


# BMJ Open Mixed-methods implementation study of a virtual culturally tailored diabetes self-management programme for African and Caribbean communities (HEAL-D) in south London and its scaling up across NHS regions in England: study protocol

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## ABSTRACT

**Introduction** The National Health Service Insight Prioritisation Programme was established to accelerate the implementation and evaluation of innovation that supports post-pandemic working. Supporting this, the Academic Health Science Network and National Institute for Health and Care Research Applied Research Collaboration in South London are testing and evaluating the implementation and scale-up of a type 2 diabetes (T2D) intervention. T2D is estimated to be three times more prevalent in UK African and Caribbean communities than in white Europeans. To tackle ethnic inequities in T2D healthcare access, an evidence-based, culturally tailored self-management and education programme for African and Caribbean adults (Healthy Eating & Active Lifestyles for Diabetes, HEAL-D) has been codeveloped with people with lived experience. Initially a face-to-face programme, HEAL-D pivoted to virtual delivery in response to COVID-19. The purpose of this study is to explore the (1) feasibility and acceptability of a virtual delivery model for HEAL-D in south London and (2) factors affecting its scale-up across other areas in England.

**Methods and analysis** The study will have two strands: (1) mixed-methods prospective evaluation of HEAL-D virtual delivery in south London using routinely collected service-level data, service delivery staff and service user interviews and observations; and (2) prospective qualitative study of the scale-up of this virtual delivery comprising interviews and focus groups with members of the public, and diabetes services commissioners and providers across England. Qualitative data will be analysed using thematic analysis. Quantitative analysis will use descriptive statistics and reporting summary tables and figures. The study will be grounded in well-established implementation frameworks and service user involvement.

**Ethics and dissemination** ‘Minimal Risk Registration’ ethical clearance was granted by King’s College London’s Research Ethics Office (ref: MRA-21/22-28498). Results

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study design will enable the rapid gathering of insights and identification of practical barriers and enablers to implementation, while delivering maximum benefit to service users.
- ⇒ A key strength is the codesign and delivery of the study, which brings together a collaboration between the Health Innovation Network and Applied Research Collaboration South London, in partnership with people from African and Caribbean communities with a lived experience of diabetes.
- ⇒ A limitation of the approach is the absence of a control group and the use of routinely collected data, which means the study is unable to determine true causation or effectiveness.

will be published in a peer-reviewed journal and summaries provided to the study funders and participants.

## INTRODUCTION

### National Insights Prioritisation Programme

Approximately 1 year after the emergence of the COVID-19 pandemic in England, the National Health Service (NHS) began considering what could be learnt from the ongoing COVID-19 pandemic response such that effective innovations that were necessitated by the pandemic could be sustained within routine services (and, conversely, what innovations may require removal because they were no longer fit for purpose or did not add value). To this effect, in 2021 the NHS Insight Prioritisation Programme (NIPP) was established by the Accelerated Access Collaborative and the National Institute for Health and Care

Research (NIHR) to accelerate the implementation and evaluation of innovation that supports postpandemic ways of working, builds service resilience and delivers benefits and value to patients in England. The objectives for NIPP are to (1) facilitate NIHR Applied Research Collaborations' (ARCs; which carry out applied health research to improve patient care) and the Academic Health Science Networks' (AHSNs; which aim to support spread and adoption of promising innovations) contribution to the NHS Reset and Recovery plan by producing insights rapidly for promising innovations, (2) identify innovations that will contribute to Integrated Care Systems and regional needs, and (3) build local capacity and expertise for evaluation and implementation.

### AHSNs and ARCs

AHSNs were established by NHS England to accelerate spread and adoption of innovation in health and care. There are 15 AHSNs across England, each working locally, as well as nationally, as intermediaries to bring together partners from across the health and care system to 'transform lives through healthcare innovation' at pace and scale.<sup>1</sup> The NIHR funds 15 ARCs to undertake applied health and care research based on local population needs. Each ARC is a partnership between local universities, NHS organisations, local authorities and AHSN (N.B. ARC and AHSN geographical boundaries are coterminous). In south London (UK), the NIHR ARC South London and AHSN (called the Health Innovation Network, or HIN) have a specific focus on implementation—the former leads on implementation science projects, while the latter leads on practical implementation support to evidenced innovations. Within the south London context, implementation science is understood as 'the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice', with the ultimate aim to improve the quality and effectiveness of care.<sup>2</sup> The HIN specifically takes an implementation science informed approach to supporting its work on spread and adoption of innovation.<sup>3,4</sup>

As part of the NIPP, the HIN and the NIHR ARC South London are collaborating on the implementation and evaluation of a culturally tailored self-management and education intervention for UK African and Caribbean communities with type 2 diabetes (T2D), Healthy Eating and Active Lifestyles for Diabetes (HEAL-D)—described in detail in the next section.

### Diabetes and HEAL-D

It is estimated that T2D affects between 3.5% and 5% of the UK population,<sup>5</sup> however, the prevalence in UK African and Caribbean communities is estimated to be up to three times higher than that of white Europeans.<sup>6</sup> This increased prevalence, coupled with evidence of ethnic disparities in outcomes,<sup>7,8</sup> results in these communities being disproportionately affected by T2D.

To tackle ethnic inequities in T2D healthcare access, an evidence-based, culturally tailored T2D self-management and education programme for adults of African and Caribbean heritage has been developed. HEAL-D was co-developed between 2016 and 2018 in collaboration with people living with T2D and community leaders from African and Caribbean community organisations.<sup>9</sup> The programme encompasses culturally tailored, group-based, face-to-face education, behaviour change and participatory physical activity, delivered by trained dietitians and lay educators.<sup>10</sup>

A randomised controlled feasibility trial, conducted in 2018–2019 and published in 2021, demonstrated that the HEAL-D programme is highly acceptable for both participants and healthcare providers.<sup>11</sup> Following its initial development as a face-to-face intervention, HEAL-D pivoted to virtual delivery and is now delivered as a series of live sessions over video call (hereafter, HEAL-D online) in response to the COVID-19 pandemic. HEAL-D online has now been commissioned across south London, with referrals managed through a centralised online booking hub, Diabetes Book & Learn, which is designed to improve access to diabetes courses in south London. Individuals can be referred to Diabetes Book & Learn via healthcare professionals or self-referral, and the service enables people to choose a course to suit them, wherever they live or work, using online booking or a phone booking line.

To date, studies have not explored the online version of HEAL-D. Therefore, to support further commissioning of the service, it is necessary to understand if an online self-management and education programme for T2D is acceptable and accessible to people from African and Caribbean communities. In addition, studies have not explored the delivery of HEAL-D outside south London and if the service can be implemented at scale.

### Study aims

Through the NIPP, the HIN and NIHR ARC South London will evaluate the local implementation of HEAL-D online in south London and its scale-up across other regions in England. The primary aims of this study are to evaluate the feasibility and acceptability of the HEAL-D online service across south London and to assess scalability requirements beyond south London. Specifically, the evaluation will explore (1) service user and service delivery staff acceptability, (2) outcomes delivered for service users and service, (3) factors influencing the implementation of HEAL-D online in south London and (4) the scaling of the service from an operational delivery and commissioning perspective.

The study will have two strands (1) an evaluation of HEAL-D online in south London and (2) a study of the scale-up of HEAL-D online beyond south London.

The two strands will address the following questions:

### Evaluation of HEAL-D online in South London

1. Is HEAL-D online acceptable for service users?

2. Is HEAL-D online acceptable and feasible for service delivery staff?
3. What benefits do service users gain from participating in HEAL-D online?
4. Does HEAL-D online improve service outcomes?
5. How does a digital model of delivery affect participation?
6. What factors affect the feasibility of implementation and delivery of HEAL-D online in south London?

**Scaling-up of HEAL-D online across England**

1. What factors affect the scale-up of HEAL-D online from an operational delivery and commissioning perspective? Specifically linked to:

- Feasibility to implement and deliver HEAL-D online at pilot sites.
- Understanding the potential impact of a digital model of participation.

**METHODS AND ANALYSIS**

**Study design**

This is a mixed-methods prospective evaluation of HEAL-D online in south London and a prospective qualitative study on scaling the HEAL-D online service.

Tables 1 and 2 outline the evaluation framework and metrics. The evaluation framework is based on the established implementation outcome framework proposed

**Table 1** Evaluation framework for HEAL-D online service evaluation in South London

Evaluation question	Measure(s)/metrics	Data source(s)/collection method(s)
Service user outcomes (satisfaction, symptoms and function)		
Is HEAL-D online acceptable for service users?	Service user perceptions — exploring experience, satisfaction, suitability and accessibility	Service user interviews. Service user questionnaire (post-course) by service provider.
	Service activity data as a measure of service user engagement with the virtual HEAL-D programme: attendance rates, dropout rates, completion rates and DNA rates	Service provider
What benefits do service users gain from participating in HEAL-D online?	Perceived outcomes	Service user interviews. Service user questionnaire (post-course) by service provider
	PROM reporting disease status and well-being using Problem Areas In Diabetes (PAID-5) questionnaire.	Service provider
Service outcomes (eg, effectiveness, efficiency/costs, safety, equity)		
Is HEAL-D online acceptable and feasible for service delivery staff?	Staff perceptions — exploring general experience, satisfaction, feasibility, issues of inclusion/equity and potential improvements	Service delivery staff interviews. Observations of sessions using fidelity checklist.
Does HEAL-D online improve service outcomes?	Service activity data: attendance rates, dropout rates, completion rates and DNA rates	Service provider
	Potential efficiencies — potential changes to time, costs or resources (positive/negative)	Service delivery staff interviews. Project documentation.
How does a digital model affect participation?	Service user demographic data: age range, gender, ethnicity (African/Caribbean) and comorbidities	Service provider
	Service user and service delivery staff perceptions	Service delivery staff and service user interviews
Implementation outcomes (eg, acceptability, adoption, fidelity)		
What factors affect the implementation and scale-up of the service (from an operational delivery and commissioning perspective)?	Defining core elements of the pathway and service model	Service delivery staff and service user interviews. Project documentation
	Feasibility to implement and deliver	Service delivery staff and service user interviews
	Fidelity of service delivery	Service delivery staff and service user interviews. Observations of sessions using fidelity checklist.
	Costs (of implementation)	Input unit costs—interviews with service user delivery staff and project documentation
	Feasibility of routinely collecting clinical outcome data for: hemoglobin A1c (HbA1c), blood pressure and cholesterol	Service provider

DNA, did not attend; HEAL-D, Healthy Eating & Active Lifestyles for Diabetes; PROM, patient-reported outcome measure.

**Table 2** Evaluation framework for scaling-up HEAL-D online study

Evaluation question	Measure(s)/metrics	Data source(s)/collection method(s)
What factors affect the scale-up of the service from an operational delivery and commissioning perspective?	Feasibility of scaling up service in other locations—using EPIS framework	Stakeholder interviews (commissioners and service providers) Documentation (local pathways, standard operating procedures, project plans)
	Perceptions of the potential impact of a digital model of participation	Interviews and focus groups with stakeholders and members of the public from African and Caribbean communities with diabetes

EPIS, Exploration-Preparation-Implementation-Sustainment; HEAL-D, Healthy Eating & Active Lifestyles for Diabetes.

by Proctor *et al.*<sup>12</sup> in which patient-level outcomes are impacted by service-level outcomes, which in turn are influenced by implementation outcomes (the latter defined as the observable effects of deliberate and purposive actions to implement a new service, such as HEAL-D online).

### Patient and public involvement

Co-design has been integral to development of HEAL-D, and the original intervention was designed in collaboration with members of African and Caribbean communities in south London.<sup>10</sup> Patient and public involvement (PPI) will continue to be key throughout the course of this project and a group of people with African and Caribbean heritage will be recruited to support the study. These individuals will be service users who have completed the HEAL-D online programme and lay partners who have offered to support future development of the programme.

These individuals will form a reference group, and a series of workshops will be held with them at key stages—including to inform the development of study materials and to inform the analysis and reporting of the findings.

### Theoretical frameworks

The evaluation is grounded on well-established implementation frameworks. First, we will apply an established model for multilevel outcome assessment for such evaluations.<sup>12</sup> The model includes patient-level, service-level and implementation outcomes. Second, the ‘Exploration-Preparation-Implementation-Sustainment’ (EPIS) framework will inform the approach to analysis.<sup>13</sup> EPIS is an evidence-based framework providing a temporal lens to explore the different stages of the implementation process, incorporating service and system-level contextual factors that may impact on early phase preparatory work, subsequent implementation and medium to longer-term sustainability.

### Setting

#### Evaluation of HEAL-D online in South London

The evaluation will focus on the delivery of HEAL-D online in south London. HEAL-D online has been commissioned for 12 months (starting in February 2022) as a pilot service and will be hosted via Diabetes Book & Learn. The programme will be managed and delivered

by Guy’s and St Thomas’ NHS Foundation Trust (GSTT), London, UK.

#### Scaling-up of HEAL-D online

The scale-up study will explore how HEAL-D online could be scaled, implemented and adopted in other regions in England.

### Participants and recruitment

Unless otherwise stated, participants will not have participated in previous HEAL-D evaluations.

All sample sizes have been determined based on feasibility, considering the total sample available and the principle of saturation that we expect to observe in what participants will report. For the latter, we have used established guidance that suggests that early themes may appear in interview analysis of approximately 6 individuals, and stabilise within 12 interviews; taken together, our sampling framework establishes these recommended numbers within a feasible timescale and resource available to carry out the evaluation.<sup>14</sup> In addition, the sample size will be increased accordingly if, once the target sample is achieved, saturation is not met.

#### Evaluation of HEAL-D online in South London

##### HEAL-D online service users

HEAL-D online has been commissioned for approximately 100 service users (ie, approximately 10–15 courses) as part of routine care via Diabetes Book & Learn. The programme will be delivered by GSTT as the service provider. The evaluation will use data collected as part of routine care provided to HEAL-D online service users, which includes a postcourse questionnaire (online supplemental appendix 1). The questionnaire will be used to identify participants who are willing to take part in interviews. The study will aim to invite 20 individuals to participate in an in-depth interview, but data collection will be guided by the principle of saturation.<sup>14</sup> The questionnaire and interviews will assess individual experiences of participating in the programme to understand the feasibility and acceptability of HEAL-D online.

##### Service delivery staff

The evaluation will seek perspectives from staff involved in implementing and delivering HEAL-D online in south

London. A target of 10 staff (eg, dietitians, physiotherapists, lay educators, service managers) will be invited to participate in an interview. Some service delivery staff may have taken part in previous HEAL-D evaluations.<sup>11</sup>

Purposive sampling will be used for all qualitative data collection to ensure the evaluation considers a range of perspectives. For service user interviews, this sampling will be guided by considering age, gender and time since diagnosis, whereas for service delivery staff this will consider different professional groups.

#### Scaling-up of HEAL-D online

##### *Commissioners and providers of diabetes services*

Approximately 15 key individuals from commissioning and provider organisations from other regions in England will be invited to take part in semi-structured interviews.

##### *Members of African and Caribbean communities*

Approximately 22 adult members of the public from African and Caribbean communities who have a lived experience of T2D will be invited to participate in focus groups and interviews. Community members will be approached via community organisations with information about the study and an invitation to participate.

All participants in the study will be asked to provide informed written consent prior to data collection.

#### Data collection methods and sources

##### *Evaluation of HEAL-D online in South London*

The study will use (1) service-level data routinely collected by the service provider, (2) data from service delivery staff interviews, (3) data from service user interviews and questionnaires, (4) observations of HEAL-D online and (5) project documentation. [Table 1](#) outlines the data collection methods and data sources in more detail.

Data routinely collected by the service provider will be used to meet the study aims ([table 1](#)). Approximately 100 service users will access the service during the study period. This will include data on service user demographic characteristics (age range, gender, ethnicity and comorbidities), attendance rates, drop-out and did not attend rates, completion rates and the Problem Areas In Diabetes (PAID-5) questionnaire.<sup>15</sup> PAID-5 is a patient-reported outcome measure to explore disease status and well-being for people with diabetes. Demographic data will be used to understand potential health inequities/access issues, including digital exclusion. The study will not examine clinical outcome data to determine effectiveness, as this falls outside the scope. However, it will explore the feasibility of routinely collecting clinical outcome data for hemoglobin A1c (HbA1c), blood pressure and cholesterol. This is to help understand the factors affecting the routine collection of clinical outcome data (eg, quality, completeness, burden) as part of ongoing service improvement and the factors affecting the implementation and scale-up of the service.

A postcourse telephone questionnaire is administered by the service provider as part of routine care

(online supplemental appendix 1). The questionnaire collects post-course PAID-5 scores along with service user experience, satisfaction and perceived benefits of the programme.

One-to-one semi-structured interviews with HEAL-D online service users (n=20) will be used to understand experience, satisfaction, acceptability and perceived outcomes. Interview participants will also be asked about the implications of a digital model for this type of structured education for diabetes. One-to-one semi-structured interviews with service delivery staff (n=10) will be used to explore acceptability, feasibility, issues of inclusion and equity, potential improvements, and the factors affecting the implementation and scale-up of the service.

Input unit costs and core elements of the service and pathway will be explored to understand the factors that affect the implementation and scale-up of the service (from an operational delivery and commissioning perspective), which will be collected via project documentation and interviews.

Fidelity is the extent to which an intervention is delivered as intended and is important in understanding the relationship between intervention, its implementation and outcomes.<sup>16</sup> The study will establish a checklist to assess fidelity to the core components and principles underpinning HEAL-D online, which will include aspects of the structure and format, ethos, quality of delivery (eg, providers are trained to deliver HEAL-D), participant adherence, and staff and participant perceptions on relevance and acceptability. The checklist will be piloted and refined, as necessary. To manage the burden of data collection for the study team, staff and patients, a range of pragmatic methods will be used to assess fidelity against the checklist:

- ▶ Self-reporting by service users and service delivery staff via interviews - participants will be asked to explore items in the fidelity checklist.
- ▶ Patient adherence numbers (ie, the number of attendees per session per course)—using routinely collected data from the training provider.
- ▶ Observation of HEAL-D online sessions—using the fidelity checklist, a senior staff member in the service provider team will observe one session per HEAL-D online course (ie, over 10–15 courses), with the study team choosing the session at random.

#### Scaling-up of HEAL-D online

[Table 2](#) outlines the data collection methods and data sources in more detail for the scaling-up of HEAL-D.

One-to-one semi-structured interviews (n=6) and focus groups (n=16, 2 focus groups of 8 people each) with members of the public from African and Caribbean communities with lived experience of diabetes will be used to understand their perspective about the provision of online learning (eg, accessibility, acceptability, benefits, risks and limitations). These will be used to understand perceptions of the potential acceptability and implications of a digital model of participation in a structured

education programme for diabetes. The combination of interviews and focus groups is to ensure perspectives are obtained from people who may be unable to attend a focus group due to personal circumstances (eg, caring responsibilities, mobility issues).

In addition, semistructured interviews (n=15) will be conducted with commissioners and providers of diabetes services in other areas of England, which will be used to understand the feasibility of a scaling up model from an operational delivery and commissioning perspective.

For both aspects of the study (ie, evaluation of HEAL-D online in south London and scaling up of HEAL-D online), all interviews and focus groups will be conducted via video call, telephone or in person (as appropriate with COVID-19 guidelines and participant preference). All topic guides will be piloted and refined where necessary. Online supplemental appendices 2 and 3 outline the key lines of enquiry that will be used to inform the development of the topic guides for the qualitative data collection (interviews and focus groups). These topic guides will be finalised with input from key stakeholders, including public representatives, and will be piloted as part of the development process.

### Data analysis and interpretation

Data analysis, interpretation and reporting will be informed by a workshop held with the PPI reference group.

### Qualitative data

Thematic analysis will be used to analyse qualitative data following the approach outlined by Braun and Clarke.<sup>17</sup> Interview recordings will be transcribed professionally, identified information will be removed and transcripts will be coded in NVivo. Ten per cent of the interview data will be double coded and consensus will be reached through a dialogue. Coded themes will be reviewed using the Exploration-Preparation-Implementation-Sustainment (EPIS) framework and discussed among the study team.<sup>18</sup>

### Quantitative data

Analysis will use descriptive statistics (mean, SD, range, percentages) and reporting summary tables and figures. Where relevant and feasible, data will be compared between the face-to-face delivery of HEAL-D in the existing feasibility study of the intervention.<sup>11</sup>

## DISCUSSION

This study will evaluate the implementation and scale-up of HEAL-D online, as part of the NIPP, which aims to gather rapid insights to support the NHS' recovery to COVID-19. The study comprises (1) mixed-methods evaluation to understand the feasibility and acceptability of a virtually delivered, culturally tailored diabetes self-management programme for African and Caribbean communities (HEAL-D online) in south London and (2)

a prospective qualitative study exploring the scaling up of HEAL-D online.

The study design has been chosen to rapidly gather insights and to identify practical barriers and enablers to implementation, while delivering maximum benefit to participants and service users. A key strength of the approach is the co-design and delivery of the study, which brings together a collaboration between the HIN (which directly supports scaled implementation of evidenced interventions, such as HEAL-D) and ARC South London (which studies implementation processes and outcomes), in partnership with people from African and Caribbean communities with a lived experience of diabetes. The known limitation of the approach is the absence of a control group and the use of routinely collected data, which means the study is unable to determine true causation or effectiveness. However, it does allow the assessment of the implementation and scale-up of HEAL-D online in a real-world setting to inform rapid service improvement and transformation to address an unmet need for underserved communities.

## ETHICS AND DISSEMINATION PLAN

Ethical clearance for this study was granted by King's College London's Research Ethics Office under the 'Minimal Risk Registration' procedure (registration confirmation reference number MRA-21/22-28498). All participants will provide written informed consent to participate, including for their interviews to be recorded.

Results will be published in an international peer-reviewed journal and summaries will be provided to the study funders as well as reference group members and study participants.

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**Contributors** LG, AW, ZL, NC and NS conceived of and proposed the study with SL, SI and OB contributing to further study development. SL wrote the first draft of the manuscript. All authors contributed edits to the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. The authors read and approved the final manuscript.

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**Competing interests** NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions and human factors to healthcare organisations. LG is involved in the delivery of the HEAL-D programme that is being evaluated in this research. The other authors have no conflicts of interest to declare.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

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