s) for their change in subsequent SAPs. No formal stopping rules or interim analyses have been pre-defined, beyond the internal feasibility assessment.

The analyses of the quantitative trial data will be based on intention-to-treat and will include all randomised participants analysed according to their randomised treatment.

10.4 Summary of baseline data and flow of patients

A CONSORT diagram showing the flow of participants through the study will be produced. Data will be checked for outliers and missing values and validated using the defined score ranges. Baseline demographics will be summarised by treatment group and for the total population using number (percentage) for categorical variables and mean (standard deviation) for continuous variables (unless they are found to be skewed in which case median and interquartile range will be presented). Statistical tests will not be conducted to compare baseline characteristics by treatment group.

10.5 Primary outcome analysis

Primary analysis of change in HbA1c at 12 months will be conducted using a mixed effects model with a random effect for the group attended, individuals in the control arm will be treated as groups of size 1 [71]. Treatment arm, centre and baseline HbA1C will be included as fixed effects.

The primary analysis will be repeated to include an interaction term between treatment and mode of delivery (F2F or online) to explore any differential treatment effect among groups. The presence of an interaction will be tested using a likelihood ratio test.

10.6 Secondary outcome analysis

The analysis exploring the change in treatment effect over time for the secondary outcomes will follow the methodology of the primary analysis, with an additional random effect for individual to account for within-individual correlation over time, a fixed effect for time and an interaction between treatment and time effect.

Mediation analysis will be conducted using multilevel structural equation modelling [72].

10.7 Subgroup analyses

The pre-specified subgroup analyses of the primary outcome will assess whether the effectiveness of the intervention is dependent on baseline HbA1c or centre. This will be assessed by adding

interaction terms between group allocation and the potential effect modifiers to the linear regression, one at a time.

10.8 Interim analysis and criteria for the premature termination of the trial

An internal feasibility assessment will assess the feasibility of completing the trial within desired timeframes (see Section 7.6). Upon completion of the internal pilot the feasibility of recruitment and engagement will be assessed through the production of an interim CONSORT diagram. A table summarising the number and patterns in session attendance of HEAL-D will be produced for the intervention arm only. No formal interim analyses will be conducted. There are no pre-specified stopping guidelines for the main trial.

10.9 Procedure(s) to account for missing or spurious data

To account for missing data multiple imputation will be undertaken, provided we have strong predictors of missingness and an appropriate imputation model. Diagnostic checks will be performed to assess this. The missing data mechanism will be assumed to be missing at random. Individual analyses on each imputed dataset will be combined using Rubin's rules. Sensitivity analyses will be conducted to assess the robustness of the primary conclusions to the imputation strategy used.

10.10 Economic evaluation analysis

The primary aim of the health economic evaluation will be to assess the within-trial incremental cost-effectiveness of both versions of the HEAL-D programme compared to standard DSMES programmes. This will be undertaken though a cost-utility analysis of the programme with participant outcomes measured in quality-adjusted life years (QALYs) gained. Secondary aims include: 1. whether within-trial cost-effectiveness conclusions are affected by a consideration of long-term cost and QALY outcomes extrapolated from observed clinical end-points within the clinical trial; 2. whether the programme is likely to be cost-effective when delivered at scale in routine practice, accounting for costs of implementation and expected population reach/engagement levels.

Inferences regarding the cost-effectiveness of HEAL-D will be made with reference to the incremental cost-effectiveness ratio (ICER), using varying cost-effectiveness thresholds (inclusive of those adopted by NICE) for identifying whether new health programmes offer the NHS sufficient value for money[63]. The resource and cost implications of HEAL-D will be evaluated from an NHS/Personal social services perspective. All analyses will be undertaken probabilistically to reflect uncertainty in key economic and clinical parameters of relevance.

The short-term costs and benefits of HEAL-D will be quantified using data collected over the period of the trial, including resource inputs allocated to programme delivery and implementation (e.g., training activity), wider service utilisation among trial participants over follow-up (using the self-report AD-SUS), and short-term health-related quality of life outcomes (based on the EQ5D-5L instrument). For secondary analysis long-term resource and QALY impacts will estimated using the UKPDS Outcomes model[64]. The UKPDS is a micro-simulation modelling tool that can be applied to make extrapolations regarding the incidence of complications (micro- and macro-vascular) and associated cost, QoL and survival trajectories.

In further secondary analysis we will draw on data and evidence from the main evaluation of programme cost-effectiveness to assess whether it would be cost-effective to deliver alternative versions of HEAL-D at scale within routine service settings within a defined locality and population (south London). We will utilise existing frameworks and toolkits[65, 66] to estimate the potential costs of implementation at scale and will evaluate the cost-effectiveness of scale-up allowing for implementation costs and population engagement/reach.

10.11 Analysis of the mixed methods process evaluation

10.11.1 Qualitative analysis

Interviews and workshop recordings will be transcribed verbatim by an external company. Information unsuitable for recording will be summarised by researcher' notes. Transcripts will not include any identifying information; individual's names and personal details will not be included in the completed transcripts but will be recorded and stored separately. Similarly, any written notes taken during the interviews will not include any identifiable personal data. NVivo (QSR International) software will be used to manage the qualitative data and to facilitate analysis. Once the data has been uploaded to NVivo, recordings will be destroyed.

Deductive and inductive thematic analysis of interviews, workshops, logs and observations, using QSR NVivo Framework, will be followed by triangulation of qualitative and quantitative data using a meta-matrix[73]. We will examine divergence and similarity across study groups (e.g., online vs. F2F, by centre), and within the triangulated data to develop a comprehensive understanding of intervention delivery and fidelity, recruitment and engagement, mechanisms of impact (i.e., which components of the intervention were perceived to be particularly effective, for which participants, in which contexts). Overall, this will provide an explanatory context for eventual trial findings. Thematic analysis [74] will be undertaken with the interview transcripts, informed by the TDF and the COM-B framework, towards identifying barriers and facilitators for engagement and maintenance of behaviour change[65]. For the thematic analysis, using NVivo software, two researchers will independently double-code 10% of randomly selected transcripts to develop a coding framework. Further transcripts will be double-coded one by one until inter-rater reliability is such that the framework is agreed. Remaining transcripts will then be single-coded (i.e., by one of the two researchers). Themes will be developed through discussion with the wider team. To indicate the frequency with which themes occur, we will use "all" (100%), "almost all" (>85%), "most" (>75%), "the majority" (>50%), "some" (>10%), and "a few" (>=10%). We will use the Consolidated Criteria for Reporting Qualitative Research tool [75].

10.11.2 Quantitative analysis

Data from questionnaires, data logs and the structured observation tool will be analysed using descriptive statistics. Number (percentage) will be used for categorical variables and mean (standard deviation) for normally distributed continuous variables Skewed will be reported using medians and interquartile ranges.

11. DATA MANAGEMENT

11.1 Data collection and management

Case Report Forms (CRF) will be completed for each participant enrolled into the trial. The CRFs will be the primary data collection instrument for the trial. All data requested on the CRF must be recorded, any missing data will be explained. If a space on the CRF is left blank because the procedure was not completed or the question was not asked, "N/C" will be written. If the item is not applicable to the individual case, "N/A" will be recorded. All entries will be printed legibly in black ink. If any entry error is made, it will be corrected by drawing a single straight line through the incorrect entry and the correct data will be entered above it. All such changes will be initialled and dated.

All hard and electronic copies of data collected in this study will be identified by a unique pseudonymised study identification code. The link between the participant and their study ID number will be retained by the host NHS organisation in a secure office environment and with access restricted to members of the research team. All electronic data will be password protected and accessible only by delegated members of the research team during the active phase of the study and until the data have been analysed. Paper copies such as CRFs will be stored in a locked cabinet.

All research data, whether online or paper-based, will be transcribed onto the research database by a delegated member of the research team. All study documentation containing identifiable participant data will be managed in accordance with ICH-GCP, UK Policy Framework for Health and Social Care

Research and the most up-to-date version of the Data Protection Act 2018 and General Data Protection Regulation (GDPR).

If a participant wishes to withdraw, they will be documented as a withdrawal and their personal identifiable data will be archived, unless they have consented to be contacted about future research.

For the qualitative interviews within the process evaluation, ongoing consent to continue will be confirmed verbally and audio recorded prior to the start of the interview. Audio recordings will be labelled with a study identifier and will be destroyed after analysis. Transcripts will be anonymised and securely stored six years post-study duration.

Study data will be archived in line with University of Leicester (UoL) policy; currently six years post-study duration.

11.2 Trial database

The trial data will be captured electronically in a bespoke REDcap database system. The system will be designed and developed by the PCTU in accordance with its SOPs for data collection and management. The database will undergo validation and user acceptance testing prior to its deployment for trial data. The database will be hosted on a secure server within Queen Mary University London, with validated procedures in place to ensure data security, backup and disaster recovery. Access to the database will be by password-protected user accounts to prevent unauthorised access, and the database will be encrypted at rest.

Electronic storage of the database is on a restricted area of a file server. The server is in a secure location and access is restricted to a few named individuals. Access to the building in which the QMUL server is situated is via an electronic tag and individual rooms are kept locked when unoccupied.

All study data will be entered into the database by appropriately trained staff with restricted access. The workstations access the network via a login name and password (changed regularly). No data are stored on individual workstations.

A data management plan will be agreed which will cover all aspects of managing the data such as, data entry, data checking, query management and cleaning, data transfer, quality control procedures, data extractions, database freeze and lock.

Index lists with study ID codes and names will be held separately from the trial data.

For the process evaluation the recordings will be uploaded to the transcription company's secure site and will be deleted after transcription. Confidentiality of the transcribers is ensured under their terms of employment with the transcription company. Digital recordings of interviews/focus groups will be stored securely and held separately from transcripts and information of participants' identities. All focus group participants will be asked to treat the discussion as strictly confidential. In reporting the results of the process evaluation, care will be taken to use quotations which do not reveal the identity of respondents.

The CI will have overall responsibility for the data stored within the database. The CI will ensure that this information is kept confidential. All documents will be stored securely and kept in strict confidence in compliance with the GDPR and Data Protection Act 2018. Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

11.3 Access to Data

Participating sites' source data, study documents, and participant notes will be made available for monitoring, auditing and inspections by the appropriate regulatory authorities, the Sponsor, and NHS host organisation.

All study documentation will be retained in a secure location during the conduct of the study. Personal identifiable data will be retained following the end of the study, for the following purposes:

- their contact details (name, email and telephone number) being kept to invite them to dissemination events and/or participation in future research.
- NHS number being kept to link their research data to routine health data.

In these circumstances, personal identifiable details such as name, contact details and NHS number will be stored at individual sites in password protected spreadsheets, then uploaded by secure file transfer processes to the PCTU BCC Safehaven. Following completion of the study, the data will be transferred by secure file transfer processes to UoL and stored in a password protected spreadsheet, on a secure server for up to 6 years, and then destroyed. All electronic data will be stored on secure network systems, to which only the relevant study personnel will have access. For the purposes of this study, the UoL will act as the Data Controller for data for both the trial, SWAP and process evaluation. NVivo (used to manage the qualitative interviews) is encrypted and only the account owner has access to and control over the data.

11.4 Archiving

Archiving of the study data analysis, data and essential study records will be authorised by the Sponsor following submission of the end of trial report. Personal identifiable data generated by the study will be retained for 3 years before being destroyed. Documents will be archived in a secure location for a minimum of six years after the completion of the study, in accordance with UoL SOPs. The data will be archived locally in accordance with participating Trust SOPs and/or in the Sponsor archiving facility. No study-related records, including hospital medical notes, will be destroyed unless or until the Sponsor gives authorisation to do so.

12. MONITORING, AUDIT & INSPECTION

The UoL, as Sponsor, operates a risk-based monitoring and audit programme, to which this study will be subject. In addition, the PCTU conduct their own risk assessments and audits of TMFs for studies they support.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Ethics Committee (REC) review & reports

Once the initial sponsor review process is complete and a sponsor reference number has been allocated, and all requested documentation has been received and checked authorisation from the UoL's Research Governance Office will be issued to book further review of the proposed research. The protocol, informed consent form, PIS, interview topic guides, questionnaires and any proposed advertising material will be submitted to an appropriate REC and HRA for written approval. Agreement in principle is subject to the research receiving all relevant regulatory permissions. Submission for regulatory approvals will be submitted via Integrated Research Application System (IRAS). The CI will ensure that all regulatory approvals, confirmation of capacity and capability from NHS sites and sponsor greenlight are in place before participants are approached. The Research Governance Office's SOPs will be followed for the duration of the trial. A trial master file will be maintained for the duration of the study and will be stored for 6 years after the study has ended. All correspondence with the REC will be retained in the Trial Master File/Investigator Site File.

Amendments will be submitted to the sponsor in the first instance for review and approval. The CI, in agreement with the sponsor, will then submit information to the appropriate body for them to issue approval for the amendment. Amendments will be implemented upon receiving Sponsor Green Light or in accordance with the Sponsor Amendment SOP.

An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended

prematurely, the CI will notify the REC, including the reasons for the premature termination. Otherwise, the CI (or delegate) will notify the REC of the end of the study. Within one year after the end of the study, the CI (or delegate) will submit a final report with the results, including any publications/abstracts, to the REC.

This study will be conducted according in full conformity with the current revision of the Declaration of Helsinki (last amended October 2000, with additional footnotes added 2002 and 2004) and the UK Policy Framework for Health and Social Care Research (2017). It will also be conducted according to ICH-GCP relevant regulations.

14. PEER REVIEW

This protocol has been peer-reviewed by two individual experts external to the investigators institution who are not involved in the trial in any way. Each have relevant knowledge relating to the management of T2D and the necessary expertise to assess the methodological (quantitative and qualitative) and statistical aspects of the trial. Prior to submission the protocol has also undergone internal review within the Leicester Diabetes Research Centre, and the trial sponsor (the UoL). Appropriate ammendments have been made in response to all reviews.

15. PUBLIC AND PATIENT INVOLVEMENT

PPI/E Representative(s) for HEAL-D have shared their experiences of living with T2D and have been actively involved in preparing the funding application for this study, pre-award. Their input is integral to the entirety of the research. They have been involved during the development of this protocol, have shaped the methods used to recruit participants and gather data, with the aim of enhancing uptake and retention. PPI/E members and the public have also supported the ethical application process, including reviewing all participant facing documentation, lay summaries and shaping the dissemination strategy outlined below (Section 23).

In line with our PPI/E strategy during the pre-funding and protocol phases, we have used strategies to successfully engage with seldom heard, under-represented groups with T2D. This includes the involvement of two PPI/E co-applicants who will attend community-based activities (events, festivals etc.), to establish and maintain partnerships, and overcome barriers to engagement based on perspectives of research. They will facilitate initial recruitment to PPI/E and research activities, and support retention by maintaining contact throughout each individual's involvement.

The study PPI/E co-investigators will meet regularly during the trial and contribute to decision-making throughout. They may attend TMG meetings where required but will otherwise contribute ahead of these meetings and receive feedback after. Relevant training will be provided as required or desired.

For all activities, we will ensure a pragmatic approach to scheduling is adopted which caters for the complex lives and/or working patterns of individuals with T2D. This may include facilitation of childcare where appropriate. Different methods of contact (face-to-face, digital etc.) will be used according to preference. Members will be recognised for their time and expertise, and reimbursed in accordance with NIHR guidance.

16. REGULATORY COMPLIANCE

The trial will not commence until all relevant regulatory approvals, Confirmation of Capacity and Capability and Sponsor Green Light are in place. Before any site can enrol participants into the study, the CI/PI or designee will ensure that appropriate approvals from participating organisations are in place.

17. PROTOCOL COMPLIANCE

A protocol deviation is defined as any un-intended change or departure from the protocol which does not result in harm to the study participants or significantly affect the scientific value of the study. Minor deviations can occur frequently during the trial. Visit window deviations or difficulty obtaining samples at specified times will be considered minor deviations as they do not have the potential to cause harm to the participant or impact the integrity of the trial.

Major deviations are events that cause or could cause harm to participants or others or that affect the fidelity of the research. Where deviations frequently reoccur, this may meet the criteria for a Serious Breach of GCP and will be reported in line with Sponsor SOPs. For the purposes of this regulation, a 'serious breach' is a breach which is likely to affect to a significant degree:

- the safety or physical or mental integrity of the participants of the study; or
- the scientific value of the study

Prospective, planned deviations or waivers to the protocol will not be allowed. Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the CI and Sponsor immediately. The study team will monitor and review protocol compliance. If a protocol breach occurs, then the PI for each site will document this in adherence to the UoL's SOP Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol for Trials. The PI will seek advice from the CI and the sponsor as required.

18. DATA PROTECTION AND PATIENT CONFIDENTIALITY

The CI will have access to the trial documentation and will be the data custodian. Participants' personal data included in study-related databases shall be treated in confidence and in compliance with ICH-GCP, the UK Policy Framework for Health and Social Care and the UK GDPR. When processing or archiving personal data, the Sponsor or its representative shall take all appropriate measures to safeguard and prevent access to this data by any unauthorised third party. All investigators and trial site staff will comply with the requirements of the Data Protection Act/GDPR with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. They will also keep up to date with organisational training in relation to information governance.

Each participant will be assigned a unique identification number upon recruitment. The database will be password protected and only researchers collecting data will have access to this database. All personalised information for participants will be kept confidentially at the recruiting site unless there is specific consent and approval for transfer of this to another site for study-related purposes.

All electronic participant identifiable information will be held on a secure, password-protected database accessible only to essential personnel. Paper documentation will be stored in a locked filing cabinet in the relevant research office. Neither hard copies nor electronic files containing personal information will be removed from the research office or stored in a non-secure manner electronically. The study research team will comply with the Data Protection Policy of the collaborating Universities and local NHS Trusts. Direct access to source data / documents will be required for study-related monitoring. All paper and electronic data will be retained for at least 6 years after completion of the study. Long-term storing will comply with the UoL archiving SOP.

Biological samples taken for the study will be destroyed once analysed in accordance with the Human Tissue Act 2004.

19. FINANCIAL

The HEAL-D centre agreement will set out centre level costs approved in the funding application. Centre agreements will be agreed for all centres and as such will be documented through this process. Note that centre agreements, once agreed will provide details of the funds available for each centre and any associated performance related requirements. In addition, the approved SoECAT provides details costs.

20. INDEMNITY

Sponsorship and insurance for trial design and management will be provided by the University of Leicester.

If a participant is harmed due to negligence, this will be covered by the local NHS Trust(s) indemnity arrangements for all participants in clinical trials. If a study participant wishes to make a complaint about any aspects of the way they have been treated or approached during the research project, the standard National Health Service complaint system will be available to them. Details of this are made available to participants the PIS.

21. POST TRIAL CARE

Provisions will be put in place for post-trial access for all participants who still need an intervention identified as individually beneficial in the trial. This information will be disclosed to participants during the informed consent process. For participants requiring ongoing care the following actions will be taken

- physical activity: participants will be referred on to local services and physical activity providers which meet their needs and interests.
- psychosocial care: Any participant requiring ongoing psychosocial support will be referred to their primary care provider to help them to access appropriate local services and support.

22. ACCESS TO THE FINAL TRIAL DATASET

The CI will have access to the full dataset. Direct access will be granted to authorised representatives from the Sponsor and host institutions for monitoring and/or audit of the study to ensure compliance with regulations. Site investigators may access the full dataset if a formal request describing their plans is approved by the steering group.

23. DISSEMINATION POLICY

We have developed a comprehensive dissemination plan to enable us to communicate our research progress throughout the project, working in conjunction with our PPI members. Our plan ensures we raise expert and public awareness of the intervention and the planned programme of implementation, if proven effective, to local, national and international audiences. As agreed with our PPI co-applicants, a PPIE community engagement plan will be developed with our PPIE group with plans for engagement and dissemination activities using a combination of platforms such as social media/website, radio, and written information via newspapers relevant to BABC communities, to ensure communication about the study reaches them. We will form a stakeholder group, consisting of representatives from key organisations and sectors, particularly community organisations that work with BABC communities e.g. Caribbean and African Health Network (CAHN; Greater Manchester), West Bromwich African Caribbean Resource Centre in the West Midlands, Black, Asian minority ethnic Research Advisory Group (BRAG) and Diabetes Africa; progress and findings will be shared with the stakeholder group at biannual meetings and opportunities for wider dissemination will be identified. Representation from Diabetes UK, the main UK charity for T2D, will enable us to disseminate to healthcare professionals, researchers, BABC people living with T2D and their carers. We will directly inform commissioners of diabetes education services and ICBs, who commission T2D services to extend commissioning beyond London. We will work closely with our local AHSNs and ARCs; these have been instrumental in the dissemination of HEAL-D thus far in south London; we will build on these existing relations and in our partner centres to enable us to disseminate our work to decision-makers such as NHS England and Office for Health Improvement and Disparities. Our study website will continuously disseminate progress and results to our participants through a participant-specific WhatsApp platform and through using creative methods such as public contributor blogs, videos, infographics (designed in partnership with our PPI group) and links to radio interviews with public contributors and to the general public, healthcare professionals and commissioners. We will use our extensive professional networks/connections and social media to

engage with local/national media, local/national community groups, professional bodies (e.g., Royal College of General Practitioners, British Dietetic Association, Royal College of Nursing), charities (e.g., Diabetes UK) and NHSE/NIHR infrastructure.

On completion of the trial, the data (including the main trial, health economic analyses, process evaluation and SWAP) will be analysed and tabulated and a final trial report prepared. The CI will be responsible for ensuring the results of the trial are disseminated through peer review journals, conference presentations and other local mechanisms at all participating centres irrespective of the outcome. Authorship will be determined by the CI according to contribution to the trial and the guidelines of leading medical journals. All publications will quote the clinical trials registration number and will acknowledge the participating investigators, TSC, the Sponsor and the NIHR. Guidance provided by the NIHR in relation to dissemination and publication will be adhered to. Relevant CONSORT statement(s) and checklists will be reviewed prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals.

The main output from the proposed study will be robust evidence of the clinical effectiveness of the HEAL-D intervention. The results will be of relevance and interest to patients and the public, primary/secondary healthcare organisations, public health bodies and local authorities, applied healthcare audiences and the academic community. Dissemination will be supported by staff funded by the programme, local, national, and international infrastructure (including NIHR Leicester Biomedical Research Centre (BRC), Applied Research Collaborative (ARC) East Midlands, the Centre for BME Health, and Leicester Changing Diabetes) and NIHR dissemination support structures (including NIHR INVOLVE). Communications from the lead site will be supported by the communications leads for Leicester Hospitals and the local NIHR Regional network, and their research partnerships.

In addition, results will be disseminated to all groups via diverse means. All participants will receive a written report regarding the results of the trial. Ongoing review and revision of our dissemination strategy will be undertaken throughout the programme, in partnership with PPI/E partners, to maximise impact and ensure relevance and accessibility to a wide range of groups.

We aim to publish the full results in a high impact medical journal and conferences, with the intention of reaching a global audience. The outcome of this multi-centre RCT has the capacity to change UK and global practice and may be implemented in other English-speaking countries with minimal adaptation. Through the expertise and standing of all the (co-)applicants, we anticipate that the findings of this study will be incorporated into national and international guidelines.

NIHR must be notified prior to any publication (whether in oral, written or other form). A draft copy of any proposed publication must be sent to NIHR at the same time as submission for publication or at least 28 days before the date intended for publication, whichever is earlier. All publications must acknowledge NIHR financial support and include a disclaimer as directed by NIHR. In the absence of specific direction, disclaimers should read: "This study/project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (NIHR-151372). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care." The following statement should also be included: "This work uses data provided by patients and collected by the NHS as part of their care and support and would not have been possible without access to these data". On publication, the first author or LG must ensure communication with NIHR as outlined below.

For publications, a full dissemination plan will be drawn up outlining:

- publishing rights for participating investigators.
- time limits and review requirements for publication.
- participant access to trial data.

- public access to an anonymised participant level dataset, and statistical code for generating the results will be drawn up in collaboration with all participating centres.

The following table outlines some, but not all, of the publications which are anticipated to arise from the trial:

List of anticipated publications for HEAL-D Trial

Publication		Publication type	Publication outline
1	Trial protocol (incl. statistical analysis plan)	Full manuscript	Protocol for HEAL-D trial, including clinical and cost effectiveness, internal pilot, process evaluation, and multiple long-term conditions study within a project.
2	Clinical effectiveness (primary & secondary outcomes)	Full manuscript	Effectiveness of HEAL-D versus standard DSMES programme on primary and secondary outcomes at 12 months follow-up.
3	2-year outcome	Full manuscript	Effectiveness of HEAL-D versus standard DSMES programme on secondary outcomes at 24 months follow-up, and time course effects.
4	Cost-effectiveness	Full manuscript	Health economic evaluation assessing the incremental cost-effectiveness of the HEAL-D programme compared to standard DSMES, and the cost-effectiveness of delivering the programme at scale, accounting for assumptions regarding the value of additional parameters of relevance.
5	Process evaluation	Full manuscript	Evaluation of intervention delivery, fidelity and implementation, examining views on and experiences of the intervention among participants, those delivering the intervention and other stakeholders; how the intervention is implemented; contextual factors across centres affecting the intervention; and subgroup effects.
6	Multiple Long-Term Conditions (MLTC) Study	Full manuscript	Assessing the impact of MLTC on the uptake of and engagement with HEAL-D and the impact of the intervention on the MLTC.
7	Approaches for maximising trial participation among underserved communities living with type 2 diabetes	Conference abstract	Description of PPIE work, main findings of how to tailor trial recruitment and retention processes to maximise engagement.
8	Recruitment & attendance data	Conference abstract	Recruitment, randomisation and participant flow data.
9	Face-to-face versus online DSMES attendance	Conference abstract	Data on participant choice and reasons for choice of face-to-face versus online attendance.
10	6-month outcomes – clinical measures	Conference abstract	Retention data and effectiveness of HEAL-D versus standard DSMES programme on clinical outcomes (e.g. HbA1c, blood pressure, lipids, weight, waist) at 6 months follow-up.

11	6-month outcomes – patient reported measures	Conference abstract	Retention data and effectiveness of HEAL-D versus standard DSMES programme on patient reported outcomes (e.g. quality of life, diabetes knowledge, well-being, self-efficacy) at 6 months follow-up.
12	Process evaluation	Conference abstract	COM-B analysis – mechanisms of impact.

24. TRIAL STEERING COMMITTEE

A trial steering committee (TSC) will be formed and take responsibility for the overall oversight of the trial. The TSC will comprise of an independent chair, at least 3 other independent expert members including an independent statistician, a lay person, the Chief Investigator and the principal investigators from the participating centres. The trial statistician and key co-investigators may attend as needed. The TSC terms of reference and roles and responsibilities will align with NIHR policy:

- To meet prior to study commencement to agree roles and responsibilities and review the protocol.
- To meet at least annually, with a minimum of two of the four independent members present at each meeting.
- To identify and agree milestones, and to monitor and supervise the progress of the trial against these milestones.
- To consider and advise on the implications for the trial of any new evidence from both within the trial and other sources, or of any proposed changes to the trial.
- To provide independent advice to the investigators, the NIHR HTA Programme, the research sponsor, the host institution, and the contractor on appropriate aspects of the trial.
- To report to the NIHR HTA Programme following meetings through annual progress reports to be signed off/approved by the independent Chair and in addition (if necessary) by direct communication from the independent Chair, bringing serious concerns or disagreements to the urgent attention to the HTA Programme, and to other parties as appropriate.

TSC meetings will be held annually, organised by the trial manager or delegate. TSC meetings will be minuted and disseminated to all attendees and the trial sponsor.

25. TRIAL MANAGEMENT GROUP

A trial management group (TMG) consisting of the CI, site leads, core delivery staff (including trial statistician) and other co-investigators and collaborators where required will meet regularly (approximately bimonthly or more regularly as required) to oversee and coordinate delivery of the trial.

26. REFERENCES

1. Public Health England, *Diabetes Prevalence Model*. 2016.
2. Einarson, T.R., et al., *Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017.* Cardiovasc Diabetol, 2018. **17**(1): p. 83.
3. Harding, J.L., et al., *Global trends in diabetes complications: a review of current evidence.* Diabetologia, 2019. **62**(1): p. 3-16.
4. Global Burden of Metabolic Risk Factors for Chronic Diseases, C., *Cardiovascular disease, chronic kidney disease, and diabetes mortality burden of cardiometabolic risk factors from 1980 to 2010: a comparative risk assessment.* Lancet Diabetes Endocrinol, 2014. **2**(8): p. 634-47.
5. Gedebjerg, A., et al., *Prevalence of micro- and macrovascular diabetes complications at time of type 2 diabetes diagnosis and associated clinical characteristics: A cross-sectional baseline study of 6958 patients in the Danish DD2 cohort.* J Diabetes Complications, 2018. **32**(1): p. 34-40.
6. Kosiborod, M., et al., *Vascular complications in patients with type 2 diabetes: prevalence and associated factors in 38 countries (the DISCOVER study program).* Cardiovasc Diabetol, 2018. **17**(1): p. 150.
7. UKPDS Group, *Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33).* Lancet, 1998. **352**(September 12): p. 17.
8. Cochran, J. and V.S. Conn, *Meta-analysis of quality of life outcomes following diabetes self-management training.* Diabetes Educ, 2008. **34**(5): p. 815-23.

9. Roy, T. and C.E. Lloyd, *Epidemiology of depression and diabetes: a systematic review.* J Affect Disord, 2012. **142 Suppl**: p. S8-21.
10. Kilbourne, A.M., et al., *How does depression influence diabetes medication adherence in older patients?* Am J Geriatr Psychiatry, 2005. **13**(3): p. 202-10.
11. Hex, N., et al., *Estimating the current and future costs of Type 1 and Type 2 diabetes in the United Kingdom, including direct health costs and indirect societal and productivity costs*. 2012, York Health Economics Consortium Ltd: University of York, United Kingdom.
12. Becker, E., et al., *Health Survey for England 2004. The health of minority ethnic groups*, K. Sproston and J. Mindell, Editors. 2006, Joint Health Surveys Unit, National Centre for Social Research, Department of Epidemiology and Public Health at the Royal Free and University College Medical School: London.
13. Paul, S.K., et al., *Comparison of body mass index at diagnosis of diabetes in a multi-ethnic population: A case-control study with matched non-diabetic controls.* Diabetes Obes Metab, 2017. **19**(7): p. 1014-1023.
14. Lanting, L.C., et al., *Ethnic differences in mortality, end-stage complications, and quality of care among diabetic patients: a review.* Diabetes Care, 2005. **28**(9): p. 2280-8.
15. James, G.D., et al., *Type 2 diabetes: a cohort study of treatment, ethnic and social group influences on glycated haemoglobin.* BMJ Open, 2012. **2**(5).
16. Cunningham, A.T., et al., *The effect of diabetes self-management education on HbA1c and quality of life in African-Americans: a systematic review and meta-analysis.* BMC Health Serv Res, 2018. **18**(1): p. 367.
17. Wilson, C., et al., *Patient access to healthcare services and optimisation of self-management for ethnic minority populations living with diabetes: a systematic review.* Health Soc Care Community, 2012. **20**(1): p. 1-19.
18. Lakhani, M., *No patient left behind: how can we ensure world class primary care for black and minority ethnic people?* 2008, Department of Health: London.
19. National Institute for Health and Care Excellence, *Diabetes in adults*. 2016.
20. National Institute for Health and Care Excellence, *Diabetes - type 2: QOF indicators*. 2021.
21. Department of Health, *National Service Framework for Diabetes: Standards*. 2001.
22. National Health Service (NHS) England. *Enhancing the quality of life for people living with long term conditions – The House of Care.* . [cited 2021 19/09/2021]; Available from: https://www.england.nhs.uk/ourwork/clinical-policy/ltc/house-of-care/.
23. Deakin, T., et al., *Group based training for self-management strategies in people with type 2 diabetes mellitus.* Cochrane Database Syst Rev, 2005(2): p. CD003417.
24. Odgers-Jewell, K., et al., *Effectiveness of group-based self-management education for individuals with Type 2 diabetes: a systematic review with meta-analyses and meta-regression.* Diabet Med, 2017. **34**(8): p. 1027-1039.
25. Pillay, J., et al., *Behavioral Programs for Type 2 Diabetes Mellitus: A Systematic Review and Network Meta-analysis.* Ann Intern Med, 2015. **163**(11): p. 848-60.
26. He, X., et al., *Diabetes self-management education reduces risk of all-cause mortality in type 2 diabetes patients: a systematic review and meta-analysis.* Endocrine, 2017. **55**(3): p. 712-731.
27. Chatterjee, S., et al., *Diabetes structured self-management education programmes: a narrative review and current innovations.* Lancet Diabetes Endocrinol, 2018. **6**(2): p. 130-142.
28. Coonrod, B.A., J. Betschart, and M.I. Harris, *Frequency and determinants of diabetes patient education among adults in the U.S. population.* Diabetes Care, 1994. **17**(8): p. 852-8.
29. Wierenga, M.E. and K.L. Wuerthrich, *Diabetes program attrition: differences between two cultural groups.* Health Val, 1995. **19**: p. 9.
30. Brown, K., M. Avis, and M. Hubbard, *Health beliefs of African-Caribbean people with type 2 diabetes: a qualitative study.* Br J Gen Pract, 2007. **57**(539): p. 461-9.
31. Stone, M., et al., *Making education in diabetes culturally appropriate for patients.* Practice Nursing, 2006. **17**(12): p. 5.
32. Attridge, M., et al., *Culturally appropriate health education for people in ethnic minority groups with type 2 diabetes mellitus.* Cochrane Database Syst Rev, 2014(9): p. CD006424.
33. Cross, T., et al., *Towards a culturally competent system of care*. Vol. 1. 1989, Washington D.C.: Georgetown University Child Development Center, CASSP Technical Assistance Center.
34. Liu, J.J., et al., *Adapting health promotion interventions to meet the needs of ethnic minority groups: mixed-methods evidence synthesis.* Health Technol Assess, 2012. **16**(44).

35. Wadi, N.M., et al., *Culturally tailored lifestyle interventions for the prevention and management of type 2 diabetes in adults of Black African ancestry: a systematic review of tailoring methods and their effectiveness.* Public Health Nutr, 2021: p. 1-15.
36. Davies, M.J., et al., *Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial.* BMJ, 2008. **336**(7642): p. 491-5.
37. Deakin, T.A., et al., *Structured patient education: the diabetes X-PERT Programme makes a difference.* Diabet Med, 2006. **23**(9): p. 944-54.
38. Murray, E., et al., *Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care.* BMJ Open, 2017. **7**(9): p. e016009.
39. Hadjiconstantinou, M., et al., *A perspective piece on Diabetes Self-Management Education and Support (DSMES) programmes for under-represented groups with T2DM in the UK.* British Journal of Diabetes, 2021. **21**(1): p. 3-10.
40. Moore, A.P., et al., *Designing the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) self-management and support programme for UK African and Caribbean communities: a culturally tailored, complex intervention under-pinned by behaviour change theory.* BMC Public Health, 2019. **19**(1): p. 1146.
41. Goff, L.M., et al., *Development of Healthy Eating and Active Lifestyles for Diabetes (HEAL-D), a culturally-tailored diabetes self-management education and support programme for black-British adults: a participatory research approach.* Diabet Med, 2021: p. e14594.
42. James Lind Alliance, *James Lind Alliance Priority Setting Partnership - Type 2 diabetes*. 2017.
43. UK Public General Act, *Health and Social Care Act*. 2012.
44. NHS England. *Core20PLUS5 - An approach to reducing health inequalities*. 2022 [cited 2022 19 April]; Available from: https://www.england.nhs.uk/about/equality/equality-hub/core20plus5/.
45. NHS England, *The NHS Long Term Plan*. 2019.
46. Office for National Statistics, *2011 Census analysis: Ethnicity and religion of the non-UK born population in England and Wales: 2011*. 2015.
47. Institute of Health Equity, *Fair Society, Healthy Lives: The Marmot Review*. 2010: London.
48. Public Health England, *Disparities in the risk and outcomes of COVID-19*. 2020, Public Health England.
49. World Health Organisation, *WHO Guideline: recommendations on digital interventions for health system strengthening*. 2019.
50. Hedman, E., *Therapist guided internet delivered cognitive behavioural therapy.* BMJ, 2014. **348**: p. g1977.
51. Quinn, L.M., M.J. Davies, and M. Hadjiconstantinou, *Virtual Consultations and the Role of Technology During the COVID-19 Pandemic for People With Type 2 Diabetes: The UK Perspective.* J Med Internet Res, 2020. **22**(8): p. e21609.
52. Woolley, A.K., et al., *Online patient education interventions in type 2 diabetes or cardiovascular disease: A systematic review of systematic reviews.* Prim Care Diabetes, 2019. **13**(1): p. 16-27.
53. Carter, E.L., G. Nunlee-Bland, and C. Callender, *A patient-centric, provider-assisted diabetes telehealth self-management intervention for urban minorities.* Perspect Health Inf Manag, 2011. **8**: p. 1b.
54. Loveman, E., G.K. Frampton, and A.J. Clegg, *The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review.* Health Technol Assess, 2008. **12**(9): p. 1-116, iii.
55. Hirsch, J.D. and C.M. Morello, *Economic impact of and treatment options for type 2 diabetes.* Am J Manag Care, 2017. **23**(13 Suppl): p. S231-S240.
56. Association, A.D., *6. Glycemic targets: standards of medical care in diabetes—2019.* Diabetes care, 2019. **42**(Supplement_1): p. S61-S70.
57. Harman, N.L., et al., *Selecting Core Outcomes for Randomised Effectiveness trials In Type 2 diabetes (SCORE-IT): a patient and healthcare professional consensus on a core outcome set for type 2 diabetes.* BMJ Open Diabetes Research and Care, 2019. **7**(1): p. e000700.
58. Dyson, P.A., et al., *Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes.* Diabet Med, 2011. **28**(11): p. 1282-8.
59. Michie, S., M.M. van Stralen, and R. West, *The behaviour change wheel: a new method for characterising and designing behaviour change interventions.* Implement Sci, 2011. **6**: p. 42.
60. Quandt, S.A., et al., *Assessment of a short diabetes knowledge instrument for older and minority adults.* Diabetes Educ, 2014. **40**(1): p. 68-76.
61. Samuel-Hodge, C.D., et al., *Reliability and validity of a measure of perceived diabetes and dietary competence in African American women with type 2 diabetes.* Diabetes Educ, 2002. **28**(6): p. 979-88.

62. Crawford, M.J., et al., *Lamotrigine for people with borderline personality disorder: a RCT.* Health Technol Assess, 2018. **22**(17): p. 1-68.
63. National Institute for Health and Care Excellence, *NICE health technology evaluations: the manual*. 2022.
64. Hayes, A.J., et al., *UKPDS outcomes model 2: a new version of a model to simulate lifetime health outcomes of patients with type 2 diabetes mellitus using data from the 30 year United Kingdom Prospective Diabetes Study: UKPDS 82.* Diabetologia, 2013. **56**(9): p. 1925-33.
65. Cidav, Z., et al., *A pragmatic method for costing implementation strategies using time-driven activity-based costing.* Implement Sci, 2020. **15**(1): p. 28.
66. Sohn, H., et al., *Costing the implementation of public health interventions in resource-limited settings: a conceptual framework.* Implement Sci, 2020. **15**(1): p. 86.
67. Sekhon, M., M. Cartwright, and J.J. Francis, *Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework.* BMC Health Serv Res, 2017. **17**(1): p. 88.
68. Guthrie, B., et al., *Adapting clinical guidelines to take account of multimorbidity.* BMJ, 2012. **345**: p. e6341.
69. Bisquera, A., et al., *Identifying longitudinal clusters of multimorbidity in an urban setting: A population-based cross-sectional study.* Lancet Reg Health Eur, 2021. **3**: p. 100047.
70. Eldridge, S.M. and S. Kerry, *A practical guide to cluster randomised trials in health services research*. 2012: John Wiley & Sons Ltd.
71. Flight, L., et al., *Recommendations for the analysis of individually randomised controlled trials with clustering in one arm - a case of continuous outcomes.* BMC Med Res Methodol, 2016. **16**(1): p. 165.
72. Preacher, K.J., M.J. Zyphur, and Z. Zhang, *A general multilevel SEM framework for assessing multilevel mediation.* Psychol Methods, 2010. **15**(3): p. 209-33.
73. Wendler, M.C., *Triangulation using a meta-matrix.* J Adv Nurs, 2001. **35**(4): p. 521-5.
74. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qual Res Psychol, 2006. **3**(2): p. 24.
75. Tong, A., P. Sainsbury, and J. Craig, *Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.* Int J Qual Health Care, 2007. **19**(6): p. 349-57.

Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
NSA02	1.1	09/05/2024	Dru Johnson	The trial registration has been provided on page 1. The duration of accelerometery was corrected on page 21, from 7 to 10 days, matching the details in section 7.9.2.6 and the schedule of procedures. It was incorrectly stated in section 7.9.2.3 that the mean of 3 waist circumference measurements would be reported. Only one measurement will be taken, so this has been corrected. Self-reported sleep duration and chronotype were listed under 'Demographic and medical history' in the schedule of procedures, rather than under 'outcome questionnaires', which has been corrected (page 28). Self-reported sleep duration and chronotype had been mistakenly omitted from the list of exploratory endpoints in section 3.3.3 (page 21), table of endpoints/outcomes 3.4 (page 23), section 7.9.2.6 (page 41), and

				the trial assessment schedule (page 46). This has been corrected, so that self-reported sleep duration and chronotype are now listed in these sections as well as the schedule of procedures. Following a minor amendment to the study protocol whereby accelerometery will no longer be conducted at the 6-month and 2-year participant visits, the protocol has been updated to reflect this, in the schedule of procedures (page 27), trial flow chart, and Trial assessment schedule (page 45). A relevant sentence stating this change has also been added in section 7.9.1 (page 38). The accelerometers used will provide both sleep and physical activity outcomes, as indicated in section 7.9.2.6. However, only the physical activity accelerometery measurement had been included in the trial assessment schedule on page 45, whereas sleep measurement had been mistakenly omitted. This has been corrected and the relevant measurement added to this table. A reference that was mistakenly omitted has been added for a citation on pages 50 and 62 (NICE, 2020). It had previously been determined by the trial lead health economist that a sub-group analysis based on multiple long-term conditions would not be performed due to a lack of statistical power. However, this had not been reflected in the trial protocol. Therefore, details of this analysis have been deleted from sections 7.11 (page 50) and 10.10 (page 62).

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee/HRA.